OHSU Health System
Office of Clinical Integration and Evidence-Based Practice
Obesity Management
Evidence Summary

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Objective:
To critically review the evidence on identification, assessment and management for patients with overweight or obesity, including children, adolescents and adults.

Inclusion Criteria:
- Adult patients with a BMI >/=30 kg/m2
- Adult patients with a BMI >/=25 kg/m2 with co-morbidities
- Pediatric patients in the 85th weight percentile or greater
- Including patients with co-morbidities (such as heart disease, hypertension, dyslipidemia, type II diabetes, osteoarthritis, sleep apnea, certain malignancies, and all-cause mortality)

Exclusion Criteria:

- Adult patients with a BMI less than 25 kg/m2
- Pediatric patients below the 85th percentile
- Patients with anorexia nervosa
- Pregnant women

Definitions:

Body Mass Index (BMI): A person's weight in kilograms divided by his or her weight in meters squared. For adults, The National Institutes of Health (NIH) now defines normal weight, overweight, and obesity according to BMI rather than the traditional height/weight charts. BMI can be used as a screening tool for health risk, but is not a diagnostic of the body fatness of an individual.

Weight Percentile: A percentile shows the relative position of the child's BMI, weight, or height among children of the same sex and age. Commonly used in pediatrics to screen for obesity.

Overweight: Adults with a BMI with a range of 25.0 to 30; Children between the 85th and 95th percentile.

Obese: Adults with a BMI of 30.0 or higher; Children in the 95th percentile or greater.

BMI Classifications

- Class 1: BMI of 30 to <34.9
- Class 2: BMI of 35 to <39.9
- Class 3: BMI of 40 or higher. Class 3 obesity is sometimes categorized as "extreme" or "severe" obesity

Waist Circumference (WC): Another way to estimate potential chronic disease risk is to measure waist circumference. Increased abdominal fat is a risk marker for developing obesity-related conditions (central obesity). The following criteria for waistline can put patients at higher risk:

- An adult male whose waist circumference is more than 40 inches
- An adult non-pregnant woman whose waist circumference is more than 35 inches

Target Guideline Users:

- All clinicians who serve patients with overweight/obesity across the health system

Review Preparation:

The following age groups should be considered for all clinical questions: children, adolescents, and adults

Identification

1. What is the optimal approach (assessment tools, appropriate language, and identification tactics) to identify pediatric and adult patients who are overweight and obese? How does the approach differ between pediatric and adult patients?

Assessment

2. What are the key elements of an appropriate health assessment for pediatric and adult patients have overweight or obese to evaluate an individual's health status and risks?

Management

For pediatric and adult patients who are overweight or obese:

3. What is the comparative effectiveness of nutritional interventions (standard calorie-deficit diet (calorie reduction, portion control), very-low-calorie diet (VLCD), hypocaloric meal-replacement diet, diets that do not restrict calories but vary macronutrients (high-fiber diet, high-protein diet, low-carbohydrate diet, low-fat diet, high fat/keto diet), and diets that emphasize healthy eating patterns (whole foods, healthy diet index)? What is the optimal intensity of nutritional interventions for improving health, well-being, and weight loss?
4. What is the comparative effectiveness of physical activity interventions (aerobic exercise, resistance training, combined aerobic and resistance training, walking activities, standing desks)? What is the optimal intensity of physical activity interventions for improving health, well-being, and weight loss?
5. What is the comparative effectiveness of behavioral interventions (mental health interventions, group, individual, mixed, peer-based, parenting and family-based, technology-based, print-based)? What is the optimal intensity of behavioral interventions for improving health, well-being, and weight loss?
6. What is the comparative effectiveness of lifestyle interventions (combined physical activity, nutritional, behavioral)? What is the optimal lifestyle intervention for improving health, well-being, and weight loss?
7. What is the comparative harms and benefits of different pharmacological therapies (Orlistat, Phentermine, Topiramate, Phentermine/Topiramate, Lorcaserin, Buproprion, Bupropion/Naltrexone, Liraglutide, Diethylproprion, Metformin, Pramlintide, Zonisamide) for achieving weight loss and improving health and well-being? What is the optimal dose, duration and combination of pharmacological therapies?
8. What are the harms and benefits of surgical procedures (metabolic and bariatric procedures such as roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, sleeve gastrectomy, biliopancreatic diversion with duodenal switch) to treat obesity, weight-related complications?
9. What are the harms and benefits of endoscopic procedures (space-occupying devices, gastric capacity reduction methods, endoluminal devices, endoluminal ablation) to treat obesity and weight-related complications?
10. What is the thresholds for considering nutritional, activity-based, lifestyle-based, pharmacological, and surgical or endoscopic approaches to weight loss and management of obesity-related comorbidities?
11. What are the long-term outcomes of bariatric and metabolic interventions in children and young people with obesity?
12. In patients who are overweight or obese, what is the best approach for managing co-morbidities? (diabetes risk reduction, type 2 diabetes, hypertension, cardiovascular disease, congestive heart failure, nonalcoholic fatty liver disease, polycystic ovary syndrome, infertility, male hypogonadism, obstructive sleep apnea, asthma, osteoarthritis, depression, gastro-esophageal reflux, cancer).

13. What is the optimal combination of lifestyle interventions (nutritional interventions, physical activity, behavioral interventions, pharmacological therapies, surgical procedures, endoscopic procedures) for improving health and well-being?
14. What is the optimal approach to integrate community resources into obesity management services? What is the effectiveness of community resources amongst different ethnicities/races?
15. What is the optimal approach to address the social determinants of health (lack of fresh produce in corner stores, food deserts, lack of stable housing, wage/income equality) in obesity management services?

Maintenance of Health

16. How are obesity management interventions determined to be successful (weight loss, co-morbidity improvement or resolution, quality of life, mortality)?
17. For patients successful with weight loss interventions (lifestyle, pharmacologic, bariatric and metabolic surgeries), what strategies are effective for maintenance of weight loss and health?

Follow-up

18. What is the appropriate follow-up (length, interventions, etc.) with patients who are actively attending to lifestyle changes for obesity management?
19. In patients who have undergone bariatric surgery, what post-operative lifestyle intervention programs (exercise, behavioral, dietary or long-term pharmacologic therapy) improve long-term weight loss and weight-loss maintenance?

Weight Bias and Stigma

20. What interventions targeting health care providers and/or organizations reduce weight bias (less time with patient, less rapport building, patient delaying or avoiding treatment) towards patients living with overweight or obesity?
21. In patients living with overweight or obesity, what is the preferred language (obese, elevated weight) and approach for health care professionals to discuss weight and treatment? Do these preferences vary by ethnicity or socio-economic status?
22. Does weight bias among health care providers and/or organizations lead to adverse health outcomes independent of physiologic and mechanical impact of excess adiposity among persons living with overweight or obesity?

Obesity Management
Existing External Guidelines/Pathways/Order Sets

Existing External Guidelines

External Guideline	Organization and Author	Last Update
Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults	US Preventive Services Task Force	2018
Clinical Practice Guideline for Multicomponent Behavioral Treatment of Obesity and Overweight in Children and Adolescents	American Psychological Association	2018
Screening for Obesity in Children and Adolescents	US Preventive Services Task Force	2017
Preventing Obesity and Eating Disorders in Adolescents	American Academy of Pediatrics	2016
Update on Office-based Strategies for the Management of Obesity	American Academy of Family Physicians (AAFP)	2016
Clinical Practice Guidelines for Comprehensive Medical care of Patients with Obesity	American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)	2016
Interventions for the Treatment of Overweight and Obesity in Adults	Academy of Nutrition and Dietetics	2016
Algorithm for the Assessment and Management of Childhood Obesity in Patients 2 Years and Older	American Academy of Pediatrics Institute for Healthy Childhood Weight	2015
Recommendations for prevention of weight gain and use of behavioral and pharmacologic interventions to manage overweight and obesity in adults in primary care	Canadian Task Force on Preventive Health Care	2015
European Guidelines for Obesity Management in Adults	Management Task Force of the European Association for the Study of Obesity	2015
Identification, assessment and management of overweight and obesity in children, young people and adults	National Institute for Health and Care Excellence	2014
VA/DoD Clinical Practice Guideline for Screening and Management of Overweight and Obesity	Department of Veterans Affairs and Department of Defense (VA/DoD)	2014
Guideline for the Management of Overweight and Obesity in Adults	American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)	2013
Adolescent health screening and counseling	American Academy of Family Physicians (AAFP)	2012
Evaluation of the Overweight/Obese Child – Practical Tips for the Primary Health Care Provider	Childhood Obesity Task Force of the European Association for the Study of Obesity	2010
Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report	American Academy of Pediatrics	2007

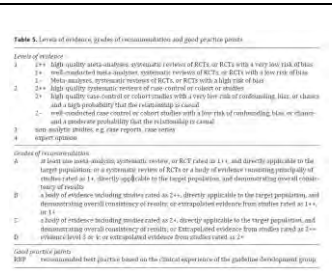
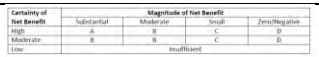
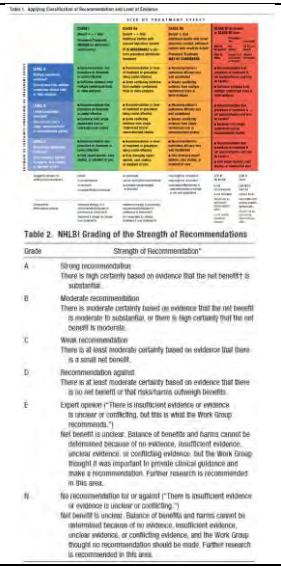
The published clinical guidelines were evaluated for this review using the **University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale.** The scale is based on the Institute of Medicine's "Standards for Developing Trustworthy Clinical Practice Guidelines" (IOM), as well as a review of the AGREE.

Guideline Issuer and Date	APA 2018	USPSTF 2017/ 2018	AAP 2016	AAFP 2016/ 2010	AACE/ ACE 2016	AHA/ ACC/ TOS 2016	CHA 2016	AND 2016	HERC 2016	ETF 2015	CTFPHC 2015	NICE 2014	VA/DoD 2014	COTF 2010	AAP 2007
1. Transparency	A	A	C	C	A	A	B	B	A	B	B	A	A	C	C
2. Conflict of interest	A	A	C	C	B	B	NR	NR	B	B	B	A	C	B	C
3. Development group	B	A	C	B	B	A	C	C	B	B	B	A	A	B	C
4. Systematic Review	A	A	B	B	A	A	C	A	A	B	A	A	A	B	B
5. Supporting evidence	A	A	B	B	A	A	B	A	A	B	A	A	A	B	B
6. Recommendations	A	A	C	A	A	A	B	A	A	B	A	B	A	C	C
7. External Review	B	A	C	C	A	A	NR	NR	A	C	A	C	C	C	C
8. Currency and updates	B	A	B	B	B	B	B	B	B	B	B	B	B	C	C

See appendix B for full description of the Trustworthy Guideline grading system.

Guideline Evidence Evaluation Systems

	APA 2018	USPSTF 2017/2018	AAP 2016	AAFP 2016/2010	AACE/ACE 2016	CHA 2016	AND 2016	CTFPHC 2015
Evidence Evaluation	Follows recommendation from the Institute of Medicine (2011a) and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group (Guyatt et al., 2011), the panel considered four factors as it drafted recommendations: 1) overall strength of the evidence; 2) the balance of benefits vs. harms/burdens; 3) patient values and preferences; and 4) applicability (generalizability across populations, interventions, comparators, outcomes, timing, and settings). Based on the combination of these factors, the panel made a strong or weak recommendation for or against the treatment or treatment strategy or made a statement that there was insufficient evidence to be able to make a recommendation.		Evidence evaluation system not described, no formal rating of recommendations	Evidence evaluation system not described, no formal rating of recommendations		Evidence evaluation system not described, no formal rating of recommendations	This Academy position paper includes the authors' independent review of the literature in addition to systematic review conducted using the Academy's Evidence Analysis Process and information from the Academy's Evidence Analysis Library (EAL). Topics from the EAL are clearly delineated. For a detailed description of the methods used in the Evidence Analysis Process, go to www.andevidencelibrary.com/eaprocess. Recommendations are assigned a rating by an expert work group based on the grade of the supporting evidence and the balance of benefit vs harm. Recommendation ratings are Strong, Fair, Weak, Consensus, or Insufficient Evidence. Recommendations can be worded as conditional or imperative statements. Conditional statements clearly define a specific situation and most often are stated as an "if, then" statement, while imperative statements are broadly applicable to the target population without restraints on their pertinence. Evidence-based information for this and other topics can be found at www.andevidencelibrary.com and subscriptions for nonmembers can be purchased at www.andevidencelibrary.com/store.cfm.	

	ETF 2015	NICE 2015	VA/DoD 2014	AHA/ACC/TOS 2013	COTF 2010	AAP 2007
Evidence Evaluation		The evidence for outcomes from the included RCTs and, where appropriate, observational studies were evaluated and presented using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/).			Evidence evaluation system not described, no formal rating of recommendations	Evidence evaluation system not described, no formal rating of recommendations

Review of Relevant Evidence: Search Strategies and Databases Reviewed

Search Strategies	Document Strategies Used
Search Terms/Strategies Used:	
Database Searched	
Years Searched - All Questions	
Language	English
Age of Subjects	

Evidence Found with Searches

Check type of evidence found	Summary of Evidence – All Questions	Number of articles obtained
☐	Systematic reviews/Meta-analysis	
☐	Randomized controlled trials	
☐	Non-randomized studies	
☐	Government/State agency regulations	
☐	Professional organization guidelines/white papers, etc.	

Evaluating the Quality of the Evidence

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. For more detailed information, see Appendix A.

Recommendation	
STRONG	Desirable effects clearly outweigh undesirable effects or vice versa.
CONDITIONAL	Desirable effects closely balanced with undesirable effects.
Quality	**Type of Evidence**
High	Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very Low	Any estimate of effect is very uncertain.

Question #1. What is the optimal approach (assessment tools, appropriate language, and identification tactics) to identify pediatric and adult patients who have overweight or obesity? How does the approach differ between pediatric and adult patients?

Children and Adolescents: Guideline Recommendations

The 2018 **American Psychological Association (APA)** guideline stated in the treatment of obesity and overweight in children and adolescents:

- The age of the children is a consideration. Evidence suggests treatment may work especially well for young children, supporting the importance of intervening as early as possible.
- Practitioners should develop knowledge, skills, and awareness related to weight bias and stigma (differential and negative treatment and attitudes experienced by people who have overweight or obesity). Health professionals and family members have been identified as the most frequent sources of weight stigma for individuals with obesity.

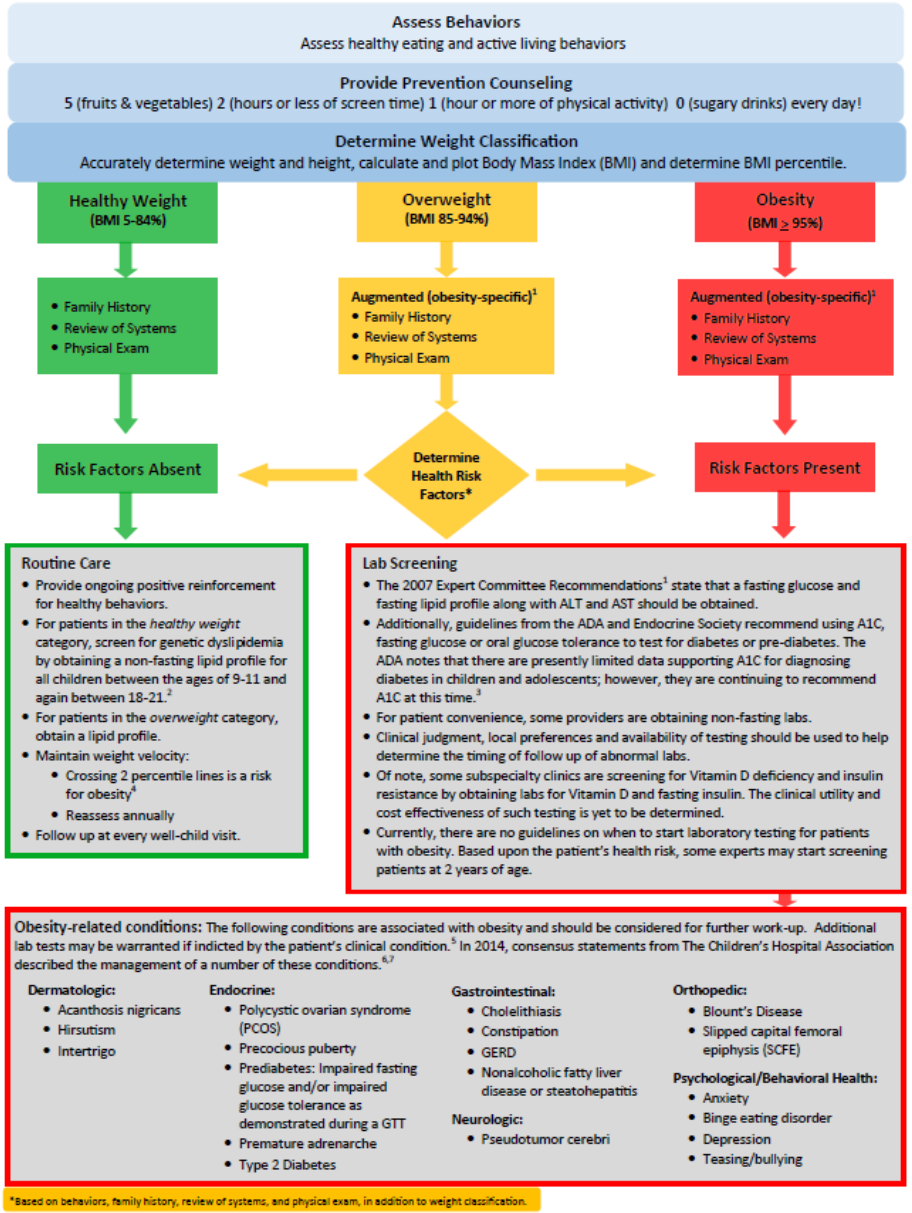
In 2017, **US Preventive Services Task Force** (USPSTF) recommended the following for children and adolescent 6 years and older:

- *Screening Tests*: BMI measurement, using height and weight, is the recommended screening test for obesity. Obesity if defined as an age- and sex-specific BMI in the 95th percentile or greater (**Grade B)**.

The 2015 **American Academy of Pediatrics Institute for Health Childhood Weight** released the following assessment and management algorithm for childhood obesity:

Algorithm for the Assessment and Management of Childhood Obesity in Patients 2 Years and Older

This algorithm is based on the 2007 Expert Committee Recommendations,[1] new evidence and promising practices.



Algorithm was based on the **2007 AAP Expert Committee Recommendations** Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity:

TABLE 1 Terminology for BMI Categories

BMI Category	Former Terminology	Recommended Terminology
<5th percentile	Underweight	Underweight
5th–84th percentile	Healthy weight	Healthy weight
85th–94th percentile	At risk of overweight[ab]	Overweight[c]
≥95th percentile	Overweight[ab] or obesity[a]	Obesity[cd]

[a] Expert committee recommendations, 1998.[15]
[b] CDC recommendations, 2002.[2]
[c] International Obesity Task Force, 2000.[45]
[d] Institute of Medicine, 2005.[16]

TABLE 2 BMI Tools

Tools	BMI Calculation	BMI Percentile Classification	BMI Percentile Plotting	BMI *z* Score[a]
Standard calculator[b]	X			
BMI wheel	X			
BMI nomogram	X			
BMI growth curves		X	X	
Internet-based calculator[c]	X	X		X
Personal digital assistant program[d]	X	X		[e]
Electronic health record	X	X	X	X

BMI calculation, percentile classification, and BMI percentile plotting are required to monitor a child's growth over time.
[a] Generally not needed in clinical care.
[b] Metric: kilograms/meters/meters; English: pounds/inches/inches × 703.
[c] Example: www.rch.org.au/genmed/clinical.cfm?doc_id=2603.
[d] Example: http://hp2010.nhlbihin.net/bmi_palm.htm.
[e] Potential application; not currently available.

TABLE 3 Cutoff Points for 99th Percentile BMI According to Age and Gender

Age, y[a]	99th Percentile BMI Cutoff Point, kg/m²	
	Boys	Girls
5	20.1	21.5
6	21.6	23.0
7	23.6	24.6
8	25.6	26.4
9	27.6	28.2
10	29.3	29.9
11	30.7	31.5
12	31.8	33.1
13	32.6	34.6
14	33.2	36.0
15	33.6	37.5
16	33.9	39.1
17	34.4	40.8

The data were derived from ~500 children in each year from 5 through 11 years of age and ~850 children in each year from 12 through 17 years of age (adapted from Freedman et al,[24] with permission).

[a] Cutoff points are at the midpoint of the child's year (eg, 5.5 years).

Additionally, the 2007 **American Academy of Pediatrics** Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report stated:

Assessment Recommendations

- The expert committee recommends that physicians and allied health care providers perform, at a minimum, a yearly assessment of weight status for all children and that this assessment include calculation of height, weight (measured appropriately), and BMI for age and plotting of those measures on standard growth charts.

- With regard to classification, the expert committee recommends that individuals 2 to 18 years of age with BMI of >/=95th percentile for age and gender or BMI of >30 (whichever is smaller) should be considered obese and individuals with BMI of >/=85th percentile but <95th percentile for age and gender should be considered overweight; this term replaces "at risk of overweight."
- The expert committee recommends the use of 99th percentile BMI values for age as cutoff points (indicated by using a table with cutoff points for the 99th percentile BMI according to age and gender), to allow for improved accessibility of the data in the clinical setting and for additional study.
- The expert committee recommends against the routine clinical use of skinfold thickness measurements in the assessment of obesity in children.
- The expert committee was unable to recommend waist circumference measurements for routine clinical use at the present time, because of incomplete information and the lack of specific guidance for clinical application.

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following in 2014:

- Aim to create a supportive environment that helps a child who is overweight or who has obesity, and their family, make lifestyle changes.

Identification and classification of overweight and obesity

- Use clinical judgement to decide when to measure a person's height and weight. Opportunities include registration with a general practice, consultation for related conditions (such as type 2 diabetes and cardiovascular disease) and other routine health checks.

Measures of overweight and obesity

- Use BMI as a practical estimate of adiposity in adults. Interpret BMI with caution because it is not direct measure of adiposity.
- Think about waist circumference, in addition to BMI, to people with a BMI less than 35 kg/m^2.

  Children
  - Use BMI (adjusted for age and gender) as a practical estimate of adiposity in children and young people. Interpret BMI with caution because it is not a direct measure of adiposity.
  - Waist circumference is not recommended as a routine measure. Use it to give additional information on the risk of developing other long-term health problems.
    - *Adults and Children*
  - Do not use bioimpedance as a substitute for BMI as a measure of general adiposity.
  - *Children*
  - Relate BMI measurement in children and young people to the BMI charts to give age- and gender-specific information.
  - Tailored clinical intervention should be considered for children with a BMI at or above the 91st centile, depending on the needs of the individual child and family.

In 2012, the **American Academy Family Physician (AAFP)** recommended the following for Adolescent health screening and counseling:

- Adolescents should be screened for obesity, and offered behaviorally based counseling if indicated. **Grade B**

Children and Adolescents: Primary Literature:

2017 Preventive Services Task Force Evidence Report concluded

- In 2005, the USPSTF found that age- and sex-adjusted BMI (calculated as weight in kilograms divided by the square of height in meters) percentile is the accepted measure for detecting overweight or obesity in children and adolescents because it is feasible for use in primary care, a reliable measure, and associated with adult obesity.
- The USPSTF founded equate evidence to bound the harms of screening and comprehensive, intensive behavioral interventions for obesity in children and adolescents as small to none, based on the likely minimal harms of using BMI as a screening tool, the absence of reported harms in the evidence on behavioral interventions, and the noninvasive nature of the interventions.

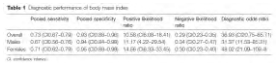
Table 4. Summary of Evidence

Topic	No. of Studies (Design), No. of Participants	Summary of Findings	Consistency/Precision	Limitations (Includes Reporting Bias)	Overall Study Quality	Applicability
KQ1, KQ1a, KQ1b, KQ1c: Benefits of Screening						
	0 (NA)	NA	NA	NA	NA	NA
KQ2: Harms of Screening						
	0 (NA)	NA	NA	NA	NA	NA

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Body Mass Index (BMI)
Outcome: Diagnostic performance

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient

		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Javed, A., et al. Year Published: 2015 Location: Mayo Clinic, Rochester, MN Journal: *Pediatric Obesity*	To perform a systematic review and meta-analysis of studies assessing the diagnostic performance of BMI to detect adiposity in children up to 18 years.	**Size:** 37 studies with 53,521 patients. **Inclusion Criteria**: (i) the study must have assessed the diagnostic performance of BMI to identify excess adiposity in children aged 0–18 years; (ii) provided a 2 x 2 diagnostic table to allow for meta-analysis or information to calculate these values; and (iii) used a reference standard for body composition (e.g. DXA, ADP, HW). **Exclusion Criteria:** Studies were excluded if they only assessed cardiometabolic risk factors without use of any reference standard methods for measuring adiposity.	**Type:** Systematic Review	**Results: Commonly used BMI cut-offs for obesity showed pooled sensitivity to detect high adiposity of 0.73 (confidence interval [CI] 0.67-0.79), specificity of 0.93 (CI 0.88-0.96) and diagnostic odds ratio of 36.93 (CI 20.75-65.71). Males had lower sensitivity. Moderate heterogeneity was observed (I^2 = 48%)** explained in meta-regression by differences across studies in race, BMI cut-off, BMI reference criteria (Center for Disease Control vs. International Obesity Task Force) and reference standard method assessing adiposity. 	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Javed, A., et al. (2015). "Diagnostic performance of body mass index to identify obesity as defined by body adiposity in children and adolescents: a systematic review and meta-analysis." Pediatric Obesity **10**(3): 234-244.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Pediatrics
Modality: Edmonton Obesity Staging System
Outcome: Diagnostic accuracy

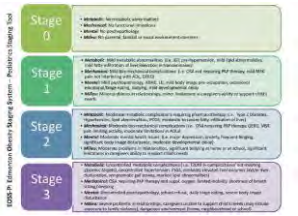
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☐ Low ☒ Very Low					
Risk of Bias across studies: ☒ High ☐ Medium ☐ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - *Unknown* ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Hadjiyannakis, S., et al. Year Published: 2016 Location: Children Hospital of Eastern Ontario, Canada Journal: *Paediatrics & child health*	To propose a new clinical staging system (the Edmonton Obesity Staging System for Pediatrics, EOSS-P), adapted from the adult-oriented EOSS.	**Size:** Clinical staging system not tested on patients.	**Type:** Proposal article **Methods:** The EOSS-P was developed to stratify patients according to severity of obesity-related comorbidities and barriers to weight management into four graded categories (0 to 3) within four main health domains: metabolic, mechanical, mental health and social milieu (the 4Ms). 	**Results:** No results included	**Study Limitations:** ☐ None **Non-Randomized Studies** ☒ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up ***No patients included in article***

			 **TABLE 2** **The Edmonton Obesity Staging System for Pediatrics and stage-based management plan*** **Stage** — **Management plan** 0 — Ongoing monitoring of obesity related risk factors and healthy lifestyle/behavioural counselling by the primary health care provider at regular visits. 1 — Ongoing monitoring of obesity-related risk factors and healthy lifestyle/behavioural counselling by primary health care provider in conjunction with dietitian/mental health) provider depending on individual needs 2 — Referral to multidisciplinary paediatric obesity clinic for comprehensive assessment; receive more intensive, family-centred counselling and lifestyle/behavioural intervention; plan regular follow-up clinical appointments. 3 — Referral to tertiary level, multidisciplinary paediatric obesity clinic for comprehensive assessment, which may include subspecialty care to manage comorbidities; receive more intensive, family-centred counselling and lifestyle/behavioural intervention; consider complementary, intensive therapeutic options (eg, bariatric surgery); plan regular follow-up clinical appointments. *Persistence in stage 1, 2 or 3 over an extended period (eg, 12 months) should result in intensification of management strategy after the exclusion of non-modifiable risk factors		
Author: Grammatikopoulou, M. G., et al. Year Published: 2018 Location: Athens, Greece Journal: *Journal of Endocrinological Investigation*	To apply the EOSS-P on a Greek pediatric cohort and assess risk factors associated with each stage, compared to normal weight controls.	**Size:** 361 children and adolescents (2 – 14 years old). Control Group = 158, Obese Group - 203 **Inclusion Criteria:** Visited hospital between 2008-2010 and had sufficient medical records for evaluation. **Exclusion Criteria:** Children younger than 2 years old were excluded from the sample.	**Type:** Cohort Study **Intervention:** Two groups were formed, control having normal body weight and a group comprising obese children. Anthropometry, blood pressure, blood and biochemical markers, comorbidities and obesogenic lifestyle parameters were recorded and the EOSS-P was applied. Validation of EOSS-P stages was conducted by juxtaposing them with IOTF-defined weight status. Obesogenic risk factors' analysis was conducted by constructing	**Results:** The majority of obese children were stratified to stage 1 (46.0%), 17.0% were on stage 0, and 37% on stage 2. The validation analysis revealed that EOSS-P stages greater than 0 were associated with diastolic blood pressure and levels of glucose, cholesterol, LDL, and ALT. **Reduced obesity odds were observed among children playing outdoors and increased odds for every screen time hour, both in the GA and in the multivariate analyses (all *P* < 0.05). Although participation in sports > 2 times/week was**	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

			gender-and-age-adjusted (GA) and multivariate logistic models.	**associated with reduced obesity odds in the GA analysis (OR = 0.57, 95% CI = 0.33-0.98, *P* linear = 0.047), it lost its significance in the multivariate analysis (*P* linear = 0.145).** Analogous results were recorded in the analyses of the abovementioned physical activity risk factors for the EOSS-P stages. Linear relationships were observed for fast-food consumption and IOTF-defined obesity and higher than 0 EOSS-P stages. Parental obesity status was associated with all EOSS-P stages and IOTF-defined obesity status.	

References:

1. Hadjiyannakis, S., et al. (2016). "The Edmonton Obesity Staging System for Pediatrics: A proposed clinical staging system for paediatric obesity." Paediatrics & child health **21**(1): 21-26.
2. Grammatikopoulou, M. G., et al. (2018). "Edmonton obesity staging system among pediatric patients: a validation and obesogenic risk factor analysis." Journal of Endocrinological Investigation **41**(8): 947-957.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children
Modality: Parental perceptions
Outcome: Accuracy of childrens' weight

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient

		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Lundahl, A., et al. Year Published: 2014 Location: University of Nebraska-Lincoln, NE Journal: *Pediatrics*	To determine the proportion of parents worldwide who underestimate their children's weight and moderators of such misperceptions.	**Size:** 69 articles with 15,791 participants. **Inclusion Criteria:** Studies in which primary caregivers' perceptions of their children's weight (>/=2 years of age) were assessed via Likert scale questions, classification into weight categories, pictorial methods, or reporting of height and weight, and were subsequently compared with recognized standards for defining overweight (e.g., International Obesity Task Force) based on anthropometric measurements. **Exclusion Criteria:** Nonpublished, non-English, and/or qualitative studies, as well as those that did not include objective anthropometric measurements of child weight/height to compare perceptions to or those that did not pair parent and child data.	**Type:** Systematic Review	**Results: Adjusted effect sizes revealed that 50.7% (95% confidence interval 31.1%-70.2%) of parents underestimate their overweight/obese children's weight.** Significant moderators of this effect included child's age and BMI. A total of 52 articles (representing 59 samples; n = 64,895) were included in the normal-weight meta-analysis. **Pooled effect sizes indicated that 14.3% (95% confidence interval 11.7%-17.4%) of parents underestimate their children's normal-weight status.** Significant moderators of this effect included child gender, parent weight, and the method (visual versus nonvisual) in which perception was assessed.	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

Author: Rietmeijer-Mentink, M., et al. Year Published: 2013 Location: University Medical Center, Rotterdam, The Netherlands Journal: *Maternal & Child Nutrition*	To systematically study differences between parental perceptions and the actual weight status of children.	**Size:** 51 articles (including 35,103 children) **Inclusion Criteria:** Study investigated the perception of parents/caregivers, the children were aged 2–18 years and the outcome was the difference between measured weight status (classified by BMI) and weight status as observed by parents on the child level. **Exclusion Criteria:** Diagnostic and Statistical Manual of Mental Disorders (DSM) classified eating disorders, medical conditions affecting the weight (e.g. Down syndrome, PraderWilli syndrome) and qualitative studies.	**Type:** Systematic Review	**Results:** The methodological quality of the studies ranged from poor to excellent. Pooled results showed that according to objective criteria 11 530 children were overweight; of these, 7191 **(62.4%) were incorrectly perceived as having normal weight by their parents. The misperception of overweight children is higher in parents with children aged 2-6 years compared with parents of older children. Sensitivity (correct perception of overweight) of the studies ranged from 0.04 to 0.89, while specificity (correct perception of normal weight) ranged from 0.86 to 1.00.** There were no significant differences in sensitivity or specificity for different cut-off points for overweight, or between newer and older studies.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

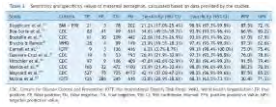
References:

1. Lundahl, A., et al. (2014). "Parental underestimates of child weight: a meta-analysis." Pediatrics **133**(3): e689-703.
2. Rietmeijer-Mentink, M., et al. (2013). "Difference between parental perception and actual weight status of children: a systematic review." Maternal & Child Nutrition **9**(1): 3-22.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents (Aged 2 – 19 years old)
Modality: Mothers' perception
Outcome: Nutritional status

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies: ☐ High ☐ Medium ☒ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Francescatto, C., et al. Year Published: 2014 Location: Institution Universidad Gama Filho, Brazil Journal: *Jornal de Pediatria*	To explore and describe the studies that have as a primary outcome the identification of mothers' perception of the nutritional status of their children.	**Size:** 17 studies, including 57,7000 children and adolescents. **Inclusion Criteria:** Articles that investigated the perception of mothers on the nutritional status of their children; studies of children aged between 2 and 19 years where the outcome was the assessment of the difference between the actual nutritional status (classified by body mass index [BMI]) and nutritional status perceived by the mother.	**Type:** Systematic Review	**Results:** The proportion of mothers who inadequately perceived the nutritional status of their children was high, and was the most common underestimation for children with overweight or obesity. **The sensitivity ranged from 6.2% to 54.6%, indicating low capacity of mothers to perceive overweight in their children. Specificity was higher than 90.0% for nine of ten studies, indicating good capacity of mothers to recognize the nutritional status of their children when they had normal weight.** 	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Francescatto, C., et al. (2014). "Mothers' perceptions about the nutritional status of their overweight children: a systematic review." Jornal de Pediatria **90**(4): 332-343.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Self-reported data
Outcome: Diagnostic accuracy

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - # of patients included not presented in paper*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: He, J., et al. Year Published: 2017 Location: University of Macau, China Journal: *Obesity Research & Clinical Practice*	To estimate the accuracy of using the self-reported body mass index (BMIsr) for screening children and adolescents for overweight and obesity status by quantitatively synthesizing individual studies in the research literature.	**Size:** 23 studies **Inclusion Criteria:** (a) Study was a published peer-reviewed journal article; (b) the study was published in English; (c) the age of the participants was no more than 21 years to be consistent with the Stages of Adolescent Development; (d) study compared the results of screening for overweight and obesity status between the BMI based on physical measures of height and weight and the BMI based on self-reported height and weight (BMIsr); (e) The numbers of true and false positives can be extracted from the study.	**Type:** Systematic Review	**Results:** For screening children and adolescents with overweight and obesity, **the use of BMIsr presented a pooled sensitivity of 0.76 (95% CI, 0.76-0.77), a pooled specificity of 0.96 (95% CI, 0.96-0.97) and a pooled DOR of 92.4 (95% CI: 74.3-114.8).** Moderator analyses showed that the sample regions (America vs. Europe vs. Asia), weight status screening references (IOTF vs. CDC vs. Nation-specific standard) and weight status screened (overweight vs. obesity) had contributed to the inconsistent findings	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				concerning the screening accuracy across the studies.	

References:

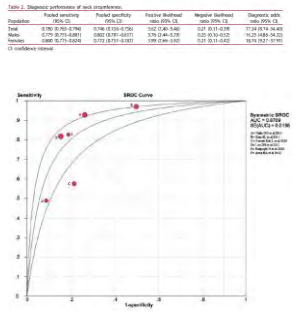
1. He, J., et al. (2017). "Accuracy of using self-reported data to screen children and adolescents for overweight and obesity status: A diagnostic meta-analysis." Obesity Research & Clinical Practice **11**(3): 257-267.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Neck circumference
Outcome: Diagnostic performance

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Ma, C., et al. Year Published: 2017 Location: First Hospital of Qinhuangdao, China Journal: *Annals of Human Biology*	To perform a meta-analysis to assess the performance of neck circumference (NC) for the assessment of overweight and obesity.	**Size:** 6 studies evaluating 11,214 children and adolescents aged 6 – 18. **Inclusion Criteria:** The study must have (i) assessed the diagnosis performance of neck circumference to identify	**Type:** Systematic Review	**Results: NC showed pooled sensitivity to detect high body mass index of 0.780 (95% confidence interval [CI] = 0.765-0.794), specificity of 0.746 (95% CI = 0.736-0.756) and a diagnostic odds ratio of 17.343 (95% CI = 8.743-34.405).**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised

		overweight or obesity in children and adolescents aged 0–18 years; (ii) provided a 2 x 2 diagnostic table to allow for meta-analysis or information to calculate these values; and (iii) used a reference standard for body mass index. **Exclusion Criteria:** Editorials, opinions and reviews.			☐ Inappropriate pooled analysis

References:

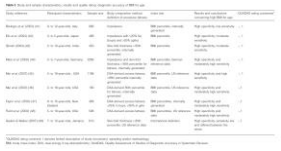
1. Ma, C., et al. (2017). "Diagnostic performance of neck circumference to identify overweight and obesity as defined by body mass index in children and adolescents: systematic review and meta-analysis." Annals of Human Biology **44**(3): 223-229.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Body mass index (BMI) vs. waist circumference
Outcome: Diagnostic accuracy

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☒ High ☐ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**

Author: Reilly, J.J., et al. Year Published: 2010 Location: University of Glasgow, UK Journal: *Obesity Reviews*	To review evidence on the use of body mass index (BMI) and waist circumference for diagnosis of high body fat content and adverse cardiometabolic risk factors in children and adolescents.	**Size:** 27 studies, 7168 participants. **Inclusion Criteria:** Studies were only included if study participants were in the age range 0–18 years and if 'diagnostic accuracy' of BMI and/or waist was reported (with summary statistics, such as sensitivity and specificity, area under the curve, predictive values, receiver operator characteristic analysis). **Exclusion Criteria:** Abstracts were excluded because they failed to provide the necessary level of detail on study findings and methods. Studies were excluded if they reported only associations between BMI, waist and fatness or cardiometabolic risk factors as the present review addressed the specific issue of the accuracy of classification of obesity based on BMI and waist circumference.	**Type:** Systematic Review	**Results:** Ten studies compared diagnostic accuracy of BMI vs. waist circumference: they **reported no improved identification of adverse cardiometabolic risk profiles from waist circumference over that provided by high BMI.** Eight studies compared BMI with national reference data vs. the international approach: 5/8 found significantly poorer accuracy (lower sensitivity) using BMI with the international approach; 3/8 found similar sensitivity; in 7/7 studies that compared specificity this was similar. 	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

References:

1. Reilly, J. J., et al. (2010). "Accuracy of simple clinical and epidemiological definitions of childhood obesity: systematic review and evidence appraisal." Obesity Reviews **11**(9): 645-655.

Adults: Guideline Recommendations

The 2018 **US Preventive Services Task Force** on preventing obesity-related morbidity and mortality in adults uses the following terms to define categories of increased BMI:

- "Overweight" is a BMI of 25 to 29.9
- "Obesity" is a BMI of 30 or higher
- Obesity can be categorized as class I (BMI of 30.0 to 34.9), class 2 (BMI of 35.0 to 39.9), or class 3 (BMI of >/=40).

The 2016 **American Academy of Family Physicians (AAFP)** recommended:

- Physicians should screen all patients over 18 years for obesity with measurement of body mass index (BMI) or waist circumference. **Grade B**

The 2016 **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

Core Recommendations for medical care of patients with obesity:

- The evaluation of patients for risk and existing burden of weight-related complications is a critical component of care and should be considered in clinical decisions and the therapeutic plan for weight-loss therapy **(Grade D).**

Chronic Disease Prevention and Treatment

- The modality and intensity of obesity interventions should be based on the primary, secondary, and tertiary phases of disease prevention; this 3-phase paradigm for chronic disease aligns with the pathophysiology and natural history of obesity and provides a rational framework for appropriate treatment at each phase of prevention **(Grade C; BEL 4, upgraded due to high relevance to natural history of the disease)**.

Table 5. Definitions, Goals, and Methods for Phases of Prevention in Chronic Disease: General Practices in Chronic Disease and Specific Practices in Obesity

Phase of Intervention	Definition and Goals	Methods of Prevention
Primary Prevention	GENERAL: • Prevent a disease from occurring	GENERAL: • Eliminate risk factors, remove causes, or increase resistance to disease
	OBESITY: • Prevent the development of overweight and obesity	OBESITY: • Educate the public • Built environment • Promote healthy eating and regular physical activity
Secondary Prevention	GENERAL: • Halt the progression of disease from its early stage prior to complications to a more severe stage • Arrest the disease process to prevent complications or sequelae	GENERAL: • Use a screening test and follow-up diagnosis, followed by treatment
	OBESITY: • Prevent future weight gain and the development of weight-related complications in patients with overweight or obesity	OBESITY: • Screen using BMI • Diagnose using BMI and evaluation for complications • Treat with lifestyle/behavioral intervention ± weight-loss medications
Tertiary Prevention	GENERAL: • Use clinical activities that reduce complications and prevent further deterioration	GENERAL: • Use treatment strategies that limit adverse consequences of a disease on health
	OBESITY: • Treat with weight-loss therapy to eliminate or ameliorate weight-related complications and prevent disease progression	OBESITY: • Treat with lifestyle/behavioral intervention plus weight-loss medications • Consider bariatric surgery

Abbreviation: BMI = body mass index.

Optimally screening or aggressively case-find for overweight and obesity:

- All adults should be screened annually using a BMI measurement; in most populations a cutoff point of ≥25 kg/m2 should be used to initiate further evaluation of overweight or obesity **(Grade A; BEL 2, upgraded due to high relevance)**.

Best anthropomorphic criteria for defining excess adiposity in diagnosis of overweight and obesity:

- BMI should be used to confirm an excessive degree of adiposity and to classify individuals as having overweight (BMI 25-29.9 kg/m2) or obesity (BMI ≥30 kg/m2), after taking into account age, gender, ethnicity, fluid status, and muscularity; therefore, clinical evaluation and judgment must be used when BMI is employed as the anthropometric indicator of excess adiposity, particularly in athletes and those with sarcopenia **(Grade A; BEL 2, upgraded due to high relevance)**.
- Other measurements of adiposity (eg, bioelectric impedance, air/water displacement plethysmography, or dual-energy x-ray absorptiometry) may be considered at the clinician's discretion if BMI and physical examination results are equivocal or require further evaluation **(Grade C, BEL 2, downgraded due to evidence gaps)**. However, the clinical utility of these measures is limited by availability, cost, and lack of outcomes data for validated cutoff points **(Grade B; BEL 2)**.

Table 6. Classification of Overweight and Obesity by BMI and Waist Circumference (31 [EL 4; NE])

Classification	BMI		Waist	
	BMI (kg/m²)	Comorbidity Risk	Waist Circumference and Comorbidity Risk	
			Men ≤40 in (102 cm) Women ≤35 in (88 cm)	Men >40 in (102 cm) Women >35 in (88 cm)
Underweight	<18.5	Low but other problems		
Normal weight	18.5–24.9	Average		
Overweight	25–29.9	Increased	Increased	High
Obese class I	30–34.9	Moderate	High	Very high
Obese class II	35–39.9	Severe	Very high	Very high
Obese class III	≥40	Very severe	Extremely high	Extremely high

Abbreviations: BMI = body mass index; in = inches.

Waist circumference as addition to BMI to indicate adiposity risk

- When evaluating patients for adiposity-related disease risk, waist circumference should be measured in all patients with BMI <35 kg/m2 **(Grade A; BEL 2, upgraded due to high relevance)**. In many populations, a waist circumference cutoff point ≥94 cm in men and ≥80 cm in women should be considered at risk and consistent with abdominal obesity; in the United States and Canada cutoff points that can be used to indicate increased risk are ≥102 cm for men and ≥88 cm for women **(Grade A; BEL 2, upgraded due to high relevance)**.

Table 7. Waist Circumference Thresholds for Abdominal Obesity (32 [EL4; NE])

POPULATION	ORGANIZATION	MEN	WOMEN
Europid	IDF	≥94 cm ≥37 inches	≥80 cm ≥31 inches
Caucasian	WHO	≥94 cm (⬆ risk) ≥37 inches ≥102 cm (⬆⬆ risk) ≥40 inches	≥80 cm (⬆ risk) ≥31 inches ≥88 cm (⬆⬆ risk) ≥35 inches
United States	AHA/NHLBI (ATPIII)	≥102 cm ≥40 inches	≥88 cm ≥35 inches
Canada	Health Canada	≥102 cm ≥40 inches	≥88 cm ≥35 inches
European	European Cardiovasc. Societies	≥102 cm ≥40 inches	≥88 cm ≥35 inches
Asian (including Japanese)	IDF	≥90 cm ≥35 inches	≥80 cm ≥31 inches
Asian	WHO	≥90 cm ≥35 inches	≥80 cm ≥31 inches
Japanese	Japanese Obesity Society	≥85 cm ≥33 inches	≥90 cm ≥35 inches
China	Cooperative Task Force	≥85 cm ≥33 inches	≥80 cm ≥31 inches
Middle East, Mediterranean	IDF	≥94 cm ≥37 inches	≥80 cm ≥31 inches
Sub-Saharan African	IDF	≥94 cm ≥37 inches	≥80 cm ≥31 inches
Ethnic Central and South American	IDF	≥90 cm ≥35 inches	≥80 cm ≥31 inches

Abbreviations: AHA = American Heart Association; ATPIII = Adult Treatment Panel III; IDF = International Diabetes Federation; WHO = World Health Organization.

BMI and waist circumference at all levels of BMI, ethnicities, gender, and age

- BMI cutoff point value of ≥23 kg/m2 should be used in the screening and confirmation of excess adiposity in South Asian, Southeast Asian, and East Asian adults **(Grade B; BEL 2)**.
- Region- and ethnic-specific cutoff point values for waist circumference should be used as measures of abdominal adiposity and disease risk; in South Asian, Southeast Asian, and East Asian adults, men with values ≥85 cm and women ≥74 to 80 cm should be considered at risk and consistent with abdominal obesity **(Grade B; BEL 2)**.

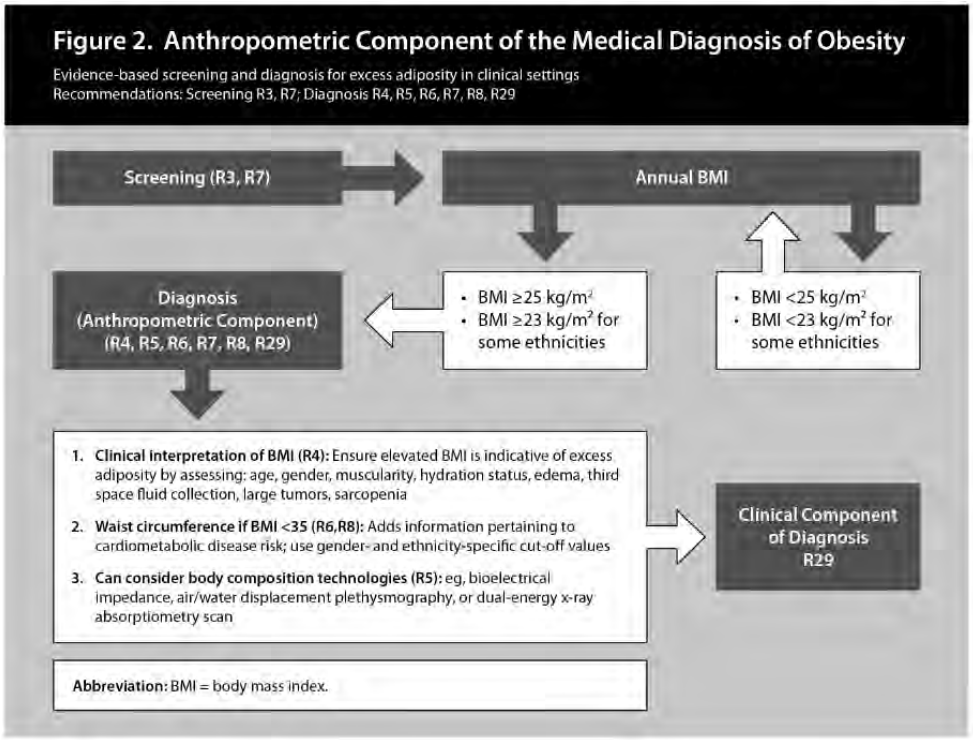


Figure 5. Diagnosis and Medical Management of Obesity

DIAGNOSIS		COMPLICATION-SPECIFIC STAGING AND TREATMENT		
Anthropometric Component (BMI kg/m²)	Clinical Component	Disease Stage	Chronic Disease Phase of Prevention	Suggested Therapy (based on clinical judgment)
<25 <23 in certain ethnicities waist circumference below regional/ethnic cutoffs		Normal weight (no obesity)	Primary	• **Healthy lifestyle:** healthy meal plan/physical activity
25–29.9 23–24.9 in certain ethnicities	Evaluate for presence or absence of adiposity-related complications and severity of complications • Metabolic syndrome • Prediabetes • Type 2 diabetes • Dyslipidemia • Hypertension • Cardiovascular disease • Nonalcoholic fatty liver disease • Polycystic ovary syndrome • Female infertility • Male hypogonadism • Obstructive sleep apnea • Asthma/reactive airway disease • Osteoarthritis • Urinary stress incontinence • Gastroesophageal reflux disease • Depression	Overweight stage 0 (no complications)	Secondary	• **Lifestyle therapy:** Reduced-calorie healthy meal plan/physical activity/behavioral interventions
≥30 ≥25 in certain ethnicities		Obesity stage 0 (no complications)	Secondary	• **Lifestyle therapy:** Reduced-calorie healthy meal plan/physical activity/behavioral interventions • **Weight-loss medications:** Consider after lifestyle therapy fails to prevent progressive weight gain (BMI ≥27)
≥25 ≥23 in certain ethnicities		Obesity stage 1 (1 or more mild-moderate complications)	Tertiary	• **Lifestyle therapy:** Reduced-calorie healthy meal plan/physical activity/behavioral interventions • **Weight-loss medications:** Consider after lifestyle therapy fails to achieve therapeutic target or initiate concurrent with lifestyle therapy. (BMI ≥27)
≥25 ≥23 in certain ethnicities		Obesity stage 2 (at least 1 severe complication)	Tertiary	• **Lifestyle therapy:** Reduced-calorie healthy meal plan/physical activity/behavioral interventions • **Add weight-loss medication:** Initiate concurrent with lifestyle therapy. (BMI ≥27) • **Consider bariatric surgery:** (BMI ≥35)

a. All patients with BMI ≥25 have either overweight stage 0, obesity stage 0, obesity stage 1, or obesity stage 2, depending on the initial clinical evaluation for presence and severity of complications. These patients should be followed over time and evaluated for changes in both anthropometric and clinical diagnostic components. The diagnoses of overweight/obesity stage 0, obesity stage 1, and obesity stage 2 are not static, and disease progression may warrant more aggressive weight-loss therapy in the future. BMI values ≥25 have been clinically confirmed to represent excess adiposity after evaluation for muscularity, edema, sarcopenia, etc.
b. Stages are determined using criteria specific to each obesity-related complication; stage 0 = no complication; stage 1 = mild-to-moderate; stage 2 = severe.
c. Treatment plans should be individualized; suggested interventions are appropriate for obtaining the sufficient degree of weight loss generally required to treat the obesity-related complication(s) at the specified stage of severity.
d. BMI ≥27 is consistent with the prescribing information mandated by the US Food and Drug Administration for weight-loss medications.

Abbreviation: BMI = body mass index.

The 2015 **European Guidelines** for Obesity Management in Adults recommended the following:

Table 1. BMI categories (WHO 1997)

Category	BMI, kg/m^2
Underweight	<18.5
Healthy weight	18.5–24.9
Pre-obese state	25.0–29.9
Obesity grade I	30.0–34.9
Obesity grade II	35.0–39.9
Obesity grade III	≥40

In 2015 **Canadian Task Force on Preventative Health Care** recommended the following:

- Practitioners should use clinical judgement to decide the frequency with which patients should have their weight and health status assessed.

Box 2: Summary of recommendations for clinicians and policy-makers

Measurement of BMI

This recommendation applies to adults (≥ 18 yr) presenting to primary care. These recommendations do not apply to people with eating disorders or who are pregnant.

- We recommend measuring height, weight and calculating BMI* at appropriate† primary care visits. *(Strong recommendation; very low-quality evidence)*

Prevention of weight gain

This recommendation applies to apparently healthy adults (≥ 18 yr) who present to primary care. The recommendation does not apply to people with eating disorders, or who are underweight, pregnant, overweight or obese (BMI ≥ 25).

- We recommend that practitioners not offer formal, structured interventions‡ aimed at preventing weight gain in normal-weight adults.§ Adults who are overweight or obese may be candidates for weight-loss treatment. *(Weak recommendation; very low-quality evidence)*

Management of overweight and obesity

These recommendations apply to adults (≥ 18 yr) who are overweight or obese (BMI 25–39.9). Pregnant women and people with health conditions where weight loss is inappropriate are excluded. These guidelines do not apply to people with a BMI of 40 or greater, who may benefit from specialized bariatric programs.

- For adults who are obese (BMI 30–39.9) and are at high risk of diabetes,¶ we recommend that practitioners offer or refer to structured behavioural interventions‡ aimed at weight loss. *(Strong recommendation; moderate-quality evidence)*
- For adults who are overweight or obese, we recommend that practitioners offer or refer to structured behavioural interventions‡ aimed at weight loss. *(Weak recommendation; moderate-quality evidence)*
- For adults who are overweight or obese, we recommend that practitioners not routinely offer pharmacologic interventions (orlistat or metformin) aimed at weight loss.** *(Weak recommendation; moderate-quality evidence)*

Note: BMI = body mass index.
*BMI categories are as follows: underweight (BMI < 18.5); normal weight (BMI 18.5–24.9); overweight (BMI 25.0–29.9); obese (BMI ≥ 30).
†Appropriate visits include wellness visits, visits for medication renewal and other visits where the primary care practitioner deems it appropriate.
‡Formal structured interventions are behavioural modification programs that involve several sessions or interactions that take place over weeks to months. Interventions examined for prevention of weight gain included behaviourally based prevention interventions focused on diet, increasing exercise, making lifestyle changes or any combination of these. These could be offered in primary care settings or settings where primary care practitioners may refer patients, such as credible commercial or community programs. Recommended interventions for management of overweight and obesity include intensive behaviourally based interventions focused on diet, increasing exercise, making lifestyle changes or any combination of these. Lifestyle interventions generally included counselling, education or support, and/or environmental changes in addition to changes in exercise and/or diet.
§Practitioners should use their judgment in determining whether some individuals may benefit from being offered or referred to interventions for weight-gain prevention, such as individuals with metabolic risk factors, high waist circumference, or family history of type 2 diabetes or cardiovascular disease. For adults who express concerns about weight gain or who are motivated to make lifestyle changes, practitioners should also consider offering or referring to prevention interventions and must help each person arrive at a management decision consistent with his or her values and preferences.
¶High-risk status is defined by a 10-year risk of diabetes of 33% or greater,[12] which can be assessed using the CANRISK (Canadian Diabetes Risk) or FINDRISC (Finnish Type 2 Diabetes Risk Score) risk assessment tools.[20,21]
**The task force examined the use of metformin and orlistat for weight loss only and not for the treatment of other conditions, such as diabetes.

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following in 2014:

- Aim to create a supportive environment that helps a child who is overweight or who has obesity, and their family, make lifestyle changes.

Identification and classification of overweight and obesity

- Use clinical judgement to decide when to measure a person's height and weight. Opportunities include registration with a general practice, consultation for related conditions (such as type 2 diabetes and cardiovascular disease) and other routine health checks.

Measures of overweight and obesity

- Use BMI as a practical estimate of adiposity in adults. Interpret BMI with caution because it is not direct measure of adiposity.
- Think about waist circumference, in addition to BMI, to people with a BMI less than 35 kg/m^2.

Adults and Children

- Do not use bioimpedance as a substitute for BMI as a measure of general adiposity.

Classification of overweight and obesity

Adults:

- Define the degree of overweight or obesity in adults using the following table:

Classification	BMI (kg/m^2)
Healthy weight	18.5–24.9
Overweight	25–29.9
Obesity I	30–34.9
Obesity II	35–39.9
Obesity III	40 or more

- Interpret BMI with caution in highly muscular adults because it may be a less accurate measure of adiposity in this group. Some other population groups, such as people of Asian family origin and older people, have comorbidity risk factors that are of concern at different BMIs (lower for adults of an Asian family origin and higher for older people). Use clinical judgement when considering risk factors in these groups, even in people not classified as overweight or obese.
- Base assessment of the health risks associated with being overweight or obese in adults on BMI and waist circumference as follows:

BMI classification	Waist circumference		
	Low	High	Very high
Overweight	No increased risk	Increased risk	High risk
Obesity I	Increased risk	High risk	Very high risk
For men, waist circumference of less than 94 cm is low, 94–102 cm is high and more than 102 cm is very high For women, waist circumference of less than 80 cm is low, 80–88 cm is high and more than 88 cm is very high			

- Give adults information about their classification of clinical obesity and the impact this has on risk factors for developing other long-term health problems.
- Base the level of intervention to discuss with the patient initially as follows:

BMI classification	Waist circumference			Comorbidities present
	Low	High	Very high	
Overweight	1	2	2	3
Obesity I	2	2	2	3
Obesity II	3	3	3	4
Obesity III	4	4	4	4

1	General advice on healthy weight and lifestyle
2	Diet and physical activity
3	Diet and physical activity; consider drugs
4	Diet and physical activity; consider drugs; consider surgery

- The level of intervention should be higher for patients with comorbidities, regardless of their waist circumference. Adjust the approach as needed, depending on the person's clinical need and potential to benefit from losing weight.

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

- Screen adult patients to establish a diagnosis of overweight or obesity by calculating body mass index (BMI), and document the presence of overweight or obesity in the medical record. **[B]**
- Screen for overweight and obesity at least annually. **[EO]**
- Assess for the presence of obesity-associated conditions among overweight patients or patients with increased waist circumference. **[B]**
- Perform a targeted assessment on overweight and obese patients. In addition to the basic medical history and physical examination, assess for factors contributing to obesity. **[EO]**

The **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** in 2013 recommended:

Table 4. Summary of Recommendations for Obesity

Recommendations	NHLBI Grade	NHLBI ES	ACC/AHA COR	ACC/AHA LOE
Identifying Patients Who Need to Lose Weight (BMI and Waist Circumference)				
1a. Measure height and weight and calculate BMI at annual visits or more frequently.	E (Expert Opinion)	CQ2	I	C
1b. Use the current cutpoints for overweight (BMI 25.0–29.9 kg/m^2) and obesity (BMI ≥30 kg/m^2) to identify adults who may be at elevated risk of CVD and the current cutpoints for obesity (BMI ≥30 kg/m^2) to identify adults who may be at elevated risk of mortality from all causes.	A (Strong)	CQ2	I	B
1c. Advise overweight and obese adults that the greater the BMI, the greater the risk of CVD, type 2 diabetes, and all-cause mortality.	A (Strong)	CQ2	I	B
1d. Measure waist circumference at annual visits or more frequently in overweight and obese adults. Advise adults that the greater the waist circumference, the greater the risk of CVD, type 2 diabetes, and all-cause mortality. The cutpoints currently in common use (from either NIH/NHLBI or WHO/IDF) may continue to be used to identify patients who may be at increased risk until further evidence becomes available.	E (Expert Opinion)	CQ2	IIa	B

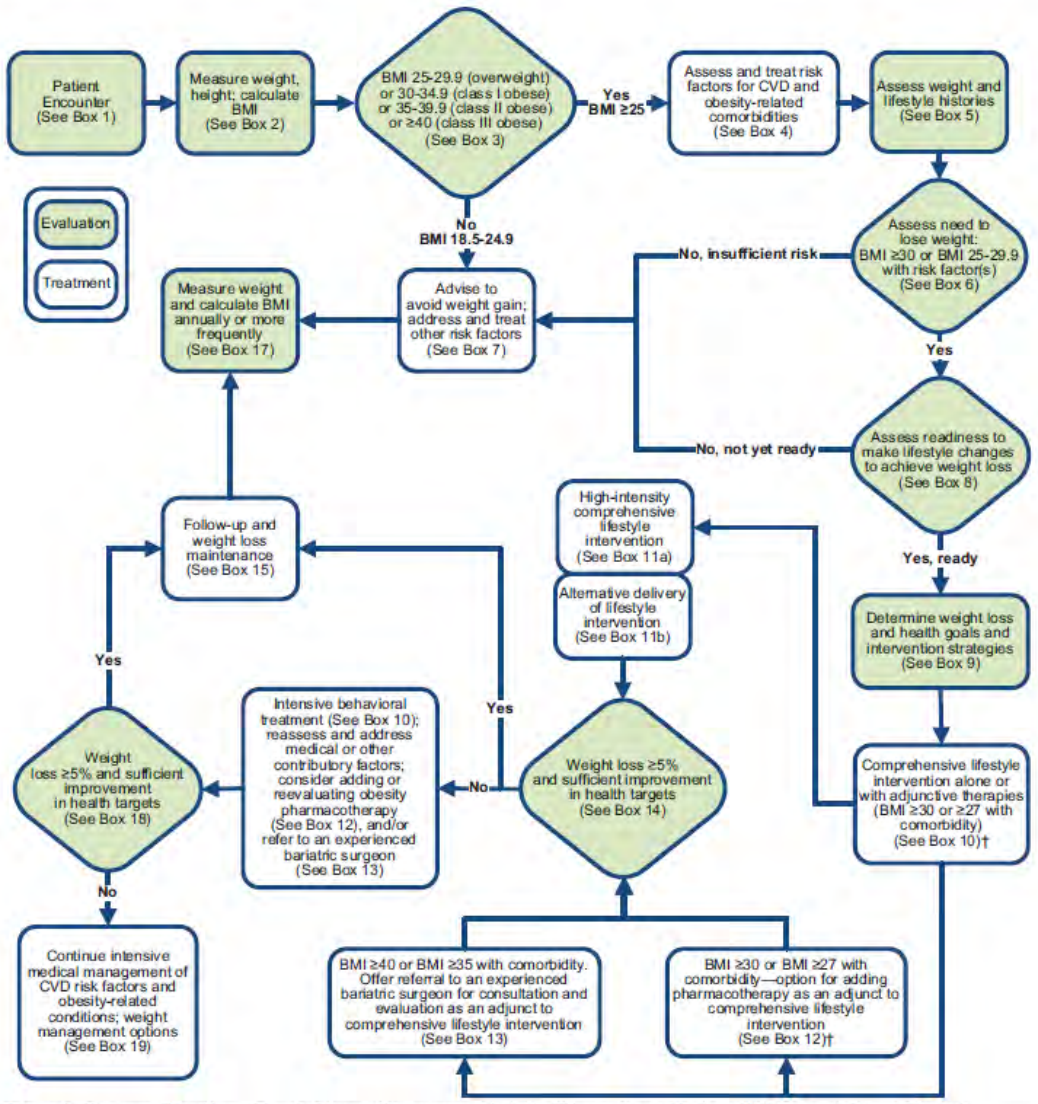


Figure 1. Treatment Algorithm—Chronic Disease Management Model for Primary Care of Patients With Overweight and Obesity*.
*This algorithm applies to the assessment of overweight and obesity and subsequent decisions based on that assessment. Each step (designated by a box) in this process is reviewed in Section 2.2 and expanded on in subsequent sections. †BMI cutpoint determined by the FDA and listed on the package inserts of FDA-approved obesity medications. BMI indicates body mass index; CVD, cardiovascular disease; and FDA, US Food and Drug Administration.

- **Box 1: Patient Encounter for Obesity Prevention and Management** – A patient encounter for obesity prevention and management is defined as an interaction with a PCP who assesses a patient's weight status to determine presence of overweight or obesity and need for further assessment and treatment.
- **Box 2: Measure Weight and Height; Calculate BMI** – With the patient wearing light clothing or an examination gown and no shoes, weight and height are measured and the BMI calculated. BMI can be calculated manually (weight in kg/[height in meters]^2 or electronically by using the electronic medical record or other resources. The BMI should be documented in the patient medical record.
- **Box 3: BMI 25 – 29.9 (overweight), BMI 30-34.9 (class I obese), BMI 35-39.9 (class II obese), or BMI >/=40 class III obese [extreme obesity])** – These BMI cutpoints define overweight and class I to III obese individuals and identifying adults who may be at increased risk for CVD and other obesity-related conditions. Within these categories, additional personal risk assessment is needed because degree of risk can vary.

Adult: Primary Literature:

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adult
Modality: Edmonton obesity staging system
Outcome: Postoperative outcome and 30-day mortality after metabolic surgery

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☐ Low
☒ Very Low

Risk of Bias across studies:
☒ High
☐ Medium
☐ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - *Unknown*

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Chiappetta, S., et al. Year Published: 2016 Location: Germany	To determine whether the Edmonton Obesity Staging System (EOSS) can be used in	**Size:** 534 patients	**Type:** Prospective Study	**Results: The mean BMI was 45.57 kg/m² (range 35-64.5) for LRYGB**	**Study Limitations:** ☐ None **Non-Randomized Studies**

Journal: *Surgery for Obesity & Related Diseases*	predicting postoperative outcome and 30-day mortality after metabolic surgery.	**Inclusion Criteria:** Patients undergoing LSG, LRYGB, or LOLGB as the first surgical treatment for severe obesity. **Exclusion Criteria:** Bariatric Surgery in a patient's medical history.	**Methods:** Prospective data was collected for patients undergoing laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-Y gastric bypass (LRYGB), or laparoscopic omega-loop gastric bypass (LOLGB). The data collected included preoperative EOSS score, gender, age, BMI, waist circumference, waist-to-hip ratio, co-morbidities, early postoperative complications, and 30-day mortality.	**patients (n = 168), 53.27 kg/m (range 35.1-82.1) for LSG patients (n = 282), and 49.42 kg/m (range 36-73.1) for LOLGB patients (n = 84). The total postoperative complication rate was 8.99%. The most common EOSS stage was 2 (70.6% of patients), followed by stages 3 (12.55%), 1 (11.61%), and 0 (5.06%). The postoperative complication rates after LRYGB, LSG, and LOLGB were 0% for EOSS 0 and 1.61% for EOSS 1. The postoperative complication rates were 8.22% for EOSS 2 and 22.39% for EOSS 3.**	☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up

References:

1. Chiappetta, S., et al. (2016). "The importance of the Edmonton Obesity Staging System in predicting postoperative outcome and 30-day mortality after metabolic surgery." Surgery for Obesity & Related Diseases **12**(10): 1847-1855.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adult Modality: BMI Outcome: Detection of body adiposity		
Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Okorodudu, D. O., et al. Year Published: 2010 Location: University of Missouri Journal: *International Journal of Obesity*	To perform a systematic review and meta-analysis of studies that assessed the performance of body mass index (BMI) to detect body adiposity.	**Size:** 25 studies; 31,968 patients. **Inclusion Criteria:** (1) study must have assessed the performance of BMI to identify excess boy fat; (2) provided standard values of diagnostic performance (for example sensitivity, specificity, positive predictive value, negative predictive value); and (3) used a body composition technique (for example dual energy X-ray absorptiometry, air-displacement plethsymorgraphy, hydrostatic weighing) as cold standard.	**Type:** Systematic Review	**Results: Commonly used BMI cutoffs to diagnose obesity showed a pooled sensitivity to detect high adiposity of 0.50 (95% confidence interval (CI): 0.43-0.57) and a pooled specificity of 0.90 (CI: 0.86-0.94). Positive LR was 5.88 (CI: 4.24-8.15), I (2)=97.8%; the negative LR was 0.43 (CI: 0.37-0.50), I (2)=98.5%; and the DOR was 17.91 (CI: 12.56-25.53), I (2)=91.7%. Analysis of studies that used BMI cutoffs >or=30 had a pooled sensitivity of 0.42 (CI: 0.31-0.43) and a pooled specificity of 0.97 (CI: 0.96-0.97).** Cutoff values and regional origin of the studies can only partially explain the heterogeneity seen in pooled DOR estimates.	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Okorodudu, D. O., et al. (2010). "Diagnostic performance of body mass index to identify obesity as defined by body adiposity: a systematic review and meta-analysis." International Journal of Obesity **34**(5): 791-799.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adult having extreme obesity
Modality: Body composition parameters
Outcome: Fat-free mass (FFM, kg), fat mass (FM, kg), and body fat (BF, %)

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - *Unknown* ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Hames, K.C., et al. Year Published: 2014 Location: University of Pittsburgh Journal: *Obesity*	To compare body composition parameters estimated by air displacement plethysmography (ADP) to dual X-ray absorptiometry (DXA) in body mass index (BMI) classifications that include extremely obese (BMI >= 40.0 kg/m(2)), and to examine if differences between analyses were influenced by BMI.	**Size:** 109 participants **Inclusion Criteria:** Men and women greater than 18 years of age. **Exclusion Criteria:** Women who were pregnant.	**Type:** Diagnostic Study **Intervention:** Patients' fat free mass (FFM,kg), fat mass (FM,kg) and body fat (BF,%) were analyzed with both technologies.	**Results: All outcome measures of ADP and DXA were highly correlated (r >= 0.95, P < 0.001 for FFM, FM, and BF), but Bland-Altman analyses revealed significant bias (P < 0.01 for all). ADP estimated greater FFM and lower FM and BF (P < 0.01 for all). BMI explained 27% of the variance in differences between FFM measurements (P < 0.001), and 37 and 33% of the variances in differences between FM and BF measurements, respectively (P < 0.001 for both). Within normal weight and overweight classifications, ADP estimated greater FFM and lower FM and BF (P < 0.001 for all), but the opposite occurred within the extremely obese classification; ADP estimated lower FFM and greater FM and BF (P < 0.05 for all).**	**Study Limitations:** ☐ None ***Diagnostic Studies*** ☒ Patients not enrolled in consecutive or random manner ☐ Case-control study ☐ No independent, blind comparison between index test and reference test ☐ Not all patients received reference test

References:

1. Hames, K. C., et al. (2014). "Body composition analysis by air displacement plethysmography in normal weight to extremely obese adults." Obesity **22**(4): 1078-1084.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adult
Modality: Waist-to-height, waist circumference, BMI
Outcome: Diagnostic accuracy

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) – *Unknown* ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - # of patients included in analysis not included*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Browning, L.M., et al. Year Published: 2010 Location: UK Journal: *Obesity Reviews*	To differentiate the screening potential of waist-to-height ratio (WHtR) and waist circumference (WC) for adult cardiometabolic risk in people of different nationalities and to compare both with body mass index (BMI).	**Size:** 31 studies **Inclusion Criteria:** Studies using receiver operating characteristics (ROC) curves for assessing the discriminatory power of anthropometric indices in distinguishing adults with hypertension, type-2 diabetes, dyslipidaemia, metabolic syndrome, and general cardiovascular outcomes (CVD). **Exclusion Criteria**: Literature reviews, intervention studies, studies in children and adolescents.	**Type:** Systematic Review	**Results:** Using data on all outcomes, averaged within study group, **WHtR had significantly greater discriminatory power compared with BMI. Compared with BMI, WC improved discrimination of adverse outcomes by 3% (P < 0.05) and WHtR improved discrimination by 4-5% over BMI (P < 0.01). Most importantly, statistical analysis of the within-study difference in AUC showed WHtR to be significantly better than WC for diabetes, hypertension, CVD and all outcomes (P < 0.005) in men and women.** For the first time, robust statistical evidence	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

				from studies involving more than 300 000 adults in several ethnic groups, shows the superiority of WHtR over WC and BMI for detecting cardiometabolic risk factors in both sexes. Waist-to-height ratio should therefore be considered as a screening tool. **Table 2** AUC value with 95% confidence intervals for anthropometric indices against health outcomes in men and women Mean AUC / Lower 95% / Upper 95% / *P* value for comparison with BMI **Diabetes** Men (*n* = 22 groups) BMI 0.663 0.639 0.686 WC 0.699 0.680 0.718 0.020 WHtR 0.711 0.694 0.728 0.001 Women (*n* = 24 groups) BMI 0.699 0.668 0.730 WC 0.742 0.720 0.765 0.026 WHtR 0.752 0.728 0.775 0.007 **HT** Men (*n* = 18 groups) BMI 0.654 0.627 0.682 WC 0.677 0.652 0.701 0.24 WHtR 0.690 0.668 0.713 0.047 Women (*n* = 19 groups) BMI 0.693 0.659 0.726 WC 0.718 0.690 0.746 0.25 WHtR 0.732 0.707 0.757 0.06 **Dyslipidaemia/high TG** Men (*n* = 16 groups) BMI 0.675 0.655 0.696 WC 0.690 0.651 0.709 0.81 WHtR 0.685 0.661 0.709 0.55 Women (*n* = 17 groups) BMI 0.653 0.630 0.677 WC 0.683 0.658 0.707 0.09 WHtR 0.699 0.663 0.716 0.047 **MS** Men (*n* = 12 groups) BMI 0.721 0.697 0.746 WC 0.747 0.703 0.792 0.32 WHtR 0.750 0.697 0.803 0.33 Women (*n* = 13 groups) BMI 0.724 0.699 0.750 WC 0.754 0.720 0.787 0.176 WHtR 0.762 0.735 0.790 0.047 **CVD** Men (*n* = 6 groups) BMI 0.616 0.572 0.661 WC 0.669 0.620 0.717 0.12 WHtR 0.707 0.658 0.756 0.007 Women (*n* = 6 groups) BMI 0.633 0.552 0.713 WC 0.683 0.604 0.761 0.38 WHtR 0.704 0.619 0.789 0.23 **All outcomes (mean of measured outcomes for each study)** Men (*n* = 31 groups) BMI 0.667 0.650 0.684 WC 0.694 0.678 0.709 0.026 WHtR 0.704 0.689 0.719 0.002 Women (*n* = 39 groups) BMI 0.691 0.658 0.704 WC 0.714 0.696 0.731 0.022 WHtR 0.725 0.709 0.741 0.002 Statistical test (Q statistic) for heterogeneity in effect sizes between indices (WC vs. BMI; WHtR vs. BMI). For more powerful test of the hypothesis that the difference between WC and WHtR equals zero, see Table 3. AUC, area under the curve; BMI, body mass index; CVD, cardiovascular disease; HT, hypertension; MS, metabolic syndrome; TG, triglyceride; WC, waist circumference; WHtR, waist-to-height ratio.	

References:

1. Ashwell, M., et al. (2012). "Waist-to-height ratio is a better screening tool than waist circumference and BMI for adult cardiometabolic risk factors: systematic review and meta-analysis." Obesity Reviews **13**(3): 275-286

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Waist-to-height, waist circumference, BMI
Outcome: Predictors of diabetes and CVD

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

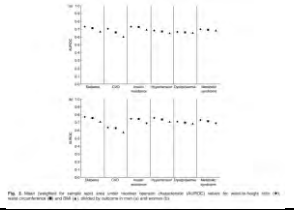
☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - # of patients not included*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Browning, L.M., et al. Year Published: 2010 Location: UK Journal: *Nutrition Research Reviews*	To explore waist-to-height ratio (WHtR) and waist circumference (WC) or BMI as predictors of diabetes and CVD.	**Size:** 78 articles **Inclusion Criteria:** (1) human subjects, male, female or mixed, any age, adults or children, any ethnic group; (2) primary studies, either prospective or cross-sectional design; (3) WHtR and either BMI or WC measured at least once; (4) studies must also have a mortality, a cardiometabolic disease endpoint or cardiometabolic risk outcome measure, and present the relationship between obesity and the disease endpoint or risk outcome.	**Type:** Systematic Review	**Results:** Twenty-two prospective analyses showed that WHtR and WC were significant predictors of cardiometabolic outcomes more often than BMI, with similar OR, sometimes being significant predictors after adjustment for BMI. Observations from cross-sectional analyses, forty-four in adults, thirteen in children, supported these predictions. **Receiver operator characteristic (ROC) analysis revealed mean area under ROC (AUROC) values of 0.704, 0.693 and 0.671 for WHtR, WC and BMI, respectively.** Mean boundary values for WHtR, covering all	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		Exclusion Criteria: (1) literature reviews, intervention studies (although include and use baseline data if they fit inclusion criteria); (2) papers not written in English.		cardiometabolic outcomes, from studies in fourteen different countries and including Caucasian, Asian and Central American subjects, were 0.50 for men and 0.50 for women. **WHtR and WC are therefore similar predictors of diabetes and CVD, both being stronger than, and independent of, BMI.** To make firmer statistical comparison, a meta-analysis is required. The AUROC analyses indicate that WHtR may be a more useful global clinical screening tool than WC, with a weighted mean boundary value of 0.5, supporting the simple public health message 'keep your waist circumference to less than half your height'. 	

References:

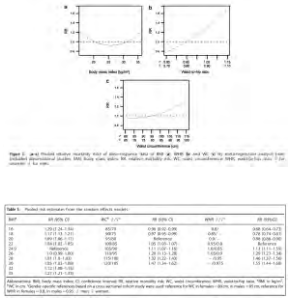
1. Browning, L. M., et al. (2010). "A systematic review of waist-to-height ratio as a screening tool for the prediction of cardiovascular disease and diabetes: 0.5 could be a suitable global boundary value." Nutrition Research Reviews **23**(2): 247-269.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: General and abdominal obesity parameters
Outcome: Relation to mortality

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies: ☒ High ☐ Medium ☐ Low	**Low Quality Rating if:** ☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Carmienke, S., et al. Year Published: 2013 Location: Germany Journal: *European Journal of Clinical Nutrition*	To systematically review the associations of body mass index (BMI), waist-to-hip ratio (WHR), waist circumference (WC) and waist-to-height ratio (WHtR) with all-cause mortality in prospective cohort studies.	**Size:** 18 studies, comprising 689,465 participants and 48,421 deaths during 5-24 years of follow-up. **Inclusion Criteria:** (i) Prospective cohort studies and observational follow-up studies of non-intervention groups of community-based randomised controlled trials, which analysed (ii) allcause mortality as an outcome, (iii) reported BMI and at least one abdominal AP (WC, WHR or WHtR) as exposure variables at baseline, (iv) had a sample size of at least 4000 participants, (v) a follow-up of at least 3 years and (vi) participants with a baseline age of at least 18 years. **Exclusion Criteria**: Articles examining pregnant women, terminally ill or frail patients, groups with specific diseases or residents in nursing homes. Due to differences in the AP	**Type:** Systematic Review	**Results:** The studies were heterogeneous, mainly due to differences in categorization of anthropometric parameters (AP) and different approaches to statistical analysis. **Both general and abdominal obesity measures were significantly associated with mortality. In analyses using categorical variables, BMI and WC showed predominantly U- or J-shaped associations with mortality, whereas WHR and WHtR demonstrated positive relationships with mortality. All measures showed similar risk patterns for upper quantiles in comparison to reference quantiles. The parameters of general and abdominal obesity each remained significantly associated with mortality when adjusted for the other.** This evidence suggests that abdominal obesity measures such as WC or WHR, show information independent to measures of general obesity	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		mortality relationships between the various ethnic groups in both general and abdominal obesity parameters, studies were excluded with <75% Caucasian participants in order to reduce complexity of the analyses. Also excluded were cross-sectional analyses, case reports, comments, letters, reviews and study samples that combined analyses with another risk factor of mortality.		and should be used in clinical practice, in addition to BMI, to assess obesity-related mortality in adults. 	

References:

1. Carmienke, S., et al. (2013). "General and abdominal obesity parameters and their combination in relation to mortality: a systematic review and meta-regression analysis." European Journal of Clinical Nutrition **67**(6): 573-585.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Genetic testing
Outcome: Identifying factors for obesity

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☐ Low
☒ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☒ High ☐ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - *Unknown* ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - Unknown*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations

Author: Collins, J., et al. Year Published: 2014 Location: Monash University, Australia Journal: *Journal of Human Nutrition & Dietetics*	A systematic review of the literature was undertaken to identify the factors associated with an interest in having predictive genetic testing for obesity, type II diabetes and heart disease amongst unaffected adults.	**Size:** 1 study **Inclusion Criteria:** (i) observational or experimental studies; (ii) written in English; (iii) conducted with adults living in the community without an existing diagnosis of the disease being studied (i.e. healthy adults); (iv) measuring interest or willingness to undergo a hypothetical predictive genetic test to determine personal risk of developing obesity, type II diabetes or heart disease; and (v) reporting factors (e.g. demographic, health, psychological factors) associated with interest in the test. **Exclusion Criteria**: Studies relating to genetic testing of foetuses or children were excluded, as were those related to monogenic inherited forms of cardiovascular disease (i.e. long QT syndrome), obesity (i.e. Prada–Willi syndrome) or diabetes (i.e. maturity onset diabetes in the young).	**Type**: Systematic Review	**Results: Interest in predictive genetic testing for obesity was greatest amongst those who perceived the risk of disease to be high and/or the outcomes of testing to be beneficial.**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

References:

1. Collins, J., et al. (2014). "A systematic review of the factors associated with interest in predictive genetic testing for obesity, type II diabetes and heart disease." Journal of Human Nutrition & Dietetics **27**(5): 479-488.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Patients with CAD
Modality: Central (waist circumference [WC] and waist-hip ratio [WHR]) and total obesity (body mass index [BMI]) measures
Outcome: Mortality

Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low					
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Coutinho, T., et al. Year Published: 2011 Location: Mayo Clinic Journal: *Journal of the American College of Cardiology*	To examine the association of central (waist circumference [WC] and waist-hip ratio [WHR]) and total obesity (body mass index [BMI]) measures with mortality in coronary artery disease (CAD) patients.	**Size:** 6 studies, 15,923 subjects **Inclusion Criteria:** Prospective cohort studies in which all reported subjects had: 1) CAD at baseline (defined as a previous history of myocardial infarction, percutaneous coronary intervention, and/or coronary artery bypass grafting); 2) measures of either WC or WHR; 3) mortality data on the basis of measures of WC or WHY; and 4) minimum follow-up of 6 months.	**Type:** Systematic Review	**Results:** There were 5,696 deaths after a median follow-up of 2.3 (interquartile range 0.5 to 7.4) years. **Central obesity was associated with mortality (hazard ratio [HR]: 1.70, 95% confidence interval [CI]: 1.58 to 1.83), whereas BMI was inversely associated with mortality (HR: 0.64, 95% CI: 0.59 to 0.69). Central obesity was also associated with higher mortality in the subset of subjects with normal BMI (HR: 1.70, 95% CI: 1.52 to 1.89) and BMI >=30 kg/m(2) (HR: 1.93, 95% CI: 1.61 to 2.32).**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Coutinho, T., et al. (2011). "Central obesity and survival in subjects with coronary artery disease: a systematic review of the literature and collaborative analysis with individual subject data." Journal of the American College of Cardiology **57**(19): 1877-1886.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: All age groups
Modality: Neck circumference (NC)
Outcome: Diagnostic accuracy

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☐ Medium
☒ Low

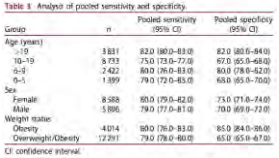
Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - Unknown*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Kroll, C., et al. Year Published: 2017 Location: Brazil Journal: *Annals of Human Biology*	To demonstrate the accuracy of neck circumference (NC) as a measure for assessing overweight and obesity in both sexes in different age groups.	**Size:** 11 studies **Inclusion Criteria**: Studies that measured NC to assess overweight and obesity in humans using BMI as the reference and without age restriction were eligible. **Exclusion Criteria**: Studies that did no use NC to diagnose overweight or obesity, that did not use BMI to evaluate weight status or that included patients with some comorbidity, studies that did not report sensitivity and specificity.	**Type:** Systematic Review	**Results: The best sensitivity and specificity were found for the age >19 years (82.0%, 82.0%), female (80.0%, 73.0%), and obese (80.0%, 85.0%) categories** 	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Kroll, C., et al. (2017). "The accuracy of neck circumference for assessing overweight and obesity: a systematic review and meta-analysis." Annals of Human Biology **44**(8): 667-677.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Index of overweight and obesity
Outcome: Cardiovascular risk factors

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☐ Medium
☒ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Lee, C.M., et al. Year Published: 2008 Location: University of Sydney, Australia Journal: *Journal of Clinical Epidemiology*	To determine which simple index of overweight and obesity is the best discriminator of cardiovascular risk factors.	**Size:** 10 studies, 88,514 subjects. **Inclusion Criteria:** Studies on adults (aged >/=18 years) that used ROC analysis to compare the discriminatory power of cardiovascular risk factors among all of the four indices and provided the area under the ROC curve (AUC) with 95% CI for BMI, WC, WHR, and WHtR for hypertension, type-2 diabetes, and/or dyslipidemia.	**Type:** Systematic Review	**Results:** *Hypertension:* **Statistical comparison of the AUC scores between each of the measures of abdominal obesity with BMI indicated that only WHtR (in males) was slightly, but significantly, better at discriminating hypertension compared with BMI (AUC for CMI = 0.64 vs AUC for WHtR = 0.68; P = 0.04). Females consistently had higher pooled AUCs, but significant difference between males and females was found only for BMI (P = 0.06).** The combinations of BMI and abdominal obesity measurs (WC, WHR, or	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				WHtR, in turn did not increase the discriminary capability of BMI for hypertension. *Type-2 diabetes* **Measures of abdominal obesity tended to give higher AUC compared with BMI, in both sexes, with the highest pooled AUC found for WHtR (0.73 for males and 0.76 for females) and the lowest pooled AUC found for BMI (0.67 for males and 0.69 for females). The tests for heterogeneity between each of the abdominal obesity measures with BMI showed significant differences between BMI and WHtR in males only (AUC for BMI = 0.67 vs. AUC for WHtR = 0.73; P < 0.01).** AUC values tended to be higher in females than in males, however, no statistically significant difference was observed between the two sexes. Similarly, the combinations of BMI and abdominal obesity measures (WC, WHR, or WHtR), in turn, did not increase discriminatory capability of BMI for type-2 diabetes. *Dyslipidemia* **Measures of abdominal obesity tended to give higher AUC compared with BMI, in both sexes, with the highest pooled AUC found for WHtR (0.67 for males and 0.68 for**	

				females) and the lowest pooled AUC (both 0.64) found for WC in males and BMI in females, but the differences were no significant. With the exception of BMI, females tended to have higher (but no significantly higher) AUC values than males. The combinations of BMI and abdominal obesity measures (WC, WHR, or WHtR), in turn, did not increase the discriminatory capability of BMI for dyslipidemia.	

References:

1. Lee, C. M., et al. (2008). "Indices of abdominal obesity are better discriminators of cardiovascular risk factors than BMI: a meta-analysis." Journal of Clinical Epidemiology **61**(7): 646-653.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Elderly adults
Modality: BMI, WC, BF
Outcome: Diagnostic accuracy

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - Unknown*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**

Author: Collins, J., et al. Year Published: 2014 Location: University of Pittsburg Journal: *Journal of Human Nutrition & Dietetics*	To conduct a systematic review of the literature was undertaken to identify the factors associated with an interest in having predictive genetic testing for obesity, type II diabetes and heart disease amongst unaffected adults.	**Size:** 5 studies **Inclusion Criteria:** Studies including average age >/=60 years.	**Type:** Systematic Review	**Results:** Although the correlation between BMI and BF percentage declines with age, most studies showed a reasonably **high correlation (0.73 to 0.93), even in quite elderly samples.** A single study showed a quite low correlation in men (0.37) and women (0.51) >65 years old. **The correlation between WC and BF percentage was fairly high (0.64 to 0.78),** whereas that between WHR and BF percentage was low. In one study, **elevated WC had high specificity (97% to 100%) but low sensitivity (33% to 64%)** for detecting generalized obesity (elevated BMI) or central obesity (elevated WHR). Two studies explored other anthropometric differences. One determined gender- and race/ethnicity-specific WC cut-off points corresponding to a BMI or 30 and found that the derived WC values did not differ appreciably by race/ethnicity. The other found that among Asians, a relatively low BMI corresponded with high BF (>40% in women and >30% in men).	**Study Limitations:** ☐ None ***Systematic Review*** ☒ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. McTigue, K. M., et al. (2006). "Obesity in older adults: a systematic review of the evidence for diagnosis and treatment." Obesity **14**(9): 1485-1497.

Question #2. What are the key elements of an appropriate health assessment for pediatric and adult patients who have overweight or obesity to evaluate an individual's health status and risks?

Pediatric: Guideline Recommendations:

In 2017, **US Preventive Services Task Force** (USPSTF) recommended the following for children and adolescent 6 years and older:

- *Risk Assessment*: All children and adolescents are at risk for obesity and should be screened; specific risk factors include parental obesity, poor nutrition, low levels of physical activity, inadequate sleep, sedentary behaviors, and low family income **(Grade B)**.
- *Blood Pressure in Children and Adolescents (Hypertension)*: The USPSTF concludes that the current evidence in insufficient to assess the balance of benefits and harms of screening for primary hypertension in asymptomatic children and adolescents to prevent subsequent cardiovascular disease in childhood or adulthood.
- *Lipid Disorders in Children and Adolescents*: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for lipid disorders in children and adolescents 20 years or younger.

In 2016, the **American Academy of Pediatrics** Preventing Obesity and Eating Disorders in Adolescents provided the following key features in identifying feeding disorders and eating disorders:

TABLE 1 Key Features of DSM-5 Diagnostic Criteria for Feeding Disorders and EDs

AN
- Restriction of food eaten leading to lower than expected body weight
- Intense fear of weight gain or being fat
- Body image distortion

Types: restricting or binge eating/purging

BN
- Binge eating in which
  - a larger amount of food is eaten within a 2-hour period compared with peers; and
  - there is a perceived lack of control during the time of the binge
- Repeated use of unhealthy behaviors after a binge to prevent weight gain: (vomiting; abuse of laxatives, diuretics, or other medications; food restriction; or excessive exercise)
- Behaviors occur at least once a week for 3 months
- Self-worth is overly based on body shape and weight
- Behaviors occur distinctly apart from AN

Binge-eating disorder
- Recurrent episodes of binge eating in which
  - a larger amount of food is eaten within a 2-hour period compared with peers; and
  - there is a perceived lack of control during the time of the binge

Bingeing episodes are associated with at least 3 of the following:
- eating faster than normal;
- eating until overly full;
- eating large quantities of food when not hungry;
- eating alone because of embarrassment about the quantity of food eaten; and
- feeling badly emotionally after eating

- Upset about bingeing
- Bingeing behavior occurs at least once a week for 3 months
- Bingeing is not followed by the use of unhealthy behaviors to purge and does not occur during AN or BN

Avoidant/restrictive food intake disorder
- A feeding problem that results in at least one of the following:
  - significant weight loss or failure to meet the expected weight or height gain in children;
  - significant nutritional deficiency;
  - dependence on nonfood nutrition, such as nasogastric feedings or oral nutritional supplements; or
  - marked interference with psychosocial functioning
- The problem is not attributable to food availability or cultural ideas
- The problem is
  - not attributable to AN, and there is no distortion in body image; and
  - not attributable to another condition, medical or mental

Other specified feeding disorder or ED

Atypical AN: all criteria for anorexia, but weight is normal

BN (of low frequency and/or limited duration): all criteria except for frequency

Binge-eating disorder (of low frequency and/or limited duration): all criteria except for frequency

Purging disorder: recurrent purging in an effort to lose weight without bingeing

Source: DSM-5.[27]

In 2007, the **American Academy of Pediatrics** Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report stated:

Assessment

- ***Risks:*** When a child's BMI is above the 85th percentile, the clinician should assess medical and behavioral risks before initiating any intervention. Medical risks include risk of future or persistent obesity, risk of future obesity-related medical conditions, and identification of current obesity-related medical conditions. Behavioral risks include current eating habits, physical activity, and sedentary behaviors that promote energy imbalance. These evaluations must precede behavior-based treatment.

Medical Assessment

- ***Responsibility***: Screening children for obesity-related medical problems falls squarely in the purview of health care providers, especially primary care providers. Providers are responsible for considering any current obesity-associated medical conditions, such as hyperlipidemia, risks of future conditions associated with obesity and ameliorated by weight control, and rare conditions that cause obesity, such as primary Cushing syndrome or Prader-Willi syndrome. Because weight control alone may not treat many conditions adequately, diagnosis must be followed by appropriate treatment.
- ***Body Fat Assessment***: The BMI percentile, although imperfect, is the recommended screen for body fat in routine office practice. Offices should use the 2000 CDC BMI charts, rather than the International Obesity Task Force standards, because the CDC charts provide the full array of percentile levels (which makes them more appropriate for assessment of individual children), whereas the International Obesity Task Force charts provide only overweight and obesity categories.
    - Skinfold thickness measurements are not recommended. Although these measurements provide information about body fat and risks of medical conditions, they are not feasible in routine clinical care, because they are difficult to perform accurately without careful training and experience and reference data are not readily available.
    - Similarly, waist circumference measurements are not recommended currently. Waist circumference measurements can provide indirect information about visceral adiposity, which tracks with cardiovascular and metabolic risk factors, and are more easily performed than skinfold thickness measurements, but reference values for children that identify risk over and above the risk from BMI category are not available. In the future, cutoff points that provide additional information and can influence evaluation or treatment may make waist circumference measurement a useful clinical tool.
    - BMI percentile categories guide assessment of medical risk; 5th to 85th percentile is healthy weight, 85th to 94th percentile is overweight, and >/= 95th percentile is obese, with >99th percentile being an emerging category that indicates a high likelihood of immediate medical problems. Because no objective assessment to distinguish high body fat from high lean body mass is clinically practical, clinicians must also consider the family history of obesity and medical problems, the child's past BMI pattern, and the child's current medical conditions and current health behaviors as they decide whether to recommend intervention.

Family Medical History

- Several obesity-related medical conditions are familial. Family history predicts type 2 diabetes mellitus or insulin resistance, and the prevalence of childhood diabetes is especially high among several ethnic and racial backgrounds common in the United States, including Hispanic, black, and North

American Indian. Cardiovascular disease and cardiovascular disease risk factors (hyperlipidemia and hypertension) are also more common when family history is positive. Offices should review and regularly update the family history regarding first- and second-degree relatives.

TABLE 6 Physical Examination Findings in Obesity Assessment and Possible Causes

System	Findings	Possible Explanations
Anthropometric features	High BMI percentile	Overweight or obesity
	Short stature	Underlying endocrine or genetic condition
Vital signs	Elevated blood pressure	Hypertension if systolic or diastolic blood pressure >95th percentile for age, gender, and height on ≥3 occasions
Skin	Acanthosis nigricans	Common in obese children, especially when skin is dark; increased risk of insulin resistance
	Excessive acne, hirsutism	Polycystic ovary syndrome
	Irritation, inflammation	Consequence of severe obesity
	Violaceous striae	Cushing syndrome
Eyes	Papilledema, cranial nerve VI paralysis	Pseudotumor cerebri
Throat	Tonsillar hypertrophy	Obstructive sleep apnea
Neck	Goiter	Hypothyroidism
Chest	Wheezing	Asthma (may explain or contribute to exercise intolerance)
Abdomen	Tenderness	Gastroesophageal reflux disorder, gallbladder disease, NAFLD[a]
	Hepatomegaly	NAFLD[a]
Reproductive system	Tanner stage	Premature puberty in <7-y-old white girls, <6-y-old black girls, and <9-y-old boys
	Apparent micropenis	May be normal penis that is buried in fat
	Undescended testes	Prader-Willi syndrome
Extremities	Abnormal gait, limited hip range of motion	Slipped capital femoral epiphysis
	Bowing of tibia	Blount disease
	Small hands and feet, polydactyly	Some genetic syndromes

[a] These conditions are usually without signs.

Evaluation of Weight-Related Problems

- ***Screening***: Obesity-related medical conditions affect almost every organ system in the body. A review of systems and a physical examination represent an inexpensive way to screen for many of these conditions, although some conditions are without symptoms or signs. Summarized below are important

weight-related medical conditions, with their common symptoms and appropriate screening tests. Tables 5 and 6 present a review of systems and physical examination findings in the order typically followed in an office visit.

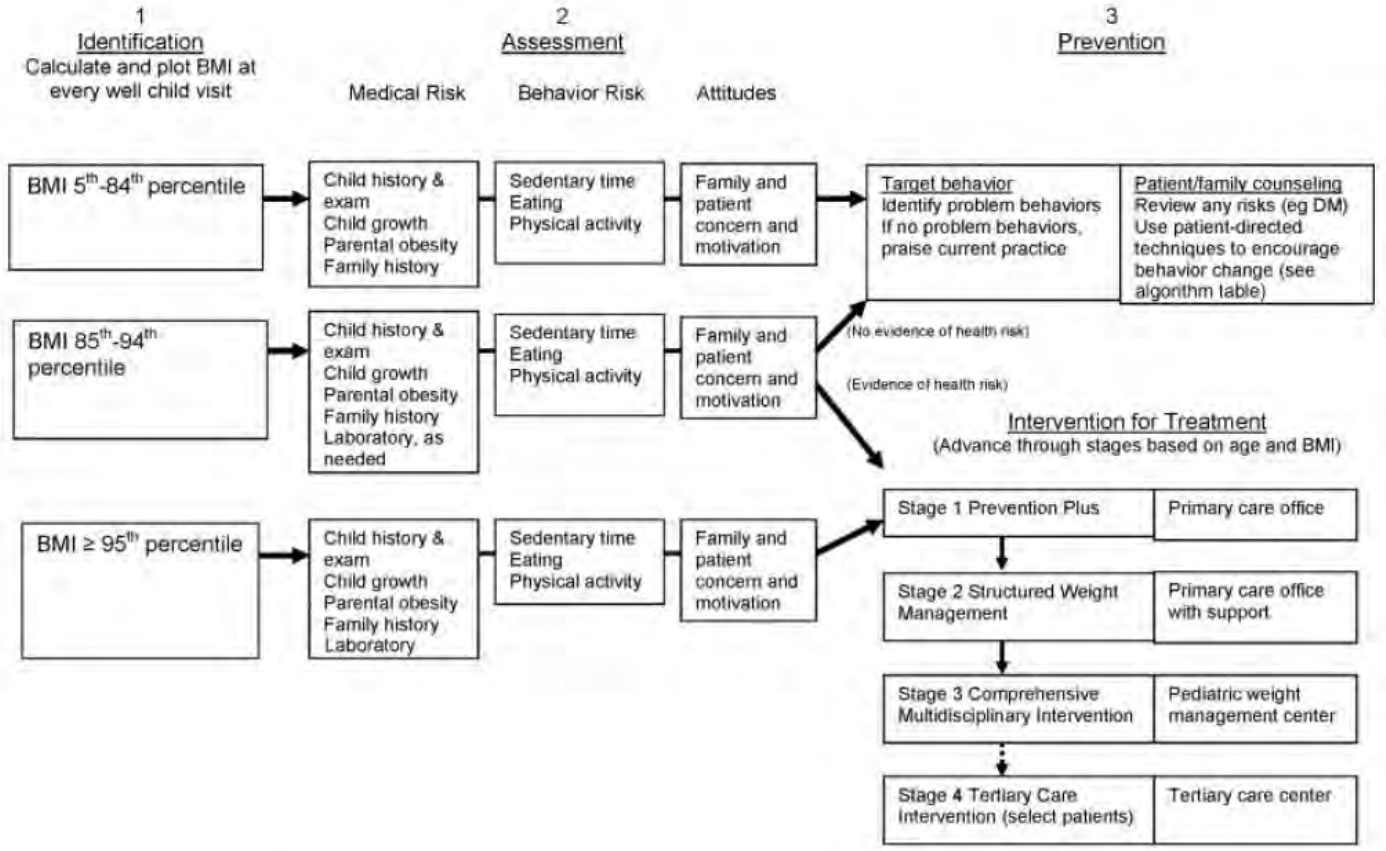


FIGURE 1
Universal assessment of obesity risk and steps to prevention and treatment. DM indicates diabetes mellitus.

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following in 2014:
Assessment

Adults and Children

- Make an initial assessment, then use clinical judgement to investigate comorbidities and other factors to an appropriate level of detail, depending on the person, the timing of the assessment, the degree of overweight or obesity, and the results of previous assessments.
- Manage comorbidities when they are identified; do not wait until the person has lost weight.
- Offer people who are not yet ready to change the chance to return for further consultations when they are ready to discuss their weight again and willing or able to make lifestyle changes. Give them information on the benefits of losing weight, healthy eating and increased physical activity.
- Recognize that surprise, anger, denial or disbelief about their health situation may diminish people's ability or willingness to change. Stress that obesity is a clinical term with specific health implications, rather than a question of how people look; this may reduce any negative feelings.
- During the consultation:
    - Assess the person's view of their weight and the diagnosis, and possible reasons for weight gain.
    - Explore eating patterns and physical activity levels.
    - Explore any beliefs about eating, physical activity and weight gain that are unhelpful if the person wants to lose weight.
    - Be aware that people from certain ethnic and socioeconomic backgrounds may be at greater risk of obesity, and may have different beliefs about what is a healthy weight and different attitudes towards weight management.
    - Find out what the person has already tried and how successful this has been, and what they learned from the experience.
    - Assess the person's readiness to adopt changes.
    - Assess the person's confidence in making changes.
- Give people and their families and/or carers information on the reasons for tests, how the tests are done and their results and meaning. If necessary, offer another consultation to fully explore the options for treatment or discuss test results.

Children

- Assessment of comorbidity should be considered for children with a BMI at or above the 98th centile.
- Take measurements to determine degree of overweight or obesity and raise the issue of weight with the child and family, then assess:
    - presenting symptoms and underlying causes of being overweight or obese
    - willingness and motivation to change
    - comorbidities (such as hypertension, hyperinsulinaemia, dyslipidaemia, type 2 diabetes, psychosocial dysfunction and exacerbation of conditions such as asthma)
    - any risk factors assessed using lipid profile (preferably done when fasting), blood pressure measurement and HbA_{1c} measurement
    - psychosocial distress, such as low self-esteem, teasing and bullying
    - family history of being overweight or obese and comorbidities
    - the child and family's willingness and motivation to change lifestyle
    - lifestyle (diet and physical activity)
    - environmental, social and family

  - growth and pubertal status
  - any medical problems and medication
  - the role of family and care workers in supporting people with learning disabilities to make lifestyle changes.
- Consider referral to an appropriate specialist for children who are overweight or obese and have significant comorbidities or complex needs (for example, learning disabilities or other additional support needs).
- In comprehensive services, assess associated comorbidities and possible causes for children and young people who are overweight or who have obesity. Use investigations such as:
  - blood pressure measurement
  - lipid profile, preferably while fasting
  - fasting insulin
  - fasting glucose levels and oral glucose tolerance test
  - liver function
  - endocrine function.
- Interpret the results of any tests used in the context of how overweight or obese the child is, the child's age, history of comorbidities, possible genetic causes and any family history of metabolic disease related to being overweight or obese.
- Make arrangements for transitional care for children and young people who are moving from pediatric to adult services.

In 2010, The **Childhood Obesity Task Force of the European Association for the Study of Obesity** recommended the following for the evaluation of the Overweight/Obese Child:

ASSESSMENT OF THE OVERWEIGHT CHILD

History Main Points

- Pregnancy history - maternal gestational diabetes (GDM), impaired intra uterine growth (IUGR), birth weight (focus on identifying infants born small for gestational age (SGA))
- Assess and plot previous anthropometric data
- Parental and sibling anthropometrics
- Parental and sibling relevant health conditions
- Use of medications by the child
- Review of systems - sleep patterns, mood assessment, physical limitations

Physical examination main points

- Weigh and assess height, calculate body mass index (BMI) and plot them !
- Assess waist circumference
- Search for dysmorphism or stigmata of underlying medical conditions
- Measure blood pressure correctly
- Look for acanthosis nigricans and for signs of hyperandrogenism in girls

Nutritional assessment main tips

- Establish a steady meal schedule
- Promote eating in the kitchen with the family
- Avoid sweetened beverages! Recommend drinking water.
- Promote consumption of healthy foods – fruit and vegetables, grains
- Promote consumption of complex carbohydrates instead of simple ones

Physical activity main tips

- Promote walking or biking to school
- Promote participation in any moderate to vigorous activity, even in small amounts
- Reduce TV/computer time to < 2 hours per day
- Suggest activities with parents or friends
- Recommended activity is at least 1 hour per day, yet any activity counts and helps.

Do not forget !

- Set realistic goals and expectations of the child and family
- Emphasize the parental role in making changes and providing a role model
- Emphasize that weight management is a lifelong process and not a brief period of modifications
- Provide positive feedbacks for changes made while keeping to repeat the main messages

childhood obesity task force

A focused and problem-oriented history assessment in the obese child has three major aims: i) to rule out an underlying organic disorder, ii) to identify the presence of co-morbidities, and iii) to assess the risk of developing co-morbidities.

History Taking Specific Points

1. Pregnancy history – ask if there were maternal gestational diabetes or other complications of pregnancy (hypertension, impaired intrauterine growth, birth weight (with focus on identifying those born small or large for gestational age)).
2. Assess and plot previous anthropometric data on appropriate growth charts. Focus on 'catch-up growth' of smaller babies, very early weight gain, and weight accrual prior to pubertal development.
3. Grand-parental, parental, and sibling anthropometrics – obesity tends to run in families.
4. Grand-parental, parental and sibling health conditions – focus on morbidity related to increased cardiovascular risk such as diabetes, dyslipidaemia, hypertension, positive history for overt cardiovascular disease below 55 years in men and below 65 years in women.
5. Use of medications by the child – specifically chronic use of glucocorticoids and/or psychotropic medications, the use of which is typically related to weight gain.
6. Review of systems – sleep patterns (snoring, nocturnal binge eating, nocturia, duration), physical limitations due to orthopaedic problems, mood assessment, eating patterns (focus in history of dieting and on binging). In female adolescents, the regularity of periods and the presence of hyperandrogenism.

Physical Examination Specific Points

1. All paediatric patients should be weighed and have their height measured at least once a year. Calculate the body mass index (BMI = weight in kilograms / height in metres2) and plot it on appropriate local BMI centile charts. It is recommended that waist circumference is measured and plotted with appropriate centiles as well. The child should stand erect with the abdomen relaxed, arms at the sides, and the feet together. Take the measurement at the end of normal expiration at the narrowest part of the torso at the level of the natural waist between the ribs and the iliac crest.
2. Search for stigmata of syndromes associated with obesity – developmental delay, dysmorphism, hypogonadism, and purple abdominal striae. Search for the presence of signs associated with simple obesity such as acanthosis nigricans or manifestations of hyperandrogenism in females.
3. Measure blood pressure in a relaxed environment after 10 min of rest and compare it to appropriate references. Make sure that the cuff is appropriate for the size of the child.
4. Examine the musculoskeletal system focusing on skeletal deformities and limitation of motion.

Additional Laboratory Specific Points

1. Complete biochemistry including liver function and a fasting lipid profile. Obesity is commonly associated with nonalcoholic fatty liver disease, elevated alanine transaminase (ALT) levels as well as other liver function abnormalities. The typical dyslipidaemia seen in obese children includes elevated triglycerides and reduced HDL (high-density lipoprotein)-cholesterol. The presence of this lipid profile is highly suggestive of significant insulin resistance.

2. Complete blood count – surprisingly, nutritional deficiencies, and specifically iron deficiency, are common in obese children.
3. Evaluation of glucose metabolism – the sensitivity of a fasting glucose measurement to detect glucose intolerance in overweight/obese children is low. In a child at risk for altered glucose metabolism (severe obesity, positive family history of T2DM or gestational diabetes, presence of acanthosis nigricans, or a suggestive history of polydipsia/polyuria) – a standard oral glucose tolerance test should be performed.
4. Additional tests based on clinical suspicion of a medical disorder/obesity syndrome – such as thyroid function tests, urinary free cortisol collection etc. should be performed as necessary.

Nutritional Assessment Specific Points

1. Identify timing and locations of meals – ask about snacking patterns in between meals, during the evening and night. Ask about where the meals are eaten, such as in the kitchen/dining room, living room, or bedroom, and if they are eaten in front of the television or computer.
2. Quantify sweetened beverage consumption – including all soft drinks, fruit juices as well as chocolate milk.
3. Assess positive components of the diet, such as fruit and vegetables, fish, and grains.
4. Assess portion sizes – although the quality of food is critical, quantity can sometimes be an issue as well. Compare portion sizes with parents and other family members.
5. Ask what the child eats during school time.

Physical Activity Assessment Specific Points

1. Assess hours per day of sedentary activities – such as television watching and computer time.
2. Ask about any additional activity and participation in organized sports outside of the school system.
3. Ask how the child gets to school – walking, cycling, car, public transport.
4. Assess family activities – do the parents and siblings engage in any physical activity?

Children and Adolescents: Primary Literature

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Children and adolescents Modality: Screening for hypertension Outcome: Prevent cardiovascular disease
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☐ Low ☒ Very Low

Risk of Bias across studies: ☐ High ☐ Medium ☒ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - *Unknown* ☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Thompson, M., et al. Year Published: 2013 Location: Oregon Health and Science University Journal: *Pediatrics*	To conduct a systematic review for the US Preventive Services Task Force recommendation on the effectiveness of screening asymptomatic children and adolescents for hypertension in order to prevent cardiovascular disease.	**Size:** 2 studies, 9119 participants. **Inclusion Criteria:** Primary care clinics, well-child/adolescent visits, school or community-based screening, asymptomatic, otherwise healthy children and adolescents, 0-18 years of age, with no known diagnosis of hypertension. **Exclusion Criteria**: Pediatric specialty/subspecialty clinics, inpatient, or long-term care settings, emergency or urgent care facilities, pregnant adolescents.	**Type:** Systematic Review	**Results:** No studies evaluated the effects of screening for hypertension on health outcomes. Two studies of screening tests for elevated blood pressure reported moderate sensitivities (0.65, 0.72) and specificities (0.75, 0.92). **No serious treatment-related adverse effects were reported.**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Thompson, M., et al. (2013). "Screening for Hypertension in Children and Adolescents to Prevent Cardiovascular Disease." Pediatrics **131**(3): 490-525.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Lipid screening
Outcome: Detection of familial hypercholesterolemia

Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☐ Low ☒ Very Low					
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - Unknown ☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Lozano, P., et al. Year Published: 2016 Location: Kaiser Permanente Research Affiliates Evidence-based Practice Center, Seattle, Washington Journal: *JAMA*	To systematically review the evidence on benefits and harms of screening adolescents and children for heterozygous Familial Hypercholesterolemia (FH) for the US Preventive Services Task Force (USPSTF).	**Size:** 2 studies, 83,241 participants. **Inclusion Criteria:** studies of asymptomatic children and adolescents aged 0 to 20 years at screening were included. Acceptable screening interventions were lipid panel (fasting or nonfasting lipid measurement, TC or LDL-C alone or in combination with high-density lipoprotein cholesterol [HDL-C]) delivered in a universal or selective screening strategy. **Exclusion Criteria:** Screening studies that focused on genetic screening alone or cascade screening (which involves case-finding among relatives of people with confirmed FH), Screening studies of populations with known	**Type:** Systematic Review	**Results:** Based on 2 studies (n = 83 241), the diagnostic yield of universal screening for FH in childhood is 1.3 to 4.8 cases per 1000 screened. **There was no eligible evidence on the benefits or harms of FH screening in childhood.**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		dyslipidemia, a diagnosis associated with secondary dyslipidemia, or a documented family history of FH			

References:

1. Lozano, P., et al. (2016). "Lipid Screening in Childhood and Adolescence for Detection of Familial Hypercholesterolemia: Evidence Report and Systematic Review for the US Preventive Services Task Force Evidence Report: Childhood Screening for Familial Hypercholesterolemia Evidence Report: Childhood Screening for Familial Hypercholesterolemia." JAMA **316**(6): 645-655.

Adult: Guideline Recommendations:

The 2016 **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

Core recommendations for medical care of patients with obesity:

- The principal outcome and therapeutic target in the treatment of obesity should be to improve the health of the patient by preventing or treating weight-related complications using weight loss, not the loss of body weight *per se* **(Grade D)**.
- The evaluation of patients for risk and existing burden of weight-related complications is a critical component of care and should be considered in clinical decisions and the therapeutic plan for weight-loss therapy **(Grade D)**.

Clinical Component of the Diagnosis of Obesity:

Diabetes risk, metabolic syndrome, and prediabetes

- Patients with overweight or obesity and patients experiencing progressive weight gain should be screened for prediabetes and type 2 diabetes and evaluated for metabolic syndrome by assessing waist circumference, fasting glucose, A1C, blood pressure, and lipid panel, including triglycerides and HDL-c **(Grade A; BEL 2, upgraded due to high clinical relevance)**.
- Due to variable risk for future diabetes, patients with overweight or obesity should be evaluated for risk of type 2 diabetes, which can be estimated or stratified using indices or staging systems that employ clinical data, glucose tolerance testing, and/or metabolic syndrome traits **(Grade B; BEL 2)**.

Type 2 diabetes

- Patients with type 2 diabetes should be evaluated for the presence of overweight or obesity **(Grade A; BEL 2, upgraded due to high relevance)**.

Dyslipidemia

- All patients with overweight or obesity and individuals experiencing progressive weight gain should be screened for dyslipidemia with a lipid panel that includes triglycerides, HDL-c, calculated LDL-c, total cholesterol, and non-HDL cholesterol; all patients with dyslipidemia should be evaluated for the presence of overweight or obesity **(Grade A; BEL 2, upgraded due to high relevance)**.

Hypertension

- Blood pressure should be measured in all patients with overweight or obesity as a screen for the presence of hypertension or prehypertension; all patients with hypertension should be evaluated for the presence of overweight or obesity **(Grade A; BEL 2, upgraded due to high relevance)**.

Cardiovascular disease and cardiovascular disease mortality

- Risk factors for cardiovascular disease should be assessed in patients with overweight or obesity **(Grade A; BEL 2, upgraded due to high relevance)**.
- Patients with overweight or obesity should be screened for active cardiovascular disease by history, physical examination, and with additional testing or expert referral based on cardiovascular disease risk status **(Grade A; BEL 2, upgraded due to high relevance)**.

Nonalcoholic fatty liver disease and nonalcoholic steatohepatitis

- Screening for nonalcoholic fatty liver disease should be performed in all patients with overweight or obesity, type 2 diabetes, or metabolic syndrome with liver function testing, followed by ultrasound or other imaging modality if transaminases are elevated; all patients with nonalcoholic fatty liver disease should be evaluated for the presence of overweight or obesity **(Grade B; BEL 2)**.

Polycystic ovary syndrome (PCOS)

- Premenopausal female patients with overweight or obesity and/or metabolic syndrome should be screened for polycystic ovary syndrome by history and physical examination; all patients with polycystic ovary syndrome should be evaluated for the presence of overweight or obesity **(Grade B; BEL 2)**.

Female infertility

- Women with overweight or obesity should be counseled when appropriate that they are at increased risk for infertility and, if seeking assisted reproduction, should be informed of lower success rates of these procedures regarding conception and the ability to carry the pregnancy to live birth **(Grade B; BEL 2)**.
- All female patients with infertility should be evaluated for the presence of overweight or obesity **(Grade B; BEL 2)**.

Male hypogonadism

- All men who have an increased waist circumference or who have obesity should be assessed for hypogonadism by history and physical examination and be tested for testosterone deficiency if indicated; all male patients with hypogonadism should be evaluated for the presence of overweight or obesity **(Grade B; BEL 2)**.
- All male patients with type 2 diabetes should be evaluated to exclude testosterone deficiency **(Grade B; BEL 2)**.

Obstructive sleep apnea

- All patients with overweight or obesity should be evaluated for obstructive sleep apnea during medical history and physical examination; this is based on the strong association of these disorders with each other **(Grade B; BEL 2)**.

- Polysomnography and other sleep studies, at home or in a sleep lab, should be considered for patients at high risk for sleep apnea based on clinical presentation, severity of excess adiposity, and symptomatology **(Grade D)**.
- All patients with obstructive sleep apnea should be evaluated for the presence of overweight or obesity **(Grade B; BEL 2)**.

Asthma/reactive airway disease

- All patients with overweight or obesity should be evaluated for asthma and reactive airway disease based on the strong association of these disorders with each other **(Grade B; BEL 2)**.
- Based on medical history, symptomatology, and physical examination, spirometry and other pulmonary function tests should be considered for patients at high risk for asthma and reactive airway disease **(Grade D)**.
- All patients with asthma should be evaluated for the presence of overweight or obesity **(Grade D)**.

Osteoarthritis

- All patients with overweight or obesity should be screened by symptom assessment and physical examination for osteoarthritis of the knee and other weight-bearing joints **(Grade B; BEL 2)**.
- All patients with osteoarthritis should be evaluated for the presence of overweight or obesity **(Grade D)**.

Urinary stress incontinence

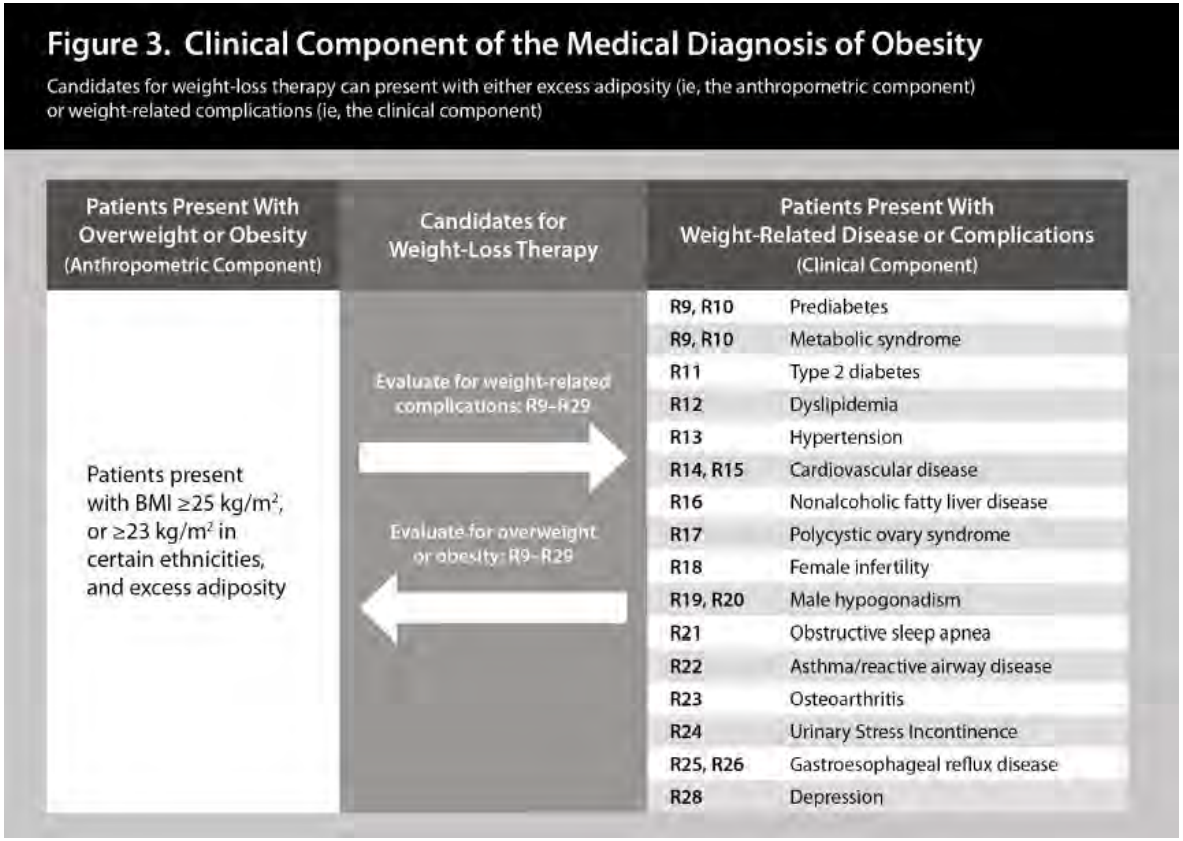
- All female patients with overweight or obesity should be screened for urinary incontinence by assessing symptomatology, based on the strong association of these disorders with each other; all patients with urinary stress incontinence should be evaluated for the presence of overweight or obesity **(Grade B; BEL 2)**.

Gastroesophageal reflux disease (GERD)

- Patients with overweight or obesity or who have increased waist circumferences should be evaluated for symptoms of GERD **(Grade B; BEL 2)**; all patients with GERD should be evaluated for the presence of overweight or obesity **(Grade C; BEL 3)**.
- Patients with obesity and GERD symptoms should be evaluated by endoscopy if medical treatment fails to control symptoms **(Grade B; BEL 2)**.
- Endoscopy should be considered in patients with obesity and GERD symptoms prior to bariatric surgery **(Grade B; BEL 2)**.

Depression

- Patients with overweight or obesity should be screened for depression; all patients with depression should be evaluated for the presence of overweight or obesity **(Grade B; BEL 2)**.



Evaluation

- All patients with overweight or obesity should be clinically evaluated for weight-related complications because BMI alone is not sufficient to indicate the impact of excess adiposity on health status; therefore, the diagnostic evaluation of patients with obesity should include an anthropometric assessment of adiposity and a clinical assessment of weight-related complications **(Grade A; BEL 2, upgraded due to high relevance)**.
- Patients with overweight or obesity should be reevaluated at intervals to monitor for any changes in adiposity and adiposity-related complications over time **(Grade A; BEL 2, upgraded due to high relevance)**.

The 2015 **European Guidelines** for Obesity Management in Adults recommended the following:

Clinical Evaluation of the Obese Patient: A comprehensive history, physical examination and laboratory assessment relevant to the patient's obesity should be obtained {**Recommended Best Practice (RBP)**}.

History Taking
- – Ethnicity
- – Family history
- – Dietary habits
- – Physical activity frequency and nature
- – Eating pattern and possible presence of an eating disorder (binge eating disorder, night eating syndrome, bulimia)
- – Presence of depression and other mood disorders
- – Other determinants, e.g., genetic, drugs, endocrine abnormalities, psychosocial factors, chronic stress, smoking cessation etc.
- – Health consequences of obesity
- – Patient expectations and motivation for change
- – Previous treatments for obesity.

Physical Examination
- – Measure weight and height (from which BMI is calculated), WC, blood pressure (appropriate size cuff) {**grade 3**}
- – Assess the presence and impact of obesity-related diseases (diabetes, hypertension, dyslipidaemia; cardiovascular, respiratory and joint diseases; non-alcoholic fatty liver disease (NAFLD), sleep disorders etc.) {**RBP**}
- – Look for the presence of acanthosis nigricans as a sign of insulin resistance {**RBP**}.

Table 2. A guide to deciding the initial level of intervention to discuss with the patient

BMI, kg/m^{2*}	WC, cm*		Co-morbidities
	men < 94, women < 80	men ≥ 94, women ≥ 80	
25.0–29.9	L	L	L ± D
30.0–34.9	L	L ± D	L ± D±S**
35.0–39.9	L ± D	L ± D	L ± D ± S
≥40.0	L ± D ± S	L ± D ± S	L ± D ± S

L = Lifestyle intervention (diet and physical activity); D = consider drugs; S = consider surgery.

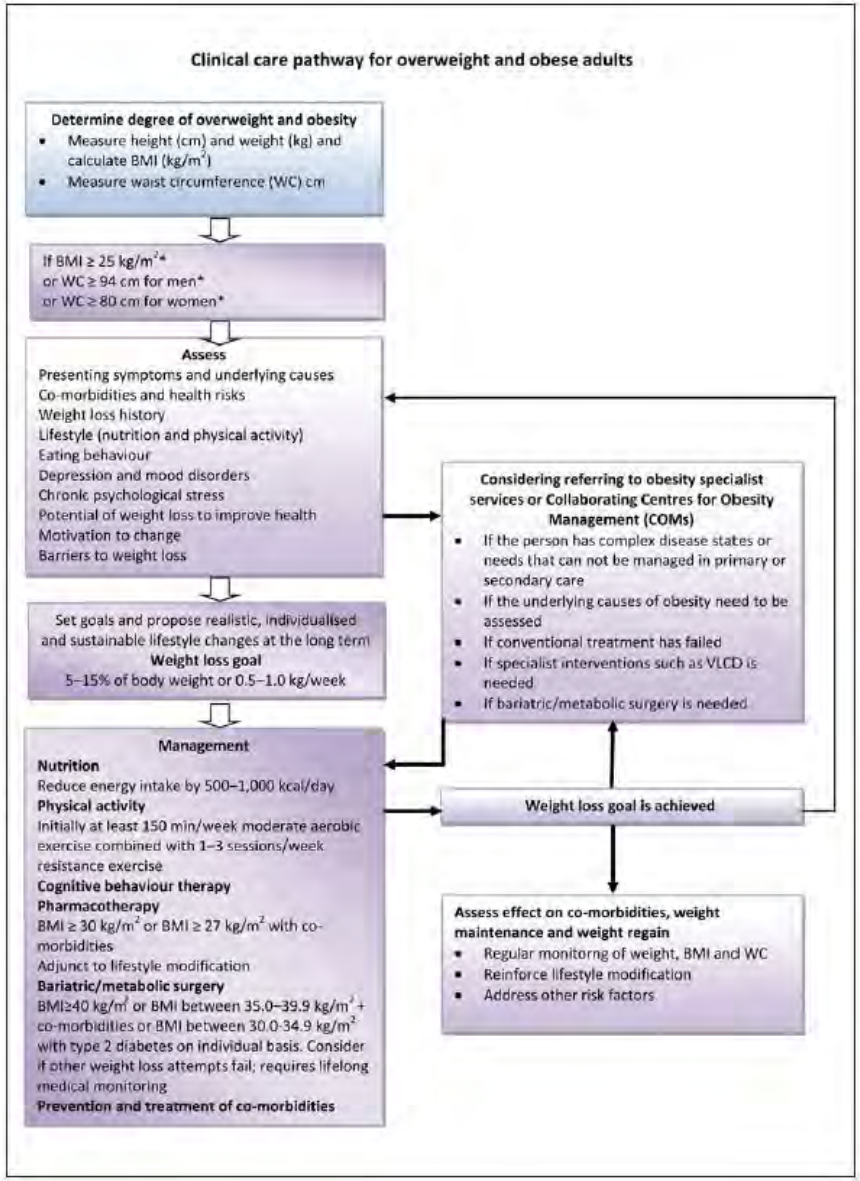
*BMI and waist circumference cut-off points are different for some ethnic groups.

**Patients with type 2 diabetes on individual basis.

Laboratory Examinations

The minimum data set required will include {**RBP**}:

– Fasting blood glucose
– Serum lipid profile (total, HDL and LDL cholesterol, triglycerides)
– Uric acid
– Thyroid function (thyroid-stimulating hormone (TSH) level)
– Liver function (hepatic enzymes)
– Cardiovascular assessment, if indicated {**RBP**}
– Endocrine evaluation if Cushing's syndrome or hypothalamic disease suspected
– Liver investigation (ultrasound, biopsy) if abnormal liver function tests suggest NAFLD or other liver pathology
– Sleep laboratory investigation for sleep apnea.


Clinical care pathway for overweight and obese adults
Determine degree of overweight and obesity
Measure height (cm) and weight (kg) and calculate BMI (kg/m²)
Measure waist circumference (WC) cm
If BMI ≥ 25 kg/m²*
or WC ≥ 94 cm for men*
or WC ≥ 80 cm for women*
Assess
Presenting symptoms and underlying causes
Co-morbidities and health risks
Weight loss history
Lifestyle (nutrition and physical activity)
Eating behaviour
Depression and mood disorders
Chronic psychological stress
Potential of weight loss to improve health
Motivation to change
Barriers to weight loss
Set goals and propose realistic, individualised and sustainable lifestyle changes at the long term
Weight loss goal
5–15% of body weight or 0.5–1.0 kg/week
Management
Nutrition
Reduce energy intake by 500–1,000 kcal/day
Physical activity
Initially at least 150 min/week moderate aerobic exercise combined with 1–3 sessions/week resistance exercise
Cognitive behaviour therapy
Pharmacotherapy
BMI ≥ 30 kg/m² or BMI ≥ 27 kg/m² with co-morbidities
Adjunct to lifestyle modification
Bariatric/metabolic surgery
BMI≥40 kg/m² or BMI between 35.0–39.9 kg/m² + co-morbidities or BMI between 30.0-34.9 kg/m² with type 2 diabetes on individual basis. Consider if other weight loss attempts fail; requires lifelong medical monitoring
Prevention and treatment of co-morbidities
Considering referring to obesity specialist services or Collaborating Centres for Obesity Management (COMs)
If the person has complex disease states or needs that can not be managed in primary or secondary care
If the underlying causes of obesity need to be assessed
If conventional treatment has failed
If specialist interventions such as VLCD is needed
If bariatric/metabolic surgery is needed
Weight loss goal is achieved
Assess effect on co-morbidities, weight maintenance and weight regain
Regular monitorng of weight, BMI and WC
Reinforce lifestyle modification
Address other risk factors

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following in 2014:

Assessment
Adults and Children

- Make an initial assessment, then use clinical judgement to investigate comorbidities and other factors to an appropriate level of detail, depending on the person, the timing of the assessment, the degree of overweight or obesity, and the results of previous assessments.
- Manage comorbidities when they are identified; do not wait until the person has lost weight.
- Offer people who are not yet ready to change the chance to return for further consultations when they are ready to discuss their weight again and willing or able to make lifestyle changes. Give them information on the benefits of losing weight, healthy eating and increased physical activity.
- Recognize that surprise, anger, denial or disbelief about their health situation may diminish people's ability or willingness to change. Stress that obesity is a clinical term with specific health implications, rather than a question of how people look; this may reduce any negative feelings.
- During the consultation:
    - Assess the person's view of their weight and the diagnosis, and possible reasons for weight gain.
    - Explore eating patterns and physical activity levels.
    - Explore any beliefs about eating, physical activity and weight gain that are unhelpful if the person wants to lose weight.
    - Be aware that people from certain ethnic and socioeconomic backgrounds may be at greater risk of obesity, and may have different beliefs about what is a healthy weight and different attitudes towards weight management.
    - Find out what the person has already tried and how successful this has been, and what they learned from the experience.
    - Assess the person's readiness to adopt changes.
    - Assess the person's confidence in making changes.
- Give people and their families and/or carers information on the reasons for tests, how the tests are done and their results and meaning. If necessary, offer another consultation to fully explore the options for treatment or discuss test results.

Adults

- Take measurements to determine degree of overweight or obesity and discuss the implications of the person's weight. Then, assess:
    - any presenting symptoms
    - any underlying causes of being overweight or obese
    - eating behaviors
    - any comorbidities (for example type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, dyslipidaemia and sleep apnea)
    - any risk factors assessed using lipid profile (preferably done when fasting), blood pressure measurement and HbA_{1c} measurement
    - the person's lifestyle (diet and physical activity)
    - any psychosocial distress
    - any environmental, social and family factors, including family history of overweight and obesity and comorbidities

  - the person's willingness and motivation to change lifestyle
  - the potential of weight loss to improve health
  - any psychological problems
  - any medical problems and medication
  - the role of family and care workers in supporting people with learning disabilities to make lifestyle changes.
- Consider referral to comprehensive services if:
  - the underlying causes of being overweight or obese need to be assessed
  - the person has complex disease states or needs that cannot be managed adequately (for example, the additional support needs of people with learning disabilities)
  - conventional treatment has been unsuccessful
  - drug treatment is being considered for a person with a BMI of more than 50 kg/m_2
  - specialist interventions (such as a very-low-calorie diet) may be needed
  - surgery is being considered.

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

- Screen adult patients to establish a diagnosis of overweight or obesity by calculating body mass index (BMI), and document the presence of overweight or obesity in the medical record. **[B]**
- Screen for overweight and obesity at least annually. **[EO]**
- Assess for the presence of obesity-associated conditions among overweight patients or patients with increased waist circumference. **[B]**
- Perform a targeted assessment on overweight and obese patients. In addition to the basic medical history and physical examination, assess for factors contributing to obesity. **[EO]**

Box 1: Common Obesity-Associated Conditions*

- Hypertension**
- Type 2 diabetes and pre-diabetes**
- Dyslipidemia**
- Metabolic syndrome
- Obstructive sleep apnea
- Degenerative joint disease
- Non-alcoholic fatty liver disease

*Increased waist circumference is considered an obesity comorbidity equivalent

** At least moderate evidence exists for modifying these conditions with weight loss. See Appendix E for details.

Box 2: Elements of Medical Assessment of Overweight or Obesity

- History of overweight/obesity and previous weight loss attempts
- Current motivation for, and barriers to, weight loss
- Current and past psychiatric history
- Over-the-counter and prescription medication use
- Alternative and complementary therapy use
- Dietary and physical activity behaviors or limitations
- Tobacco and alcohol use
- Family history and obesity in family members
- Comorbidities and other conditions which may contribute to obesity
- Social history including support systems

Physical examination of the overweight and obese patient includes:

- Height and weight
- Calculated BMI
- Measurement of waist circumference
- Blood pressure

Laboratory tests may be obtained as clinically appropriate based on medical history and physical examination. These may include:

- Lipid profile
- ALT/AST
- Fasting blood glucose/A1C

The **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** in 2013 recommended:

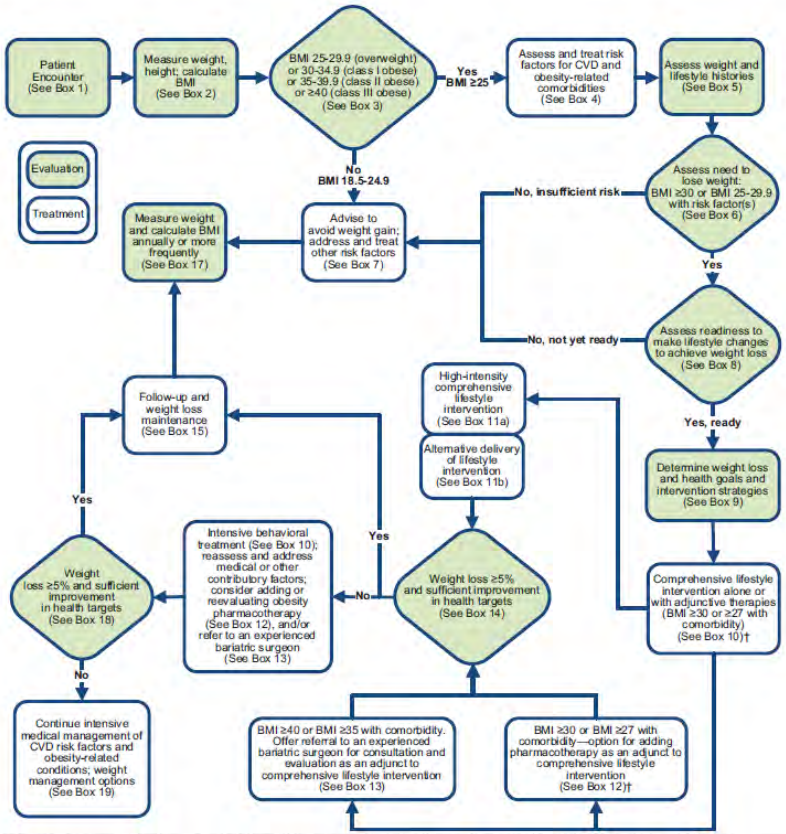


Figure 1. Treatment Algorithm—Chronic Disease Management Model for Primary Care of Patients With Overweight and Obesity*. *This algorithm applies to the assessment of overweight and obesity and subsequent decisions based on that assessment. Each step (designated by a box) in this process is reviewed in Section 2.2 and expanded on in subsequent sections. †BMI cutpoint determined by the FDA and listed on the package inserts of FDA-approved obesity medications. BMI indicates body mass index; CVD, cardiovascular disease; and FDA, US Food and Drug Administration.

- **Box 4: Assess and Treat Cardiovascular Risk Factors and Obesity-Related Comorbidities** – Assess risk of CVD and/or presence of obesity-related comorbidities. Risk assessment for CVD and diabetes in a person with overweight or class I to III obesity includes history; physical examination; and clinical and laboratory assessments, including BP, fasting blood glucose, and fasting lipid panel (expert opinion). A waist circumference measurement is

recommended for individuals with BMI 25-34.9 kg/m2 to provide additional information on risk. It is unnecessary to measure waist circumference in patients with BMI ≥35 kg/m2 because the waist circumference will likely be elevated and will add no additional risk information. The Expert Panel recommends, by expert opinion, using the current cutpoints (>88 cm [>35 in] for women and >102 cm [>40 in] for men) as indicative of increased cardiometabolic risk. Because obesity is associated with increased risk of hypertension, dyslipidemia, diabetes, and a host of other comorbidities, the clinician should assess for associated conditions. The Expert Panel recommends, by expert opinion, that intensive management of cardiovascular risk factors (hypertension, dyslipidemia, prediabetes, or diabetes) or other obesity-related medical conditions (eg, sleep apnea) be instituted if they are found, regardless of weight loss efforts.

- **Box 5: Assess Weight and Lifestyle Histories** – The Expert Panel recommends, by expert opinion, that the clinician assess weight and lifestyle histories and determine other potential contributory factors: Ask questions about history of weight gain and loss over time, details of previous weight loss attempts, dietary habits, physical activity, family history of obesity, and other medical conditions or medications that may affect weight. Answers to these questions may provide useful information about the origins of or maintaining factors for overweight and obesity, including success and difficulties with previous weight loss or maintenance efforts. This information can help the clinician determine any adjustments to the patient's medical regimen that can assist weight management efforts and provide appropriate advice on lifestyle change. The information may also impact recommendations for treatment.
- **Box 6: Assess Need to Lose Weight** –
    - *YES: BMI ≥30 or BMI 25-29.9 with additional risk factor(s):* Weight loss treatment is indicated for ≥1) obese individuals and 2) overweight individuals with 1 indicators of increased cardiovascular risk (eg, diabetes, prediabetes, hypertension, dyslipidemia, elevated waist circumference) or other obesity-related comorbidities.
    - *NO: BMI <25 or BMI 25-29.9 without additional risk*. Normal-weight patients (BMI 18.5-24.9 kg/m2 should be advised to avoid weight gain (Box 7). Patients who are overweight (BMI 25-29.9 kg/m2) who do not have indicators of increased cardiovascular risk (eg, diabetes, prediabetes, hypertension, dyslipidemia, elevated waist circumference) or other obesity-related comorbidities should be advised to avoid additional weight gain.
- **Box 7: Advise to Avoid Weight Gain and Address Other Risk Factors** –
    - *Normal weight*: Individuals who are normal weight (BMI 18.5-24.9 kg/m2) and do not have a history of overweight or obesity should be counseled on the desirability of avoiding weight gain to prevent the health risks of increased body weight.
    - *Overweight without additional risk factors or normal weight with a history of overweight or obesity*: For individuals who are overweight (BMI 25-29.9 kg/m2) and who do not have indicators of increased cardiovascular risk (eg, diabetes, prediabetes, hypertension, dyslipidemia, elevated waist circumference) or other obesity-related comorbidities, and for individuals who have a history of overweight and are now normal weight with risk factors at acceptable levels, advise patients to frequently measure their own weight and to avoid weight gain by adjusting their food intake if they start to gain more than a few pounds. Also, advise patients that engaging in regular physical activity will help them avoid weight gain.

  - *Overweight or obese individuals who would benefit from weight loss but who are not currently prepared or able to lose weight*: Periodically assess the patient's interest in and readiness for weight loss as shown in Box 8, and counsel the patient on the desirability of avoiding additional weight gain to prevent greater health risk. Regardless of patient's interest in or readiness for weight loss intervention, any cardiovascular risk factors and obesity-related health conditions should be evaluated and treated.
- **Box 8: Assess Readiness to Make Lifestyle Changes to Achieve Weight Loss and Identify Barriers to Success** – The Expert Panel advises (expert opinion) that the clinician and patient agree on whether weight loss is appropriate. The clinician, together with the patient, should assess whether the patient is prepared and ready to undertake the measures necessary to succeed at weight loss before beginning comprehensive counseling efforts. The clinician can ask, "How prepared are you to make changes in your diet, to be more physically active, and to use behavior change strategies such as recording your weight and food intake?" These are the components of a comprehensive lifestyle intervention. The decision to undertake weight loss efforts must be made in the context of competing priorities (eg, smoking cessation may supersede a weight loss effort; life events may make the effort at weight reduction futile until a future time). If the patient is not prepared to undertake these changes, attempts to counsel the patient on how to make lifestyle changes are likely to be counterproductive.
- **Box 9: Determine Weight Loss and Health Goals and Intervention Strategies** – Clinician and patient devise weight loss and health goals and comprehensive lifestyle treatment strategies to achieve these goals.
  - *Recommended goals for weight loss*: A realistic and meaningful weight loss goal is an important first step. Although sustained weight loss of as little as 3%-5% of body weight may lead to clinically meaningful reductions in some cardiovascular risk factors, larger weight losses produce greater benefits. The Expert Panel recommends as an initial goal the loss of 5%-10% of baseline weight within 6 months.
  - *Recommended methods for weight loss*: Weight loss requires creating an energy deficit through caloric restriction, physical activity, or both. An energy deficit of ≥500 kcal/d typically may be achieved with dietary intake of 1200- 1500 kcal/d for women and 1500-1800 kcal/d for men. The choice of calorie-restricted diet can be individualized to the patient's preferences and health status (CQ3). Very-low-calorie diets (<800 kcal/d) should be used only in limited circumstances in a medical care setting where medical supervision and a high intensity lifestyle intervention can be provided. If a specialized diet for CVD risk reduction, diabetes, or other medical conditions is also prescribed, referral to a nutrition professional is recommended (CQ3).
  - *Recommendations for management of medical conditions during weight loss*: While weight loss treatment is ongoing, manage risk factors such as hypertension, dyslipidemia, and other obesity-related conditions. This includes monitoring the patient's requirements for medication change as weight loss progresses, particularly for antihypertensive medications and diabetes medications that can cause hypoglycemia.

In 2015 **Canadian Task Force on Preventative Health Care** recommended the following:

- A noninvasive, validated risk-assessment tool (e.g. CANRISK [Canadian Diabetes Risk] or FINRISC [Finnish Type 2 Diabetes Risk Score]) be used to calculate risk of type 2 diabetes in overweight and obese patients. Current guidance on diabetes screening suggests that risk assessment be done at least every three to five years in people at high risk of diabetes developing within 10 years.

Question #3. What is the comparative effectiveness of nutritional interventions (standard calorie-deficit diet (calorie reduction, portion control), very-low-calorie diet (VLCD), hypocaloric meal-replacement diet, diets that do not restrict calories but vary macronutrients (high-fiber diet, high-protein diet, low-carbohydrate diet, low-fat diet, high fat/keto diet), and diets that emphasize healthy eating patterns (whole foods, healthy diet index)? What is the optimal intensity of nutritional interventions for improving health, well-being, and weight loss?

2015-2020 Dietary Guidelines at a Glance

Source: U.S. Department of Agriculture


1
Follow a healthy eating pattern across the lifespan. All food and beverage choices matter. Choose a healthy eating pattern at an appropriate calorie level to help achieve and maintain a healthy body weight, support nutrient adequacy, and reduce the risk of chronic disease.
Follow a healthy eating pattern over time to help support a healthy body weight and reduce the risk of chronic disease.
A Healthy Eating Pattern Includes:
Fruits
Vegetables
Protein
Dairy
Grains
Oils
A Healthy Eating Pattern Limits:
Saturated Fats & Trans Fats
Added Sugars
Sodium
2
Focus on variety, nutrient density, and amount. To meet nutrient needs within calorie limits, choose a variety of nutrient-dense foods across and within all food groups in recommended amounts.
Choose a variety of nutrient-dense foods from each food group in recommended amounts.
Example Meal:
Lettuce & Celery
Vegetables
Grains
Whole-Grain Bread
Apples & Grapes
Fruits
Dairy
Fat-Free Milk
Chicken Breast & Unsalted Walnuts
Protein
Oils
Mayonnaise


3
Limit calories from added sugars and saturated fats and reduce sodium intake. Consume an eating pattern low in added sugars, saturated fats, and sodium. Cut back on foods and beverages higher in these components to amounts that fit within healthy eating patterns.
Consume an eating pattern low in added sugars, saturated fats, and sodium.
Example Sources of:
Added Sugars
Saturated Fats
Sodium
4
Shift to healthier food and beverage choices. Choose nutrient-dense foods and beverages across and within all food groups in place of less healthy choices. Consider cultural and personal preferences to make these shifts easier to accomplish and maintain.
Replace typical food and beverages choices with more nutrient-dense options. Be sure to consider personal preferences to maintain shifts over time.
Example:
Shift
Meal A
Meal B


Everyone has a role in helping to create and support healthy eating patterns in places where we learn, work, live, and play.
5
Support healthy eating patterns for all. Everyone has a role in helping to create and support healthy eating patterns in multiple settings nationwide, from home to school to work to communities.

Reference:

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at http://health.gov/dietaryguidelines/2015/guidelines/.

Children and adolescents: Guideline Recommendations

In 2016, the **American Academy of Pediatrics** Preventing Obesity and Eating Disorders in Adolescents stated the following on evidence-based management strategies associated with both obesity and eating disorders (EDs) in teenagers:

Cross-sectional and longitudinal observational studies have identified the following certain behaviors associated with both obesity and EDs in adolescents:

1. Dieting. Dieting, defined as caloric restriction with the goal of weight loss, is a risk factor for both obesity and EDs. In a large prospective cohort study in 9- to 14-year-olds (N = 16 882) followed for 2 years, dieting was associated with greater weight gain and increased rates of binge eating in both boys and girls. Similarly, in a prospective observational study in 2516 adolescents enrolled in Project Eating Among Teens (Project EAT) followed for 5 years, dieting behaviors were associated with a twofold increased risk of becoming overweight and a 1.5-fold increased risk of binge eating at 5-year follow-up after adjusting for weight status at baseline. Stice et al showed that girls without obesity who dieted in the ninth grade were 3 times more likely to be overweight in the 12th grade compared with nondieters. These findings and others suggest that dieting is counterproductive to weight management efforts. Dieting also can predispose to EDs. In a large prospective cohort study in students 14 to 15 years of age followed for 3 years, dieting was the most important predictor of a developing ED. Students who severely restricted their energy intake and skipped meals were 18 times more likely to develop an ED than those who did not diet; those who dieted at a moderate level had a fivefold increased risk.

2. Family meals. Family meals have been associated with improved dietary intake and provide opportunities for modeling behavior by parents, even though family meals have not been shown to prevent obesity across ethnic groups. A higher frequency of family meals is associated with improved dietary quality, as evidenced by increased consumption of fruits, vegetables, grains, and calcium-rich foods and fiber and reduced consumption of carbonated beverages. Eating family meals together 7 or more times per week resulted in families consuming 1 serving more of fruits and vegetables per day compared with families who had no meals together. These improvements in dietary intake were sustained 5 years later during young adulthood. Family meals also have been shown to protect girls from disordered eating behaviors. Most recently, a prospective study in more than 13 000 preadolescents and adolescents found that eating family dinners most days or every day during the previous year was protective against purging behaviors, binge eating, and frequent dieting. The trend was similar in both females and males, although not statistically significant in males. In girls, family meals perceived to be enjoyable were protective from extreme weight-control behaviors. Postulates for why family meals are protective include the following: families will consume healthier foods than teenagers would choose on their own; parents can model healthy food choices; family meals provide a time for teenagers and parents to interact; and parents can monitor their child's eating and address issues earlier when they are aware of their child's eating behavior.

In 2016, the **Children's Hospital Association** recommended registered dietitians (RDs) play an integral role in a comprehensive multidisciplinary weight management programs for overweight and obese youth. This level of intervention is classified as a Stage 3 approach in the current paradigm for treatment of pediatric obesity and has been found to be most effective in improving weight status when clinician contact time is provided at a medium (26 to 75 hours) to high intensity (>75 hours) over a 6-12 month period. The consensus recommendations for nutrition assessment and treatment are provided below:

Consensus Statements for Nutrition Assessment:

Nutrition assessment components vary depending on the clinical setting, patient population, physical findings, availability of laboratory values, and the clinical judgment of the RD. Consensus statements for nutrition assessment in Stage III Pediatric Weight Management programs were formulated based on the results from two surveys and subcommittee discussion, starting with survey items for which >50 percent of respondents indicated use of the concept. FOCUS on a Fitter Future (FFF) RDs agreed unanimously that these values should be utilized. The statements can be used as guides when assessing a child or adolescent with the medical diagnosis of obesity, in conjunction with other available clinical tools. Note: these may be gathered by, or in conjunction with, other providers on the team.

A. Nutrition assessment of anthropometric measures should include the following:
    a. Weight
    b. Height
    c. BMI
    d. BMI percentile/z-score
    e. BMI change
    f. Weight change
    g. Height change
    h. Growth pattern indices/percentile ranks

    Note: The current Centers for Disease Control (CDC) growth charts do not allow for plotting of BMI above the 97th percentile for age. Current practice calculates exact BMI percentile/z-score whenever possible. New growth charts developed at Children's Hospital Colorado define a child's BMI as a percentage of the 95th percentile. These may be used for monitoring a patient's progress over time as well.
B. Nutrition assessment should include assessment of biochemical values.
C. Nutrition assessment is more comprehensive when it includes the physical findings.
D. Nutrition assessment of food and nutrition-related history should include the following
    a. Food and nutrient intake – meal/snack patterns, nutrient composition, current and previous regimens, food intolerance and allergies
    b. Medication/herbal supplements use – medications, OTC medications, and herbal supplements
    c. Knowledge/beliefs/attitudes – feelings/emotions toward nutrition, readiness to change, understanding of nutrition concepts
    d. Behavior – activities and actions taken to achieve goals

e. Food and supply availability – factors that affect availability of safe, healthy food and supplies
f. Physical activity and function – evaluate physical, cognitive, sleep habits and sedentary habits
g. Nutrition-related patient/client-centered measures – perception of nutrition intervention impact

E. Assessment of client history should include the following:
   a. Personal – language, age, education, role in family, ethnicity
   b. Client/Family Medical – disease states, conditions, illnesses
   c. Social – socioeconomic status, housing, medical care support

Consensus Statements for Nutrition Treatment:

Treatment of overweight or obese children and adolescents can play an important role in preventing long-term complications from obesity as well as improving quality of life and self-esteem. The following consensus statements provide a basic framework for treatment. General counseling approaches are introduced first, followed by more specific lifestyle-based treatments, and then dietary interventions recognized to be effective for pediatric weight management. The overall treatment goal is to provide a positive experience and an achievable plan of care that will help patients successfully achieve a healthier weight and improve health outcomes.

Nutrition treatment should include the following:

- Use family/patient-centered counseling techniques, with the spirit of motivational interviewing.
- If families have not received recommendations in earlier intervention stages or would benefit from behavior changes in the following areas, address these before advancing to other topics. These five areas are easily identified, have an evidence base for effective weight loss and/or maintenance in the family setting and when addressed, may yield improvements in dietary intake and weight within a relatively short period of time.
  - sugar-sweetened beverages (including juice)
  - breakfast consumption
  - meal & snack timing
  - family meals/feeding dynamics
  - eating out
- Interactions and counseling should be culturally sensitive to maximize success.
- When patients present with concerning maladaptive or disordered eating patterns (boredom/emotional eating, binging, etc.), the RD works with the rest of the team, including mental health professionals, to address these issues. Treatment may need to focus on these eating behaviors and related mental health issues before addressing other problems noted in the nutrition assessment.
- Patients and their families need to be followed at a frequency that will facilitate behavior and lifestyle changes to support attainment and maintenance of a healthier weight.

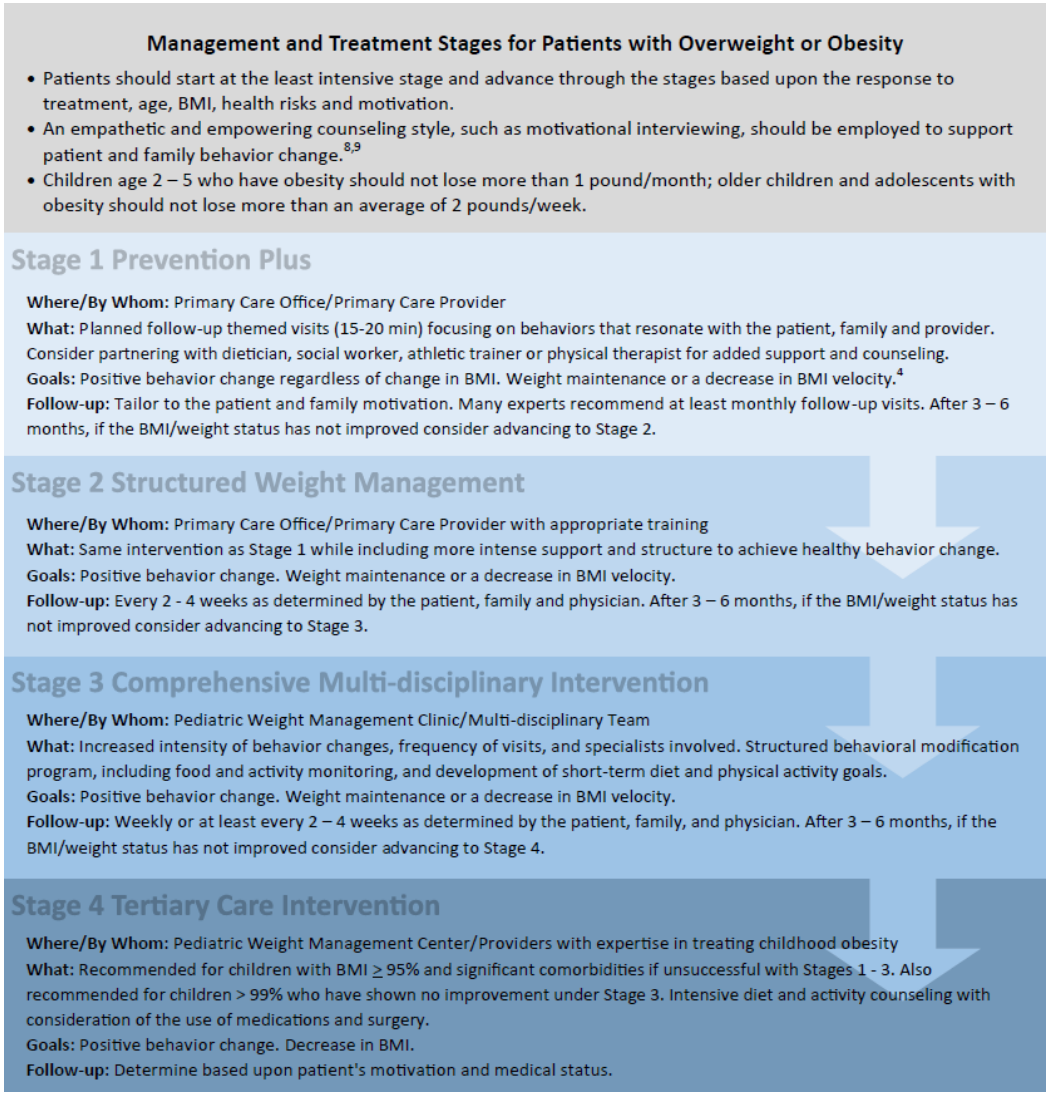
- Specific plans and goals set with families work best if they are focused on food and diet-related behaviors.

Recommendations for comorbid conditions:

Treatment for co-morbid conditions in a Stage 3 program will include the overarching goals of weight stabilization or loss of excess weight, resulting in an improved BMI and BMI percentile/z-score. RDs use medical nutrition therapy to provide specific strategies for dietary and other lifestyle changes according to the specific co-morbidity. In the case of familial hyperlipidemia, healthy lifestyle habits will provide a foundational advantage for additional medical treatment. Thus, RDs provide medical nutrition therapy along with recommendations to support movement toward a healthier weight/BMI.

For additional co-morbid conditions not surveyed in this document, including acanthosis nigricans, insulin resistance, dyslipidemia, hypertension, and fatty liver disease, RDs follow current evidence-based disease-specific treatment protocols for medical nutrition therapy.

The 2015 **American Academy of Pediatrics Institute for Health Childhood Weight** released the following assessment and management algorithm for childhood obesity:



Based on the 2007 **American Academy of Pediatrics** Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report stated:

Target Behaviors
The expert committee recommends that clinicians advise patients and their families to adopt and to maintain the following specific eating, physical activity, and sedentary behaviors. These healthy habits may help prevent excessive weight gain and also are unlikely to cause harm, on the basis of current knowledge. The level of evidence is indicated, and the prevention report provides references. Evidence supports the following:

1. limiting consumption of sugar-sweetened beverages (CE);
2. encouraging consumption of diets with recommended quantities of fruits and vegetables; the current recommendations from the US Department of Agriculture (USDA) (www.mypyramid.gov) are for 9 servings per day, with serving sizes varying with age (ME);
3. limiting television and other screen time (the American Academy of Pediatrics recommends no television viewing before 2 years of age and thereafter no more than 2 hours of television viewing per day), by allowing a maximum of 2 hours of screen time per day (CE) and removing televisions and other screens from children's primary sleeping area (CE) (although a relationship between obesity and screen time other than television viewing, such as computer games, has not been established, limitation of all screen time may promote more calorie expenditure);
4. eating breakfast daily (CE);
5. limiting eating out at restaurants, particularly fast food restaurants (CE) (frequent patronage of fast food restaurants may be a risk factor for obesity in children, and families should also limit meals at other kinds of restaurants that serve large portions of energy-dense foods);
6. encouraging family meals in which parents and children eat together (CE) (family meals are associated with a higher-quality diet and with lower obesity prevalence, as well as with other psychosocial benefits); and
7. limiting portion size (CE) (the USDA provides recommendations about portions, which may differ from serving sizes on nutrition labels, and a product package may contain > 1 serving size).

The prevention writing group also suggests, on the basis of analysis of available data and expertise, the following behaviors:

1. eating a diet rich in calcium (the USDA provides recommendations about serving size and daily number of dairy product servings);
2. eating a diet high in fiber;
3. eating a diet with balanced macronutrients (energy from fat, carbohydrates, and protein in proportions for age, as recommended by Dietary Reference Intakes);
4. encouraging exclusive breastfeeding to 6 months of age and maintenance of breastfeeding after introduction of solid food to 12 months of age and beyond, consistent with American Academy of Pediatrics recommendations;
5. promoting moderate to vigorous physical activity for at least 60 minutes each day; and
6. limiting consumption of energy-dense foods.

In 2014, the **UK's National Institute for Health and Care Excellence** (NICE) the following dietary recommendations:

Adults and children

- Tailor dietary changes to food preferences and allow for a flexible and individual approach to reducing calorie intake.
- Do not use unduly restrictive and nutritionally unbalanced diets, because they are ineffective in the long term and can be harmful.
- Encourage people to improve their diet even if they do not lose weight, because there can be other health benefits.

Children

- A dietary approach alone is not recommended. It is essential that any dietary recommendations are part of a multicomponent intervention.
- Any dietary changes should be age appropriate and consistent with healthy eating advice.
- For overweight and obese children and young people, total energy intake should be below their energy expenditure. Changes should be sustainable.

In 2010, The **Childhood Obesity Task Force of the European Association for the Study of Obesity** recommended the following:

Nutritional Assessment

The goals of proper nutrition in childhood are to achieve a normal body weight and develop healthy eating habits that will last a lifetime. The first step in successful nutritional counselling is the assessment of calorie intake and food habits. Nutritional assessments should include an evaluation of current intake (most importantly fruit and vegetables, sweetened beverages, fast food, portion sizes) as well as meal and snack patterns (e.g. frequency and quality of meals such as breakfast). Ideally, a clinician with specialised nutrition training, who has the primary responsibility for evaluating and making recommendations related to food behaviour, should perform the assessment. A number of simple questions asked by any practitioner, however, are adequate for an initial overview of nutritional habits as a comprehensive dietary assessment is difficult to perform and is time-consuming in a primary care setting. The following questions focus on dietary behaviours that have the strongest evidence for associations with energy balance and that are modifiable.

Specific Points

1. Identify timing and locations of meals – ask about snacking patterns in between meals, during the evening and night. Ask about where the meals are eaten, such as in the kitchen/dining room, living room, or bedroom, and if they are eaten in front of the television or computer.
2. Quantify sweetened beverage consumption – including all soft drinks, fruit juices as well as chocolate milk.
3. Assess positive components of the diet, such as fruit and vegetables, fish, and grains.
4. Assess portion sizes – although the quality of food is critical, quantity can sometimes be an issue as well. Compare portion sizes with parents and other family members.
5. Ask what the child eats during school time.

Practical Tips

1. Attempt to establish a steady schedule of meals with minimal snacking in between. If snacking occurs, recommend fruit and vegetables.
2. Eat meals in the kitchen/dining room and never in front of the television or computer. Family dinners are strongly recommended.
3. Avoid all sweetened beverages. Water is best for children.
4. Promote consumption of fruit and vegetables as much as possible.
5. Promote consumption of complex carbohydrates instead of simple carbohydrates if possible (e.g., whole wheat products).
6. Encourage consumption of low fat such as lean meat and non-fried foods.

References:

1. Children's Hospital Association (2016). "Nutrition Interventions for Stage III Pediatric Weight Management: Consensus of Registered Dietitians on Best Practice." Accessed on July 2nd, 2019 at **https://www.childrenshospitals.org/issues-and-advocacy/population-health/obesity/focus-on-a-fitter-future/nutrition-interventions-for-stage-iii-pediatric-weight-management.**

Children and Adolescents: Primary Literature

<table>
<tr><td colspan="3"><u>BODY OF EVIDENCE APPRAISAL TABLE FOR:</u>
<u>Population:</u> 5- to 18-year-olds
<u>Modality:</u> Very low-energy diet (VLED) programs
<u>Outcome:</u> Weight-related outcomes</td></tr>
<tr><td colspan="3"><u>Quality (certainty) of evidence for: (outcome)</u>
☐ High
☒ Moderate
☐ Low
☐ Very Low</td></tr>
<tr><td><u>Risk of Bias across studies:</u>
☐ High
☒ Medium
☐ Low</td><td><u>Low Quality Rating if:</u>
☒ Studies inconsistent (wide variation of treatment effect across studies, population, interventions, or outcomes varied)

☐ Studies are indirect (PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)

☐ Studies are imprecise (when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)</td><td><u>Other Considerations:</u>
Lower Quality Rating if:
☐ Publication Bias (e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect</td></tr>
</table>

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Andela, S., et al. Year Published: 2019 Location: University of Sydney, Australia Journal: *Obesity Reviews*	To evaluate the efficacy and safety of very low-energy diet (VLED) programs for weight loss in children and adolescents with obesity.	**Size:** 24 eligible studies (16 pre-post studies, 4 non-randomized trials, two RCTs, and two chart reviews); total of 674 participants across all studies. **Inclusion Criteria:** (a) Examined the use of a formulated meal replacement or food-based VLED containing less than or equal to 3360 kJ/day (≤800 kcal/day) or less than 50% of the estimated energy requirement, (b) included participants less than or equal to 18 years old identified as having obesity by the relevant study, and (c) reported at least one weight-related outcome including, but not limited to, weight (kg) and body mass index (BMI; kg/m2). All study designs were considered because of the anticipated limited number of articles published on this topic. **Exclusion Criteria**: Studies that utilized a VLED program during pregnancy as well as studies in languages other than English were excluded.	**Type:** Systematic Review	**Results:** Weight-related outcomes significantly improved post-intervention in all studies. **Meta-analysis of 20 studies indicated a mean 10.1 kg (95% confidence interval [CI], 8.7-11.4 kg, P< 0.001; I2 = 92.3%) weight loss following interventions lasting 3 to 20 weeks.** Moderator analysis indicated greater weight loss in adolescent-only studies (10-18 years) and formulated meal replacement interventions and inpatient settings. **Meta-analysis of seven studies reporting weight at follow-up (5-14.5 months from baseline) indicated 5.3 kg mean weight loss (CI, 2.5-8.0 kg, P < 0.001; I2 = 50.6%).** Details of adverse events were limited. Risk of bias: Most studies were rated as being of neutral quality (n = 21), with only three studies classified as being of positive quality. The primary reason for a neutral classification was lack of a comparison group (n = 18).	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Andela, S., et al. (2019). "Efficacy of very low-energy diet programs for weight loss: A systematic review with meta-analysis of intervention studies in children and adolescents with obesity." Obesity Reviews **20**(6): 871-882.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children aged 7 – 12 years
Modality: Carbohydrate (CHO)-modified diets vs. standard portion-control (PC) diet
Outcome: BMI *z* score

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Kirk, S., et al. Year Published: 2012 Location: Cincinnati Children's Hospital Medical Center Journal: *Journal of Pediatrics*	To compare the effectiveness and safety of carbohydrate (CHO)-modified diets with a standard portion-controlled (PC) diet in obese children.	**Size:** 102 obese children **Inclusion Criteria:** 7-12 years, a fasting blood glucose level </= mg/dL, and a body mass index (BMI) *z* score of 1.60-2.65. Absence of developmental or physical disabilities, the ability to function independently in group exercise sessions, and parent/guardian commitment to attending study sessions. **Exclusion Criteria:** Medical conditions, such as cardiac, pulmonary, thyroid, renal, or liver disease; hyperlipidemia; diabetes; or significant mental illness.	**Type:** RCT **Intervention:** Obese children aged 7-12 years were randomly assigned to a 3-month intervention of a low-CHO (LC), reduced glycemic load (RGL), or standard PC diet, along with weekly dietary counseling and biweekly group exercise. Anthropometry, dietary adherence, and clinical measures were evaluated at baseline and 3, 6, and 12 months. Analyses applied intention-to-treat longitudinal mixed models.	**Results:** Eighty-five children (83%) completed the 12-month assessment. Daily caloric intake decreased from baseline to all time points for all diet groups (P<.0001), although LC diet adherence was persistently lower (P<.0002). **At 3 months, body mass index *z* score was lower in all diet groups (LC, -0.27 +/- 0.04; RGL, -0.20 +/- 0.04; PC, -0.21 +/- 0.04; P<.0001) and was maintained at 6 months, with similar results for waist circumference and percent body fat**.	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

				At 12 months, participants in all diet groups had lower body mass index z scores than at baseline (LC, -0.21 +/- 0.04; RGL, -0.28 +/- 0.04; PC, -0.31 +/- 0.04; P<.0001), and lower percent body fat, but no reductions in waist circumference were maintained. All diets demonstrated some improved clinical measures.	

References:

1. Kirk, S., et al. (2012). "Role of carbohydrate modification in weight management among obese children: a randomized clinical trial." Journal of Pediatrics **161**(2): 320-327.e321.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Obese Hispanic children and adolescents (7-15 years of age)
Modality: Low glycemic load or a low-fat dietary intervention
Outcome: Body weight

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**

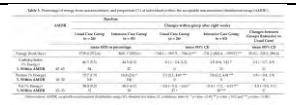
Author: Mirza, N.M., et al. Year Published: 2013 Location: Children's National Medical Center, Washington, DC Journal: *American Journal of Clinical Nutrition*	To compare the effects of an low-fat dietary (LGD) and a low-fat diet (LFD) on body composition and components of metabolic syndrome in obese Hispanic youth.	**Size:** 113 children **Inclusion Criteria:** Hispanic children aged 7-15 y with a BMI >/= 95th percentile for age and sex who were otherwise healthy. **Exclusion Criteria:** Any medical condition that would interfere with study objectives or procedures, such as preexisting T2D, Cushing syndrome, untreated hypothyroidism, pervasive developmental disorder, severe asthma, untreated depression, use of medications known to promote weight gain or loss, and obesity-associated genetic syndromes.	**Type:** RCT **Intervention:** Obese Hispanic children were randomly assigned to consume an LGD or an LFD in a 2-y intervention program. Body compositions and laboratory assessments were obtained at baseline, and 3, 12, and 24-mo after intervention. Intervention consisted of 12 weekly nutrition education and dietary counseling sessions.	**Results:** Compared with the LFD, the LGD decreased the glycemic load per kilocalories of reported food intakes in participants at 3-mo (P = 0.02). **Both groups had a decreased BMI z score (P < 0.003), which was expressed as a standard z score relative to CDC age- and sex-specific norms, and improved waist circumference and systolic blood pressure (P < 0.05) at 3, 12, and 24 mo after intervention.** **However, there were no significant differences between groups for changes in BMI, insulin resistance, or components of metabolic syndrome (all P > 0.5).**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

References:

1. Mirza, N. M., et al. (2013). "Effects of a low glycemic load or a low-fat dietary intervention on body weight in obese Hispanic American children and adolescents: a randomized controlled trial." American Journal of Clinical Nutrition **97**(2): 276-285.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Children and adolescents with abdominal obesity Modality: Mediterranean diet Outcome: Nutrient adequacy		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if:

		☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Ojeda-Rodriguez, A., et al. Year Published: 2018 Location: University of Navarra, Spain Journal: *Nutrients*	To evaluate a lifestyle intervention on nutrient adequacy and diet quality in children and adolescents with abdominal obesity.	**Size:** 107 participants **Inclusion Criteria:** Children aged 7 to 16 years, with a waist circumference above the 90th percentile. **Exclusion Criteria:** Prevalent pre-diabetes, food intolerance, eating disorders or psychiatric disease, pharmacological treatment, regular alcohol consumption or special diet treatment.	**Type:** RCT **Intervention:** Participants were assigned either to a usual care group or to an intensive care group that followed a moderate hypocaloric Mediterranean diet and received nutritional education. Intake adequacy was evaluated using Dietary Reference Intakes and diet quality through the Diet Quality Index for Adolescents (DQI-A), the Healthy Lifestyle Diet-Index (HLD-I) and the Mediterranean Diet Quality Index (KIDMED). Intervention consisted of a two-year program that comprises an eight-week phase with a total follow-up period of 22 months.	**Results:** Subjects from usual care (n = 26) and intensive care (n = 81) groups had similar baseline clinical measurements, except for glucose levels. **The change in glucose levels between group was statistically significant (p = 0.033), but did not remain statistically significant in ANCOVA model when it was adjusted for baseline BMI-SDS and glucose levels (p = 0.367).** **Both groups achieved a significant reduction in BMI standard deviation score (BMI-SDS), glucose and total cholesterol levels**. Intake of Calcium, Iodine and vitamin D were higher in the intensive care group, with enhanced compliance with recommendations. Higher dietary scores were associated with lower micronutrient inadequacy. DQI-A and HLD-I were significantly higher in the intensive care group vs. usual care group after the treatment.	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☒ Difference in important prognostic factors at baseline

References:

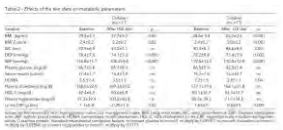
1. Ojeda-Rodriguez, A., et al. (2018). "Improved Diet Quality and Nutrient Adequacy in Children and Adolescents with Abdominal Obesity after a Lifestyle Intervention." Nutrients **10**(10): 13.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children
Modality: Hypocaloric low glycemic index vs. hypocaloric high glycemic index
Outcome: BMI

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Parillo, M., et al. Year Published: 2012 Location: A. Cardarelli Hospital, Naples, Italy Journal: *Journal of Endocrinological Investigation*	To compare the effects of two diets, hypocaloric low glycemic index (LGI) vs. hypocaloric high glycemic index (HGI) with similar energy intakes, but different glycemic indexes in a pediatric outpatient setting.	**Size:** 22 children **Inclusion Criteria**: Children with a BMI *Z*-score >2	**Type:** RCT **Intervention**: Patients were randomly allocated to a hypocaloric LGI (GI:60), or to a hypocaloric high glycemic index (HGI) diet (GI:90). The	**Results:** In both groups there were significant decreases in BMI, BMI Z-score, blood pressure, and high-sensitivity C-reactive protein. Only LGI diets produced a significant decrease in waist circumference and	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT

		Exclusion Criteria: Children with acute or chronic disease or on pharmacologic therapy.	LGI and HGI diets were almost equivalent for macronutrient composition. Anthropometric and biochemical parameters were measured at baseline and after 6 months.	homeostasis model assessment. **Analysis of variance demonstrated that the BMI Z-score decrease from baseline values was significantly greater after the LGI diet than after the HGI diet [-0.20 (95% confidence interval (CI) -0.29 to -0.10) vs -0.34 (95%CI -0.43 to -0.24)], mean difference between groups -0.14 (95%CI -0.27 to -0.01), p<0.05). Changes in triglyceride concentrations were significantly lower in LGI as compared to HGI diet (p<0.05).** 	☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☒ Difference in important prognostic factors at baseline

References:

1. Parillo, M., et al. (2012). "Metabolic changes after a hypocaloric, low-glycemic-index diet in obese children." Journal of Endocrinological Investigation **35**(7): 629-633.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Children 8-17 years of age with fatty liver Modality: Low-glycemic load vs. low-fat diet Outcome: Weight and fasting insulin		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☐ Low ☒ Very Low		
Risk of Bias across studies: ☒ High ☐ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect

		☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Ramon-Krauel, M., et al. Year Published: 2013 Location: Boston Children's Hospital Journal: *Childhood Obesity*	To compare the effects of a low-glycemic-load (GL) versus conventional low-fat diet in obese children with fatty liver.	**Size:** 17 children **Inclusion Criteria:** Obese children with hepatic steatosis, defined as >/= 9% liver fat content.	**Type:** RCT **Intervention:** Children were randomly assigned to an experimental (low-GL) or conventional (low-fat) dietary treatment group. Both groups received nutrition education, behavioral counseling, and exercise recommendations of comparable intensity, throughout a 6-month intervention (nine visits and seven telephone calls with a dietitian). The primary outcome, hepatic fat content by proton magnetic resonance spectroscopy (MRS), and secondary outcomes related to the risk for diabetes and cardiovascular disease were measured at baseline and 6 months.	**Results:** Reported glycemic load decreased in the low-glycemic-load group and reported dietary fat decreased in the low-fat group. At baseline, liver fat was 23.8% [standard deviation (SD) 12.2] in the low glycemic-load group and 29.3% (14.1) in the low-fat group. **Liver fat decreased substantially in both groups at 6 months expressed as absolute percentage change, with no between-group differences [- 8.8 (standard error (SE) 4.1) vs. - 10.5 (3.7)%, respectively, p = 0.76 for group · time interaction].** Secondary outcomes also improved on both diets, with no between-group differences. Baseline and change in ALT were strongly associated with hepatic fat content.	**Study Limitations:** ☐ None ***RCTs*** ☐ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☒ Difference in important prognostic factors at baseline

References:

1. Ramon-Krauel, M., et al. (2013). "A low-glycemic-load versus low-fat diet in the treatment of fatty liver in obese children." Childhood Obesity **9**(3): 252-260.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children aged 4-9 years
Modality: U.S. primary care pediatric obesity treatment
Outcome: BMI and Dietary Intake

Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low					
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Raynor, H. A., et al. Year Published: 2012 Location: University of Tennessee Journal: *Pediatric Obesity*	To examine the efficacy of U.S. primary care paediatric obesity treatment recommendations, within two randomized trials.	**Size:** 182 families **Inclusion Criteria**: Children aged 4–9 years, body mass index (BMI) ≥ 85th percentile).	**Type:** RCT **Intervention:** Families were recruited for two separate trials and randomized within trial to a 6-month intervention. Each trial had one intervention that increased child growth monitoring frequency and feedback to families (GROWTH MONITORING). Each trial also had two interventions, combining GROWTH MONITORING with an 8-session, behavioral, parent-only intervention targeting two energy-balance behaviors (Trial 1: reducing snack foods and sugar sweetened beverages [DECREASE] and increasing fruits, vegetables, and low-fat dairy [INCREASE]; Trial 2: decreasing sugar sweetened	**Results:** There were no significant differences between the interventions at baseline in dietary intake for either the child or parent. Child: **For fruit and vegetable and snack food intake, there was a main effect of time, with a significant ($p < 0.01$) increase in fruits and vegetable consumption from 0 to 6 months, while snack food intake significantly ($p < 0.01$) decreased from 0 to 6 months. There were no differences found between the interventions in change in fruit and vegetable, or snack food intake. For sugar sweetened beverages, an interaction of intervention x time was found, with DECREASE significantly ($p < 0.01$) reducing intake from 0 to 6 months. A main effect of**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline

			beverages and increasing physical activity. General guidelines were provided, which included: 1) starting with children as young as 3 years of age; 2) monitoring growth outcomes regularly (i.e., monthly); 3) applying a family-based model; and 4) using behavior modification techniques to change the child's eating and activity behaviors. The Committee also emphasized that two or three energy-balance behaviors should be targeted during treatment	**time occurred for energy intake, with energy intake significantly ($p < 0.05$) decreasing from 0 to 6 months and 0 to 12 months. There were no differences found between the interventions in change in energy intake. No change in intake in low-fat dairy was found.** Parent: There was a significant main effect of time for snack food and sugar sweetened beverage intake. **Snack food intake significantly ($p < 0.05$) decreased from 0 to 12 months and sugar sweetened beverage intake significantly ($p < 0.05$) decreased from 0 to 6 months. A main effect of time was also found for energy intake, with energy intake significantly ($p < 0.01$) decreasing from 0 to 6 months and 0 to 12 months. There were no differences found between the interventions in change in dietary intake. No change in intake in fruits and vegetables, and low-fat dairy was found.**	

References:

1. Raynor, H. A., et al. (2012). "Efficacy of U.S. paediatric obesity primary care guidelines: two randomized trials." Pediatric Obesity **7**(1): 28-38.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Mediterranean-style diet
Outcome: Metabolic syndrome components

Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low					
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Velazquez-Lopez, L., et al. Year Published: 2014 Location: Instituto Mexicano del Seguro Social, Mexico City, Mexico Journal: *BMC Pediatrics*	To assess the efficacy of the Mediterranean style diet (MSD) to decrease cardiovascular risk factors in children and adolescents with obesity.	**Size:** 49 children and adolescents. **Inclusion Criteria:** Body Mass Index (BMI) ≥95th percentile and any MetS component, according to modified International Diabetes Federation (IDF) criteria for children and adolescents; waist circumference (WC) ≥90th percentile; fasting glucose ≥ 100 mg/dL; TG ≥150 mg/dL; HDL-C ≤ 40 mg/dL; systolic blood pressure (SBP) ≥130 mmHg and/ or diastolic blood pressure (DBP) ≥85 mmHg.	**Type:** RCT **Intervention:** Participants were randomly assigned to an MSD rich in polyunsaturated fatty acids, fiber, flavonoids and antioxidants (60% of energy from carbohydrate, 25% from fat, and 15% from protein, (n = 24); or a standard diet (55% of carbohydrate, 30% from fat and 15% from protein, (n = 25), the caloric ingest was individualized. At baseline and 16-week of intervention, the glucose, triglycerides (TG), total cholesterol (TC), HDL-C, LDL-C were measured as well as the body composition and anthropometric data. The diet compliance was determined by the 24-hour recalls.Paired Student's t and Macnemar's test were used to compare	**Results: The MSD group had a significant decrease in BMI, lean mass, fat mass, glucose, TC, TG, HDL-C and LDL-C. (p < 0.05); the diet compliance increased consumption of omega 9 fatty acids, zinc, vitamin E, selenium, and decreased consumption of saturated fatty acids (p < 0.05). The standard diet group decrease in glucose levels and frequency of glucose >100 mg/dL (p < 0.05).**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

			effects in biochemical, body composition, anthropometric, and dietary variables.		

References:

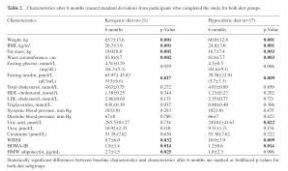
1. Velazquez-Lopez, L., et al. (2014). "Mediterranean-style diet reduces metabolic syndrome components in obese children and adolescents with obesity." BMC Pediatrics **14**: 175.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Ketogenic diet vs. hypocaloric diet
Outcome: Metabolic impact

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

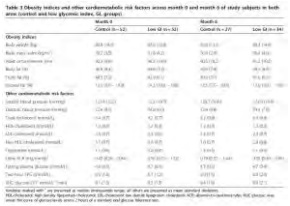
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Partsalaki, I., et al. Year Published: 2012 Location: University of Patras School of Medicine, Greece Journal: *Journal of Pediatric Endocrinology & Metabolism*	To compare the efficacy and metabolic impact of ketogenic and hypocaloric diets in obese children and adolescents.	**Size:** 58 participants **Inclusion Criteria:** Children and adolescents aged 8 -18 with a BMI >95th percentile. All subjects were not following any specialized diet and had normal liver, respiratory,	**Type:** RCT **Intervention:** Participants were randomly recruited from the outpatient clinic and assigned to either a ketogenic diet or a hypocaloric diet was a goal to lose at least 10% of their initial	**Results: Both groups significantly reduced their weight, fat mass, waist circumference, fasting insulin, and HOMA-IR (p = 0.009 for ketogenic and p = 0.014 for hypocaloric), but the differences were greater in the ketogenic group. Both**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT

		kidney, and gastrointestinal functions. All children with thyroid dysfunction were on treatment with thyroxine and were euthyroid during the entire study. **Exclusion Criteria**: Individuals with diabetes or genetically associated obesity syndromes were excluded from the study.	body weight. The duration of the study was 6 months. Anthropometric measurements, body composition, oral glucose/insulin tolerance test, lipidemic profile, high molecular weight (HMW) adiponectin, whole-body insulin sensitivity index (WBISI), and homeostatic model assessment-insulin resistance (HOMA-IR) were determined before and after each diet.	**groups increased WBISI significantly, but only the ketogenic group increased HMW adiponectin significantly (p = 0.025).** 	☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

References:

1. Partsalaki, I., et al. (2012). "Metabolic impact of a ketogenic diet compared to a hypocaloric diet in obese children and adolescents." Journal of Pediatric Endocrinology & Metabolism **25**(7-8): 697-704.

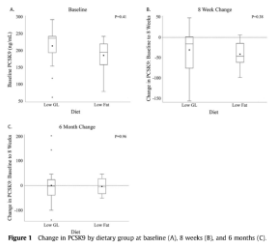
BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adolescents aged 15-18 years Modality: Low glycemic index (GI) diet Outcome: BMI		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Kong, A. P., et al. Year Published: 2014 Location: The Chinese University of Hong Kong Journal: *BMC Public Health*	To evaluate the impact of low GI diet versus a conventional Chinese diet on the body mass index (BMI) and other obesity indices of obese adolescents.	**Size:** 104 adolescents (52 in low GI group and 52 in control group). **Inclusion Criteria:** BMI >/= 95th percentile, healthy with no major medical illnesses and not on any chronic medications.	**Type:** RCT **Intervention:** Obese adolescents were identified from territory-wide, population-recruited survey. Eligible subjects were randomized to either an intervention with low GI diet (consisting of 45-50% carbohydrate, 30-35% fat and 15-20% protein) or conventional Chinese diet as control (consisting of 55-60% carbohydrate, 25-30% fat and 10-15% protein). Subjects allocated to the low GI group were counselled by a dietitian at week 0, 2, 4, 6, 8 and thereafter at 8-week intervals, for a total of 7 sessions during the 6-month intervention period. Each session lasted approximately 30 minutes on an individual basis. Parents of the subject were encouraged to join the counselling sessions.	**Results: After adjustment for age and sex, subjects in the low GI group had a significantly greater reduction in obesity indices including BMI, body weight and waist circumference (WC) compared to subjects in the control group (all p <0.05). After further adjustment for physical activity levels, WC was found to be significantly lower in the low GI group compared to the conventional group (p = 0.018).** 	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline

References:

1. Kong, A. P., et al. (2014). "A randomized controlled trial to investigate the impact of a low glycemic index (GI) diet on body mass index in obese adolescents." BMC Public Health **14**: 180.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Obese and overweight adolescents with CVD risk factors
Modality: Calorically restricted diets
Outcome: Proprotein convertase subtilisin kexin type 9 (PCSK9)

Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☐ Low ☒ Very Low					
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Levenson, A. E., et al. Year Published: 2017 Location: Boston Children's Hospital Journal: *Nutrition Metabolism & Cardiovascular Diseases*	To examine the effects of an intensive nutritional intervention on PCSK9 levels in overweight adolescents with cardiovascular disease (CVD) risk factors.	**Size:** 27 adolescents **Inclusion Criteria**: Overweight or obese (BMI >/= 85th percentile) children and adolescents, aged -21 years, with at least three CVD risk factors including fasting TG level >100 mg/dl, HDL-C <45 mg/dL for boys aged 15-19 years and <50 mg/dL for all other participants, systolic blood pressure >90th percentile for gender, age, and height, and fasting glucose >/= 100 mg/dL or fasting insulin level > 15 uU/mL. **Exclusion Criteria**: Current or anticipated pregnancy, weight >275 lbs (125 kg), major medical illness, medications that might significantly affect CVD risk factors or weight, or abnormalities at the screening	**Type:** RCT **Intervention**: Adolescents with CVD risk factors were assigned to either a low fat or low glycemic load diet. During an 8-week "Intensive Phase," assigned meals were delivered to the home, and all participants received weekly in-person home nutrition counseling and phone calls. The subjects then underwent a 4-month "Maintenance Phase" without food provision and with no in-person contact. Anthropometric measurements, laboratory data, and serum PCSK9 protein levels were measured at baseline, 8 weeks, and 6 months.	**Results: PCSK9 decreased by 16.5% at 8 weeks (201.2 +/- 56.3 vs 165.6 +/- 58.4 ng/mL; p < 0.001); PCSK9 levels returned to baseline levels at 6 months, after the Maintenance Phase.** Change in PCSK9 was associated with change in fasting insulin, HOMA-IR, and AUC insulin, independent of weight loss. 	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline

		assessment that required pharmacotherapy.			

References:

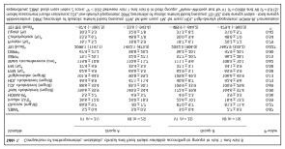
1. Levenson, A. E., et al. (2017). "Calorically restricted diets decrease PCSK9 in overweight adolescents." Nutrition Metabolism & Cardiovascular Diseases **27**(4): 342-349.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adolescents aged 12 – 15 years old
Modality: Fixed diet vs. calorie-counting diet
Outcome: Weight loss, metabolic profile and food intake

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

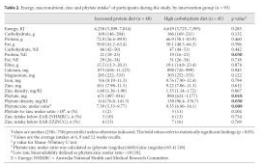
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Mended, M.D., et al. Year Published: 2017 Location: University of Sao Paulo, Brazil Journal: *European Journal of Clinical Nutrition*	To compare the weight loss of obese adolescents on two different low-calorie diets: fixed diet plan and calorie-counting diet.	**Size:** 66 adolescents **Inclusion Criteria**: Adolescents aged 12–15 years old with obesity (ZBMIX+2.0 according to World Health Organization).	**Type:** RCT **Intervention**: Adolescents were randomly assigned to group A and group B. Group A received a fixed diet plan to assist in the choice of foods aimed at changing eating behavior. Group B underwent a calorie-counting diet, in which each patient received a table	**Results: There was a reduction in the ZBMI in both groups (P<0.0001), without significant difference between them (P=0.87).** There was a significant reduction in insulin, and homeostasis model assessment insulin resistance (HOMA-IR), with no difference between groups. A	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome)

			list with equivalent points for food and drinks, and was instructed to record all daily food or drink intake and calculate the total score of points consumed. During the study, the participants attended eight visits over 6 months. Diet, physical activity through metabolic equivalents, anthropometry and clinical profile were evaluated in all visits.	reduction in total energy intake of the groups was found, with an increase in the proportion of protein and reduction in carbohydrates. In this cohort of severely obese adolescents, fixed diet plan and calorie-counting diet led to a similar reduction of ZBMI, metabolic markers and total energy intake. 	☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

References:

1. Mendes, M. D., et al. (2017). "Effects of two diet techniques and delivery mode on weight loss, metabolic profile and food intake of obese adolescents: a fixed diet plan and a calorie-counting diet." European Journal of Clinical Nutrition **71**(4): 549-551

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adolescents Modality: Low-energy diets Outcome: Zinc status and cardiometabolic markers		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Ho, M., et al. Year Published: 2016 Location: University of Sydney, Australia Journal: *Annals of Nutrition & Metabolism*	To determine the effects of low-energy diets differing in macronutrient composition on zinc intake, estimated zinc bioavailability (phytate:zinc molar ratio) and plasma zinc concentration and associations between zinc status and cardiometabolic markers in obese adolescents with clinical insulin resistance (IR).	**Size:** 87 **Inclusion Criteria**: 10-17 years, body mass index z-score 2.3 +/- 0.37, patients has either pre-diabetes or clinical features of insulin resistance (IR). Clinical features of IR were defined as a fasting insulin (pmol/l)/glucose (mmol/l) ratio >20 with one or more of the following: acanthosis nigricans, polycystic ovary syndrome, hypertension, fasting high density lipoprotein (HDL)-cholesterol <1.03 mmol/l or fasting triglycerides ≥ 1.7 mmol/l.	**Type:** Secondary analysis of RCT outcomes **Intervention**: Participants were randomized to either a high carbohydrate diet (55–60% of total energy as carbohydrate, 30% fat and 15% protein) or a moderate-carbohydrate, increased-protein diet (40–45% of total energy as carbohydrate, 30% fat and 25–30% protein). Both diets were prescriptive and 2 different energy levels were prescribed depending upon age: 6,000–7,000 kJ (10–14 years) or 7,000–8,000 kJ (15–17 years). All participants were treated with metformin (500 mg twice daily). The RESIST trial was a 12-month RCT. Measurements from baseline to 12 weeks were used for this analysis. Dietary intake was assessed by 24-hour dietary recalls at 6, 9 and 12 weeks using a standardized 3-pass methodology.	**Results**: **Zinc intake did not differ between the 2 diet groups (p = 0.612). The high-carbohydrate group had a higher phytate intake (894 vs. 671 mg, p = 0.018) and phytate:zinc molar ratio (9.4 vs. 7.4, p = 0.009) than the increased-protein group.** Plasma zinc concentration did not change from baseline in either of the diet groups, but correlated positively with zinc intake (r = 0.235, p = 0.042) and % energy from protein (r = 0.383, p = 0.001), and inversely with % energy from carbohydrate (r = -0.296, p = 0.010). 	**Study Limitations:** ☒ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

References:

1. Ho, M., et al. (2016). "Zinc Intake, Zinc Bioavailability and Plasma Zinc in Obese Adolescents with Clinical Insulin Resistance Following Low Energy Diets." Annals of Nutrition & Metabolism **69**(2): 135-141.

Adult: Guideline Recommendations

In 2016, the **Academy of Nutrition and Dietetics** recommended the following in the position paper on interventions for the treatment of overweight and obesity in adults.

- The registered dietitian nutritionist (RDN) should collaborate with the individual regarding a realistic weight-loss goal such as one of the following: up to 2 lb per week, up to 10% of baseline body weight, or a total of 3% to 5% of baseline weight if cardiovascular risk factors (hypertension, hyperlipidemia, and hyperglycemia) are present. **(Rating: Strong, Imperative)**

Socioecological Model of Obesity Intervention:

- The RDN should assess the following data in order to individualize the comprehensive weight-management program for overweight and obese adults: food and nutrition-related history; anthropometric measures; biochemical data, medical tests and procedures; nutrition-focused physical findings; and client history. **(Rating: Strong, Imperative)**
- The RDN should assess the energy intake and nutrient content of the diet. **(Rating: Strong, Imperative)**
- If indirect calorimetry is available, the RDN should use a measured resting metabolic rate (RMR) to determine energy needs in overweight or obese adults. **(Rating: Consensus, Conditional)**
- If indirect calorimetry is not available, the RDN should use the Mifflin-St. Jeor equation using actual weight to estimate RMR in overweight or obese adults. **(Rating: Strong, Conditional)**
- The RDN should multiply the RMR by one of the following physical activity factors to estimate total energy needs: sedentary (1.0 or more to less than 1.4); low active (1.4 or more to less than 1.6); active (1.6 or more to less than 1.9); and very active (1.9 or more to less than 2.5). **(Rating: Consensus, Imperative)**
- The RDN should assess motivation, readiness and self-efficacy for weight management based on behavior change theories and models (such as cognitive behavioral therapy, transtheoretical model, and social cognitive theory/social learning theory). **(Rating: Fair, Imperative)**

Dietary Intervention:

- During weight loss, the RDN should prescribe an individualized diet, including patient preferences and health status, to achieve and maintain nutrient adequacy and reduce caloric intake, based on one of the following caloric reduction strategies: 1,200 kcal to 1,500 kcal/day for women and 1,500 to 1,800 kcal/day for men; energy deficit of approximately 500 kcal/ day or 750 kcal/day; one of the evidence-based diets that restricts certain food types (such as high-carbohydrate foods, low-fiber foods, or high-fat foods) in order to create an energy deficit by reduced food intake. **(Rating: Strong, Imperative)**
- For weight loss, the RDN should advise overweight or obese adults that as long as the target reduction in calorie level is achieved, many different dietary approaches are effective. **(Rating: Strong, Imperative)**
- During weight maintenance, the RDN should prescribe an individualized diet (including patient preference and health status) to maintain nutrient adequacy and reduce caloric intake for maintaining a lower body weight. **(Rating: Strong, Imperative)**
- For weight maintenance, the RDN should advise overweight and obese adults that as long as the target reduction in calorie level is achieved, many different dietary approaches are effective. **(Rating: Strong, Imperative)**
- For weight loss and weight maintenance, the RDN should recommend portion control and meal replacements or structured meal plans as part of a comprehensive weight-management program. **(Rating: Strong, Imperative)**

The 2016 **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

Reduced-calorie meal plan an macronutrient composition

- Reducing total energy (caloric) intake should be the main component of any weight-loss intervention **(Grade A; BEL 1)**.
- Even though the macronutrient composition of meals has less impact on weight loss than adherence rates in most patients, in certain patient populations, modifying macronutrient composition may be considered to optimize adherence, eating patterns, weight loss, metabolic profiles, risk factor reduction, and/or clinical outcomes **(Grade A; BEL 1)**.

Table 9. Association of Eating Patterns and Macronutrient Composition on Weight-Loss Efficacy

Eating Pattern or Macronutrient Change	Effect	Reference [EL]
Low glycemic index/load	• ↑ Endothelial function • ↓ Glycemic variability • Effects on energy expenditure • Decreased adipocyte diameter • No incremental effect on weight loss	33 (EL 1; RCT), 34 (EL 1; RCT), 35 (EL 1; RCT, small N=13), 36 (EL 1; RCT)
Low carbohydrate	• Improved glycemic status and lipids • Improved other cardio-metabolic risk factors • Improved renal function • No incremental effect on weight loss (some studies show more short-term weight loss)[1]	37 (EL 4; NE), 38 (EL 1; RCT), 39 (EL 1; RCT), 40 (EL 1; RCT), 41 (EL 1; RCT), 42 (EL 1; RCT), 43 (EL 2; NRCT), 44 (EL 1; RCT), 45 (EL 1; RCT), 46 (EL 1; RCT), 47 (EL 1; RCT)
High protein	• Longer benefit on WC, %fat • Improved cardio-metabolic risk factors • Decreased adipocyte diameter • Animal (not plant) proteins associated with markers of inflammation • Less relative loss of muscle mass • No incremental effect on weight loss	33 (EL 1; RCT), 38 (EL 1; RCT), 45 (EL 1; RCT), 48 (EL 1; RCT), 49 (EL 1; RCT), 50 (EL 1; RCT), 51 (EL 1; RCT), 52 (EL 1; RCT), 53 (EL 1; RCT)
Moderate carbohydrate – moderate protein	• Improved body composition, lipid, ppINS • No incremental effect on weight loss	37 (EL 4; NE), 54 (EL 1; RCT)
Low fat	• Beneficial effects on lipids • Benefits on lipids replacing with unsaturated fat • Improved renal function • No incremental effect on weight loss	37 (EL 4; NE), 41 (EL 1; RCT), 47 (EL 1; RCT), 55 (EL 1; RCT), 56 (EL 1; RCT)
High fat	• With lactation: when hypocaloric, great weight loss compared with hypocaloric low-carbohydrate diet	57 (EL 2; PCS)
Mediterranean-style	• Decreased risk certain cancers • EVOO supplementation – no effect on weight • Reduces cardio-metabolic risk factors and MetS • Reduces markers of inflammation • Improves hepatic steatosis and insulin sensitivity • Improves renal function • No incremental effect on weight loss	40 (EL 1; RCT), 58 (EL 1; RCT, post-hoc analysis), 59 (EL 2; PCS, post-hoc analysis), 60 (EL 1; RCT, secondary analysis), 61 (EL 2; PCS), 62 (EL 1; RCT), 63 (EL 1; RCT), 64 (EL 2; PCS), 65 (EL 2; PCS), 66 (EL 1; RCT)

Abbreviations: EL = evidence level; EVOO = extra-virgin olive oil; MetS = metabolic syndrome; ppINS = postprandial insulin response; WC = waist circumference.

[1] Incremental effect in comparison to a isocaloric control diet does not occur or is inconsistent.
[2] Short-term is < 1 year.

Figure 4. Lifestyle Therapy

Evidence-based lifestyle therapy for treatment of obesity should include 3 components
Recommendations: R64 through R75

Meal Plan (R64, R65, R66)	Physical Activity (R64, R67, R68, R69, R70, R71)	Behavior (R64, R72, R73, R74, R75)
• Reduced-calorie healthy meal plan • ~500–750 kcal daily deficit • Individualize based on personal and cultural preferences • Meal plans can include: Mediterranean, DASH, low-carb, low-fat, volumetric, high protein, vegetarian • Meal replacements • Very low-calorie diet is an option in selected patients and requires medical supervision Team member or expertise: dietitian, health educator	• Voluntary aerobic physical activity progressing to >150 minutes/week performed on 3–5 separate days per week • Resistance exercise: single-set repetitions involving major muscle groups, 2–3 times per week • Reduce sedentary behavior • Individualize program based on preferences and take into account physical limitations Team member or expertise: exercise trainer, physical activity coach, physical/occupational therapist	An interventional package that includes any number of the following: • Self-monitoring (food intake, exercise, weight) • Goal setting • Education (face-to-face meetings, group sessions, remote technologies) • Problem-solving strategies • Stimulus control • Behavioral contracting • Stress reduction • Psychological evaluation, counseling, and treatment when needed • Cognitive restructuring • Motivational interviewing • Mobilization of social support structures Team member or expertise: health educator, behaviorist, clinical psychologist, psychiatrist

The 2016 **American Academy of Family Physicians (AAFP)** recommended:

- Adherence to a diet with a deficit of 500 kcal per day, regardless of macronutrient composition, is most effective for weight loss. Simple and realistic diet modifications have the highest likelihood of success.

The 2015 **European Guidelines** for Obesity Management in Adults recommended the following:

Nutrition and Dieting

- The use of self-recorded food diary allows a qualitative assessment of the diet. In addition, it can be used to help the patient identify meal frequency (night eating, snacking, meal skipping) perceptions and beliefs about emotional eating behaviour (cognition), eating habits (behaviour) and environmental challenges to following a healthy diet **{RBP}**.
- Before giving dietary advice it might be useful to address motivation for change: How important is weight loss for the patients, and how confident the individual patient is to successfully and sustainably achieve body weight reduction? Dietary advice should encourage healthy eating and emphasise the need to increase consumption of vegetables, beans, legumes, lentils, grain, unsweetened cereals and fibre, and to substitute low-fat dairy products and meats for high-fat alternatives. It should also emphasise increased intake of seafood. It is recommended to avoid foods containing added sugars and solid fats, as well as consumption of sugary drinks and alcohol-containing beverages **{level 1, 2}**.
- An appropriate dietary regimen can be achieved in a number of ways: General Advice **{level 3, 4}**
  – Decrease energy density of foods and drinks
  – Decrease the size of food portions
  – Avoid snacking between meals
  – Do not skip breakfast and avoid eating in the night time
  – Manage and reduce episodes of loss of control or binge eating.

Specific Advice

- Energy (calorie) restriction should be individualised and take account of nutritional habits, physical activity, co-morbidities and previous dieting attempts. Prescribing an energy-restricted diet may require the intervention of a nutritionist (dietitian) **{RBP}**.
- Balanced hypocaloric diets result in clinically meaningful weight loss regardless of which macronutrients they emphasise. An emphasis put on the macronutrient proportion in the various diets (low fat, low carbohydrate or high protein etc.) has not proved better than a balanced hypocaloric diet, except for low-glycaemic load diets (carbohydrate content of the diet × glycaemic index) in the short term **{level 1}**. Despite various ranges of macronutrient composition, these diets have beneficial effects on reducing risk factors for cardiovascular disease and type 2 diabetes as well as on promoting adherence, diet acceptability and sustainability, satiety and satisfaction. Balanced hypocaloric diets can be tailored to individual patients on the basis of their personal and cultural preferences and may therefore have the best chance for long-term success (e.g. Mediterranean diet). A 15–30% decrease in energy (calorie) intake from habitual intake in a weight-stable individual is sufficient and appropriate. However, underreporting of energy intake by obese patients is common. There is a great variation in energy requirements between the individuals which is dependent on the individual's

gender, age, BMI and physical activity level. Tables predicting energy requirements taking into account gender, age, BMI and physical activity ratio can be used. An easy rule of thumb is a daily energy requirement of 25 kcal/kg for either gender but, for the same body weight, this creates a greater energy deficit in men.

- The recommended weight-reducing dietary regimen tailored to an individual's need usually provides an energy deficit of 600 kcal/day **{grade A, B}**.
- A 600 kcal (2,600 kJ) daily deficit will predict a weight loss of about 0.5 kg weekly. Thus for an obese sedentary woman with a BMI of 32 kg/m 2 and with an estimated daily intake of 2,100 kcal (8,800 kJ), a diet prescribing 1,400–1,600 kcal (6,000–7,000 kJ) would be appropriate [50, 54] **{level 2}**.
- Diets providing 1,200 kcal/day or more are classified as hypocaloric balanced diets (HBD) or balanced deficit diets. Diets providing less than 1,200 kcal/day might yield micronutrient deficiencies, which could exert untoward effects not only on nutritional status but also on the weight management outcome. However, in clinical practice a further reduction in caloric intake might be required. In this case the appropriate use of dietary supplements may prevent such nutritional deficits. In clinical practice low-calorie diets (LCDs) and very-low-calorie diets (VLCDs) are used. LCDs, consisting of normal meals and partial meal replacements, have an energy content between 800 and 1,200 kcal/day. VLCDs usually provide less than 800 kcal/day and may be used only as part of a comprehensive programme under the supervision of an obesity specialist or another physician trained in nutrition and dietetics. Their administration should be limited for specific patients and for short periods of time. VLCDs are unsuitable as a sole source of nutrition for children and adolescents, pregnant or lactating women and the elderly. Meal replacement diets (substitution of one or two daily meal portions by VLCD) may contribute to nutritionally well-balanced diet and weight loss maintenance **{level 2}**.

In 2015 **Canadian Task Force on Preventative Health Care** recommended the following:

Adults at high risk of diabetes

- For adults who are obese (BMI 30–39.9) and are at high risk of type 2 diabetes, we recommend that practitioners offer or refer to structured behavioural interventions aimed at weight loss. Structured interventions are intensive behavioural modification programs involving several sessions over weeks to months. Recommended interventions include behaviourally based interventions focused on diet, exercise or lifestyle changes, alone or in combination. Lifestyle changes include counselling, education or support, and/or environmental changes in addition to changes in exercise and/or diet. **(Strong recommendation; moderate-quality evidence)**

In 2014, the **UK's National Institute for Health and Care Excellence** (NICE) the following dietary recommendations:

Adults and children

- Tailor dietary changes to food preferences and allow for a flexible and individual approach to reducing calorie intake.
- Do not use unduly restrictive and nutritionally unbalanced diets, because they are ineffective in the long term and can be harmful.
- Encourage people to improve their diet even if they do not lose weight, because there can be other health benefits.

Adults

- The main requirement of a dietary approach to weight loss is that total energy intake should be less than energy expenditure.
- Diets that have a 600 kcal/day deficit (that is, they contain 600 kcal less than the person needs to stay the same weight) or that reduce calories by lowering the fat content (low-fat diets), in combination with expert support and intensive follow-up, are recommended for sustainable weight loss.
- Consider low-calorie diets (800–1600 kcal/day), but be aware these are less likely to be nutritionally complete.
- Do not routinely use very-low- calorie diets (800 kcal/day or less) to manage obesity (defined as BMI over 30).
- Only consider very-low-calorie diets, as part of a multicomponent weight management strategy, for people who are obese and who have a clinically-assessed need to rapidly lose weight (for example, people who need joint replacement surgery or who are seeking fertility services). Ensure that:
    - the diet is nutritionally complete
    - the diet is followed for a maximum of 12 weeks (continuously or intermittently)
    - the person following the diet is given ongoing clinical support.
- Before starting someone on a very-low-calorie diet as part of a multicomponent weight management strategy:
    - Consider counselling and assess for eating disorders or other psychopathology to make sure the diet is appropriate for them
    - Discuss the risks and benefits with them
    - Tell them that this is not a long-term weight management strategy, and that regaining weight may happen and is not because of their own or their clinician's failure
    - Discuss the reintroduction of food following a liquid diet with them.
- Provide a long-term multicomponent strategy to help the person maintain their weight after the use of a very-low-calorie diet. (See recommendation 35).
- Encourage people to eat a balanced diet in the long term, consistent with other healthy eating advice.

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

Dietary Approaches	
26. Offer any of several diets that produce a caloric deficit and have evidence for weight loss efficacy and safety (e.g., low-carbohydrate, Dietary Approaches to Stop Hypertension (DASH), low-fat).	A
27. Offer very-low-calorie diets for weight loss, but only for short durations (12-16 weeks) and under close medical supervision.	B
28. Offer meal replacements to achieve low-calorie or very low-calorie diets.	A

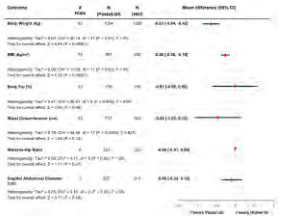
The **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** in 2013 recommended:

Diets for Weight Loss (Dietary Strategies for Weight Loss)

3a.	Prescribe a diet to achieve reduced calorie intake for obese or overweight individuals who would benefit from weight loss, as part of a comprehensive lifestyle intervention. Any one of the following methods can be used to reduce food and calorie intake: a. Prescribe 1200–1500 kcal/d for women and 1500–1800 kcal/d for men (kilocalorie levels are usually adjusted for the individual's body weight); b. Prescribe a 500-kcal/d or 750-kcal/d energy deficit; or c. Prescribe one of the evidence-based diets that restricts certain food types (such as high-carbohydrate foods, low-fiber foods, or high-fat foods) in order to create an energy deficit by reduced food intake.	A (Strong)	CQ3	I / A
3b.	Prescribe a calorie-restricted diet, for obese and overweight individuals who would benefit from weight loss, based on the patient's preferences and health status, and preferably refer to a nutrition professional* for counseling. A variety of dietary approaches can produce weight loss in overweight and obese adults, as presented in CQ3, ES2.	A (Strong)	CQ3	I / A

Adult: Primary Literature

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adult Modality: Pasta consumption Outcome: Adiposity		
Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect

		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Chiavaroli, L., et al. Year Published: 2018 Location: University of Toronto, Canada Journal: *BMJ Open*	To synthesise the evidence of the effect of pasta on measures of adiposity.	**Size:** 32 trial comparisons involving 2448 participants **Inclusion Criteria**: RCTs that investigated the effect of pasta consumed alone or in the context of low-GI dietary patterns that emphasised pasta in comparison with higher-GI diets that did not include pasta on body weight or other measures of global (BMI, body fat) or abdominal (waist circumference, waist-to-hip ratio, sagittal abdominal diameter or visceral adipose tissue as assessed by imaging modalities) adiposity in participants of all health backgrounds. Trials were included if the intervention arm assessed the effect of pasta consumed alone or assessed the effect of a low-GI diet that emphasised pasta as part of the low-GI dietary advice. **Exclusion Criteria**: Trials were excluded if they had diet duration of <3 weeks, did not intend to use a calorie-matched and macronutrient-matched comparator arm that was higher in GI, included pregnant or breastfeeding women or children, or did not	**Type:** Systematic Review	**Results:** No trial comparisons of the effect of pasta alone were identified and 32 trial comparisons (n=2448 participants) of the effect of pasta in the context of low-GI dietary patterns were found. **Pasta in the context of low-GI dietary patterns significantly reduced body weight (MD=-0.63 kg; 95% CI -0.84 to -0.42 kg) and BMI (MD=-0.26 kg/m(2); 95% CI -0.36 to -0.16 kg/m(2)) compared with higher-GI dietary patterns. There was no effect on other measures of adiposity.** The certainty of the evidence was graded as moderate for body weight, BMI, WHR and SAD and low for WC and body fat. 	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		provide suitable end-point data. When multiple publications existed for the same study, the article with the most information was included (n=6). Published abstracts were not included.			

References:

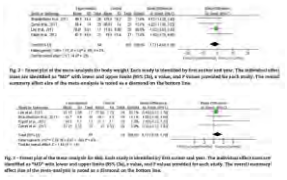
1. Chiavaroli, L., et al. (2018). "Effect of pasta in the context of low-glycaemic index dietary patterns on body weight and markers of adiposity: a systematic review and meta-analysis of randomised controlled trials in adults." BMJ Open **8**(3): e019438.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Probiotics
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Park, S. and J. H. Bae Year Published: 2015 Location: Hoseo University, Asan, Korea Journal: *Nutrition Research*	To summarize and critically evaluate the evidence from clinical trials that have tested the effectiveness of probiotics or foods containing probiotics as a treatment for weight loss.	**Size:** 9 studies **Inclusion Criteria**: Type of study: randomized controlled trial; Type of intervention: probiotics supplementation without restrictions regarding dose, route of administration,	**Type:** Systematic Review	**Results: The meta-analysis of showed no significant effect of probiotics on body weight and BMI (body weight, n = 196; mean difference, -1.77; 95% confidence interval, -4.84 to 1.29; P = .26; BMI, n = 154; mean difference, 0.77; 95% confidence interval, -**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised

		or dosage interval. The control was no probiotic supplementation or placebo; Type of outcome measure: BMI and body weight. **Exclusion Criteria**: Studies involving pregnant females and infants.		**0.24 to 1.78; P = .14).** However, the total number of RCTs included in the analysis, the total sample size, and the methodological quality of the primary studies were too low to draw definitive conclusions. 	☐ Inappropriate pooled analysis

References:

1. Park, S. and J. H. Bae (2015). "Probiotics for weight loss: a systematic review and meta-analysis." Nutrition Research **35**(7): 566-575.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Macronutrient composition of different diets
Outcome: Food cravings

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN

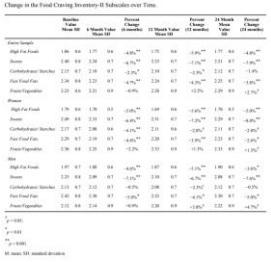
☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations

Author: Anton, S.D., et al. Year Published: 2012 Location: LSU System, Baton Rouge, LA Journal: *Eating & Weight Disorders: EWD*	To investigate whether the fat and protein content of four different diets affected changes in specific food cravings in overweight and obese adults.	**Size:** 811 adults **Inclusion Criteria**: Overweight men and women [(Body Mass Index (BMI) range = 25.0 – 40.9 kg/m2)] between the ages of 30 and 70 years. **Exclusion Criteria**: Presence of a chronic disease condition, use of medications known to affect body weight, and insufficient motivation or perceived ability to adhere to program guidelines based on a screening interview and questionnaire.	**Type**: RCT **Intervention**: Participants were randomly assigned to one of four dietary interventions, stratified by site: (1) Low fat (20% of energy), Average protein (15% of energy); (2) Moderate fat (40%), average protein (15%); (3) Low fat (20%), high protein (25%); (4) Moderate fat (40%), high protein (25%). During the first 26 weeks of the study, participants attended one hour group sessions for 3 out of every 4 weeks. The frequency of group meetings decreased to 2 out of 4 weeks for the remaining 18 months of the study (i.e., weeks 27– 104). During these group sessions, participants were provided with nutrition education and were also taught behavioral strategies (e.g., goal setting and problem solving) to help them adhere to their dietary assignment. During the entire two-year program, participants met individually with their assigned dietitian every 8 weeks. The Food Craving Inventory-II (FCI-II) was administered to assess the subjective experience of food cravings across 33 different foods at months 6, 12 and 24.	**Results:** With few exceptions, the type of diet that participants were assigned did not differentially affect changes in specific food cravings. **Participants assigned to the high fat diets, however, had reduced cravings for carbohydrates at Month12 (p< .05) and fruits and vegetables at Month 24. Also, participants assigned to high protein diets had increased cravings for sweets at Month 6 (p< .05). Participants in all four dietary conditions reported significant reductions in food cravings for specific types of foods (i.e., high fat foods, fast food fats, sweets, and carbohydrates/starches; all ps< .05). Cravings for fruits and vegetables, however, were increased at Month 24 (p< .05).** Calorically restricted diets (regardless of their macronutrient composition) yielded significant reductions in cravings for fats, sweets, and starches whereas cravings for fruits and vegetables were increased. 	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

References:

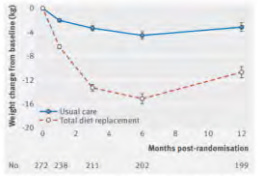
1. Anton, S. D., et al. (2012). "Diet type and changes in food cravings following weight loss: findings from the POUNDS LOST Trial." Eating & Weight Disorders: EWD **17**(2): e101-108.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Total diet replacement (TDR) program
Outcome: Weight change

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☒ High ☐ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Astbury, N. M., et al. Year Published: 2018 Location: Oxfordshire, UK Journal: *BMJ*	To test the effectiveness and safety of a total diet replacement (TDR) programme for routine treatment of obesity in a primary care setting.	**Size:** 278 adults **Inclusion Criteria**: Adults with a BMI of at least 30 kg/m^2 and whose health would benefit from weight loss. **Exclusion Criteria**: People who had received or were scheduled for bariatric surgery, those participating in a weight management program, or those with contraindications to the TDR according to protocol.	**Type:** RCT **Intervention**: The TDR programme comprised weekly behavioural support for 12 weeks and monthly support for three months, with formula food products providing 810 kcal/day (3389 kJ/day) as the sole food during the first eight weeks followed by reintroduction of food. Usual care comprised behavioural support for weight loss from a practice nurse and a diet	**Results: Participants in the TDR group lost more weight (−10.7 kg) than those in the usual care group (−3.1 kg): adjusted mean difference −7.2 kg (95% confidence interval −9.4 to −4.9 kg). 45% of participants in the TDR group and 15% in the usual care group experienced weight losses of 10% or more. The TDR group showed greater improvements in biomarkers of cardiovascular and metabolic risk than the usual**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

			programme with modest energy restriction. The primary outcome was weight change at 12 months analysed as intention to treat with mixed effects models. Secondary outcomes included biomarkers of cardiovascular and metabolic risk. Adverse events were recorded.	**care group. 11% of participants in the TDR group and 12% in the usual care group experienced adverse events of moderate or greater severity.**  Fig 2 | Weight change over 12 months in intention to treat population. Values represent mean (standard error of the mean)	

References:

1. Astbury, N. M., et al. (2018). "Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET): pragmatic randomised controlled trial." BMJ **362**: k3760.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Obese adults with type 2 diabetes
Modality: Very low-carbohydrate and high-carbohydrate weight-loss diets
Outcome: Psychological health

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☒ High ☐ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Brinkworth, G. D., et al. Year Published: 2016 Location: Commonwealth Scientific and Industrial Research Organisation, Australia Journal: *Journal of Internal Medicine*	To examine the long-term effects of very low-carbohydrate, high-fat (LC) diets on psychological health.	**Size:** 115 adults with type 2 diabetes (T2DM). **Inclusion Criteria**: Between 35 to 68 years, who were obese and on diabetes medication.	**Type:** RCT **Intervention**: Adults with T2DM were recruited and randomized to consume either an energy-restricted (~6 to 7 MJ), planned isocaloric LC or high carbohydrate, low-fat (HC) diet, combined with a supervised exercise programme (3 days week^{-1}) for 1 year. Body weight, psychological mood state and well-being [Profile of Mood States (POMS), Beck Depression Inventory (BDI) and Spielberger State Anxiety Inventory (SAI)] and diabetes-specific emotional distress [Problem Areas in Diabetes (PAID) Questionnaire] and quality of life [QoL Diabetes-39 (D-39)] were assessed.	**Results: Overall weight loss was 9.5 0.5 kg (mean SE), with no difference between groups (P = 0.91 time 9 diet). Significant improvements occurred in BDI, POMS (total mood disturbance and the six subscales of anger-hostility, confusion bewilderment, depression-dejection, fatigue-inertia, vigour-activity and tension-anxiety), PAID (total score) and the D-39 dimensions of diabetes control, anxiety and worry, sexual functioning and energy and mobility, P < 0.05 time. SAI and the D39 dimension of social burden remained unchanged (P ≥ 0.08 time). Diet composition had no effect on the responses for the outcomes assessed (P ≥ 0.22 time 9 diet).**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☒ Difference in important prognostic factors at baseline

References:

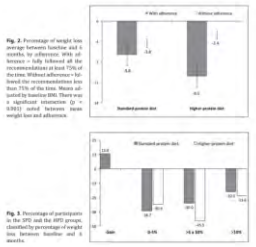
1. Brinkworth, G. D., et al. (2016). "Long-term effects of very low-carbohydrate and high-carbohydrate weight-loss diets on psychological health in obese adults with type 2 diabetes: randomized controlled trial." Journal of Internal Medicine **280**(4): 388-397.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults with metabolic syndrome (MeS)
Modality: Protein-enriched diets
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Campos-Nonato, I., et al. Year Published: 2017 Location: National Institute of Public Health (INSP), Cuernavaca , Mexico Journal: *Obesity Facts*	To determine the effect of increased protein intake on weight loss in Mexican adults with metabolic syndrome (MeS).	**Size:** 118 adults **Inclusion Criteria**: Adult men and women (aged 20-60 years) with a BMI between 25 and 45 kg/m^2 and the presence of MES, using classification from the International Diabetes Federation. **Exclusion Criteria**: Background of bariatric surgery, treatment for addiction to smoking and/or alcohol, drug abuse, psychiatric disorder, use of anti-obesity medication, soy allergy, women not using an appropriate birth control method or who were pregnant or lactating, and body weight gain or loss greater than 2% during the 3 months prior to the start of the study.	**Type:** RCT **Intervention**: Participants were randomized to prescribed hypocaloric diets (500 kcal less than resting metabolic rate) providing either 0.8 g/kg body weight (standard protein diet (SPD)) or 1.34 g/kg body weight (higher protein diet (HPD)) for 6 months. Body weight, waist circumference, percent body fat by bioimpedance analysis, fasting blood glucose, fasting insulin, hemoglobin A1c, total cholesterol, high-density lipoprotein (HDL) cholesterol, very-low-density lipoprotein (VLDL) cholesterol, triglycerides, C-reactive protein, creatinine, blood urea nitrogen, alanine aminotransferase, aspartate aminotransferase, and gamma-glutamyl transferase were measured at baseline, 3 months and at 6 months	**Results: Overall weight loss was 5.1 +/- 3.6 kg in the SPD group compared to 7.0 +/- 3.7 kg in the in HPD group. Both groups lost a significant percent of centimeters of waist circumference (SPD -6.5 +/- 2.6 cm and HPD -8.8 +/- 2.6 cm). There was no statistical difference Except for the varying weight losses the two groups did not show any further differences overall.** However in the subgroup judged to be adherent more than 75% of the time with the prescribed diets, there was a significant difference in mean weight loss (SPD -5.8% vs. HPD -9.5%) after adjusting for baseline BMI. Both groups demonstrated significant decreases in waist circumference, glucose, insulin, triglycerides, and VLDL cholesterol, but there were no differences between the groups. There were no changes in blood tests for liver or renal function.	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

References:

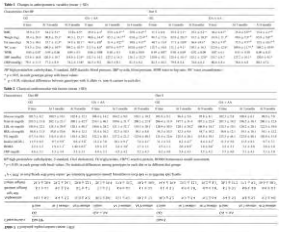
1. Campos-Nonato, I., et al. (2017). "Effect of a High-Protein Diet versus Standard-Protein Diet on Weight Loss and Biomarkers of Metabolic Syndrome: A Randomized Clinical Trial." Obesity Facts **10**(3): 238-251.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: High-protein/low-carbohydrate vs. standard hypocaloric diets
Outcome: Adipocytokine levels and cardiovascular risk factors

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**

Author: de Luis, D. A., et al. Year Published: 2015 Location: Hospital Clinico Universitario, University of Valladolid, Spain Journal: *Journal of Endocrinological Investigation*	To investigate the role of this polymorphism on cardiovascular risk factors, adipokine levels and weight loss secondary to a high-protein/low-carbohydrate vs. standard hypocaloric diets during 9 months.	**Size:** 211 **Inclusion Criteria**: BMI >30 **Exclusion Criteria**: History of cardiovascular disease or stroke during the previous 24 months, total cholesterol >250 mg/dl, triglycerides >250 mg/dl, blood pressure >140/90 mmHg, fasting plasma glucose >110 mg/dl, as well as the use of sulphonylurea, thiazolidinediones, insulin, glucocorticoids, antineoplastic agents, angiotensin-receptor blockers, angiotensin converting enzyme inhibitors and psychoactive medications.	**Type:** RCT **Intervention**: Subjects were randomly allocated to one of two diets for a period of 9 months. Diet HP (high protein–low carbohydrate hypocaloric diet) consisted a diet of 1050 cal/ day, 33 % of carbohydrates (86.1 g/day), 33 % of fats (39.0 g/ day) and 34 % of proteins (88.6 g/day). The distribution of fats was 23.5 % of saturated fats, 63.8 % of monounsaturated fats and 12.6 % of polyunsaturated fats. Diet S (standard protein hypocaloric diet) consisted a diet of 1093 cal/day, 53 % carbohydrates (144.3 g/day), 27 % fats (32.6 g), and 20 % proteins (55.6 g/day). The distribution of fats was 20.9 % of saturated fats, 67.4 % of monounsaturated fats and 11.6 % of polyunsaturated fats. The exercise program consisted of an aerobic exercise at least 3 times per week (60 min each). National composition food tables were used as reference [15] to calculate dietary intakes. The adherence of these diets was assessed each 7 days with a phone call by a dietitian to improve compliment of the calorie restriction.	**Results**: Ninety-four patients (44.5%) had the genotype GG (wild group) and 117 (55.5%) patients had the next genotypes; GA (89 patients, 42.2%) or AA (28 patients, 13.3%) (mutant group). **With both diets and in both genotype groups, body mass index, weight, fat mass, waist circumference and systolic blood pressure decreased. Anthropometric parameters were higher in non-A allele carriers than A allele carriers. With diet HP in both genotypes, LDL cholesterol, total cholesterol, leptin, insulin levels and HOMA-R decreased. With the diet S and only in wild genotype, the same parameters decreased, too.** 	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline

References:

1. de Luis, D. A., et al. (2015). "Effects of a high-protein/low-carbohydrate versus a standard hypocaloric diet on adipocytokine levels and cardiovascular risk factors during 9 months, role of rs6923761 gene variant of glucagon-like peptide 1 receptor." Journal of Endocrinological Investigation **38**(11): 1183-1189.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Low carbohydrate diet
Outcome: Weight loss maintenance

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☒ High ☐ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Ebbeling, C. B., et al. Year Published: 2018 Location: Framingham State University, MA Journal: *BMJ*	To determine the effects of diets varying in carbohydrate to fat ratio on total energy expenditure.	**Size:** 164 participants **Inclusion Criteria**: Adults aged 18-65 years with a body mass index of 25 or more.	**Type:** RCT **Intervention**: After 12% (within 2%) weight loss on a run-in diet, participants were randomly assigned to one of three test diets according to carbohydrate content (high, 60%, n=54; moderate, 40%, n=53; or low, 20%, n=57) for 20 weeks. Test diets were controlled for protein and were energy adjusted to maintain weight loss within 2 kg. To test for effect modification predicted by the carbohydrate-insulin model, the sample was divided into thirds of pre-weight loss insulin secretion	**Results: Total energy expenditure differed by diet in the intention-to-treat analysis (n=162, P=0.002), with a linear trend of 52 kcal/d (95% confidence interval 23 to 82) for every 10% decrease in the contribution of carbohydrate to total energy intake (1 kcal=4.18 kJ=0.00418 MJ).** Change in total energy expenditure was 91 kcal/d (95% confidence interval -29 to 210) greater in participants assigned to the moderate carbohydrate diet and 209 kcal/d (91 to 326) greater in those assigned to the low carbohydrate diet compared with the high carbohydrate	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☒ Difference in important prognostic factors at baseline

			(insulin concentration 30 minutes after oral glucose). The primary outcome was total energy expenditure, measured with doubly labeled water, by intention-to-treat analysis. Per protocol analysis included participants who maintained target weight loss, potentially providing a more precise effect estimate. Secondary outcomes were resting energy expenditure, measures of physical activity, and levels of the metabolic hormones leptin and ghrelin.	diet. In the per protocol analysis (n=120, P<0.001), the respective differences were 131 kcal/d (-6 to 267) and 278 kcal/d (144 to 411). Among participants in the highest third of pre-weight loss insulin secretion, the difference between the low and high carbohydrate diet was 308 kcal/d in the intention-to-treat analysis and 478 kcal/d in the per protocol analysis (P<0.004). Ghrelin was significantly lower in participants assigned to the low carbohydrate diet compared with those assigned to the high carbohydrate diet (both analyses). Leptin was also significantly lower in participants assigned to the low carbohydrate diet (per protocol).	

References:

1. Ebbeling, C. B., et al. (2018). "Effects of a low carbohydrate diet on energy expenditure during weight loss maintenance: randomized trial." BMJ **363**: k4583.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adults Modality: Almond-enriched, hypocaloric diet Outcome: Weight loss		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

		☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Foster, G. D., et al. Year Published: 2012 Location: Temple University, Philadelphia, PA Journal: *American Journal of Clinical Nutrition*	To evaluate the effects of a hypocaloric, almond-enriched diet (AED) compared with a hypocaloric nut-free diet (NFD) on body weight and cardiovascular disease risk factors in the context of an 18-mo behavioral weight-management program.	**Size:** 123 **Inclusion Criteria**: Age of 18 to 75 y and a BMI of 27–40. **Exclusion Criteria**: Uncontrolled hypertension (defined as a blood pressure .180/ 100 mm Hg), established cardiovascular disease or an inflammatory condition (eg, lupus), diabetes or use of antihyperglycemic medications, dyslipidemia requiring prescription drug therapy as defined by the National Cholesterol Education Program Adult Treatment Panel III guidelines (23), or any known allergy or sensitivity to nuts.	**Type:** RCT **Intervention**: Individuals were randomly assigned to consume an AED or NFD and instructed in traditional behavioral methods of weight control. Anthropometric and metabolic measurements were made at baseline, 6 mo, and 18 mo.	**Results: Those in the AED group lost slightly but significantly less weight than did those in the NFD group at 6 mo (-5.5 compared with -7.4 kg; P = 0.04), but there were no differences at 18 mo.** No significant differences in body composition were found between the groups at 6 or 18 mo. The AED, compared with the NFD, was associated with greater reductions in total cholesterol (P = 0.03), total:HDL cholesterol (P = 0.02), and triglycerides (P = 0.048) at 6 mo, and no differences were observed between the groups at 18 mo.	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☐ Difference in important prognostic factors at baseline

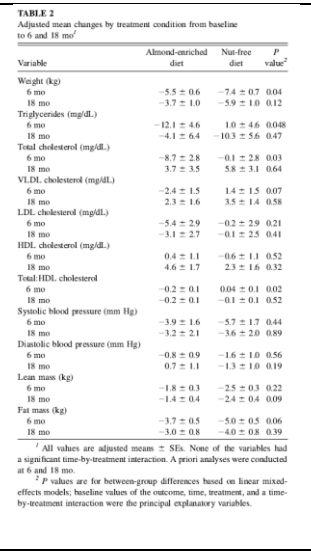
					

TABLE 2
Adjusted mean changes by treatment condition from baseline to 6 and 18 mo[1]

Variable	Almond-enriched diet	Nut-free diet	*P* value[2]
Weight (kg)			
6 mo	−5.5 ± 0.6	−7.4 ± 0.7	0.04
18 mo	−3.7 ± 1.0	−5.9 ± 1.0	0.12
Triglycerides (mg/dL)			
6 mo	−12.1 ± 4.6	1.0 ± 4.6	0.048
18 mo	−4.1 ± 6.4	−10.3 ± 5.6	0.47
Total cholesterol (mg/dL)			
6 mo	−8.7 ± 2.8	−0.1 ± 2.8	0.03
18 mo	3.7 ± 3.5	5.8 ± 3.1	0.64
VLDL cholesterol (mg/dL)			
6 mo	−2.4 ± 1.5	1.4 ± 1.5	0.07
18 mo	2.3 ± 1.6	3.5 ± 1.4	0.58
LDL cholesterol (mg/dL)			
6 mo	−5.4 ± 2.9	−0.2 ± 2.9	0.21
18 mo	−3.1 ± 2.7	−0.1 ± 2.5	0.41
HDL cholesterol (mg/dL)			
6 mo	0.4 ± 1.1	−0.6 ± 1.1	0.52
18 mo	4.6 ± 1.7	2.3 ± 1.6	0.32
Total:HDL cholesterol			
6 mo	−0.2 ± 0.1	0.04 ± 0.1	0.02
18 mo	−0.2 ± 0.1	−0.1 ± 0.1	0.52
Systolic blood pressure (mm Hg)			
6 mo	−3.9 ± 1.6	−5.7 ± 1.7	0.44
18 mo	−3.2 ± 2.1	−3.6 ± 2.0	0.89
Diastolic blood pressure (mm Hg)			
6 mo	−0.8 ± 0.9	−1.6 ± 1.0	0.56
18 mo	0.7 ± 1.1	−1.3 ± 1.0	0.19
Lean mass (kg)			
6 mo	−1.8 ± 0.3	−2.5 ± 0.3	0.22
18 mo	−1.4 ± 0.4	−2.4 ± 0.4	0.09
Fat mass (kg)			
6 mo	−3.7 ± 0.5	−5.0 ± 0.5	0.06
18 mo	−3.0 ± 0.8	−4.0 ± 0.8	0.39

[1] All values are adjusted means ± SEs. None of the variables had a significant time-by-treatment interaction. A priori analyses were conducted at 6 and 18 mo.
[2] *P* values are for between-group differences based on linear mixed-effects models; baseline values of the outcome, time, treatment, and a time-by-treatment interaction were the principal explanatory variables.

References:

1. Foster, G. D., et al. (2012). "A randomized trial of the effects of an almond-enriched, hypocaloric diet in the treatment of obesity." American Journal of Clinical Nutrition **96**(2): 249-254.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adult
Modality: Low-carbohydrate high-protein vs. low-fat diet
Outcome: Kidney-related parameters

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

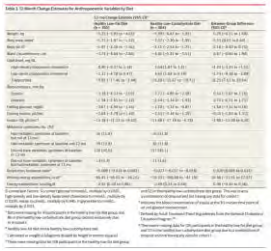
		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*			
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Friedman, A. N., et al. Year Published: 2012 Location: Indiana University School of Medicine Journal: *Clinical Journal of The American Society of Nephrology: CJASN*	To assess the relative effects of a low-carbohydrate high-protein versus low-fat diet on kidney-related parameters in obese adults over a 2-year period.	**Size:** 307 adults **Inclusion Criteria**: 18–65 years old, body mass index of 30–40 kg/m2, and body weight less than 136 kg. **Exclusion Criteria**: Serious medical illnesses, such as type 2 diabetes; took lipid-lowering medications; were pregnant or lactating; or took medications that affect body weight, including anti-obesity agents, BP of 140/90 mmHg or more	**Type:** Secondary analysis of RCT **Intervention**: Participants at three United States academic centers were randomly assigned to a low-carbohydrate high protein or a low-fat weight-loss diet for 24 months. Main outcomes included renal filtration (GFR) indices (serum creatinine, cystatin C, creatinine clearance); 24-hour urinary volume; albumin; calcium excretion; and serum solutes at 3, 12, and 24 months.	**Results: Compared with the low-fat diet, low-carbohydrate high-protein consumption was associated with minor reductions in serum creatinine (relative difference, 24.2%) and cystatin C (28.4%) at 3 months and relative increases in creatinine clearance at 3 (15.8 ml/min) and 12 (20.8 ml/min) months; serum urea at 3 (14.4%), 12 (9.0%), and 24 (8.2%) months; and 24-hour urinary volume at 12 (438 ml) and 24 (268 ml) months.** Urinary calcium excretion increased at 3 (36.1%) and 12 (35.7%) months without changes in bone density or clinical presentations of new kidney stones.	**Study Limitations:** ☒ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

References:

1. Friedman, A. N., et al. (2012). "Comparative effects of low-carbohydrate high-protein versus low-fat diets on the kidney." Clinical Journal of The American Society of Nephrology: CJASN **7**(7): 1103-1111.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Men and premenopausal women
Modality: Healthy low-fat diet or a healthy low carbohydrate diet
Outcome: Anthropometric variables

Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low					
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low		**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Gardner, C. D., et al. Year Published: 2018 Location: Stanford University Medical School Journal: *JAMA*	To determine the effect of a healthy low-fat (HLF) diet vs a healthy low-carbohydrate (HLC) diet on weight change and if genotype pattern or insulin secretion are related to the dietary effects on weight loss.	**Size:** 609 **Inclusion Criteria**: Men and premenopausal women aged 18 to 50 years with a body mass index (calculated as weight in kilograms divided by height in meters squared) of 28 to 40. **Exclusion Criteria**: Patients having uncontrolled hypertension or metabolic disease; diabetes; cancer; heart, renal, or liver disease; and being pregnant or lactating. Individuals were excluded if taking hypoglycemic, lipid lowering, antihypertensive, psychiatric, or other medications known to affect body weight or energy expenditure.	**Type:** RCT **Intervention**: Patients were randomized to healthy low-fat diet or a healthy low carbohydrate diet for 12 months. Interventions consisted primarily of class-based instruction. Primary outcome was 12-month weight change and determination of whether there were significant interactions among diet type and genotype pattern, diet and insulin secretion, and diet and weight loss.	**Results:** Among participants randomized (mean age, 40 [SD, 7] years; 57% women; mean body mass index, 33 [SD, 3]; 244 [40%] had a low-fat genotype; 180 [30%] had a low-carbohydrate genotype; mean baseline INS-30, 93 µIU/mL), 481 (79%) completed the trial. **In the HLF vs HLC diets, respectively, the mean 12-month macronutrient distributions were 48% vs 30% for carbohydrates, 29% vs 45% for fat, and 21% vs 23% for protein. Weight change at 12 months was −5.3 kg for the HLF diet vs −6.0 kg for the HLC diet (mean between-group difference, 0.7 kg [95% CI, −0.2 to 1.6 kg]). There was no significant diet-genotype pattern interaction (P = .20)**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

				or diet-insulin secretion (INS-30) interaction (P = .47) with 12-month weight loss. There were 18 adverse events or serious adverse events that were evenly distributed across the 2 diet groups. 	

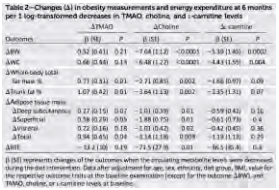
References:

1. Gardner, C. D., et al. (2018). "Effect of Low-Fat vs Low-Carbohydrate Diet on 12-Month Weight Loss in Overweight Adults and the Association With Genotype Pattern or Insulin Secretion: The DIETFITS Randomized Clinical Trial." JAMA **319**(7): 667-679.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults at risk of type 2 diabetes
Modality: Energy-reduced diets
Outcome: Changes in gut microbiota-related metabolites

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Heianza, Y., et al. Year Published: 2018 Location: Tulane University, New Orleans, LA Journal: *Diabetes Care*	To comprehensively examine how changes induced by a weight-loss diet intervention in gut microbiota-related metabolites, such as trimethylamine N-oxide (TMAO) and its precursors (choline and l-carnitine), were associated with improvements in adiposity and regional fat deposition.	**Size:** 510 individuals **Inclusion Criteria**: Individuals who were overweight or obese. **Exclusion Criteria**: Presence of diabetes or unstable cardiovascular disease, the use of medications that affect body weight (BW), and insufficient motivation.	**Type:** RCT **Intervention**: Obese individuals who were randomly assigned one of four diets varying in macronutrient intake. We examined associations of 6-month changes in blood metabolites (TMAO, choline, and l-carnitine) with improvements in body weight (BW), waist circumference (WC), body fat composition, fat distribution, and resting energy expenditure (REE).	**Results: Individuals with a greater reduction of choline (P < 0.0001) and l-carnitine (P < 0.01) rather than TMAO showed significant losses of BW and WC at 6 months. The reduction of choline was significantly predictive of decreases in body fat composition, fat distribution, and REE.** Results of sensitivity analysis showed that the baseline diabetes risk status, such as the presence of hyperglycemia (31% of the total participants) and fasting glucose levels, did not modify the associations. Early changes in choline and l-carnitine were significantly predictive of weight loss over 2 years (P < 0.05 for all). Individuals with increases in choline or l-carnitine were 2.35-times (95% CI 1.38, 4.00) or 1.77-times (1.06, 2.95) more likely to fail to lose weight (-5% or more loss) at 2 years. 	**Study Limitations:** ☐ None ***RCTs*** ☐ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☒ Difference in important prognostic factors at baseline

References:

1. Heianza, Y., et al. (2018). "Changes in Gut Microbiota-Related Metabolites and Long-term Successful Weight Loss in Response to Weight-Loss Diets: The POUNDS Lost Trial." Diabetes Care **41**(3): 413-419.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Low-carbohydrate diet vs. low-fat diet
Outcome: Cardiovascular risk factors

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☒ High
☐ Medium
☐ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Hu, T., et al. Year Published: 2015 Location: Tulane University, New Orleans, LA Journal: *Nutrients*	To examine the effects of a low-carbohydrate diet (<40 g/day) versus a low-fat diet (<30% kcal/day from total fat, <7% saturated fat) on biomarkers representing inflammation, adipocyte dysfunction, and endothelial dysfunction in a 12 month clinical trial among obese adults free of diabetes and CVD.	**Size:** 148 **Inclusion Criteria**: Men and women 22–75 years of age with a body mass index of 30 to 45 kg/m2. **Exclusion Criteria**: Individuals who had type 2 diabetes, CVD or chronic renal disease, and those who were currently using prescription weight-loss medications, undergoing weight loss surgery, or had experienced significant weight loss within six months of study entry.	**Type:** RCT **Intervention**: Participants with obesity were randomly assigned to either a low-carbohydrate diet where net carbohydrate intake (total carbohydrate minus total fiber) was restricted to <40 grams/day, or a low-fat diet which restricted total fat to <30% of daily energy, with <7% from saturated fat (consistent with national guidelines). Participants met with a study dietitian on a periodic basis and each diet group received the same behavioral curriculum which included dietary instruction	**Results: At 12 months, participants on the low-carbohydrate diet had significantly greater increases in adiponectin (mean difference in change, 1336 ng/mL (95% CI, 342 to 2330 ng/mL); p = 0.009) and greater decreases in intercellular adhesion molecule-1 concentrations (´16.8 ng/mL (´32.0 to ´1.6 ng/mL); p = 0.031) than those on the low-fat diet. Changes in other novel CVD markers were not significantly different between groups.**	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

			and supportive counseling. Blood samples were collected after the participant had fasted for 12 h. Novel CVD risk factors were measured at baseline and at three, six, and 12 months of intervention.		

References:

1. Hu, T., et al. (2015). "The Effects of a Low-Carbohydrate Diet vs. a Low-Fat Diet on Novel Cardiovascular Risk Factors: A Randomized Controlled Trial." Nutrients **7**(9): 7978-7994.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults with type 2 diabetes
Modality: Low-fat high-protein and low-fat high-carbohydrate
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Krebs, J. D., et al. Year Published: 2012 Location: University of Otago, Wellington, New Zealand Journal: *Diabetologia*	To compare the effectiveness of low-fat high-protein and low-fat high-carbohydrate dietary advice on weight loss, using group-based interventions, among	**Size:** 419 **Inclusion Criteria**: Individuals with type 2 diabetes aged 30-75 years and a BMI >27 kg/m2	**Type:** RCT **Intervention**: Individuals were randomized to be prescribed either a low-fat high-protein (30% of energy as protein, 40% as carbohydrate, 30% as fat) or	**Results: No differences between groups were found in change in weight or waist circumference during the intervention phase or the 12-month follow-up. Both groups had lost weight (2-3 kg, p<0.001) and reduced**	**Study Limitations:** ☐ None ***RCTs*** ☐ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT

	overweight people with type 2 diabetes.	**Exclusion Criteria**: Currently on weight-reducing medications, had weight loss of >5% in the past 3 months, or had a psychiatric or eating disorder. Participants were also excluded if their glycated haemoglobin (HbA1c) was >9.5% (80 mmol/mol) or they had had renal disease (estimated glomerular filtration rate 30 mg/mmol), abnormal liver enzymes, heart failure, known active malignancy or myocardial infarction in the preceding 6 months.	a low-fat high carbohydrate (15% of energy as protein, 55%as carbohydrate, 30% as fat) diet. Participants attended 18 group sessions over 12 months. Primary outcomes were change in weight and waist circumference assessed at baseline, 6 and 12 months. Secondary outcomes were body fatness, glycaemic control,lipid profile, blood pressure and renal function. A further assessment was undertaken 12 months after the intervention.	**their waist circumference (2-3 cm, p<0.001) by 12 months and largely maintained this weight loss for the following 12 months. By 6 months, the difference in self-reported dietary protein between groups was small (1.1%total energy; p<0.001). No significant differences between groups were found in secondary outcomes: body fatness, HbA1c, lipids, blood pressure and renal function. There were no important adverse effects.**	☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☒ Difference in important prognostic factors at baseline

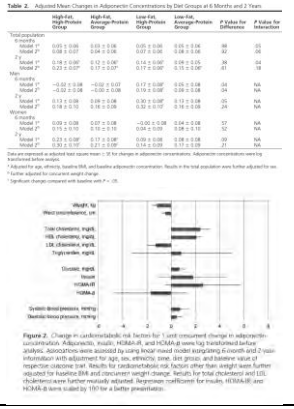
References:

1. Krebs, J. D., et al. (2012). "The Diabetes Excess Weight Loss (DEWL) Trial: a randomised controlled trial of high-protein versus high-carbohydrate diets over 2 years in type 2 diabetes." Diabetologia **55**(4): 905-914.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adult
Modality: Long-term weight-loss diets
Outcome: Macronutrients

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Ma, W., et al. Year Published: 2016 Location: Harvard T.H. Chan School of Public Health, Brigham and Women's Hospital, Louisiana State University System Journal: *Journal of Clinical Endocrinology & Metabolism*	To investigate the effects of long-term weight-loss diets with different compositions of macronutrients on longitudinal changes in circulating adiponectin concentrations and how such changes, if they exist, affect cardiometabolic risk	**Size:** 811 adults **Inclusion Criteria**: Participants with a body mass index (BMI) of 25–40 kg/m2 and aged 30–70 years	**Type:** RCT **Intervention**: Participants were randomly assigned to 1 of 4 diets: the target percentage of energy derived from fat, protein, and carbohydrate in the 4 diets were 20%, 15%, and 65% (low fat, average protein); 20%, 25%, and 55% (low fat, high protein); 40%, 15%, and45%(high fat, average protein); and 40%, 25%, and 35% (high fat, high protein). Thus, 2 diets were low fat and 2 were high fat, and 2 were average protein and 2 were high protein, constituting a 2-by-2 factorial design. Circulating concentrations of adiponectin and cardiometabolic outcomes were repeatedly measured at baseline, 6 months, and 2 years.	**Results: Weight-loss diet interventions significantly increased circulating adiponectin concentrations over 2 years, similarly in 4 diet groups (P value for difference >.05).** We found that the increase of adiponectin was significantly associated with reduction of waist circumference and low-density lipoprotein cholesterol, but associated with increase of high-density lipoprotein cholesterol (P<.001 for each), after adjusting for age, sex, ethnicity, follow-up time, diet group, baseline body mass index, baseline level of respective outcome trait, and concurrent weight change. 	**Study Limitations:** ☐ None ***RCTs*** ☒ Lack of blinding ☒ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☐ Large losses to F/U ☒ Difference in important prognostic factors at baseline

References:

1. Ma, W., et al. (2016). "Weight-Loss Diets, Adiponectin, and Changes in Cardiometabolic Risk in the 2-Year POUNDS Lost Trial." Journal of Clinical Endocrinology & Metabolism **101**(6): 2415-2422.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults with type 2 diabetes (T2DM)
Modality: Very low-carbohydrate, high– unsaturated/low–saturated fat diet (LC) vs. high–unrefined carbohydrate, low-fat diet (HC)
Outcome: Glycemic control and cardiovascular disease (CVD) risk factors

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Tay, J., et al. Year Published: 2014 Location: Preventative Health National Research Flagship, Commonwealth Scientific and Industrial Research Organisation (CSIRO), Animal, Food and Health Sciences, Adelaide, Australia 2 Discipline of Medicine, University of Adelaide, Australia Journal: *Diabetes Care*	To comprehensively compare the effects of a very low-carbohydrate, high-unsaturated/low-saturated fat diet (LC) with those of a high-unrefined carbohydrate, low-fat diet (HC) on glycemic control and cardiovascular disease (CVD) risk factors in type 2 diabetes (T2DM).	**Size:** 115 **Inclusion Criteria**: Overweight/obese adults (BMI 26–45 kg/m2 , age 35–68 years) with T2DM (previously diagnosed with HbA1c $7.0% [53 mmol/mol] and/or taking antiglycemic medication) **Exclusion Criteria**: Type 1 diabetes; proteinuria (urinary albuminto-creatinine ratio $30 mg/mmol); impaired renal function (eGFR ,60 mL/min); abnormal liver function (alanine aminotransferase [ALT], aspartate aminotransferase [AST], or g-glutamyl transferase [GGT] $2.5 times	**Type:** RCT **Intervention**: Participants were randomized hypocaloric LC diet (14% carbohydrate [<50 g/day], 28% protein, and 58% fat [<10% saturated fat]) or an energy-matched HC diet (53% carbohydrate, 17% protein, and 30% fat [<10% saturated fat]) combined with structured exercise for 24 weeks. The outcomes measured were as follows: glycosylated hemoglobin (HbA1c), glycemic variability (GV; assessed by 48-h continuous glucose monitoring), antiglycemic medication changes (antiglycemic medication	**Results**: **Both groups achieved similar completion rates (LC 79%, HC 82%) and weight loss (LC -12.0 +/- 6.3 kg, HC -11.5 +/- 5.5 kg); P >= 0.50. Blood pressure (-9.8/-7.3 +/- 11.6/6.8 mmHg), fasting blood glucose (-1.4 +/- 2.3 mmol/L), and LDL cholesterol (-0.3 +/- 0.6 mmol/L) decreased, with no diet effect (P >= 0.10). LC achieved greater reductions in triglycerides (-0.5 +/- 0.5 vs. -0.1 +/- 0.5 mmol/L), MES (-0.5 +/- 0.5 vs. -0.2 +/- 0.5), and GV indices; P <= 0.03. LC induced greater HbA1c reductions (-2.6 +/- 1.0% [-28.4 +/- 10.9 mmol/mol] vs. -1.9 +/- 1.2% [-20.8 +/- 13.1**	**Study Limitations:** ☐ None ***RCTs*** ☐ Lack of blinding ☐ Lack of allocation concealment ☐ Stopped early for benefit ☐ Incorrect analysis of ITT ☐ Selective reporting of measures (e.g., no effect outcome) ☒ Large losses to F/U ☐ Difference in important prognostic factors at baseline

		the normal upper limit) assessed at screening; any significant endocrinopathy (other than stable treated thyroid disease); history of malignancy (other than nonmelanoma); liver, respiratory, gastrointestinal, or cardiovascular disease; pregnancy or lactation; clinical depression; history of/or current eating disorder; or smoking.	effects score [MES]), and blood lipids and pressure.	**mmol/mol]; P = 0.002) and HDL cholesterol (HDL-C) increases (0.2 +/- 0.3 vs. 0.05 +/- 0.2 mmol/L; P = 0.007) in participants with the respective baseline values HbA1c >7.8% (62 mmol/mol) and HDL-C <1.29 mmol/L.**	

References:

1. Tay, J., et al. (2014). "A very low-carbohydrate, low-saturated fat diet for type 2 diabetes management: a randomized trial." Diabetes Care **37**(11): 2909-2918.

Question #4. What is the comparative effectiveness of physical activity interventions (aerobic exercise, resistance training, combined aerobic and resistance training, walking activities, standing desks)? What is the optimal intensity of physical activity interventions for improving health, well-being, and weight loss?

Physical Activity Guidelines for Americans

Key Guidelines

Below are the key guidelines included in the Physical Activity Guidelines for Americans. The later chapters provide context and additional information related to these summary statements.

Key Guidelines for Preschool-Aged Children

- Preschool-aged children (ages 3 through 5 years) should be physically active throughout the day to enhance growth and development.
- Adult caregivers of preschool-aged children should encourage active play that includes a variety of activity types.

Key Guidelines for Children and Adolescents

- It is important to provide young people opportunities and encouragement to participate in physical activities that are appropriate for their age, that are enjoyable, and that offer variety.
- Children and adolescents ages 6 through 17 years should do 60 minutes (1 hour) or more of moderate-to-vigorous physical activity daily:
  - **Aerobic:** Most of the 60 minutes or more per day should be either moderate- or vigorous-intensity aerobic physical activity and should include vigorous-intensity physical activity on at least 3 days a week.
  - **Muscle-strengthening:** As part of their 60 minutes or more of daily physical activity, children and adolescents should include muscle-strengthening physical activity on at least 3 days a week.
  - **Bone-strengthening:** As part of their 60 minutes or more of daily physical activity, children and adolescents should include bone-strengthening physical activity on at least 3 days a week.

Key Guidelines for Adults

- Adults should move more and sit less throughout the day. Some physical activity is better than none. Adults who sit less and do any amount of moderate-to-vigorous physical activity gain some health benefits.
- For substantial health benefits, adults should do at least 150 minutes (2 hours and 30 minutes) to 300 minutes (5 hours) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) to 150 minutes (2 hours and 30 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Preferably, aerobic activity should be spread throughout the week.
- Additional health benefits are gained by engaging in physical activity beyond the equivalent of 300 minutes (5 hours) of moderate-intensity physical activity a week.
- Adults should also do muscle-strengthening activities of moderate or greater intensity and that involve all major muscle groups on 2 or more days a week, as these activities provide additional health benefits.

Key Guidelines for Older Adults

The key guidelines for adults also apply to older adults. In addition, the following key guidelines are just for older adults:

- As part of their weekly physical activity, older adults should do multicomponent physical activity that includes balance training as well as aerobic and muscle-strengthening activities.
- Older adults should determine their level of effort for physical activity relative to their level of fitness.
- Older adults with chronic conditions should understand whether and how their conditions affect their ability to do regular physical activity safely.
- When older adults cannot do 150 minutes of moderate-intensity aerobic activity a week because of chronic conditions, they should be as physically active as their abilities and conditions allow.

Key Guidelines for Women During Pregnancy and the Postpartum Period

- Women should do at least 150 minutes (2 hours and 30 minutes) of moderate-intensity aerobic activity a week during pregnancy and the postpartum period. Preferably, aerobic activity should be spread throughout the week.
- Women who habitually engaged in vigorous-intensity aerobic activity or who were physically active before pregnancy can continue these activities during pregnancy and the postpartum period.
- Women who are pregnant should be under the care of a health care provider who can monitor the progress of the pregnancy. Women who are pregnant can consult their health care provider about whether or how to adjust their physical activity during pregnancy and after the baby is born.

Key Guidelines for Adults With Chronic Health Conditions and Adults With Disabilities

- Adults with chronic conditions or disabilities, who are able, should do at least 150 minutes (2 hours and 30 minutes) to 300 minutes (5 hours) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) to 150 minutes (2 hours and 30 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Preferably, aerobic activity should be spread throughout the week.
- Adults with chronic conditions or disabilities, who are able, should also do muscle-strengthening activities of moderate or greater intensity and that involve all major muscle groups on 2 or more days a week, as these activities provide additional health benefits.
- When adults with chronic conditions or disabilities are not able to meet the above key guidelines, they should engage in regular physical activity according to their abilities and should avoid inactivity.

- Adults with chronic conditions or symptoms should be under the care of a health care provider. People with chronic conditions can consult a health care professional or physical activity specialist about the types and amounts of activity appropriate for their abilities and chronic conditions.

Key Guidelines for Safe Physical Activity

To do physical activity safely and reduce risk of injuries and other adverse events, people should:

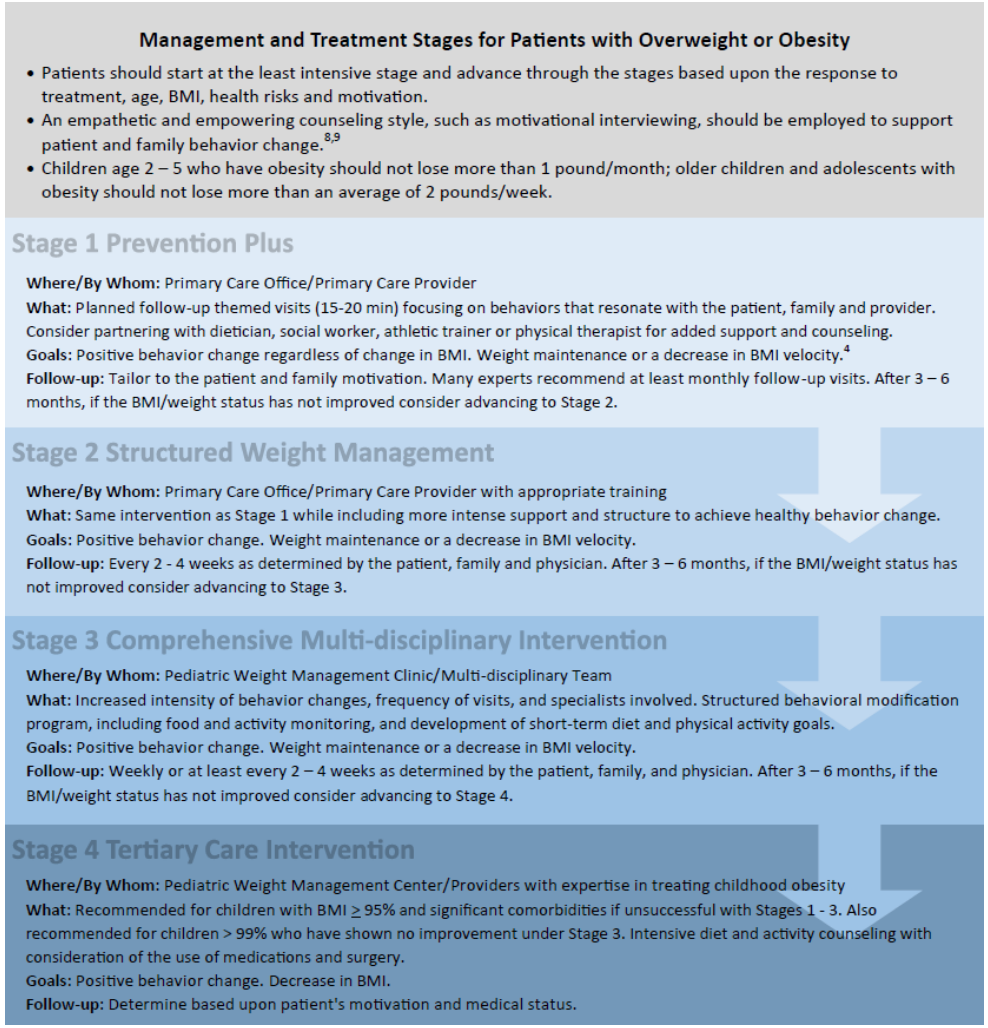
- Understand the risks, yet be confident that physical activity can be safe for almost everyone.
- Choose types of physical activity that are appropriate for their current fitness level and health goals, because some activities are safer than others.
- Increase physical activity gradually over time to meet key guidelines or health goals. Inactive people should "start low and go slow" by starting with lower intensity activities and gradually increasing how often and how long activities are done.
- Protect themselves by using appropriate gear and sports equipment, choosing safe environments, following rules and policies, and making sensible choices about when, where, and how to be active.
- Be under the care of a health care provider if they have chronic conditions or symptoms. People with chronic conditions and symptoms can consult a health care professional or physical activity specialist about the types and amounts of activity appropriate for them.

Reference:

1. Piercy, K. L., et al. (2018). "The Physical Activity Guidelines for Americans Physical Activity Guidelines for Americans Physical Activity Guidelines for Americans." JAMA **320**(19): 2020-2028.

Children and Adolescents: Guideline Recommendations

The 2015 **American Academy of Pediatrics Institute for Health Childhood Weight** released the following assessment and management algorithm for childhood obesity:



Algorithm was based on 2007 **American Academy of Pediatrics** Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report stated:

Treatment Recommendations

- The expert committee recommends the following staged approach for children between the ages of 2 and 19 years whose BMI is >85th percentile. Stage 1 is the Prevention Plus protocol. These recommendations can be implemented by the primary care physician or an allied health care provider who has some training in pediatric weight management or behavioral counseling. Stage 1 recommendations include the following. (a) Consume >/=5 servings of fruits and vegetables per day (ME). (b) Minimize or eliminate sugar-sweetened beverages (ME). (c) Limit screen time to </=2 hours per day, with no television in the room where the child sleeps (CE). (d) Engage in >/=1 hour of daily physical activity (ME). The patient and the family of the patient should be counseled to facilitate the following eating behaviors: (a) eating a daily breakfast (ME); (b) limiting meals outside the home (ME); (c) eating family meals at least 5 or 6 times per week (ME); and (d) allowing the child to self-regulate his or her meals and avoiding overly restrictive behaviors (CE for children <12 years of age and suggested for children >12 years of age). Providers should acknowledge cultural differences and help families to adapt recommendations to meet these differences (suggest). Within this category, the goal should be weight maintenance, with growth resulting in decreasing BMI as age increases. Monthly follow-up assessment should be performed. After 3 to 6 months, if no improvement in BMI or weight status has been noted, then advancement to stage 2 is indicated, on the basis of patient/family readiness to change. Stage 2 is a structured weight management protocol. These recommendations can be implemented by a primary care physician or an allied health care provider who is highly trained in weight management. Stage 2 recommendations include the following: (a) development of a plan for use of a balanced macronutrient diet, emphasizing small amounts of energy-dense foods (suggest); (b) provision of structured daily meals and snacks (breakfast, lunch, dinner, and 1 or 2 snacks per day) (suggest); (c) supervised active play of >/=60 minutes per day (ME); (d) screen time of </=1 hour per day (suggest; CE for </=2 hours); (e) increased monitoring (eg, screen time, physical activity, dietary intake, and restaurant logs) by provider, patient, and/or family (CE); and (f) reinforcement for achieving targeted behavior goals (not weight goals) (suggest). Within this category, the goal should be weight maintenance that results in decreasing BMI as age and height increase; however, weight loss should not exceed 1 lb/month for children 2 to 11 years of age or an average of 2 lb/week for older overweight/obese children and adolescents. If there is no improvement in BMI or weight status after 3 to 6 months, then the patient should advance to stage 3. Stage 3 is a comprehensive multidisciplinary intervention. At this level of intervention, optimally the patient should be referred to a multidisciplinary obesity care team. Eating and activity goals are the same as in stage 2. Activities within this category should also include the following: (a) planned negative energy balance achieved through structured diet and physical activity (ME); (b) structured behavioral modification program, including food and activity monitoring and development of short-term diet and physical activity goals (CE); (c) involvement of primary caregivers/family members for behavioral modification for children <12 years of age (CE); (d) provision of training for all families to improve the home environment (suggest); and (e) frequent office visits. Weekly visits for a minimum of 8 to 12 weeks seem to be most efficacious (CE), and subsequent monthly visits help maintain new behaviors. Group visits may be more cost-effective and have therapeutic benefit (ME). Systematic evaluation of body measurements, dietary intake, and physical activity should be conducted at baseline and at specific intervals throughout the program. Within this category, the goal should be weight maintenance or gradual weight loss until BMI is <85th percentile. Weight loss should not exceed 1 lb/month for children 2 to 5 years of age or 2 lb/week for older obese children and adolescents.

In 2016, the **American Academy of Pediatrics** Preventing Obesity and Eating Disorders in Adolescents provided the following key features in identifying feeding disorders and eating disorders:

TABLE 4 Principles of Family-Based Treatment of EDs and Role of the Pediatrician

Principles of treatment
• Parents are not to blame
• Parents are vital to therapeutic success
• Parents are responsible for weight restoration
• Separate the child from the illness
• Nonauthoritarian approach
Three phases of treatment
• Phase 1: parents restore patient's weight
• Phase 2: control transferred back to the child or adolescent
• Phase 3: focuses on adolescent developmental issues and termination of treatment
Examples of the role the pediatrician can play
• Act as a consultant to the parents and therapist
• Explain the medical seriousness of the ED
• Monitor and manage the medical status of the adolescent
• Empower the parents in decision-making
• Communicate with the patient, family, and therapist

Role of the Pediatricians in the Prevention of Obesity and Eating Disorders in Adolescents:

1. Discourage dieting, skipping of meals, or the use of diet pills; instead, encourage and support the implementation of healthy eating and physical activity behaviors that can be maintained on an ongoing basis. The focus should be on healthy living and healthy habits rather than on weight.
2. Promote a positive body image among adolescents. Do not encourage body dissatisfaction or focus on body dissatisfaction as a reason for dieting.
3. Encourage more frequent family meals.
4. Encourage families not to talk about weight but rather to talk about healthy eating and being active to stay healthy. Do more at home to facilitate healthy eating and physical activity.
5. Inquire about a history of mistreatment or bullying in overweight and obese teenagers and address this issue with patients and their families.
6. Carefully monitor weight loss in an adolescent who needs to lose weight to ensure the adolescent does not develop the medical complications of semistarvation.

Time constraints in a busy pediatric practice are significant. Weight issues can be a topic of sensitivity and therefore can be time consuming. The evidence-based suggestions in this report can be implemented in relatively brief encounters and can be an excellent first step for teenagers and families to promote a healthy lifestyle.

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following for Physical Activity in 2014:

Children

- Encourage children and young people to increase their level of physical activity, even if they do not lose weight as a result, because of the other health benefits exercise can bring (for example, reduced risk of type 2 diabetes and cardiovascular disease). Encourage children to do at least 60 minutes of moderate or greater intensity physical activity each day. The activity can be in 1 session or several sessions lasting 10 minutes or more.
- Be aware that children who are already overweight may need to do more than 60 minutes' activity.
- Encourage children to reduce inactive behaviours, such as sitting and watching television, using a computer or playing video games.
- Give children the opportunity and support to do more exercise in their daily lives (for example, walking, cycling, using the stairs and active playl). Make the choice of activity with the child, and ensure it is appropriate to the child's ability and confidence.
- Give children the opportunity and support to do more regular, structured physical activity, (for example football, swimming or dancing). Make the choice of activity with the child, and ensure it is appropriate to the child's ability and confidence.

<table>
<tr><td colspan="3"><u>BODY OF EVIDENCE APPRAISAL TABLE FOR:</u>
<u>Population:</u> Children and adolescents
<u>Modality:</u> Exercise alone
<u>Outcome:</u> Weight loss</td></tr>
<tr><td colspan="3"><u>Quality (certainty) of evidence for: (outcome)</u>
☐ High
☒ Moderate
☐ Low
☐ Very Low</td></tr>
<tr><td><u>Risk of Bias across studies:</u>
☐ High
☒ Medium
☐ Low</td><td><u>Low Quality Rating if</u>:
☐ Studies inconsistent (wide variation of treatment effect across studies, population, interventions, or outcomes varied)

☐ Studies are indirect (PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)

☐ Studies are imprecise (when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)</td><td><u>Other Considerations:</u>
Lower Quality Rating if:
☐ Publication Bias (e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect</td></tr>
</table>

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Atlantis, E., et al. Year Published: 2006 Location: University of Sydney, Australia Journal: *International Journal of Obesity*	To determine the efficacy of exercise alone for treating overweight in children/adolescents.	**Size:** 14 studies, 369 participants **Inclusion Criteria**: Studies of isolated or adjunctive exercise/physical activity treatment in overweight/obese children or adolescents which reported any overweight outcome. (1) studies were RCTs, (2) cohorts were of children or adolescents (aged o18 years) defined as being overweight/obese, (3) pre- and post-test or change in any overweight outcome was reported, (4) at least one exercise or physical activity treatment arm was investigated either in isolation or as an adjunct to an alternative treatment simultaneously prescribed to the control/comparison group (e.g., exercise plus caloric intake of 1000 kcal/days vs caloric intake of 1000 kcal/days). **Exclusion Criteria**: Studies which reported previously published data, or which included normal weight subjects in either treatment and/or comparison/ control groups were excluded, as well as nonrandomized trials.	**Type:** Systematic Review	**Results: The pooled SMD was -0.4 (-0.7, -0.1, P=0.006) for percent body fat, and -0.2 (-0.6, 0.1, P=0.07) for central obesity outcomes, whereas the pooled WMD was -2.7 kg (-6.1 kg, 0.8 kg, P=0.07) for body weight, all of which favored exercise.** Pooled effects on body weight were significant and larger for studies of higher doses, whereas nonsignificant and smaller effects were seen for studies of lower doses of exercise (155-180 min/weeks vs 120-150 min/weeks).	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Atlantis, E., et al. (2006). "Efficacy of exercise for treating overweight in children and adolescents: a systematic review." International Journal of Obesity **30**(7): 1027-1040.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Aerobic plus resistance exercise vs. aerobic exercise alone
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☐ Medium
☒ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Garcia-Hermoso, A., et al. Year Published: 2018 Location: Universidad de Santiago de Chile Journal: *British Journal of Sports Medicine*	To determine if the combination of aerobic and resistance exercise is superior to aerobic exercise alone for the health of obese children and adolescents	**Size:** 12 trials, 555 youths **Inclusion Criteria**: Studies that compared the effect of supervised concurrent exercise versus aerobic exercise interventions, with anthropometric and metabolic outcomes in paediatric obesity (6-18 years old).	**Type:** Systematic Review	**Results: Compared with aerobic exercise alone, concurrent exercise resulted in greater reductions in body mass (MD=-2.28 kg), fat mass (MD=-3.49%; and MD=-4.34 kg) and low-density lipoprotein cholesterol (MD=-10.20 mg/dL); as well as greater increases in lean body mass (MD=2.20 kg) and adiponectin level (MD=2.59 mug/mL). Differences were larger for longer term programmes (>24 weeks).**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Garcia-Hermoso, A., et al. (2018). "Concurrent aerobic plus resistance exercise versus aerobic exercise alone to improve health outcomes in paediatric obesity: a systematic review and meta-analysis." British Journal of Sports Medicine **52**(3): 161-166.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Exercise intervention
Outcome: Movement skills and motor coordination

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Han, A., et al. Year Published: 2018 Location: University of Sydney, Australia Journal: *Journal of Science & Medicine in Sport*	To determine the effectiveness of exercise and physical activity interventions on improving fundamental movement skill and motor coordination in overweight/ obese children and adolescents.	**Size:** 17 studies, 649 children **Inclusion Criteria**: The studies included were randomized controlled trials, intervention or longitudinal studies with FMS/MC measurements in obese participants between 0–18 years of age without non-obesity related diseases or disorders. Exercise or PA interventions included any type of structured or unstructured training, exercise or physical activities based at clinics, laboratories, schools, homes, or community during the designated period. Studies with comparison or control groups	**Type:** Systematic Review	**Results: Altogether 38 tests for locomotor, object-control, balance and complex task tests were examined in selected studies, with 33 reporting increases after interventions, while only five tests indicated no change.** The evidence strongly suggests that exercise/ physical activity interventions were effective in improving locomotor skill, object-control skill and complex tasks in overweight/obese peers. However, the results for balance were equivocal.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis – *No meta-analysis*

		were also included but this was not essential. **Exclusion Criteria**: Studies were excluded if obesity metrics and/or criteria (e.g., BMI, WC, skin fold etc.) were not utilized and measurements of FMS/MC were not provided for pre and postintervention. FMS/MC measurements included locomotor skill, object-control skill, balance and complex task (body manoeuvring).			

References:

1. Han, A., et al. (2018). "Effectiveness of exercise intervention on improving fundamental movement skills and motor coordination in overweight/obese children and adolescents: A systematic review." Journal of Science & Medicine in Sport **21**(1): 89-102.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Children and adolescents Modality: Exercise Outcome: BMI		
Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Kelley, G.A., et al. Year Published: 2015 Location: West Virginia University, Morgantown, WV Journal: *BioMed Research International*	To determine the effects of exercise on body mass index (BMI in kg m(-2)) among overweight and obese children and adolescents.	**Size:** 20 studies, 971 children **Inclusion Criteria**: (1) randomized controlled trials (assignment at participant level only), (2) control group (nonintervention, usual care, wait-list control, and attention control), (3) exercise (aerobic training, strength training, or both) ≥ 4 weeks as an independent intervention, (4) overweight and obese children and adolescents, as defined by the authors, (5) boys and/or girls 2 to 18 years of age, (6) studies published in full in any language between January 1, 1990, and November, 11, 2014, and (7) data available for calculating changes in BMI in kg·m−2. Studies were excluded based on an inappropriate population, intervention, comparison, outcome, study type, or lack of requisite data for BMI in kg·m−2.	**Type:** Systematic Review	**Results:** Average length, frequency, and duration of training were 13 weeks, 3 times per week, for 46 minutes per session. **Overall, random-effects models showed that exercise decreased BMI by 3.6% (mean: -1.08; 95% CI: -0.52 to -1.64; Q = 231.4; p < 0.001; I (2) = 90.9%; 95% CI: 87.6% to 93.4%; D (2) = 91.5%).** Trial sequential meta-analysis showed that changes in BMI crossed the monitoring boundary for a type 1 error in 2010, remaining stable thereafter. The number needed to treat was 5 while the percentile improvement was 26.9. It was estimated that approximately 2.5 million overweight and obese children in the US and 22.0 million overweight and obese children worldwide could reduce their BMI by participating in a regular exercise program. Overall quality of evidence was rated as moderate. 	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Kelley, G. A., et al. (2015). "Exercise and BMI in Overweight and Obese Children and Adolescents: A Systematic Review and Trial Sequential Meta-Analysis." BioMed Research International **2015**: 704539.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Aerobic, resistance, and combined exercise training
Outcome: Insulin resistance, fasting glucose, and fasting insulin

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☐ Medium
☒ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Marson, E.C., et al. Year Published: 2016 Location: Universidade Federal do Rio Grande do Sul, Brazil Journal: *Preventive Medicine*	To assess the associations of aerobic, resistance, and combined exercise with changes in insulin resistance, fasting glucose, and fasting insulin in children and adolescents who are overweight or obese.	**Size:** 17 studies, 961 individuals **Inclusion Criteria**: Children and adolescents (until 19 years old) of both sexes, overweight or obese, and not engaged in structured exercise for at least three months. Clinical trials should have included at least six-week of intervention period. There were no restrictions on the exercise modality, intensity, volume, and frequency. For inclusion, studies showed absolute values pre- and post-intervention period or the difference between average and dispersion values of at least	**Type:** Systematic Review	**Results: The meta-analysis showed that physical training in general was not associated with a reduction in fasting glucose levels compared to the control, but it was associated with reductions in fasting insulin levels (-3.37muU/ml; CI 95%, -5.16muU/ml to -1.57muU/ml; 54%, p=0.003) and HOMA (-0.61; CI 95%, -1.19 to -0.02; 49%, p=0.040).** In addition, each modality (aerobic, resistance, and combined) was compared to the control group. Aerobic exercise was associated with declines in fasting insulin levels (-4.52muU/ml; CI 95%, -7.40 to -1.65; 65%, p=0.002)	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		one of the following outcomes: fasting glucose, fasting insulin, and insulin resistance-HOMA.		and in HOMA (-1.33; 95% confidence interval, -2.47 to -0.18; 73%, p=0.005).	

References:

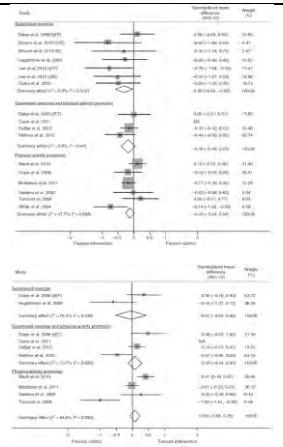
1. Marson, E. C., et al. (2016). "Effects of aerobic, resistance, and combined exercise training on insulin resistance markers in overweight or obese children and adolescents: A systematic review and meta-analysis." Preventive Medicine **93**: 211-218.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adolescents
Modality: Physical activity and exercise
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

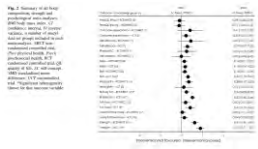
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Ruotsalainen, H., et al. Year Published: 2015 Location: Oulu University Hospital, Finland Journal: *Journal of Advanced Nursing*	To examine the effects of physical activity and exercise interventions on body mass index, subsequent physical activity and psychological symptoms for overweight and obese adolescents (12-18 years).	**Size:** 14 studies **Inclusion Criteria**: Participants had to be overweight or obese adolescents (age range 12-18 (+/-1) years). The intervention must have consisted solely of physical activity or exercise, or of physical activity/exercise along with counselling or dietary practices.	**Type:** Systematic Review	**Results:** Supervised exercise interventions most affected adolescents' body mass index. The interventions effect on adolescents' physical activity was small and heterogeneous. Two interventions positively affected psychological symptoms.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		Exclusion Criteria: Studies that addressed adolescents with long-term disease, mental health problems, intellectual disabilities or eating disorders were excluded.			

References:

1. Ruotsalainen, H., et al. (2015). "Systematic review of physical activity and exercise interventions on body mass indices, subsequent physical activity and psychological symptoms in overweight and obese adolescents." Journal of Advanced Nursing **71**(11): 2461-2477.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Children and adolescents Modality: Resistance training Outcome: Strength, body composition		
Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Schranz, N., et al. Year Published: 2013 Location: University of South Australia Journal: *Sports Medicine*	To systematically review and meta-analyse the peer-reviewed literature to determine the effect of resistance training on the strength, body composition and psychosocial status of overweight and/or obese children and/or adolescents.	**Size:** 40 studies, 2,247 participants **Inclusion Criteria**: Randomised controlled trials (RCTs), non randomised controlled trials (NRCTs) and uncontrolled trials (UCTs) which had run an exercise intervention, with a resistance training component, for overweight and/or obese children and/or adolescents, and which had examined the effect of resistance training on either strength, body composition or psychosocial outcomes.	**Type:** Systematic Review	**Results:** The overall intervention effect reported for RCTs and NRCTs was relative to the control group whereas the effect reported for UCTs shows an overall post-intervention effect.  **Typically, resistance training had very small to small effects on body composition and moderate to large effects on strength in favour of the intervention. However, the magnitude and direction of the effect of resistance training on psychological outcomes are still unclear given the limited number of studies which looked at psychosocial outcomes and the inconclusive results shown by this review.**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

References:

1. Schranz, N., et al. (2013). "What is the effect of resistance training on the strength, body composition and psychosocial status of overweight and obese children and adolescents? A Systematic review and meta-analysis." Sports Medicine **43**(9): 893-907.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children and adolescents
Modality: Resistance training
Outcome: Psychosocial status

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

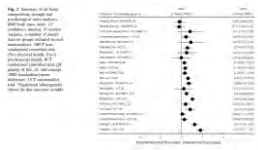
Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Schranz, N., et al. Year Published: 2013 Location: University of South Australia Journal: *Sports Medicine*	To systematically review and meta-analyse the peer-reviewed literature to determine the effect of resistance training on the strength, body composition and psychosocial status of overweight and/or obese children and/or adolescents.	**Size:** 40 studies, 2,247 participants **Inclusion Criteria**: Randomised controlled trials (RCTs), non randomised controlled trials (NRCTs) and uncontrolled trials (UCTs) which had run an exercise intervention, with a resistance training component, for overweight and/or obese children and/or adolescents, and which had examined the effect of resistance training on either strength, body composition or psychosocial outcomes.	**Type:** Systematic Review	**Results:** The overall intervention effect reported for RCTs and NRCTs was relative to the control group whereas the effect reported for UCTs shows an overall post-intervention effect.  **Typically, resistance training had very small to small effects on body composition and moderate to large effects on strength in favour of the**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

				intervention. However, the magnitude and direction of the effect of resistance training on psychological outcomes are still unclear given the limited number of studies which looked at psychosocial outcomes and the inconclusive results shown by this review.	

References:

1. Schranz, N., et al. (2013). "What is the effect of resistance training on the strength, body composition and psychosocial status of overweight and obese children and adolescents? A Systematic review and meta-analysis." Sports Medicine **43**(9): 893-907.

Adult: Guideline Recommendations:

The 2016 **American Academy of Family Physicians** recommended:

- Increased physical activity should be recommended for weight loss in combination with diet and behavioral modifications. **Grade B**

The 2016 **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

Lifestyle/behavioral therapy:

- A structured lifestyle intervention program designed for weight loss (lifestyle therapy) and consisting of a healthy meal plan, physical activity, and behavioral interventions should be available to patients who are being treated for overweight or obesity **(Grade A;BEL1)**.

Physical activity:

- Aerobic physical activity training should be prescribed to patients with overweight or obesity as a component of lifestyle intervention; the initial prescription may require a progressive increase in the volume and intensity of exercise, and the ultimate goal should be a total of ≥150 min/week of moderate exercise performed during 3 to 5 daily sessions per week **(Grade A; BEL 1)**.
- Resistance training should be prescribed to patients with overweight or obesity undergoing weight-loss therapy to help promote fat loss while preserving fat-free mass; the goal should be resistance training 2 to 3 times per week consisting of single-set exercises that use the major muscle groups **(Grade A; BEL 1)**.
- An increase in non-exercise and active leisure activity should be encouraged to reduce sedentary behavior in all patients with overweight or obesity **(Grade A; BEL 1)**.
- The prescription for physical activity should be individualized to include activities and exercise regimens within the capabilities and preferences of the patient, taking into account health-related and physical limitations **(Grade C; BEL4, upgraded due to high relevance)**.

- Involvement of an exercise physiologist or certified fitness professional in the care plan should be considered to individualize the physical activity prescription and improve outcomes **(Grade A; BEL 1)**.

Figure 4. Lifestyle Therapy

Evidence-based lifestyle therapy for treatment of obesity should include 3 components
Recommendations: R64 through R75

Meal Plan (R64, R65, R66)	Physical Activity (R64, R67, R68, R69, R70, R71)	Behavior (R64, R72, R73, R74, R75)
• Reduced-calorie healthy meal plan • ~500–750 kcal daily deficit • Individualize based on personal and cultural preferences • Meal plans can include: Mediterranean, DASH, low-carb, low-fat, volumetric, high protein, vegetarian • Meal replacements • Very low-calorie diet is an option in selected patients and requires medical supervision Team member or expertise: dietitian, health educator	• Voluntary aerobic physical activity progressing to >150 minutes/week performed on 3–5 separate days per week • Resistance exercise: single-set repetitions involving major muscle groups, 2–3 times per week • Reduce sedentary behavior • Individualize program based on preferences and take into account physical limitations Team member or expertise: exercise trainer, physical activity coach, physical/occupational therapist	An interventional package that includes any number of the following: • Self-monitoring (food intake, exercise, weight) • Goal setting • Education (face-to-face meetings, group sessions, remote technologies) • Problem-solving strategies • Stimulus control • Behavioral contracting • Stress reduction • Psychological evaluation, counseling, and treatment when needed • Cognitive restructuring • Motivational interviewing • Mobilization of social support structures Team member or expertise: health educator, behaviorist, clinical psychologist, psychiatrist

In 2015 **Canadian Task Force on Preventative Health Care** recommended the following:

- For adults who are obese (BMI 30–39.9) and are at high risk of type 2 diabetes, we recommend that practitioners offer or refer to structured behavioural interventions aimed at weight loss. Structured interventions are intensive behavioural modification programs involving several sessions over weeks to months. Recommended interventions include behaviourally based interventions focused on diet, exercise or lifestyle changes, alone or in combination. Lifestyle changes include counselling, education or support, and/or environmental changes in addition to changes in exercise and/or diet. **(Strong recommendation; moderate-quality evidence)**

The 2015 **European Guidelines** for Obesity Management in Adults recommended the following:

Management
Nutrition
Reduce energy intake by 500–1,000 kcal/day
Physical activity
Initially at least 150 min/week moderate aerobic exercise combined with 1–3 sessions/week resistance exercise
Cognitive behaviour therapy
Pharmacotherapy
BMI ≥ 30 kg/m^2 or BMI ≥ 27 kg/m^2 with co-morbidities
Adjunct to lifestyle modification
Bariatric/metabolic surgery
BMI≥40 kg/m^2 or BMI between 35.0–39.9 kg/m^2 + co-morbidities or BMI between 30.0-34.9 kg/m^2 with type 2 diabetes on individual basis. Consider if other weight loss attempts fail; requires lifelong medical monitoring
Prevention and treatment of co-morbidities

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following for Physical Activity in 2014:

Adults

- Encourage adults to increase their level of physical activity even if they do not lose weight as a result, because of the other health benefits it can bring (for example, reduced risk of type 2 diabetes and cardiovascular disease). Encourage adults to do at least 30 minutes of moderate or greater intensity physical activity on 5 or more days a week. The activity can be in 1 session or several sessions lasting 10 minutes or more.
- Advise that to prevent obesity, most people may need to do 45–60 minutes of moderate-intensity activity a day, particularly if they do not reduce their energy intake. Advise people who have been obese and have lost weight that they may need to do 60–90 minutes of activity a day to avoid regaining weight.
- Encourage adults to build up to the recommended activity levels for weight maintenance, using a managed approach with agreed goals.
  Recommend types of physical activity, including:
  - activities that can be incorporated into everyday life, such as brisk walking, gardening or cycling
  - supervised exercise programmes
  - other activities, such as swimming, aiming to walk a certain number of steps each day, or stair climbing.

  Take into account the person's current physical fitness and ability for all activities. Encourage people to also reduce the amount of time they spend inactive, such as watching television, using a computer or playing video games.

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

Physical Activity Approaches

- Offer physical activity elements (e.g. Home fitness, lifestyle, or structured/supervised physical activates) that can be combined to produce a caloric deficit leading to weight loss. **Grade A**
- Offer physical activity options that include short intermittent bursts (at least 10 minutes) as well as longer continuous exercise. **Grade A**
- Offer, as part of a comprehensive lifestyle intervention, moderate-intensity physical activity performed for at least 150 minutes/week to result in weight loss. **Grade A**
- Offer, as part of comprehensive lifestyle intervention, moderate-intensity physical activity performed for 200-300 minutes per week to prevent weight regain after initial weight loss. **Grade EO**

The **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** in 2013 recommended:

- **Box 10: Weight Loss Option—Comprehensive Lifestyle Intervention Alone or With Adjunctive Therapies** All patients for whom weight loss is recommended should be offered or referred for comprehensive lifestyle intervention (Box 11a and 11b). Comprehensive lifestyle intervention, preferably with a trained interventionist† or nutrition professional*, is foundational to weight loss (Box 11a) regardless of augmentation by medications or bariatric surgery. By expert opinion, if the weight and lifestyle history indicates that the patient has never participated in a comprehensive lifestyle intervention program as defined in CQ4 and in Box 11a, it is recommended that he or she be encouraged to undertake such a program before the addition of adjunctive therapies since a substantial proportion of patients will lose sufficient weight to improve health with comprehensive lifestyle treatment alone. This recommendation may be modified by the availability of comprehensive lifestyle intervention or by patient factors, such as medical conditions that warrant earlier initiation of more intensive treatment. If the patient has been unable to lose weight or sustain weight loss with comprehensive lifestyle intervention and he or she has a BMI ≥30 kg/m2 or BMI ≥27 kg/m2 with comorbidity, adjunctive therapies may be considered. Patients who are otherwise appropriate candidates for obesity drug treatment or bariatric surgery, whose weight and lifestyle history indicate a history of inability to achieve or sustain weight loss and who have previously participated in a comprehensive lifestyle intervention, may be offered the option to add pharmacotherapy at the time of initiation of a lifestyle intervention program (BMI ≥30 kg/m2 or BMI ≥27 kg/m2 with comorbidity) or to be referred for evaluation for bariatric surgery (BMI ≥40 kg/m2 or BMI ≥35 kg/m2 with comorbidity) (expert opinion).
- **Box 11a. Offer or Refer for High-Intensity Comprehensive Lifestyle Intervention** The most effective behavioral weight loss treatment is an in-person, high-intensity (ie, ≥14 sessions in 6 months) comprehensive weight loss intervention provided in individual or group sessions by a trained interventionist. The principal components of an effective highintensity, on-site comprehensive lifestyle intervention include 1) prescription of a moderately reduced-calorie diet, 2) a program of increased physical activity, and 3) the use of behavioral strategies to facilitate adherence to diet and activity recommendations. As shown in CQ4, comprehensive lifestyle intervention consisting of diet, physical activity, and behavior therapy produces average weight losses of approximately 8 kg in a 6-month period of frequent, in-person treatment. This approximates losses of 5%-10% of initial weight. The observed average weight loss of approximately 8 kg includes people who have variable weight loss (ie, some more and some less than average), so accurate prediction of individual weight loss is not possible. After 6 months, most patients will equilibrate (caloric intake balancing energy expenditure) and will require adjustment of energy balance if they are to lose additional weight. As demonstrated in CQ4, continued intervention contact after initial weight loss treatment is associated with better maintenance of lost weight.
- **Box 11b. Options for Alternative Modes of Delivery of Lifestyle Intervention** In primary care offices where frequent, in-person individual or group sessions led by a trained interventionist or a nutrition professional are not possible or available by referral, the physician may consider alternative modes of delivery. As found in CQ4, emerging evidence supports the efficacy, albeit with less weight loss, of electronically delivered interventions (eg, by Internet or telephone) that provide personalized feedback by a trained interventionist and of some commercial programs that provide counseling (face-to-face or telephonic) with or without prepackaged meals. The Expert Panel recommends, by expert opinion, that physicians may refer to these

alternative sources provided their outcomes are supported by scientific evidence of safety and efficacy. An additional option if a highintensity comprehensive lifestyle intervention program is not available or feasible is referral to a nutrition professional for dietary counseling.

- Higher levels of physical activity, approximately 200 to 300 min/wk, are recommended to maintain lost weight or minimize weight regain in the long term (> 1 year). **Strength of Evidence: High**
-

Recommendations	NHLBI Grade	NHLBI ES	ACC/AHA COR	ACC/AHA LOE
Lifestyle Intervention and Counseling (Comprehensive Lifestyle Intervention)				
4a. Advise overweight and obese individuals who would benefit from weight loss to participate for ≥6 months in a *comprehensive lifestyle program* that assists participants in adhering to a lower-calorie diet and in increasing physical activity through the use of behavioral strategies.	A (Strong)	CQ4	I	A
4b. Prescribe on-site, high-intensity (ie, ≥14 sessions in 6 mo) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist.†	A (Strong)	CQ4	I	A
4c. Electronically delivered weight loss programs (including by telephone) that include personalized feedback from a trained interventionist† can be prescribed for weight loss but may result in smaller weight loss than face-to-face interventions.	B (Moderate)	CQ4	IIa	A
4d. Some commercial-based programs that provide a comprehensive lifestyle intervention can be prescribed as an option for weight loss, provided there is peer-reviewed published evidence of their safety and efficacy.	B (Moderate)	CQ4	IIa	A

4e.	Use a very-low-calorie diet (defined as <800 kcal/d) only in limited circumstances and only when provided by trained practitioners in a medical care setting where medical monitoring and high-intensity lifestyle intervention can be provided. Medical supervision is required because of the rapid rate of weight loss and potential for health complications.	A (Strong)	CQ4	IIa‡	A
4f.	Advise overweight and obese individuals who have lost weight to participate long term (≥1 year) in a comprehensive weight loss maintenance program.	A (Strong)	CQ4	I	A
4g.	For weight loss maintenance, prescribe face-to-face or telephone-delivered weight loss maintenance programs that provide regular contact (monthly or more frequently) with a trained interventionist† who helps participants engage in high levels of physical activity (ie, 200–300 min/wk), monitor body weight regularly (ie, weekly or more frequently), and consume a reduced-calorie diet (needed to maintain lower body weight).	A (Strong)	CQ4	I	A

Adults: Primary Literature

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adults with cardiometabolic disorders Modality: High vs. moderate-intensity aerobic interval training Outcome: Metabolic risk factors		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Hwang, C.L. et al. Year Published: 2011 Location: National Taiwan University Journal: *Journal of Cardiopulmonary Rehabilitation & Prevention*	To compare the effectiveness of high-intensity aerobic interval training (AIT) with active recovery and continuous moderate-intensity exercise (CME) on exercise capacity and metabolic risk factors in adults with cardiometabolic disorders through a systematic review and meta-analysis.	**Size:** 6 RCTs, 153 participants (40 overweight/obesity, 19 with metabolic syndrome, and 94 with heart disease). **Inclusion Criteria**: RCTS carried out in human subjects and published in English.	**Type:** Systematic Review	**Results: Aerobic interval training significantly increased peak oxygen consumption (WMD, 3.6 mL.kg.min; 95% CI, 2.3-4.9) with a trend of decreasing fasting glucose (WMD, -0.4 mmol/L; 95% CI, -0.9 to 0.2, P = .18) compared with CME. The effects on other metabolic risk factors were similar between AIT and CME.** 	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Hwang, C. L., et al. (2011). "Effect of aerobic interval training on exercise capacity and metabolic risk factors in people with cardiometabolic disorders: a meta-analysis." Journal of Cardiopulmonary Rehabilitation & Prevention **31**(6): 378-385.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Aerobic exercise (AEx) and progressive resistance training (PRT)
Outcome: VAT modulation

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	Low Quality Rating if:	Other Considerations:
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

		☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Ismail, I., et al. Year Published: 2012 Location: University of Sydney, Australia Journal: *Obesity Reviews*	To evaluate the independent and synergistic effects of aerobic exercise (AEx) and progressive resistance training (PRT) and to directly compare the efficacy of AEx and PRT for beneficial VAT modulation	**Size:** 35 studies, 2145 individuals (702 males; 1422 females; 21 not reported) **Inclusion Criteria**: Studies were included if the exercise intervention was of 4 weeks or more. This cut-off was established to differentiate studies examining the acute effects of exercise from those examining training adaptations. Trials where participants were randomized to an intervention involving either AEx or PRT, or both, were included. Studies involving dietary control/intervention were included only if the diet was the same between the exercise and control groups. Studies with adult participants greater than or equal to 18 years were considered. Studies of individuals with type 2 diabetes were included but those of HIV-infected populations were excluded because of specific medications affecting abdominal fat.	**Type:** Systematic Review	**Results: There was a significant pooled effect size (ES) for the comparison between AEx therapy and control (-0.33, 95% CI: -0.52 to -0.14; P < 0.01) but not for the comparison between PRT therapy and control (0.09, 95% CI: -0.17 to -0.36; P = 0.49).** Of the available nine studies which directly compared AEx with PRT, the pooled ES did not reach statistical significance (ES = 0.23, 95% CI: -0.02 to 0.50; P = 0.07 favouring AEx). The pooled ES did not reach statistical significance for interventions that combined AEx and PRT therapy vs. control (-0.28, 95% CI: -0.69 to 0.14; P = 0.19), for which only seven studies were available.	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

References:

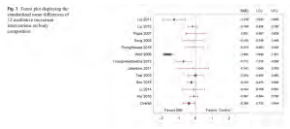
1. Ismail, I., et al. (2012). "A systematic review and meta-analysis of the effect of aerobic vs. resistance exercise training on visceral fat." Obesity Reviews **13**(1): 68-91.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adult
Modality: Tai Chi and Qigong practice
Outcome: Body composition outcomes

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Larkey, L.K., et al. Year Published: 20108 Location: Arizona State University Journal: *International Journal of Behavioral Medicine*	To conduct a systematic review on two forms of meditative movement (MM), Tai Chi and Qigong, reporting effects on changes in body composition.	**Size:** 24 studies, 1621 participants. **Inclusion Criteria**: (a) RCT study design; (b) published in the English language; (c) included participants over 18 years of age; (d) published in 1990 through March, 2017; (e) utilized TC or QG or a combination of these related practices as the intervention being tested; and with (f) any body composition measure reported as an outcome. Cross-sectional, observational, or descriptive studies and studies that combined additional confounding interventions (e.g., nutrition education) along	**Type:** Systematic Review	**Results:** Significant improvements in body composition, primarily body mass index, were noted for 41.7% of studies. A synthesis table describes the distribution of design factors, including type of comparison condition (inactive vs. active) and baseline body composition status (whether or not overweight/obese). **A meta-analysis was conducted on 12 studies with inactive controls (using a random effects model) finding a small-to-medium treatment effect (SMD = − 0.388, CI = [− 0.732, − 0.044], t = 2.48, p < 0.03) for**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

		with the TC or QG study group intervention were excluded. Articles that included more than one comparison group (e.g., active control plus non-active or wait-list control) were included, with all outcomes reported but with emphasis on the non-active control group intervention comparison.		**TC or QG interventions with a high level of heterogeneity.** 	

References:

1. Larkey, L. K., et al. (2018). "Body Composition Outcomes of Tai Chi and Qigong Practice: A Systematic Review and Meta-Analysis of Randomized Controlled Trials." International Journal of Behavioral Medicine **25**(5): 487-501.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults with serious mental illness (including healthy weight participants)
Modality: Exercise therapy
Outcome: Quality of life

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☐ Low
☒ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☒ High ☐ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Pearsall, R., et al. Year Published: 2014 Location: University of Glasgow, UK	To conduct a systematic review and meta-analysis of randomised controlled trials comparing the effect of	**Size:** 8 RCTs, 151 participants **Inclusion Criteria**: 1. Adults with schizophrenia or other	**Type:** Systematic Review	**Results:** The review found that exercise improved levels of exercise activity (n = 13, standard mean difference [SMD] 1.81, CI 0.44 to 3.18, p	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question

Journal: *BMC Psychiatry*	exercise interventions on individuals with serious mental illness.	types of schizophrenia-like psychosis, schizoaffective disorders, and bipolar affective disorder irrespective of the diagnostic criteria used, age, ethnicity and sex. 2. All patients, adults, clients, in the community or in hospital. 3. All relevant randomised controlled trials. 4. Interventions where a primary or secondary aim was to promote exercise or physical activity.		= 0.01). No beneficial effect was found on negative (n = 84, SMD = -0.54, CI -1.79 to 0.71, p = 0.40) or positive symptoms of schizophrenia (n = 84, SMD = -1.66, CI -3.78 to 0.45, p = 0.12). **No change was found on body mass index compared with usual care (n = 151, SMD = -0.24, CI -0.56 to 0.08, p = 0.14), or body weight (n = 77, SMD = 0.13, CI -0.32 to 0.58, p = 0.57).** No beneficial effect was found on anxiety and depressive symptoms (n = 94, SMD = -0.26, CI -0.91 to 0.39, p = 0.43), or quality of life in respect of physical and mental domains.	☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Pearsall, R., et al. (2014). "Exercise therapy in adults with serious mental illness: a systematic review and meta-analysis." BMC Psychiatry **14**: 117.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Different training modalities
Outcome: Anthropometric and metabolic characteristics

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*			
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Schwingshackl, L., et al. Year Published: 2013 Location: University of Vienna, Austria Journal: *PLoS ONE [Electronic Resource]*	To compare the effects of aerobic training (AET), resistance training (RT), and combined aerobic and resistance training (CT) on anthropometric parameters, blood lipids, and cardiorespiratory fitness in overweight and obese subjects	**Size:** 15 trials, 741 participants **Inclusion Criteria**: (1) Randomized controlled design; (2) minimum intervention period of 8 weeks; (3) body mass index $25 kg/m2 ; (4) age: $19 years; (5) comparison of either AET vs. RT and/or CT vs. AET and/or CT vs. RT; (6) assessment of "primary outcome" markers: BW, WC, waist to hip ratio (WHR), fat mass (FM, given in kg), lean body mass (LBM, given in kg); assessment of "secondary outcome" markers: total cholesterol (TC), lowdensity lipoprotein cholesterol (LDL-C), HDL-C, triacylglycerols (TG) and VO2 max; (7) report of post-treatment mean values (if not available mean of changes from baseline were used) with standard deviation (or data suitable to calculate these parameters: standard error, 95% confidence interval); (8) training had to be supervised, not home-based; (9) exclusion of studies with a dietary co-intervention that was not applied in all intervention groups; (10) exclusion of	**Type:** Systematic Review	**Results: Compared to RT, AET resulted in a significantly more pronounced reduction of body weight [mean differences (MD): -1.15 kg, p = 0.04], waist circumference [MD: -1.10 cm, p = 0.004], and fat mass [MD: -1.15 kg, p = 0.001] respectively. RT was more effective than AET in improving lean body mass [MD: 1.26 kg, p<0.00001]. When comparing CT with RT, MD in change of body weight [MD: -2.03 kg, p<0.0001], waist circumference [MD: -1.57 cm, p = 0.0002], and fat mass [MD: -1.88 kg, p<0.00001] were all in favor of CT. Results from the network meta-analyses confirmed these findings.**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		subjects with type 2 diabetes, and coronary heart disease.			

References:

1. Schwingshackl, L., et al. (2013). "Impact of different training modalities on anthropometric and metabolic characteristics in overweight/obese subjects: a systematic review and network meta-analysis." PLoS ONE [Electronic Resource] **8**(12): e82853.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Strength exercises
Outcome: Psychological effects

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☒ High
☐ Medium
☐ Low

Low Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

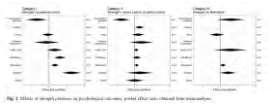
☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Ten Hoor, G. A., et al. Year Published: 2017 Location: Maastricht University, the Netherlands Journal: *Sports Medicine*	To assess the psychological effects of strength exercises for people who are overweight or obese.	**Size:** 17 studies **Inclusion Criteria**: Only studies that reported the independent effect of strength training on psychological outcomes in overweight or obese people were included. No other restrictions were applied.	**Type:** Systematic Review	**Results:** Meta-analytical techniques revealed substantial heterogeneity in effect sizes, and combined with the low number of effect size estimates for each outcome measure, this precluded meta-analysis. **Organization of the data showed that the evidence base so far does not show convincing effects of strength training on**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☒ Inappropriate pooled analysis

				psychological outcome measures. Some weak effects emerged on self-efficacy, self-esteem, inhibition, and psychological disorders (e.g., anxiety and depression). No additional or comparable effects to other interventions were found for mood, outcome expectations, quality of life, and stress. 	

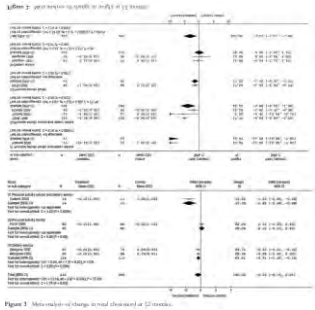
References:

1. Ten Hoor, G. A., et al. (2017). "The Psychological Effects of Strength Exercises in People who are Overweight or Obese: A Systematic Review." Sports Medicine **47**(10): 2069-2081.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Older adults
Modality: Weight loss interventions
Outcome: Health benefits

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☒ High ☐ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Witham, M. D. and A. Avenell Year Published: 2010 Location: University of Aberdeen, UK Journal: *Age & Ageing*	To systematically review the evidence for interventions designed to produce sustained weight loss in obese older adults to inform current practice.	**Size:** 7 studies **Inclusion Criteria**: Randomised controlled trials in which weight loss was a primary aim of the intervention, for which follow-up data at a minimum of 1 year were available, in which the mean age of groups was ≥60 years and the mean baseline BMI was ≥30 kg/m2, trials with placebo or no intervention for the control group and trials comparing active intervention groups. **Exclusion Criteria**: Studies which weight loss was a coincidental change produced by another type of intervention.	**Type:** Systematic Review	**Results: Meta-analysis (seven studies) demonstrated a modest but significant weight loss of 3.0 kg [95% confidence interval (CI) 5.1–0.9] at 1 year. Total cholesterol (four studies) did not show a significant change: −0.36 mmol/l (95% CI −0.75 to 0.04). There was no significant change in high-density lipoprotein, low-density lipoprotein or triglycerides. In one study, recurrence of hypertension or cardiovascular events was significantly reduced (hazard ratio 0.65, 95% CI 0.50–0.85).** Six-minute walk test did not significantly change in one study. Health-related quality of life significantly improved in one study but did not improve in a second study. 	**Study Limitations:** ☐ None ***Systematic Review*** ☒ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Witham, M. D. and A. Avenell (2010). "Interventions to achieve long-term weight loss in obese older people: a systematic review and meta-analysis." Age & Ageing **39**(2): 176-184.

Question #5. What is the comparative effectiveness of behavioral interventions (mental health interventions, group, and individual, mixed, peer-based, parenting and family-based, technology-based, print-based)? What is the optimal intensity of behavioral interventions for improving health, well-being, and weight loss?

Children and Adolescents: Guideline Recommendations

The 2015 **American Academy of Pediatrics Institute for Health Childhood Weight** released the following assessment and management algorithm for childhood obesity:

Algorithm was based on 2007 **American Academy of Pediatrics** Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report stated:

Treatment Recommendations

- The expert committee recommends the following staged approach for children between the ages of 2 and 19 years whose BMI is >85th percentile. Stage 1 is the Prevention Plus protocol. These recommendations can be implemented by the primary care physician or an allied health care provider who has some training in pediatric weight management or behavioral counseling. Stage 1 recommendations include the following. (a) Consume >/=5 servings of fruits and vegetables per day (ME). (b) Minimize or eliminate sugar-sweetened beverages (ME). (c) Limit screen time to </=2 hours per day, with no television in the room where the child sleeps (CE). (d) Engage in >/=1 hour of daily physical activity (ME). The patient and the family of the patient should be counseled to facilitate the following eating behaviors: (a) eating a daily breakfast (ME); (b) limiting meals outside the home (ME); (c) eating family meals at least 5 or 6 times per week (ME); and (d) allowing the child to self-regulate his or her meals and avoiding overly restrictive behaviors (CE for children <12 years of age and suggested for children >12 years of age). Providers should acknowledge cultural differences and help families to adapt recommendations to meet these differences (suggest). Within this category, the goal should be weight maintenance, with growth resulting in decreasing BMI as age increases. Monthly follow-up assessment should be performed. After 3 to 6 months, if no improvement in BMI or weight status has been noted, then advancement to stage 2 is indicated, on the basis of patient/family readiness to change. Stage 2 is a structured weight management protocol. These recommendations can be implemented by a primary care physician or an allied health care provider who is highly trained in weight management. Stage 2 recommendations include the following: (a) development of a plan for use of a balanced macronutrient diet, emphasizing small amounts of energy-dense foods (suggest); (b) provision of structured daily meals and snacks (breakfast, lunch, dinner, and 1 or 2 snacks per day) (suggest); (c) supervised active play of >/=60 minutes per day (ME); (d) screen time of </=1 hour per day (suggest; CE for </=2 hours); (e) increased monitoring (eg, screen time, physical activity, dietary intake, and restaurant logs) by provider, patient, and/or family (CE); and (f) reinforcement for achieving targeted behavior goals (not weight goals) (suggest). Within this category, the goal should be weight maintenance that results in decreasing BMI as age and height increase; however, weight loss should not exceed 1 lb/month for children 2 to 11 years of age or an average of 2 lb/week for older overweight/obese children and adolescents. If there is no improvement in BMI or weight status after 3 to 6 months, then the patient should advance to stage 3. Stage 3 is a comprehensive multidisciplinary intervention. At this level of intervention, optimally the patient should be referred to a multidisciplinary obesity care team. Eating and activity goals are the same as in stage 2. Activities within this category should also include the following: (a) planned negative energy balance achieved through structured diet and physical activity (ME); (b) structured behavioral modification program, including food and activity monitoring and development of short-term diet and physical activity goals (CE); (c) involvement of primary caregivers/family members for behavioral modification for children _12 years of age (CE); (d) provision of training for all families to improve the home environment (suggest); and (e) frequent office visits. Weekly visits for a minimum of 8 to 12 weeks seem to be most efficacious (CE), and subsequent monthly visits help maintain new behaviors. Group visits may be more cost-effective and have therapeutic benefit (ME). Systematic evaluation of body measurements, dietary intake, and physical activity should be conducted at baseline and at specific intervals throughout the program. Within this category, the goal

should be weight maintenance or gradual weight loss until BMI is <85th percentile. Weight loss should not exceed 1 lb/month for children 2 to 5 years of age or 2 lb/week for older obese children and adolescents.

In 2016, the **American Academy of Pediatrics** Preventing Obesity and Eating Disorders in Adolescents provided the following key features in identifying feeding disorders and eating disorders:

TABLE 4 Principles of Family-Based Treatment of EDs and Role of the Pediatrician

Principles of treatment
- Parents are not to blame
- Parents are vital to therapeutic success
- Parents are responsible for weight restoration
- Separate the child from the illness
- Nonauthoritarian approach

Three phases of treatment
- Phase 1: parents restore patient's weight
- Phase 2: control transferred back to the child or adolescent
- Phase 3: focuses on adolescent developmental issues and termination of treatment

Examples of the role the pediatrician can play
- Act as a consultant to the parents and therapist
- Explain the medical seriousness of the ED
- Monitor and manage the medical status of the adolescent
- Empower the parents in decision-making
- Communicate with the patient, family, and therapist

Role of the Pediatricians in the Prevention of Obesity and Eating Disorders in Adolescents:

1. Discourage dieting, skipping of meals, or the use of diet pills; instead, encourage and support the implementation of healthy eating and physical activity behaviors that can be maintained on an ongoing basis. The focus should be on healthy living and healthy habits rather than on weight.
2. Promote a positive body image among adolescents. Do not encourage body dissatisfaction or focus on body dissatisfaction as a reason for dieting.
3. Encourage more frequent family meals.

4. Encourage families not to talk about weight but rather to talk about healthy eating and being active to stay healthy. Do more at home to facilitate healthy eating and physical activity.
5. Inquire about a history of mistreatment or bullying in overweight and obese teenagers and address this issue with patients and their families.
6. Carefully monitor weight loss in an adolescent who needs to lose weight to ensure the adolescent does not develop the medical complications of semistarvation.

Time constraints in a busy pediatric practice are significant. Weight issues can be a topic of sensitivity and therefore can be time consuming. The evidence-based suggestions in this report can be implemented in relatively brief encounters and can be an excellent first step for teenagers and families to promote a healthy lifestyle.

The 2018 **American Psychological Association (APA)** guideline stated in the treatment of obesity and overweight in children and adolescents:

- For child and adolescent patients aged 2-18 with overweight or obesity, the panel strongly recommends the provision of family-based multicomponent behavioral interventions, with a minimum of 26 contact hours, initiated at the earliest age possible.
- There was no association to suggest severity of adiposity, parental obesity, race or ethnicity, and insufficient evidence to suggest socioeconomic status made a difference in the outcome of high intensity family based multicomponent behavioral interventions.
- There was insufficient evidence to determine the comparative effectiveness of selected strategies of family based multicomponent behavioral interventions including goals and planning, comparison of outcomes, self-monitoring of behavior, self-monitoring of outcome, contingent reward or threat, stimulus control, modeling of healthy lifestyle behaviors by parents, motivational interviewing, or parenting skills training. Therefore, practitioners have a fair amount of flexibility in selecting an efficacious family-based multicomponent behavioral intervention program of sufficient intensity that addresses physical activity, nutrition, and behavior change with strategies used to accomplish change appropriate for particular patients and local implementation needs.
- There was insufficient evidence to determine whether specific intervention characteristics or strategies were associated with patient adherence (other than attendance), engagement, or retention. Higher attendance was associated with greater efficacy but there was insufficient evidence to determine whether patient adherence (beyond attendance) was associated with efficacy.

Table 2: Summary of considered intervention components and association with effect size

Intervention Strategy	**Effect size** Regression coefficient† (95% CI)
Goals and planning*	-0.32 (-0.74 to 0.13)
Collaborative goals	0.15 (-0.07 to 0.37)
Motivational interviewing	-0.03 (-0.23 to 0.29)
Self-monitoring behavior	-0.04 (-0.26 to 0.18)
Self-monitoring of weight	-0.15 (-0.44 to 0.15)
Contingent reward or threat	-0.15 (-0.38 to 0.07)
Stimulus control	0.07 (-0.16 to 0.30)
Parental modeling	-0.08 (-0.30 to 0.15)
Parenting skills training	0.08 (-0.16 to 0.33)
Comparison of outcomes	0.20 (-0.03 to 0.43)
Intervention Characteristics	
Contact hours	-0.01 (-0.01 to -0.01)
Number of sessions[9]	-0.01 (-0.02 to -0.01)
High (≥26) contact hours	-0.43 (-0.68 to -0.18)
Duration	-0.01 (-0.03 to 0.01)
Provider Qualifications	

[9] While the results for contact hours and number of sessions were significant, the panel determined that the magnitude was so small as to be close to 0. Only when dichotomizing the number of contact hours into high and low did the size of the effect appear meaningful.

Interventionist who provided the behavioral component was a behavioral specialist	-0.28 (-0.56 to 0.01)
Psychologist on team	-0.17 (-0.44 to 0.10)
Interventionist who provided the dietary component was a dietary specialist	0.04 (-0.25 to 0.33)
Interventionist who provided the physical activity component was a physical activity specialist	0.13 (-0.18 to 0.45)
Multidisciplinary team	0.16 (-0.09 to 0.42)
Setting	
Primary care	-0.02 (-0.28 to 0.25)
Other health care	-0.10 (-0.36 to 0.16)
Non-health care/community	0.12 (-0.14 to 0.37)
Delivery Format	
Offered group sessions	0.30 (-0.00 to 0.61)
Offered individual (single-family) sessions	-0.34 (-0.67 to -0.00)
Offered individual (single-family) sessions, among trials that also provided group sessions	-0.34 (-0.73 to 0.05)
Offered sessions targeting family all together	-0.01 (-0.27 to 0.24)
Offered sessions targeting child only (without parent)	-0.02 (-0.31 to 0.26)
Offered sessions targeting parent only (without child)	-0.03 (-0.31 to 0.24)
Included an electronic delivery component	-0.20 (-0.53 to 0.13)
Included a print-based delivery component	0.07 (-0.16 to 0.30)
Included a phone-based delivery component	0.11 (-0.12 to 0.34)
Included supervised physical activity sessions	0.27 (-0.06 to 0.60)
Included supervised physical activity sessions, among interventions offering ≥26 contact hours	0.16 (-0.59 to 0.92)
Cultural Tailoring	Insufficient evidence

*Almost all trials featured this strategy so insufficient variability to yield valid meta-regression results

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following for Behavioral Interventions in 2014:

Adults and children

- Deliver any behavioural intervention with the support of an appropriately trained professional.

Children

- Include the following strategies in behavioural interventions for children, as appropriate:
  - stimulus control
  - self-monitoring
  - goal setting
  - rewards for reaching goals
  - problem solving.

  Give praise to successes and encourage parents to role-model desired behaviours.

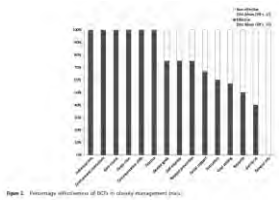
Children and Adolescents: Primary Literature

<table>
<tr><td colspan="3"><u>BODY OF EVIDENCE APPRAISAL TABLE FOR:</u>
<u>Population:</u> Children
<u>Modality:</u> Behavior change techniques
<u>Outcome:</u> Weight loss</td></tr>
<tr><td colspan="3"><u>Quality (certainty) of evidence for: (outcome)</u>
☐ High
☐ Moderate
☒ Low
☐ Very Low</td></tr>
<tr><td><u>Risk of Bias across studies:</u>
☒ High
☐ Medium
☐ Low</td><td><u>Low Quality Rating if:</u>
☒ Studies inconsistent (wide variation of treatment effect across studies, population, interventions, or outcomes varied)

☐ Studies are indirect (PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)

☐ Studies are imprecise (when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - UNKNOWN</td><td><u>Other Considerations:</u>
Lower Quality Rating if:
☐ Publication Bias (e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect</td></tr>
</table>

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Martin, J., et al. Year Published: 2013 Location: University of Sheffield, UK Journal: *International Journal of Obesity*	To conduct a systematic review of behaviour change interventions was conducted to find evidence of behaviour change techniques (BCTs) that are most effective in changing physical activity and/or eating behaviour for the prevention or management of childhood obesity.	**Size:** 17 studies **Inclusion Criteria**: Studies including at least one BCT from the CALO-RE taxonomy compared with a no-treatment control group. **Exclusion Criteria**: Interventions that solely tested the impact of physical activity, education and/or calorie controlled diets with no behaviour change element were excluded, as were interventions that combined drug treatment or surgery with BCTs.	**Type:** Systematic Review	**Results: All but three out of the nine obesity management interventions selected for review were effective according to study criteria.** 	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis – *No meta-analysis conducted*

References:

1. Martin, J., et al. (2013). "Effective behaviour change techniques in the prevention and management of childhood obesity." International Journal of Obesity **37**(10): 1287-1294.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Children age 6 to 11 years Modality: Behavioral interventions Outcome: Weight loss		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect

		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Mead, E. et al. Year Published: 2017 Location: Teesside University, UK Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of diet, physical activity and behavioural interventions (behaviour-changing interventions) for the treatment of overweight or obese children aged 6 to 11 years.	**Size:** 70 RCTs, 8461 participants **Inclusion Criteria**: RCTs that observed participants for a minimum of six months, overweight or obese participants with a mean age of six years and over, and under 12 years at the commencement of the intervention. Trials involving participants with comorbid disorders were eligible for inclusion as long as the primary focus of the intervention was to treat overweight and obese children. **Exclusion Criteria**: Studies were the interventions focused solely on the parents (with no child involvement).	**Type:** Systematic Review	**Results:** Fifty-five trials compared a behavior changing intervention with no treatment/usual care control and 15 evaluated the effectiveness of adding an additional component to a behaviour-changing intervention. Sixty-four trials were parallel RCTs, and four were cluster RCTs. The overall quality of the evidence was low or very low and 62 trials had a high risk of bias for at least one criterion. Total duration of trials ranged from six months to three years. The median age of participants was 10 years old and the median BMI z score was 2.2. **Primary analyses demonstrated that behaviour-changing interventions compared to no treatment/usual care control at longest follow-up reduced BMI, BMI z score and weight. Mean difference (MD) in BMI was -0.53 kg/m2 (95% confidence interval (CI) -0.82 to -0.24); P < 0.00001; 24 trials; 2785 participants; low-quality evidence. MD in BMI z score was -0.06 units (95%	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				CI -0.10 to -0.02); P = 0.001; 37 trials; 4019 participants; low-quality evidence and MD in weight was -1.45 kg (95% CI -1.88 to -1.02); P < 0.00001; 17 trials; 1774 participants; low-quality evidence.	

References:

1. Mead, E., et al. (2017). "Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years." Cochrane Database of Systematic Reviews **6**: CD012651.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children age 6 to 11 years
Modality: Behavioral interventions
Outcome: Adverse events

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Mead, E. et al. Year Published: 2017 Location: Teesside University, UK	To assess the effects of diet, physical activity and behavioural interventions (behaviour-changing interventions) for the treatment of overweight or	**Size:** 31 RCTs, 2105 participants **Inclusion Criteria**: RCTs that observed participants for a minimum of six months,	**Type:** Systematic Review	**Results:** Fifty-five trials compared a behavior changing intervention with no treatment/usual care control and 15 evaluated the effectiveness of adding an	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question

Journal: *Cochrane Database of Systematic Reviews*	obese children aged 6 to 11 years.	overweight or obese participants with a mean age of six years and over, and under 12 years at the commencement of the intervention. Trials involving participants with comorbid disorders were eligible for inclusion as long as the primary focus of the intervention was to treat overweight and obese children. **Exclusion Criteria**: Studies were the interventions focused solely on the parents (with no child involvement).		additional component to a behaviour-changing intervention. Sixty-four trials were parallel RCTs, and four were cluster RCTs. The overall quality of the evidence was low or very low and 62 trials had a high risk of bias for at least one criterion. Total duration of trials ranged from six months to three years. The median age of participants was 10 years old and the median BMI z score was 2.2. **Thirty-one trials reported on serious adverse events, with 29 trials reporting zero occurrences RR 0.57 (95% CI 0.17 to 1.93); P = 0.37; 4/2105 participants in the behaviour-changing intervention groups compared with 7/1991 participants in the comparator groups).** **Few trials reported health-related quality of life or behaviour change outcomes, and none of the analyses demonstrated a substantial difference in these outcomes between intervention and control.**	☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Mead, E., et al. (2017). "Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years." Cochrane Database of Systematic Reviews **6**: CD012651.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Children
Modality: Parent-only vs. parent-child
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Jull, A. and R. Chen Year Published: 2013 Location: University of Auckland, New Zealand Journal: *Obesity Reviews*	To assess the effectiveness of interventions that compared a parent-only (PO) condition with a parent-child (PC) condition.	**Size:** 4 trials, 72 participants **Inclusion Criteria**: Randomized controlled trials of a weight loss strategy that recruited overweight or obese children (defined for example by BMI-based definitions) and compared a parent-only condition to a parent[s] and child condition. The weight loss intervention could be any intervention for weight loss. Child was defined by an upper age limit of 14 years and the child must not have had a disorder that suppressed voluntary appetite control, such as Prada-Willi syndrome. The studies' outcome measures	**Type:** Systematic Review	**Results: Meta-analysis showed no significant difference in z-BMI from baseline to end of treatment between the conditions (three trials) or to end of follow up (two trials).** The trials were at risk of bias and no single trial was at lower risk of bias than others. There is an absence of high quality evidence regarding the effect of parent-only interventions for weight loss in children compared to parent-child interventions, but current evidence suggests the need for further investigation.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		must have included body mass index standard deviation score (BMI-SDS or z -BMI) or percent overweight. No date restriction was applied, but only papers published in English were included. **Exclusion Criteria**:			

References:

1. Jull, A. and R. Chen (2013). "Parent-only vs. parent-child (family-focused) approaches for weight loss in obese and overweight children: a systematic review and meta-analysis." Obesity Reviews **14**(9): 761-768.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adolescents aged 12 to 17 years
Modality: Behavioral interventions
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Al-Khudairy, L., et al. Year Published: 2017 Location: Warwick Medical School, Coventry, UK Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of diet, physical activity and behavioural interventions for the treatment of overweight or obese adolescents aged 12 to 17 years.	**Size:** 44 completed RCTs, 4,781 participants and 50 ongoing studies **Inclusion Criteria**: RCTS including overweight or obese	**Type:** Systematic Review	**Results: The mean difference (MD) of the change in BMI at the longest follow-up period in favour of BCI was -1.18 kg/m2 (95% confidence interval (CI) -1.67 to -0.69); 2774 participants; 28 trials;**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive

		adolescents with a mean study age of 12 to 17 years at commencement of intervention. **Exclusion Criteria**: Studies of critically ill, pregnant or breastfeeding women, or adolescents with a syndromic cause for their obesity (e.g. Prader-Willi syndrome).		**low quality evidence. BCI lowered the change in BMI z score by -0.13 units (95% CI -0.21 to -0.05); 2399 participants; 20 trials; low quality evidence. BCI lowered body weight by -3.67 kg (95% CI -5.21 to - 2.13); 1993 participants; 20 trials; moderate quality evidence.** The effect on weight measures persisted in trials with 18 to 24 months' follow-up for both BMI (MD -1.49 kg/m2 (95% CI -2.56 to -0.41); 760 participants; 6 trials and BMI z score MD -0.34 (95% CI -0.66 to -0.02); 602 participants; 5 trials).	☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Al-Khudairy, L., et al. (2017). "Diet, physical activity and behavioural interventions for the treatment of overweight or obese adolescents aged 12 to 17 years." Cochrane Database of Systematic Reviews **6**: CD012691.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adolescents aged 12 to 17 years Modality: Behavioral interventions Outcome: Adverse events		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - *UNKNOWN* ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient

		☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Al-Khudairy, L., et al. Year Published: 2017 Location: Warwick Medical School, Coventry, UK Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of diet, physical activity and behavioural interventions for the treatment of overweight or obese adolescents aged 12 to 17 years.	**Size:** 5 trials **Inclusion Criteria**: RCTS including overweight or obese adolescents with a mean study age of 12 to 17 years at commencement of intervention. **Exclusion Criteria**: Studies of critically ill, pregnant or breastfeeding women, or adolescents with a syndromic cause for their obesity (e.g. Prader-Willi syndrome).	**Type:** Systematic Review	**Results: The rate of adverse events in intervention and control groups was unclear with only five trials reporting harms, and of these, details were provided in only one (low quality evidence).** None of the included studies reported on all-cause mortality, morbidity or socioeconomic effects.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Al-Khudairy, L., et al. (2017). "Diet, physical activity and behavioural interventions for the treatment of overweight or obese adolescents aged 12 to 17 years." Cochrane Database of Systematic Reviews **6**: CD012691.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adolescents aged 12 to 17 years Modality: Behavioral interventions Outcome: Quality of life		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if:

		☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Al-Khudairy, L., et al. Year Published: 2017 Location: Warwick Medical School, Coventry, UK Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of diet, physical activity and behavioural interventions for the treatment of overweight or obese adolescents aged 12 to 17 years.	**Size:** 7 trials, 972 participants **Inclusion Criteria**: RCTS including overweight or obese adolescents with a mean study age of 12 to 17 years at commencement of intervention. **Exclusion Criteria**: Studies of critically ill, pregnant or breastfeeding women, or adolescents with a syndromic cause for their obesity (e.g. Prader-Willi syndrome).	**Type:** Systematic Review	**Results: Behavioral changing interventions (BCIs) at the longest follow-up moderately improved adolescent's health-related quality of life (standardised mean difference 0.44 ((95% CI 0.09 to 0.79); P = 0.01; 972 participants; 7 trials; 8 comparisons; low quality of evidence) but not self-esteem.**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Al-Khudairy, L., et al. (2017). "Diet, physical activity and behavioural interventions for the treatment of overweight or obese adolescents aged 12 to 17 years." Cochrane Database of Systematic Reviews **6**: CD012691.

Adults: Guideline Recommendations

The 2018 **US Preventive Services Task Force** recommended the following on the weight loss to prevent obesity-related morbidity and mortality in adults: Behavioral Interventions.

- The USPSTF recommends that clinicians offer or refer adults with a body mass index of 30 or higher to intensive, multicomponent behavioral interventions. **(B recommendation)**

The 2016 **American Academy of Family Physicians** recommended:

- Patients with obesity should be referred for intensive, multicomponent behavioral interventions. **Grade B**

Table 2. Motivational Interviewing Techniques

Technique	*Example*	*Rationale*
Ask permission to discuss behavior-change topic	"Would it be okay if we talked about your weight today?"	When patient gives permission, he or she is more open to the conversation
Show empathy	"Losing weight is very challenging."	Aids in building rapport, particularly in difficult discussions
Scale motivation (0 = low to 10 = high)	"On a scale of 0 to 10, with 10 being the highest, how motivated are you to try to lose weight?"	Assesses motivation to change; if very low, the patient may not be ready for change; if high, additional intervention strategies may be successful
Scale confidence (0 = low to 10 = high)	"On a scale of 0 to 10, with 10 being the highest, how confident are you that you can lose weight?"	Identifies need for interventions to overcome obstacles
Inquire about the scores on above scales	"Why did you choose 3 instead of 2? What would help you move from 3 to 4?"	Furthers the conversation on thinking about behavior change
Use decisional balance technique (explore pros and cons of change vs. no change)	"What are the pros of losing weight?" "What are the pros of not losing weight?" "What are the cons of losing weight?" "What are the cons of not losing weight?"	Helps patient and physician understand barriers to and motivators for change
Listen for change talk and reinforce it; let the patient take ownership by generating ideas for change	Patient: "I think I could try to walk more." Physician: "That's a fantastic idea that will help you move toward your goal."	Provides encouragement and helps promote confidence in patients

The 2016 **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

Lifestyle/behavioral therapy:

- A structured lifestyle intervention program designed for weight loss (lifestyle therapy) and consisting of a healthy meal plan, physical activity, and behavioral interventions should be available to patients who are being treated for overweight or obesity **(Grade A;BEL1)**.

Behavior interventions

- Lifestyle therapy in patients with overweight or obesity should include behavioral interventions that enhance adherence to prescriptions for a reduced calorie meal plan and increased physical activity (behavioral interventions can include: self-monitoring of weight, food intake, and physical activity; clear and reasonable goal-setting; education pertaining to obesity, nutrition, and physical activity; face-to-face and group meetings; stimulus control; systematic approaches for problem solving; stress reduction; cognitive restructuring [ie, cognitive behavioral therapy]; motivational interviewing; behavioral contracting; psychological counseling; and mobilization of social support structures) **(Grade A; BEL 1)**.
- The behavior intervention package is effectively executed by a multidisciplinary team that includes dietitians, nurses, educators, physical activity trainers or coaches, and clinical psychologists **(Grade C; BEL 4, upgraded due to high relevance)**. Psychologists and psychiatrists should participate in the treatment of eating disorders, depression, anxiety, psychoses, and other psychological problems that can impair the effectiveness of lifestyle intervention programs **(Grade B; BEL 2)**.

- Behavioral lifestyle intervention and support should be intensified if patients do not achieve a 2.5% weight loss in the first month of treatment, as early weight reduction is a key predictor of long-term weight-loss success **(Grade A; BEL 1)**. A stepped-care behavior approach should teach skills for problem-solving and should evaluate outcomes **(Grade A; BEL 1)**.
- Behavioral lifestyle intervention should be tailored to a patient's ethnic, cultural, socioeconomic, and educational background **(Grade B; BEL 2)**.

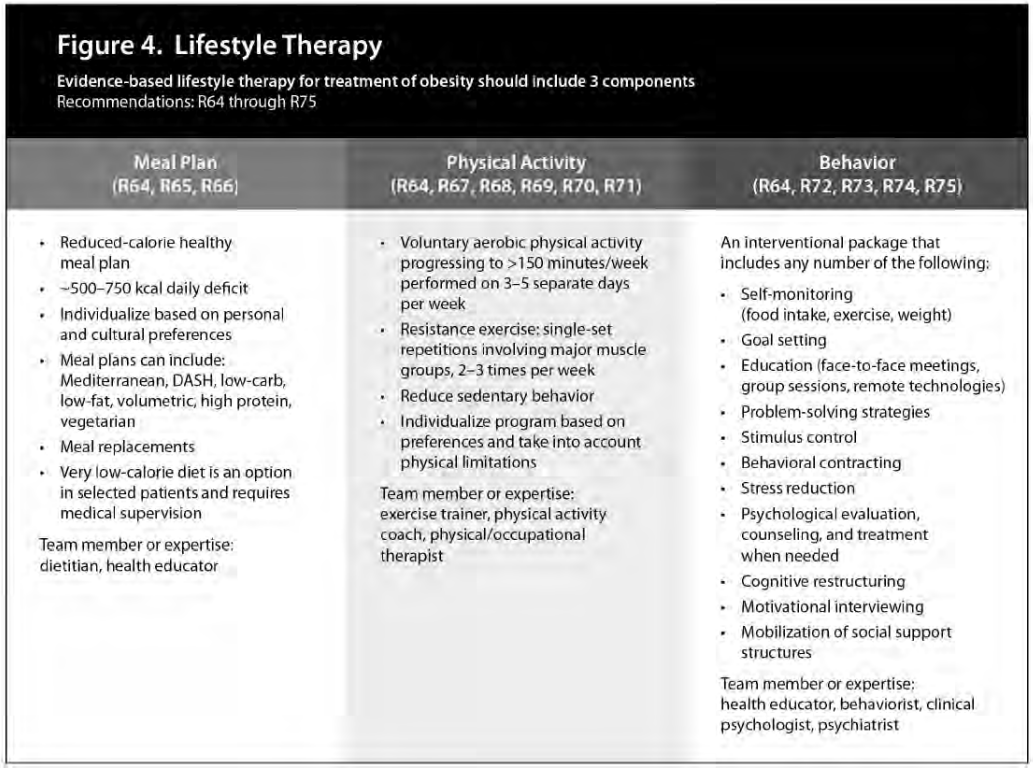


Figure 4. Lifestyle Therapy

Evidence-based lifestyle therapy for treatment of obesity should include 3 components
Recommendations: R64 through R75

Meal Plan (R64, R65, R66)	Physical Activity (R64, R67, R68, R69, R70, R71)	Behavior (R64, R72, R73, R74, R75)
• Reduced-calorie healthy meal plan • ~500–750 kcal daily deficit • Individualize based on personal and cultural preferences • Meal plans can include: Mediterranean, DASH, low-carb, low-fat, volumetric, high protein, vegetarian • Meal replacements • Very low-calorie diet is an option in selected patients and requires medical supervision Team member or expertise: dietitian, health educator	• Voluntary aerobic physical activity progressing to >150 minutes/week performed on 3–5 separate days per week • Resistance exercise: single-set repetitions involving major muscle groups, 2–3 times per week • Reduce sedentary behavior • Individualize program based on preferences and take into account physical limitations Team member or expertise: exercise trainer, physical activity coach, physical/occupational therapist	An interventional package that includes any number of the following: • Self-monitoring (food intake, exercise, weight) • Goal setting • Education (face-to-face meetings, group sessions, remote technologies) • Problem-solving strategies • Stimulus control • Behavioral contracting • Stress reduction • Psychological evaluation, counseling, and treatment when needed • Cognitive restructuring • Motivational interviewing • Mobilization of social support structures Team member or expertise: health educator, behaviorist, clinical psychologist, psychiatrist

In 2015 **Canadian Task Force on Preventative Health Care** recommended the following:

- For adults who are obese (BMI 30–39.9) and are at high risk of type 2 diabetes, we recommend that practitioners offer or refer to structured behavioural interventions aimed at weight loss. Structured interventions are intensive behavioural modification programs involving several sessions over weeks to months. Recommended interventions include behaviourally based interventions focused on diet, exercise or lifestyle changes, alone or in combination.

Lifestyle changes include counselling, education or support, and/or environmental changes in addition to changes in exercise and/or diet. **(Strong recommendation; moderate-quality evidence)**

- For adults who are overweight or obese, we recommend that practitioners offer or refer to structured behavioural interventions aimed at weight loss. Structured interventions are as defined in the previous recommendation. **(Weak recommendation; moderate-quality evidence)**

The 2015 **European Guidelines** for Obesity Management in Adults recommended the following:

Management
Nutrition
Reduce energy intake by 500–1,000 kcal/day
Physical activity
Initially at least 150 min/week moderate aerobic exercise combined with 1–3 sessions/week resistance exercise
Cognitive behaviour therapy
Pharmacotherapy
BMI ≥ 30 kg/m^2 or BMI ≥ 27 kg/m^2 with co-morbidities
Adjunct to lifestyle modification
Bariatric/metabolic surgery
BMI≥40 kg/m^2 or BMI between 35.0–39.9 kg/m^2 + co-morbidities or BMI between 30.0-34.9 kg/m^2 with type 2 diabetes on individual basis. Consider if other weight loss attempts fail; requires lifelong medical monitoring
Prevention and treatment of co-morbidities

The **UK's National Institute for Health and Care Excellence** (NICE) recommended the following for Behavioral Interventions in 2014:

Adults and children

- Deliver any behavioural intervention with the support of an appropriately trained professional.

Adults

- Include the following strategies in behavioural interventions for adults, as appropriate:
    - self-monitoring of behaviour and progress
    - stimulus control

- goal setting
- slowing rate of eating
- ensuring social support
- problem solving
- assertiveness
- cognitive restructuring (modifying thoughts)
- reinforcement of changes
- relapse prevention
- strategies for dealing with weight regain.

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

General Treatment Principles of Weight Loss

- Perform an in-depth clinical assessment in order to assess the risks and benefits of different weight management treatments and to develop a weight management plan. **Grade EO**
- Use motivational interviewing techniques to evoke patient motivation to accept and participate in weight loss treatments. **Grade EO**

Behavioral and Lifestyle Approaches

- Offer comprehensive lifestyle interventions for weight loss, in either individual or group setting. **Grade B**
- Offer telephone-based comprehensive lifestyle intervention for weight loss, either as an alternative of an adjunct to face-to-face intervention. **Grade B**
- There is insufficient evidence for or against offering internet-based comprehensive lifestyle intervention for weight loss, as an alternative or adjunct to face-to-face intervention. **Grade I**

The **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** in 2013 recommended:

- **Box 10: Weight Loss Option—Comprehensive Lifestyle Intervention Alone or With Adjunctive Therapies** All patients for whom weight loss is recommended should be offered or referred for comprehensive lifestyle intervention (Box 11a and 11b). Comprehensive lifestyle intervention, preferably with a trained interventionist† or nutrition professional*, is foundational to weight loss (Box 11a) regardless of augmentation by medications or bariatric surgery. By expert opinion, if the weight and lifestyle history indicates that the patient has never participated in a comprehensive lifestyle intervention program as defined in CQ4 and in Box 11a, it is recommended that he or she be encouraged to undertake such a program before the addition of adjunctive therapies since a substantial proportion of patients will lose sufficient weight to improve health with comprehensive lifestyle treatment alone. This recommendation may be modified by the availability of comprehensive lifestyle intervention or by patient factors, such as medical conditions that warrant earlier initiation of more intensive treatment. If the patient has been unable to lose weight or sustain weight loss with

comprehensive lifestyle intervention and he or she has a BMI ≥30 kg/m2 or BMI ≥27 kg/m2 with comorbidity, adjunctive therapies may be considered. Patients who are otherwise appropriate candidates for obesity drug treatment or bariatric surgery, whose weight and lifestyle history indicate a history of inability to achieve or sustain weight loss and who have previously participated in a comprehensive lifestyle intervention, may be offered the option to add pharmacotherapy at the time of initiation of a lifestyle intervention program (BMI ≥30 kg/m2 or BMI ≥27 kg/m2 with comorbidity) or to be referred for evaluation for bariatric surgery (BMI ≥40 kg/m2 or BMI ≥35 kg/m2 with comorbidity) (expert opinion).

- **Box 11a. Offer or Refer for High-Intensity Comprehensive Lifestyle Intervention** The most effective behavioral weight loss treatment is an in-person, high-intensity (ie, ≥14 sessions in 6 months) comprehensive weight loss intervention provided in individual or group sessions by a trained interventionist. The principal components of an effective highintensity, on-site comprehensive lifestyle intervention include 1) prescription of a moderately reduced-calorie diet, 2) a program of increased physical activity, and 3) the use of behavioral strategies to facilitate adherence to diet and activity recommendations. As shown in CQ4, comprehensive lifestyle intervention consisting of diet, physical activity, and behavior therapy produces average weight losses of approximately 8 kg in a 6-month period of frequent, in-person treatment. This approximates losses of 5%-10% of initial weight. The observed average weight loss of approximately 8 kg includes people who have variable weight loss (ie, some more and some less than average), so accurate prediction of individual weight loss is not possible. After 6 months, most patients will equilibrate (caloric intake balancing energy expenditure) and will require adjustment of energy balance if they are to lose additional weight. As demonstrated in CQ4, continued intervention contact after initial weight loss treatment is associated with better maintenance of lost weight.
- **Box 11b. Options for Alternative Modes of Delivery of Lifestyle Intervention** In primary care offices where frequent, in-person individual or group sessions led by a trained interventionist or a nutrition professional are not possible or available by referral, the physician may consider alternative modes of delivery. As found in CQ4, emerging evidence supports the efficacy, albeit with less weight loss, of electronically delivered interventions (eg, by Internet or telephone) that provide personalized feedback by a trained interventionist and of some commercial programs that provide counseling (face-to-face or telephonic) with or without prepackaged meals. The Expert Panel recommends, by expert opinion, that physicians may refer to these alternative sources provided their outcomes are supported by scientific evidence of safety and efficacy. An additional option if a highintensity comprehensive lifestyle intervention program is not available or feasible is referral to a nutrition professional for dietary counseling.
- Comprehensive lifestyle interventions usually provide a structured behavior change program that includes regular self-monitoring of food intake, physical activity, and weight. These same behaviors are recommended to maintain lost weight, with the addition of frequent (ie, weekly or more often) monitoring of body weight. **Strength of Evidence: High**

Recommendations	NHLBI Grade	NHLBI ES	ACC/AHA COR	ACC/AHA LOE
Lifestyle Intervention and Counseling (Comprehensive Lifestyle Intervention)				
4a. Advise overweight and obese individuals who would benefit from weight loss to participate for ≥6 months in a *comprehensive lifestyle program* that assists participants in adhering to a lower-calorie diet and in increasing physical activity through the use of behavioral strategies.	A (Strong)	CQ4	I	A
4b. Prescribe on-site, high-intensity (ie, ≥14 sessions in 6 mo) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist.†	A (Strong)	CQ4	I	A
4c. Electronically delivered weight loss programs (including by telephone) that include personalized feedback from a trained interventionist† can be prescribed for weight loss but may result in smaller weight loss than face-to-face interventions.	B (Moderate)	CQ4	IIa	A
4d. Some commercial-based programs that provide a comprehensive lifestyle intervention can be prescribed as an option for weight loss, provided there is peer-reviewed published evidence of their safety and efficacy.	B (Moderate)	CQ4	IIa	A
4e. Use a very-low-calorie diet (defined as <800 kcal/d) only in limited circumstances and only when provided by trained practitioners in a medical care setting where medical monitoring and high-intensity lifestyle intervention can be provided. Medical supervision is required because of the rapid rate of weight loss and potential for health complications.	A (Strong)	CQ4	IIa‡	A
4f. Advise overweight and obese individuals who have lost weight to participate long term (≥1 year) in a comprehensive weight loss maintenance program.	A (Strong)	CQ4	I	A
4g. For weight loss maintenance, prescribe face-to-face or telephone-delivered weight loss maintenance programs that provide regular contact (monthly or more frequently) with a trained interventionist† who helps participants engage in high levels of physical activity (ie, 200–300 min/wk), monitor body weight regularly (ie, weekly or more frequently), and consume a reduced-calorie diet (needed to maintain lower body weight).	A (Strong)	CQ4	I	A

Adults: Primary Literature

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adult
Modality: Mindfulness
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - UNKNOWN*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Olson, K. L. and C. F. Emery Year Published: 2015 Location: Ohio State University, Columbus, OH Journal: *Psychosomatic Medicine*	To conduct a systematic review of studies using mindfulness-based programs for weight loss evaluated study methodologies with the goal of determining the current evidence in support of mindfulness interventions for weight loss.	**Size:** 19 total: 12 published in peer-reviewed articles, 7 dissertations. **Inclusion Criteria**: a) original research articles, theses, or dissertations; b) evaluation of a mindfulness-based intervention, defined as an intervention that included at least one training session focused on mindfulness skills such as mindfulness meditation, mindful eating practices, or acceptance-based skills; c) study sample seeking treatment for weight management; and d) weight	**Type:** Systematic Review	**Results: Among the eight randomized controlled trials published in peer-reviewed journals, six documented significant weight loss among participants in the mindfulness condition, one reported no significant change, and one failed to report body mass index at program completion. None of the studies documented a relationship between changes in mindfulness and weight loss.**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis – *No meta-analysis conducted*

		measured as an outcome variable at baseline and program completion. **Exclusion Criteria**: Case study design was implemented, if the sample comprised children or adolescents, or if data were presented only at a conference and no publication or thesis/dissertation from the data was identifiable in the search.			

References:

1. Olson, K. L. and C. F. Emery (2015). "Mindfulness and weight loss: a systematic review." Psychosomatic Medicine **77**(1): 59-67.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults in primary care clinic
Modality: Motivational interviewing
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - UNKNOWN*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Barnes, R. D. and V. Ivezaj Year Published: 2015	To review the literature and conduct a meta-analyses	**Size:** 24 RCTs	**Type:** Systematic Review	**Results:** MI interventions typically were provided individually by a range of	**Study Limitations:** ☐ None ***Systematic Review***

Location: Yale University School of Medicine, New Haven, CT Journal: *Obesity Reviews*	support the effectiveness of MI for weight loss in primary care.	**Inclusion Criteria**: Randomized controlled trials of MI in primary care settings with weight as an outcome; however, weight as a secondary outcome was also included. **Exclusion Criteria**: Studies with baseline data only and no post-treatment assessment, specialty care as opposed to primary care clinics, and paediatric or adolescent samples.		clinicians and compared with usual care. Few studies provided adequate information regarding MI treatment fidelity**. Nine studies (37.5%) reported significant weight loss at post-treatment assessment for the MI condition compared with control groups. Thirteen studies (54.2%) reported MI patients achieving at least 5% loss of initial body weight.** **A number of studies (n = 10, 41.7%) reported less than 1 kg of weight loss for the treatment condition or weight gain with these interventions ranging from 12 weeks to 2 years. Half of the studies (n = 12) reported average weight losses of 1.0–4.9 kg for MI interventions, ranging from 12 weeks to 5 years. Only one study reported an average weight loss over 5 kg (i.e. 5.8 kg). When the information was available, we calculated weight loss per hour of treatment, and it ranged from 0 (25) to 2.15 kg.** In addition to overall weight loss for intervention participants, an important outcome is weight loss relative to UC or control groups. **When examining all 24 studies, 12 studies (50.0%) reported no significant weight loss compared with UC 9 studies (37.5%)**	☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				reported significant weight loss compared with UC or control groups, 1 (4.2%) reported a trend towards significance ((26), P = 0.053) and 2 (8.3%) provided MI to both conditions. When comparing the studies that implemented the MI intervention in addition to typical primary care appointments to those that incorporated MI into regularly scheduled appointments, 9 of 17 studies (52.9%) versus 2 of 7 (28.6%) studies reported the MI group experienced significant weight loss compared with control groups, respectively.	

References:

1. Barnes, R. D. and V. Ivezaj (2015). "A systematic review of motivational interviewing for weight loss among adults in primary care." Obesity Reviews **16**(4): 304-318.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adults in primary care clinic Modality: Behavioral interventions Outcome: Weight loss		
Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Booth, H.P., et al. Year Published: 2014 Location: Kings College London, UK Journal: *Family Practice*	To estimate the effect of behavioural interventions delivered in primary care on body weight in overweight and obese adults	**Size:** 15 RCTs, 4,539 participants **Inclusion Criteria**: Participants were overweight and/or obese adults in primary care, weight loss was a primary outcome and an RCT design was used. Interventions did not have to be delivered by a PCP, but participants had to be selected from their practice patient list and the intervention conducted within the primary care setting. This is reflective of the multidisciplinary teams that now deliver primary care services. Follow-up was for a minimum of 12 months.	**Type:** Systematic Review	**Results: Pooled results from meta-analysis indicated a mean weight loss of -1.36 kg (-2.10 to -0.63, P < 0.0001) at 12 months, and -1.23 kg (-2.28 to -0.18, P = 0.002) at 24 months.**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis
Author: Wadden, T.A. et al. Year Published: 2014 Location: University of Pennsylvania Journal: *JAMA*	To conduct a systematic review of behavioral counseling for overweight/ obese patients recruited from primary care, as delivered by PCPs working alone or with trained interventionists (e.g., medical assistants, registered dietitians), or by trained interventionists working independently.	**Size:** 12 trials, 3,893 participants **Inclusion Criteria**: Studies included were randomized trials that were published in the English language and had the following characteristics: 1) overweight or obese adults (i.e., body mass index [BMI] ≥25 kg/m2) recruited from primary care settings; 2) participants received behavioral weight loss counseling (also referred to as lifestyle intervention) consisting of diet, physical activity, and behavioral strategies (all three components);6 3) behavioral counseling ≥3 months, with ≥6	**Type:** Systematic Review	**Results: Mean 6-month weight changes (relative to baseline) in the intervention group ranged from −0.3 to −6.6 kg, with corresponding values of +0.9 to −2.0 kg in control group.** Weight loss in both groups generally declined with longer follow-up (12–24 months). Interventions that prescribed both reduced energy intake (e.g., ≥500 kcal/day deficit) and increased physical activity (e.g., ≥150 minutes/week of walking), with traditional behavior therapy, generally produced larger weight loss than interventions without all three specific components. In the former trials, more	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		months post-randomization follow-up; 4) intervention delivered by CMS-defined primary care practitioners, working alone or with trained interventionists, or by trained interventionists alone who provided behavioral counseling in person or remotely (e.g., telephone); 5) a comparator intervention was included; 6) outcomes included objectively measured change in weight (reported in kg, BMI units, or % change); and 7) randomized sample size ≥15 per treatment group. **Exclusion Criteria**: Trials of weight gain prevention or pharmacologic agents.		treatment sessions, delivered in person or by phone by trained interventionists, were associated with greater mean weight loss and likelihood of losing ≥5% of baseline weight.	

References:

1. Booth, H. P., et al. (2014). "Effectiveness of behavioural weight loss interventions delivered in a primary care setting: a systematic review and meta-analysis." Family Practice **31**(6): 643-653.
2. Wadden, T. A., et al. (2014). "Behavioral treatment of obesity in patients encountered in primary care settings: A systematic review." JAMA: Journal of the American Medical Association **312**(17): 1779-1791.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Behavioral Interventions
Outcome: Health outcomes

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect

		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Leblanc, E.S., et al. Year Published: 2018 Location: Kaiser Permanente Northwest, Portland, OR Journal: *JAMA*	To systematically review evidence on benefits and harms of behavioral and pharmacotherapy weight loss and weight loss maintenance interventions in adults to inform the US Preventive Services Task Force.	**Size:** 20 trials, n = 9910 **Inclusion Criteria**: Weight loss or weight loss maintenance studies in adults >/= 18 years who are candidates for weight loss/maintenance interventions. **Exclusion Criteria**: Studies on primary prevention of overweight or obesity, treatment of cardiovascular disease, management of diabetes, treatment of cancer.	**Type:** Systematically Review	**Results: Health outcomes were infrequently reported in the behavior-based weight loss and maintenance trials (20 trials [n = 9910]).** **In 4 weight loss trials (n = 4442) reporting mortality, there were no significant differences between groups over 2 to 16 years. Two weight loss trials (n = 2666) reported on cardiovascular events, with neither trial finding significant differences between groups over 3 and 10 years. Health-related quality of life (QOL) was evaluated in 17 weight loss and maintenance trials (n = 7120), with 14 showing no differences between groups on any measure; in the 3 trials that noted statistically significant findings, the differences were only for some QOL components and were of unclear clinical significance.**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. LeBlanc, E. S., et al. (2018). "Behavioral and Pharmacotherapy Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force USPSTF Evidence Report: Behavioral Interventions to Prevent Adult Obesity-Related Outcomes USPSTF Evidence Report: Behavioral Interventions to Prevent Adult Obesity-Related Outcomes." JAMA **320**(11): 1172-1191.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Behavioral interventions
Outcome: Weight loss, weight loss maintenance, or reduction in incidence or prevalence of obesity-related conditions

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Leblanc, E.S., et al. Year Published: 2018 Location: Kaiser Permanente Northwest, Portland, OR Journal: *JAMA*	To systematically review evidence on benefits and harms of behavioral and pharmacotherapy weight loss and weight loss maintenance interventions in adults to inform the US Preventive Services Task Force.	**Size:** 67 trials, n = 22,065 **Inclusion Criteria**: Weight loss or weight loss maintenance studies in adults >/= 18 years who are candidates for weight loss/maintenance interventions **Exclusion Criteria**: Studies on primary prevention of overweight or obesity, treatment of cardiovascular disease, management of diabetes, treatment of cancer.	**Type:** Systematically Review	**Results: Participants who received behavior-based weight loss interventions generally lost more weight and had greater reductions in waist circumference than those in control conditions at up to 24 months of follow-up. Intervention participants had a pooled −2.4kg (−5.3 lb) (95%CI, −2.8to −1.9kg; 67 trials [n = 22 065]; I2 = 90.0%) greater weight loss at 12 to 18 months. Mean absolute changes in weight ranged from −0.5 kg (−1.1 lb) to −9.3 kg (−20.5 lb) among intervention participants and from 1.4kg (3.0lb) to −5.6 (**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				−12.3 lb) among control participants. In addition, intervention participants were more likely to achieve 5% weight loss from baseline compared with control participants (pooled risk ratio, 1.94[95%CI, 1.70) to 2.22]; 38 trials [n = 12 231]; I2 = 67.2%), which translated into a number needed to treat of 8. Heterogeneity in the interventions, confounded with differences in the populations, settings, and trial quality, made it difficult to identify which variables (ie, number of sessions, in-person vs remote sessions, group- vs individual-based) may be driving larger effects. Although weight outcomes were less well reported beyond 12 months, weight loss remained significantly greater in intervention compared with control conditions in interventions lasting up to 36 months. Participants who received behavior-based weight loss maintenance interventions generally maintained more of their weight loss compared with those in control conditions (pooled mean difference, −1.6kg [−3.5 lb] [95% CI, −2.4 to −0.8 kg]; 8 trials [n = 1408]; I2 = 26.8%) in the intervention vs control groups.	

References:

1. LeBlanc, E. S., et al. (2018). "Behavioral and Pharmacotherapy Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force USPSTF Evidence Report: Behavioral Interventions to Prevent Adult Obesity-Related Outcomes USPSTF Evidence Report: Behavioral Interventions to Prevent Adult Obesity-Related Outcomes." JAMA **320**(11): 1172-1191.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Behavioral interventions
Outcome: Adverse events

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Leblanc, E.S., et al. Year Published: 2018 Location: Kaiser Permanente Northwest, Portland, OR Journal: *JAMA*	To systematically review evidence on benefits and harms of behavioral and pharmacotherapy weight loss and weight loss maintenance interventions in adults to inform the US Preventive Services Task Force.	**Size:** 30 trials, n = 12,824 **Inclusion Criteria**: Weight loss or weight loss maintenance studies in adults >/= 18 years who are candidates for weight loss/maintenance interventions. **Exclusion Criteria**: Studies on primary prevention of overweight or obesity, treatment of cardiovascular disease, management of diabetes, treatment of cancer.	**Type:** Systematically Review	**Results: Rates of adverse events were infrequently reported in the behavior-Based weight loss and weight loss maintenance trials (30trials [n = 12 824]). In general, there were no serious harms related to the interventions and most trials noted no differences between groups in the rates of adverse events, including cardiovascular events. In the 3 trials large enough to examine differences in musculoskeletal issues between groups, results were mixed.**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

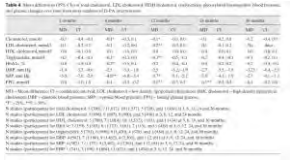
References:

1. LeBlanc, E. S., et al. (2018). "Behavioral and Pharmacotherapy Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task ForceUSPSTF Evidence Report: Behavioral Interventions to Prevent Adult Obesity-Related OutcomesUSPSTF Evidence Report: Behavioral Interventions to Prevent Adult Obesity-Related Outcomes." JAMA **320**(11): 1172-1191.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults with additional risk factors
Modality: Behavioral interventions
Outcome: Health outcomes

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Dombrowski, S. U., et al. Year Published: 2010 Location: University of Aberdeen, UK Journal: *Obesity Facts*	To assess the effects of behavioural interventions for obese adults with additional risk factors for morbidity on behaviour, weight and disease risk factors	**Size:** 44 studies **Inclusion Criteria**: Types of Studies: Published randomised controlled trials (RCTs) providing ≥12 weeks follow-up data after randomisation. No language limitations were specified. Types of Participants: Individuals with a mean/median BMI ≥30 kg/m2 . Studies focused on adult obesity with a mean/median age of ≥40 years as there is a rapid increase in obesity-related diseases including the metabolic syndrome [10] and type 2 diabetes [11] in middle age. At least one additional risk factor for morbidity was	**Type:** Systematic Review	**Results: Behavioural outcomes, weight loss, and cardiovascular disease risk factors showed consistent modest improvements over time, especially for interventions targeting both diet and PA.** 	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		required as this population is in greatest need of behaviour change to prevent long-term morbidity. Types of Interventions: Behavioural interventions aimed at changing diet and/or PA. For this review, interventions are classified by 'diet only (D-only),' 'PA only (PA-only),' or 'diet and PA (D-PA)'. Types of Outcome Measures: The outcomes examined in this review were behaviour (i.e. objective or self-reported measures of diet and/or PA), weight and risk factors (total cholesterol, low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, triglycerides, systolic (SBP) and diastolic blood pressure (DBP), glycosylated haemoglobin (HbA1c), and fasting plasma glucose (FPG)).			

References:

1. Dombrowski, S. U., et al. (2010). "Behavioural interventions for obese adults with additional risk factors for morbidity: systematic review of effects on behaviour, weight and disease risk factors." Obesity Facts **3**(6): 377-396.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Adults Modality: Behavioral weight management program Outcome: Weight loss		
Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

		☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Hartmann-Boyce, J., et al. Year Published: 2014 Location: University of Oxford, UK Journal: *Obesity Reviews*	To evaluate the effectiveness of behavioural weight management programmes and examine how programme characteristics affect mean weight loss.	**Size:** 37 studies, 16,000 participants **Inclusion Criteria**: Studies had to have recruited adults (≥18 years) with a body mass index (BMI) of ≥25 kg m−2 (or a BMI of ≥23 kg m−2 in Asian populations). Interventions had to involve multiple contacts with the provider (or multiple web sessions if an internet intervention) and be clearly defined multicomponent weight management programmes, i.e. contain diet, physical activity and behaviour change techniques with a sufficiently detailed description of each component. **Exclusion Criteria:** Studies in pregnant women, people with eating disorders and those where weight loss was used as a treatment for a medical condition such as diabetes. We also excluded programmes that involved surgery or medication or incorporated other lifestyle changes, e.g. smoking cessation.	**Type:** Systematic Review	**Results: The pooled mean difference in weight loss at 12 months was -2.8 kg (95% confidence interval [CI] -3.6 to -2.1, P < 0.001). I(2) indicated that 93% of the variability in outcome was due to differences in programme effectiveness.** Meta-analysis showed no evidence that in-person contact (mean difference 0.0 kg, 95% CI -1.8 to 1.8, P = 0.06) were related to programme effectiveness at 12 months. In meta-regression, calorie counting (-3.3 kg, 95% CI -4.6 to -2.0, P = 0.027), contact with a dietitian (-1.5 kg, 95% CI -2.9 to -0.2, P < 0.001) and use of behaviour change techniques that compare participants' behaviour with others (-1.5 kg, 95% CI -2.9 to -0.1, P = 0.032) were associated with greater weight loss. There was no evidence that other programme characteristics were associated with programme effectiveness. Most but not all behavioural weight management programmes are effective. Programmes that support	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				participants to count calories or include a dietitian may be more effective, but the programme characteristics explaining success are mainly unknown.	

References:

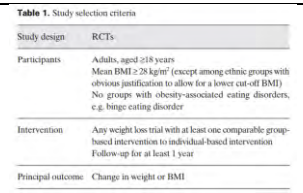
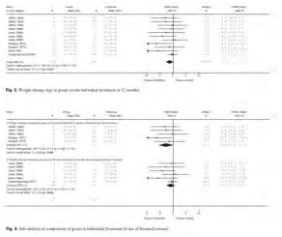
1. Hartmann-Boyce, J., et al. (2014). "Behavioural weight management programmes for adults assessed by trials conducted in everyday contexts: systematic review and meta-analysis." Obesity Reviews **15**(11): 920-932.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Group vs. individual treatment
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Paul-Ebhohimhen, V. and A. Avenell Year Published: 2009 Location: University of Aberdeen, UK Journal: *Obesity Facts*	To systematically reviewed randomised controlled trials of treatments for adult obesity to compare the effectiveness of group-based to individual-based modes of treatment delivery.	**Size:** 5 studies, 336 participants **Inclusion Criteria**:	**Type:** Systematic Review	**Results: Significantly greater (p = 0.03) weight change at 12 months was found in group-based over individual-based treatment, and sub-analyses showed that increased effectiveness was associated with the use of**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised

		 **Table 1.** Study selection criteria Study design: RCTs Participants: Adults, aged ≥18 years; Mean BMI ≥ 28 kg/m² (except among ethnic groups with obvious justification to allow for a lower cut-off BMI); No groups with obesity-associated eating disorders, e.g. binge eating disorder Intervention: Any weight loss trial with at least one comparable group-based intervention to individual-based intervention; Follow-up for at least 1 year Principal outcome: Change in weight or BMI		**financial reward and psychologist-led interventions** 	☐ Inappropriate pooled analysis

References:

1. Paul-Ebhohimhen, V. and A. Avenell (2009). "A systematic review of the effectiveness of group versus individual treatments for adult obesity." Obesity Facts **2**(1): 17-24.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults
Modality: Psychological interventions
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☐ Medium ☒ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**

Author: Shaw, K., et al. Year Published: 2005 Location: Australia Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of psychological interventions for overweight or obesity as a means of achieving sustained weight loss.	**Size:** 36 studies, 3495 participants. **Inclusion Criteria**: All randomised controlled clinical trials of psychological interventions for weight loss in overweight or obese people were considered for inclusion. Quasi-randomised trials were also considered. Studies were limited to adult participants only (aged over 18 years). Studies included adults with overweight or obesity at study baseline according to any parameter (e.g. body mass index, waist measurement, waist-to-hip ratio).	**Type:** Systematic Review	**Results:** The majority of studies assessed behavioural and cognitive-behavioural weight reduction strategies. Cognitive therapy, psychotherapy, relaxation therapy and hypnotherapy were assessed in a small number of studies. **Behaviour therapy was found to result in significantly greater weight reductions than placebo when assessed as a stand-alone weight loss strategy (WMD -2.5 kg; 95% CI -1.7 to -3.3).** When behaviour therapy was combined with a diet / exercise approach and compared with diet / exercise alone, the combined intervention resulted in a greater weight reduction. Studies were heterogeneous however the majority of studies favoured combining behaviour therapy with dietary and exercise interventions to improve weight loss. **Increasing the intensity of the behavioural intervention significantly increased the weight reduction (WMD -2.3 kg; 95% CI -1.4 to - 3.3). Cognitive-behaviour therapy, when combined with a diet / exercise intervention, was found to increase weight loss compared with diet / exercise alone (WMD -4.9 kg; 95% CI -7.3 to - 2.4).** No data on mortality, morbidity or quality of life were found.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Shaw, K., et al. (2005). "Psychological interventions for overweight or obesity." Cochrane Database of Systematic Reviews(2): CD003818.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults with moderate and severe obesity
Modality: Behavioral lifestyle interventions
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Lv, N., et al. Year Published: 2017 Location: Palo Alto Medical Foundation Research Institute, Palo Alto, California Journal: *Preventive Medicine: An International Journal Devoted to Practice and Theory*	To review evidence of behavioral lifestyle interventions for weight loss in patients having moderate and severe obesity.	**Size:** 12 studies, 1862 participants **Inclusion Criteria**: Included experimental and quasi-experimental studies of behavioral lifestyle interventions for weight loss among adults with BMI ≥35 kg/m2. Behavioral lifestyle interventions were defined as including a behavioral modification component offered to participants in a standardized way to support dietary and/or physical activity changes. Behavioral modification component was defined as a formal intervention component that	**Type:** Systematic Review	**Results:** Nine studies compared different behavioral interventions and three tested behavioral intervention(s) versus pharmacological or surgical treatments. **Among the 25 behavioral interventions in the 12 studies, 18 reported percent of participants achieving clinically significant weight loss up to 12 months (32-97% achieving 5% or 3-70% achieving 10%).** Three studies measured other cardiometabolic risk factors, but showed no significant risk reduction. Seven interventions with greater effectiveness (i.e., at least	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

		included either individual or group session(s) aimed at changing diet and/or physical activity through behavioral strategies regardless of the format of the sessions (e.g., in-person or remotely by phone or digitally) and the coaching (e.g., human coaching or automated coaching). Interventions that promoted dietary change may involve medically supervised diets, meal replacement products, and dietary restriction (including very low calorie diets - <800 kcal/day). Interventions that promoted physical activity provide education with or without supervised training. Only studies that used a comparison group, and had ≥six months of follow-up and a weight-related primary outcome were included.		31% achieving >=10% or 62% achieving >=5% weight loss up to one year) included multiple components (diet, physical activity, and behavioral strategies), long duration (e.g., one year), and/or intensive contacts (e.g., inpatient stays for clinic-based interventions, weekly contacts for community-based ones). Evidence for the effectiveness of behavioral interventions versus pharmacological or surgical treatment was limited. Comprehensive and intensive behavioral interventions can result in clinically significant, albeit modest, weight loss in this obese subpopulation but may not result significant improvements in other cardiometabolic risk factors.	

References:

1. Lv, N., et al. (2017). "Behavioral lifestyle interventions for moderate and severe obesity: A systematic review." Preventive Medicine: An International Journal Devoted to Practice and Theory **100**: 180-193.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Population: Young people (18-25 years) Modality: Behavioral/motivational interventions Outcome: Weight loss		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

		☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Poobalan, A. S., et al. Year Published: 2010 Location: Aberdeen University Medical School, UK Journal: *Obesity Reviews*	To conduct a systematic review to assess weight loss interventions in young adults (18-25 years), who are vulnerable to weight gain.	**Size:** 14 studies **Inclusion Criteria**: Literature published between 1980 and March 2008 with no language restrictions. All trials (randomized controlled trials, controlled clinical trials, non-randomized trials) and cohort studies with control groups of lifestyle interventions undertaken in young adults between the ages of 18–25 years were included in the review. **Exclusion Criteria**: Drug and surgical interventions, studies in children, adolescents and young people with chronic diseases such as cancer, eating disorders, various syndromes.	**Type:** Systematic Review	**Results: Before and after comparison of behavioural/motivational interventions (-2.40 kg; 95% CI -5.4 to 0.6) consistently showed weight loss. Behavioural/motivational interventions increased self-efficacy, the desire to control weight, boosted self-esteem, and increased satisfaction with body areas and appearance.**	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Poobalan, A. S., et al. (2010). "Weight loss interventions in young people (18 to 25 year olds): a systematic review." Obesity Reviews **11**(8): 580-592.

Question #6. What is the comparative effectiveness of lifestyle interventions (combined physical activity, nutritional, behavioral)? What is the optimal lifestyle intervention for improving health, well-being, and weight loss?

Children and Adolescents: Guideline Recommendations

From 2019 SR (Semlitsch): A multifactorial, comprehensive lifestyle intervention for at least 6 to 12 months that includes a reduction in calorie intake, an increase in physical activity, and measures to support behavioural change, is essential in the treatment of overweight and obesity.

Children and Adolescents: Guideline Recommendations

In 2018 the **American Psychological Association (APA)** recommended:

- For child and adolescent patients aged 2-18 with overweight or obesity, the panel strongly recommends that clinicians provide family-based multicomponent behavioral interventions with at least of 26 contact hours initiated at the earliest age possible. (**Strong**)

In 2017 the **Endocrine Society** recommended:

- We recommend that clinicians prescribe and support intensive, age-appropriate, culturally sensitive, family-centered lifestyle modifications (dietary, physical activity, behavioral) to promote a decrease in BMI. (**1|**⊕⊕⊕○)

In 2017 the **United States Preventive Services Task Force (USPSTF)** stated:

- The USPSTF recommends that clinicians screen for obesity in children and adolescents 6 years and older and offer or refer them to comprehensive, intensive behavioral interventions to promote improvements in weight status (**B recommendation**).
    - Comprehensive, intensive behavioral interventions with a total of ≥26 contact hours over a period of 2 to 12 months resulted in weight loss. Behavioral interventions with a total of 52 contact hours or more demonstrated greater weight loss and some improvements in cardiovascular and metabolic risk factors.
    - These effective, higher-intensity (≥26 contact hours) behavioral interventions consisted of multiple components. Although these components varied across interventions, they frequently included sessions targeting both the parent and child (separately, together, or both); offered individual sessions (both family and group); provided information about healthy eating, safe exercising, and reading food labels; encouraged the use of stimulus control (eg, limiting access to tempting foods and limiting screen time), goal setting, self-monitoring, contingent rewards, and problem solving; and included supervised physical activity sessions.
    - Intensive interventions involving 52 or more contact hours rarely took place in primary care settings but rather in settings to which primary care clinicians could refer patients. These types of interventions were often delivered by multidisciplinary teams, including pediatricians, exercise physiologists or physical therapists, dietitians or diet assistants, psychologists or social workers, or other behavioral specialists.

In 2016 the **Society for Adolescent Health and Medicine (SAHM)** stated:

- Once a diagnosis of obesity has been established, HCP should work with dietitians, behavioral health providers, and exercise specialists to guide the patient through an evaluation for comorbidities, deliver evidence-based lifestyle counseling, and if indicated, refer to more intensive treatment options such as weight loss surgery, monitored diets, or residential care.

In 2015 the **Canadian Task Force on Preventive Health Care** stated:

- These recommendations apply to children and youth 2 to 17 years of age who are overweight or obese. Children and youth with health conditions for which weight management is inappropriate are excluded. We recommend that primary care practitioners offer or refer to structured behavioural interventions aimed at healthy weight management. (**Weak recommendation; moderate quality evidence**)
    - Structured behavioural interventions are intensive behavioural modification programs that involve several sessions that take place over weeks to months, follow a comprehensive approach delivered by a specialized interdisciplinary team, involve group sessions, and incorporate family and parent involvement. Interventions examined included behaviourally based prevention interventions focused on diet, increasing exercise, making lifestyle changes or any combination of these. These can be delivered by a primary care team in the office or through a referral to a formal program within or outside of primary care, such as hospital-based, school-based or community programs.

In 2015 the **American Academy of Pediatrics** stated:

- Children older than 2 years should be managed in a Pediatric Weight Management Clinic by a Multi-disciplinary Team, using increased intensity of behavior changes, frequency of visits, and specialists involved. Structured behavioral modification program, including food and activity monitoring, and development of short-term diet and physical activity goals. The goals should be positive behavior change, weight maintenance or a decrease in BMI velocity. The follow-up should be conducted weekly or at least every 2–4 weeks as determined by the patient, family, and physician. After 3 –6 months, if the BMI/weight status has not improved consider advancing to Stage 4.

In 2014 the **National Institute for Health Care and Excellence (NICE)** stated:

- Multicomponent interventions are the treatment of choice. Ensure weight management programmes include behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake.[2006, amended 2014]
- Deliver any behavioural intervention with the support of an appropriately trained professional.[2006]

- Include the following strategies in behavioural interventions for children, as appropriate: stimulus control, self-monitoring, goal setting, rewards for reaching goals problem solving. Give praise to successes and encourage parents to role-model desired behaviours. [2006, amended 2014]

In 2013 the Australian **National Health and Medical Research Council** recommended:

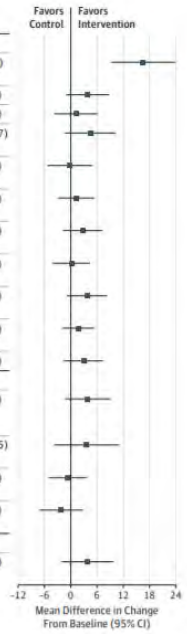
- For children and adolescents, plan weight management programs that involve frequent contact with health professionals. (**B**)
- For children and adolescents who are overweight or obese, recommend lifestyle change—including reduced energy intake and sedentary behaviour, increased physical activity and measures to support behavioural change. (**B**)

Children and Adolescents: Primary Literature

2017 US Preventive Services Task Force Evidence Report

Figure 3. Change in Quality of Life and Functioning in Behavior-Based Intervention Trials by Estimated Hours of Contact (Key Question 3)

Source	Estimated Contact Hours Through 12 mo	Time Since Randomization (Months After End of Treatment)	Measure	Intervention No.	Intervention Change From Baseline, Mean (SD)	Control No.	Control Change From Baseline, Mean (SD)	Mean Difference in Change From Baseline (95% CI)
PedsQL, parent report (range, 0-100)								
Stark et al,[54] 2011	38	12 (6)	Physical functioning	7	13.8 (8.6)	9	-2.7 (5.6)	16.50 (9.15 to 23.85)
DeBar et al,[29] 2012	37	12 (7)	Total score	85	6.7 (15.2)	76	2.9 (16.5)	3.82 (-1.09 to 8.73)
Hofsteenge et al,[32] 2014	17	6 (0)	Total score	44	3.4 (11.7)	33	2.2 (10.4)	1.20 (-3.75 to 6.15)
			Physical functioning	44	6.6 (13.6)	33	2.2 (12.6)	4.40 (-1.47 to 10.27)
			Psychosocial functioning	44	2.2 (12.3)	33	2.4 (10.7)	-0.20 (-5.36 to 4.96)
Taylor et al,[59] 2015	5	24 (0)	School functioning	89	0.7 (13.3)	92	-0.5 (15.3)	1.20 (-2.97 to 5.37)
			Physical functioning	89	-1.1 (14.9)	92	-3.8 (15.9)	2.70 (-1.80 to 7.20)
			Emotional functioning	89	0.1 (14.6)	92	0 (15)	0.10 (-4.21 to 4.41)
			Social functioning	89	-1.9 (14.7)	92	-5.6 (16.7)	3.70 (-0.89 to 8.29)
			Psychosocial functioning	89	-0.4 (11.9)	92	-2.1 (12.9)	1.70 (-1.92 to 5.32)
McCallum et al,[39] 2007	1	15 (2)	Total score	63	2.9 (13.5)	69	0 (12.9)	2.90 (-1.60 to 7.40)
CHQ, parent report (range, 0-100)								
Kalarchian et al,[33] 2009	44	12 (0)	General health perception	97	5.7 (17.8)	95	1.8 (19.1)	3.88 (-1.35 to 9.11)
			Global health	97	4.1 (24.5)	95	0.5 (27.7)	3.65 (-3.75 to 11.05)
Hofsteenge et al,[32] 2014	17	6 (0)	Psychosocial summary	44	1.7 (10.5)	33	2.4 (9.3)	-0.70 (-5.13 to 3.73)
			Physical summary	44	2 (11.7)	33	4.2 (10.6)	-2.20 (-7.19 to 2.79)
DISAKIDS, child report (range, 0-37)								
Vos et al,[61] 2011	45	12 (NA[a])	Total score	32	6.6 (11)	35	2.8 (13.6)	3.80 (-2.11 to 9.71)

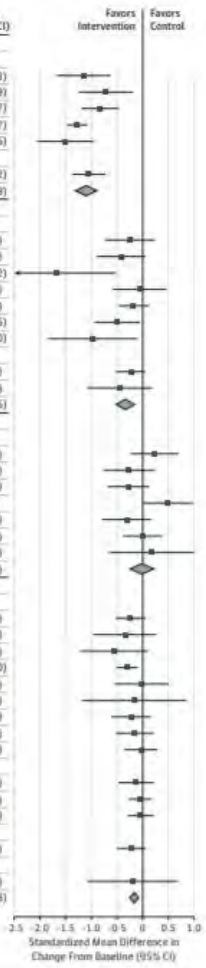


CHQ indicates Child Health Questionnaire; NA, not available; PEDsQL, Pediatric Quality of Life.

[a] Intervention had not yet ended at the 12-month assessment.

Figure 4. Change in Weight (BMI *z* Score, BMI, Weight in Kilograms, or BMI Percentile) in Behavior-Based Weight Loss Intervention Trials, by Estimated Hours of Contact, Showing DerSimonian and Laird Pooled Estimates (Key Question 4)

Source	Estimated Contact Hours Through 12 mo	Months Since Randomization (Months Since End of Treatment)	Intervention No.	Intervention Change From Baseline, Mean (SD)	Control No.	Control Change From Baseline, Mean (SD)	Standardized Mean Difference in Change From Baseline (95% CI)
Estimated contact ≥52 h							
Outcome: BMI *z* score							
Weigel et al,[64] 2008	114	12 (0)	36	−0.34 (0.48)	30	0.26 (0.57)	−1.15 (−1.68 to −0.63)
Savoye et al,[51] 2014	78	6 (0)	31	−0.05 (0.13)	27	0.04 (0.12)	−0.72 (−1.25 to −0.19)
Reinehr et al,[45] 2006	78	12 (0)	174	−0.30 (0.35)	37	0 (0.41)	−0.83 (−1.19 to −0.47)
Reinehr et al,[46] 2009	78	12 (0)	288	−0.22 (0.35)	186	0.15 (0.17)	−1.27 (−1.47 to −1.07)
Reinehr et al,[47] 2010	67	6 (0)	34	−0.26 (0.22)	32	0.05 (0.19)	−1.50 (−2.05 to −0.96)
Outcome: BMI							
Savoye et al,[52] 2007	82	12 (0)	105	−1.7 (3.1)	69	1.6 (3.2)	−1.05 (−1.37 to −0.72)
Subtotal (I^2 = 43.4%, P = .12)							−1.10 (−1.30 to −0.89)
Estimated contact 26–51 h							
Outcome: BMI *z* score							
Vos et al,[61] 2011[a]	45	12 (NA[b])	32	−0.40 (1.3)	35	−0.1 (1.1)	−0.25 (−0.73 to 0.23)
Kalavainen et al,[54] 2007	44	12 (6)	35	−0.30 (0.15)	35	−0.20 (0.30)	−0.42 (−0.89 to 0.05)
Stark et al,[58] 2011	38	12 (6)	7	−0.37 (0.41)	9	0.40 (0.49)	−1.68 (−2.85 to −0.52)
Croker et al,[26] 2012	38	6 (0)	31	−0.11 (0.16)	27	−0.10 (0.16)	−0.06 (−0.58 to 0.45)
DeBar et al,[29] 2012[a]	37	12 (7)	90	−0.15 (0.41)	83	−0.08 (0.36)	−0.18 (−0.48 to 0.12)
Sacher et al,[49] 2010	36	6 (3.75)	37	−0.30 (0.51)	45	−0.01 (0.65)	−0.49 (−0.94 to −0.05)
Stark et al,[53] 2014	30	12 (16)	11	−0.59 (0.75)	12	−0.01 (0.36)	−0.97 (−1.84 to −0.10)
Outcome: BMI							
Kalarchian et al,[33] 2009	44	12 (0)	97	0.50 (3.0)	95	1.1 (2.2)	−0.23 (−0.52 to 0.05)
Nemet et al,[42] 2005[a]	33	12 (9)	20	−1.6 (4.3)	20	0.60 (5.5)	−0.45 (−1.07 to 0.18)
Subtotal (I^2 = 24.0%, P = .23)							−0.34 (−0.52 to −0.16)
Estimated contact 6–25 h							
Outcome: BMI *z* score							
Bryant et al,[25] 2011	24	12 (0)	35	0.03 (0.24)	35	−0.03 (0.27)	0.23 (−0.24 to 0.70)
Golley et al,[31] 2007	24	12 (7)	31	−0.24 (0.43)	31	−0.13 (0.40)	−0.26 (−0.76 to 0.24)
Hofsteenge et al,[32] 2014	17	6 (0)	53	−0.12 (0.46)	44	0.02 (0.53)	−0.28 (−0.68 to 0.12)
Gerards et al,[30] 2015	17	12 (8.5)	35	0.05 (0.26)	32	−0.08 (0.27)	0.49 (0.00 to 0.98)
Nowicka et al,[41] 2008	16	12 (0)	65	−0.06 (0.46)	23	0.09 (0.53)	−0.31 (−0.79 to 0.16)
Norman et al,[65] 2016	12	12 (0)	53	−0.10 (0.36)	53	−0.10 (0.44)	0.00 (−0.38 to 0.38)
Arauz Boudreau et al,[23] 2013	11	6 (0)	13	−0.03 (0.14)	10	−0.05 (0.08)	0.17 (−0.66 to 1.00)
Subtotal (I^2 = 37.4%, P = .14)							−0.02 (−0.25 to 0.21)
Estimated contact 0–5 h							
Outcome: BMI *z* score							
Taylor et al,[59] 2015	5	12 (NA[b])	91	−0.19 (0.52)	90	−0.08 (0.43)	−0.23 (−0.53 to 0.06)
Stettler et al,[55] 2015[a]	4	12 (0)	46	−0.06 (0.50)	24	0.10 (0.41)	−0.34 (−0.95 to 0.27)
Saelens et al,[50] 2002[a]	4	7 (3)	18	−0.05 (0.22)	19	0.06 (0.17)	−0.56 (−1.22 to 0.10)
Broccoli et al,[24] 2016	4	12 (9)	186	−0.12 (0.38)	185	−0.01 (0.35)	−0.30 (−0.51 to −0.10)
Sherwood et al,[56] 2015	3	6 (0)	26	−0.02 (0.37)	29	−0.01 (0.54)	−0.02 (−0.55 to 0.51)
Looney and Raynor,[21] 2014	3	6 (0)	7	−0.16 (0.48)	8	−0.07 (0.61)	−0.16 (−1.18 to 0.85)
Wake et al,[63] 2013	3	12 (0)	56	−0.20 (0.50)	49	−0.10 (0.36)	−0.23 (−0.61 to 0.16)
Taveras et al,[58] 2015	1	12 (0)	164	−0.09 (0.33)	171	−0.04 (−0.32)	−0.16 (−0.52 to 0.21)
McCallum et al,[35] 2007	1	15 (12)	70	0 (0.61)	76	0.02 (0.55)	−0.03 (−0.36 to 0.29)
Outcome: BMI							
Taveras et al,[57] 2011	3	12 (0)	253	0.30 (1.4)	192	0.50 (1.4)	−0.13 (−0.47 to 0.21)
van Grieken et al,[60] 2013	2	24 (12)	277	1.4 (1.5)	230	1.4 (1.7)	−0.04 (−0.27 to 0.18)
Wake et al,[62] 2009	1	12 (9)	127	0.60 (2.6)	115	0.70 (2.2)	−0.04 (−0.29 to 0.21)
Outcome: BMI percentile							
Resnicow et al,[48] 2015[a]	3	24 (0)	154	−4.9 (15.2)	158	−1.8 (13.8)	−0.21 (−0.49 to 0.07)
Outcome: Weight							
Kong et al,[34] 2013	4	9 (0)	28	1.7 (4.0)	23	2.5 (4.3)	−0.19 (−1.08 to 0.69)
Subtotal (I^2 = 0.0%, P = .91)							−0.17 (−0.25 to −0.08)



BMI indicates body mass index.

[a] Study-reported repeated-measures or adjusted analysis demonstrated a statistically significant benefit.

[b] Intervention had not yet ended at 12-month assessment.

Table 2. Pooled Results for Continuous Intermediate Cardiometabolic Outcomes of Included Lifestyle-Based Weight Loss Trials With 52 or More Estimated Hours of Contact Intervention Trials (Key Question 4)[45-47,51,52,64]

Outcome	Pooled Mean Difference in Change Between Groups (95% CI)	No. of Trials	I^2	No. Included in Analysis		Model
				Intervention	Control	
Blood pressure, mm Hg						
Systolic	−6.4 (−8.6 to −4.2)	6	51.3	973	688	DerSimonian and Laird
Diastolic	−4.0 (−5.6 to −2.5)	6	17.3	973	688	DerSimonian and Laird
Lipids, mg/dL						
LDL-C	−10.0 (−21.1 to 1.1)	4	56.6	685	407	REML
HDL-C	0.4 (−2.2 to 3.0)	4	0	798	509	REML
Triglycerides	−9.1 (−27.8 to 9.6)	4	36.9	797	509	REML
Fasting plasma glucose, mg/dL	−0.8 (−3.0 to 1.2)	4	0	798	508	REML

Abbreviations: HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; REML, restricted maximum likelihood with Knapp-Hartung modification.

SI conversion factors: To convert LDL-C and HDL-C values to mmol/L, multiply by 0.0259; triglyceride values to mmol/L, multiply by 0.0113; fasting plasma glucose values to mmol/L, multiply by 0.0555.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
PICO Question: What is the comparative effectiveness of lifestyle interventions (combined physical activity, nutritional, behavioral)?
Population: Overweight/obese children
Modality: Lifestyle Interventions
Outcome: Obesity-related outcomes

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Rajjo, T., et al. Year Published: 2017 Location: Evidence-based Practice Center, Mayo Clinic Journal: *Journal of Clinical Endocrinology & Metabolism*	To appraise the quality of evidence supporting each intervention and assessed the effectiveness on different obesity-related outcomes.	**Size:** 133 RCTs **Inclusion Criteria**: RCTS including overweight or obese children (>2 years old) and adolescents and evaluating interventions to treat pediatric obesity (medication, surgery, lifestyle interventions, and community-based interventions); RCTs were eligible if they had compared any of these interventions against usual care or each other and had follow-up data for >/= 6 months. Systematic reviews including explicit inclusion and exclusion criteria and searching >1 database, title and methods had to be explicitly identified, if two systematic reviews were available for same intervention and outcomes, the more recent and closest to the AMSTAR criteria was included.	**Type:** Systematic Review	**Results:** Physical activity interventions reduced systolic blood pressure and fasting glucose (low to moderate quality of evidence). Dietary interventions with low-carbohydrate diets had a similar effect to low-fat diets in terms of body mass index (BMI) reduction (moderate quality of evidence). Educational interventions reduced waist circumference, BMI, and diastolic blood pressure (low quality of evidence). Pharmacological interventions reduced BMI (metformin, sibutramine, orlistat) and waist circumference (sibutramine, orlistat) and increased high-density lipoprotein cholesterol (sibutramine) but also raised systolic and diastolic blood pressure (sibutramine). Surgical interventions (laparoscopic adjustable gastric banding, Roux-en-Y gastric bypass, sleeve gastrectomy) resulted in the largest BMI reduction (moderate quality of evidence). Combined interventions consisting of dietary modification, physical activity, behavioral therapy, and education significantly reduced systolic and diastolic blood pressure, BMI, and triglycerides. Combined parent-child interventions and parent-only interventions had	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				similar effects on BMI (low quality of evidence).	
Author: Ho, M., et al. Year Published: 2012 Location: The Children's Hospital at Westmead Clinical School, University of Sydney, Australia Journal: *Pediatrics*	To examine the impact of lifestyle interventions incorporating a dietary component on both weight change and cardio-metabolic risks in overweight/obese children	**Size:** 38 studies **Inclusion Criteria**: Randomized controlled trial, participants overweight/obese and </= 18 years, comparing lifestyle interventions to no treatment/wait-list control, usual care, or written education materials. **Exclusion Criteria**: Studies targeting obesity prevention or maintenance of weight loss, were drug trials or interventions that dealt with eating disorders, or if they focused on children with obesity attributable to a secondary or syndromal cause.	**Type:** Systematic Review	**Results:** Lifestyle interventions produced significant weight loss compared with no-treatment control conditions: BMI (-1.25kg/m(2), 95% confidence interval [CI] -2.18 to -0.32) and BMI z score (-0.10, 95% CI -0.18 to -0.02). Studies comparing lifestyle interventions to usual care also resulted in significant immediate (-1.30kg/m(2), 95% CI -1.58 to -1.03) and posttreatment effects (-0.92 kg/m(2), 95% CI -1.31 to -0.54) on BMI up to 1 year from baseline. Lifestyle interventions led to significant improvements in low-density lipoprotein cholesterol (-0.30 mmol/L, 95% CI -0.45 to -0.15), triglycerides (-0.15 mmol/L, 95% CI -0.24 to -0.07), fasting insulin (-55.1 pmol/L, 95% CI -71.2 to -39.1) and blood pressure up to 1 year from baseline. No differences were found for high-density lipoprotein cholesterol.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Ho, M., et al. (2012). "Effectiveness of lifestyle interventions in child obesity: systematic review with meta-analysis." Pediatrics **130**(6): e1647-1671.
2. Rajjo, T., et al. (2017). "Treatment of Pediatric Obesity: An Umbrella Systematic Review." Journal of Clinical Endocrinology & Metabolism **102**(3): 763-775.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Pico Question: What is the comparative effectiveness of lifestyle interventions (combined physical activity, nutritional, behavioral)?
Population: Overweight/obese children up to the age of 6 years
Modality: Diet, physical activity and behavioral interventions
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Colquitt, J. L., et al. Year Published: 2016 Location: Effective Evidence, UK Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years.	**Size:** 7 RCTs, 923 participants **Inclusion Criteria:** Randomised controlled trials (RCTs) of diet, physical activity, and behavioural interventions for treating overweight or obesity in preschool children aged 0 to 6 years	**Type:** Systematic Review	**Results:** In trials comparing a multicomponent intervention with usual care, enhanced usual care, or information control, a greater reduction in body mass index (BMI) z score in the intervention groups was found at the end of the intervention (6 to 12 months): mean difference (MD) -0.3 units (95% confidence interval (CI) -0.4 to -0.2); P < 0.00001; 210 participants; 4 trials; low-quality evidence, at 12 to 18 months' follow-up: MD -0.4 units (95% CI -0.6 to -0.2); P = 0.0001; 202 participants; 4 trials; low-quality evidence,	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				and at 2 years' follow-up: MD -0.3 units (95% CI -0.4 to -0.1); 96 participants; 1 trial; low-quality evidence. One trial stated that no adverse events were reported; the other trials did not report on adverse events. Three trials reported health-related quality of life and found improvements in some, but not all, aspects. Other outcomes, such as behaviour change and parent-child relationship, were inconsistently measured. One three-arm trial of very low-quality evidence comparing two types of diet with control found that both the dairy-rich diet (BMI z score change MD -0.1 units (95% CI -0.11 to -0.09); P < 0.0001; 59 participants) and energy-restricted diet (BMI z score change MD -0.1 units (95% CI -0.11 to -0.09); P < 0.0001; 57 participants) resulted in greater reduction in BMI than the comparator at the end of the intervention period, but only the dairy-rich diet maintained this at 36 months' follow-up (BMI z score change in MD -0.7 units (95% CI -0.71 to -0.69); P < 0.0001; 52 participants). The energy-restricted diet had a worse BMI outcome than control at this follow-up (BMI z score change MD 0.1 units (95% CI 0.09 to 0.11); P < 0.0001; 47 participants). There was no substantial	

				difference in mean daily energy expenditure between groups. Health-related quality of life, adverse effects, participant views, and parenting were not measured.	
Author: Brown, T., et al. Year Published: 2019 Location: Durham University, UK Journal: *Cochrane Database of Systematic Reviews*	To determine the effectiveness of a range of interventions that include diet or physical activity components, or both, designed to prevent obesity in children.	**Size:** 153 RCTs **Inclusion Criteria:** Randomised controlled trials (RCTs) of diet or physical activity interventions, or combined diet and physical activity interventions, for preventing overweight or obesity in children (0-17 years) that reported outcomes at a minimum of 12 weeks from baseline.	**Type:** Systematic Review	**Results:** **Children aged 0-5 years:** There is moderate-certainty evidence from 16 RCTs (n = 6261) that diet combined with physical activity interventions, compared with control, reduced BMI (mean difference (MD) −0.07 kg/m2, 95% confidence interval (CI) −0.14 to −0.01), and had a similar effect (11 RCTs, n = 5536) on zBMI (MD −0.11, 95% CI −0.21 to 0.01). Neither diet (moderate-certainty evidence) nor physical activity interventions alone (high-certainty evidence) compared with control reduced BMI (physical activity alone: MD −0.22 kg/m2, 95% CI −0.44 to 0.01) or zBMI (diet alone: MD −0.14, 95% CI −0.32 to 0.04; physical activity alone: MD 0.01, 95% CI −0.10 to 0.13) in children aged 0-5 years.	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. Brown, T., et al. (2019). "Interventions for preventing obesity in children." Cochrane Database of Systematic Reviews(7).
2. Colquitt, J. L., et al. (2016). "Diet, physical activity, and behavioural interventions for the treatment of overweight or obesity in preschool children up to the age of 6 years." Cochrane Database of Systematic Reviews(3).

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Pico Question: What is the comparative effectiveness of lifestyle interventions (combined physical activity, nutritional, behavioral)?
Population: Overweight/obese children aged 6 to 12 years
Modality: Diet, physical activity, and behavioral interventions
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

Low Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Mead, E., et al. Year Published: 2016 Location: Teesside University, UK Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of diet, physical activity and behavioural interventions (behaviour-changing interventions) for the treatment of overweight or obese children aged 6 to 11 years.	**Size:** 70 RCTs, 8461 participants **Inclusion Criteria:** Randomised controlled trials (RCTs) of diet, physical activity, and behavioural interventions (behaviour-changing interventions) for treating overweight or obese children aged 6 to 11 years, with a minimum of six months' follow-up. We excluded interventions that specifically dealt with the treatment of eating disorders or type 2 diabetes, or included participants with a secondary or syndromic cause of obesity.	**Type:** Systematic Review	**Results:** Primary analyses demonstrated that behaviour-changing interventions compared to no treatment/usual care control at longest follow-up reduced BMI, BMI z score and weight. Mean difference (MD) in BMI was -0.53 kg/m2 (95% confidence interval (CI) -0.82 to -0.24); P < 0.00001; 24 trials; 2785 participants; low-quality evidence. MD in BMI z score was -0.06 units (95% CI -0.10 to -0.02); P = 0.001; 37 trials; 4019 participants; low-quality evidence and MD in weight was -1.45 kg (95% CI -1.88 to -1.02); P < 0.00001; 17 trials;	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				1774 participants; low-quality evidence. Thirty-one trials reported on serious adverse events, with 29 trials reporting zero occurrences RR 0.57 (95%CI 0.17 to 1.93); P = 0.37; 4/2105 participants in the behaviour-changing intervention groups compared with 7/1991 participants in the comparator groups). Few trials reported health-related quality of life or behaviour change outcomes, and none of the analyses demonstrated a substantial difference in these outcomes between intervention and control. In two trials reporting on minutes per day of TV viewing, a small reduction of 6.6 minutes per day (95% CI -12.88 to -0.31), P = 0.04; 2 trials; 55 participants) was found in favour of the intervention. No trials reported on all-cause mortality, morbidity or socioeconomic effects, and few trials reported on participant views; none of which could be meta-analysed.	
Author: Brown, T., et al. Year Published: 2019 Location: Durham University, UK Journal: *Cochrane Database of Systematic Reviews*	To determine the effectiveness of a range of interventions that include diet or physical activity components, or both, designed to prevent obesity in children.	**Size:** 153 RCTs **Inclusion Criteria:** Randomised controlled trials (RCTs) of diet or physical activity interventions, or combined diet and physical activity interventions, for preventing overweight or obesity in children (0-17 years) that	**Type:** Systematic Review	**Results:** **Children aged 6 to 12 years:** There is moderate-certainty evidence from 14 RCTs (n = 16,410) that physical activity interventions, compared with control, reduced BMI (MD −0.10 kg/m2, 95% CI −0.14 to −0.05). However, there is	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised

		reported outcomes at a minimum of 12 weeks from baseline.		moderate-certainty evidence that they had little or no effect on zBMI (MD −0.02, 95% CI −0.06 to 0.02). There is low-certainty evidence from 20 RCTs (n = 24,043) that diet combined with physical activity interventions, compared with control, reduced zBMI (MD −0.05 kg/m2, 95% CI −0.10 to −0.01). There is high-certainty evidence that diet interventions, compared with control, had little impact on zBMI (MD −0.03, 95% CI −0.06 to 0.01) or BMI (−0.02 kg/m2, 95% CI −0.11 to 0.06).	☐ Inappropriate pooled analysis

References:

1. Brown, T., et al. (2019). "Interventions for preventing obesity in children." Cochrane Database of Systematic Reviews(7).
2. Mead, E., et al. (2017). "Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years." Cochrane Database of Systematic Reviews(6).

BODY OF EVIDENCE APPRAISAL TABLE FOR:

PICO Question: What is the comparative effectiveness of lifestyle interventions (combined physical activity, nutritional, behavioral)?
Population: Overweight/obese adolescents 12 to 17 years old
Modality: Diet, physical activity, and behavioral interventions
Outcome: Weight loss

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if:

		☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Al-Khudairy, L., et al. Year Published: 2017 Location: University of Warwick, UK Journal: *Cochrane Database of Systematic Reviews*	To assess the effects of diet, physical activity and behavioural change interventions (BCI) for the treatment of overweight or obese adolescents aged 12 to 17 years.	**Size:** 28 RCTs, 2774 overweight/obese adolescents **Inclusion Criteria:** 	**Type:** Systematic Review	**Results:** Most of the trials used a multidisciplinary intervention with a combination of diet, physical activity and behavioural components. **The mean difference (MD) of the change in BMI at the longest follow-up period in favour of BCI was -1.18 kg/m2 (95% confidence interval (CI) -1.67 to -0.69); 2774 participants; 28 trials; low quality evidence. BCI lowered the change in BMI z score by -0.13 units (95% CI -0.21 to -0.05); 2399 participants; 20 trials; low quality evidence. BCI lowered body weight by -3.67 kg (95% CI -5.21 to -2.13); 1993 participants; 20 trials; moderate quality evidence. The effect on weight measures persisted in trials with 18 to 24 months' follow-up for both BMI (MD -1.49 kg/m2 (95% CI -2.56 to -0.41); 760 participants; 6 trials and BMI z score MD -0.34 (95% CI -0.66 to -0.02); 602 participants; 5 trials).**	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				There were subgroup differences showing larger effects for both BMI and BMI z score in studies comparing interventions with no intervention/wait list control or usual care, compared with those testing concomitant interventions delivered to both the intervention and control group. There were no subgroup differences between interventions with and without parental involvement or by intervention type or setting (health care, community, school) or mode of delivery (individual versus group). The rate of adverse events in intervention and control groups was unclear with only five trials reporting harms, and of these, details were provided in only one (low quality evidence). None of the included studies reported on all-cause mortality, morbidity or socioeconomic effects. BCIs at the longest follow-up moderately improved adolescent's health-related quality of life (standardised mean difference 0.44 ((95% CI 0.09 to 0.79); P = 0.01; 972 participants; 7 trials; 8 comparisons; low quality of evidence) but not self-esteem. Trials were inconsistent in how they measured dietary intake, dietary behaviours, physical activity and behavior.	

Author: Brown, T., et al. Year Published: 2019 Location: Durham University, UK Journal: *Cochrane Database of Systematic Reviews*	To determine the effectiveness of a range of interventions that include diet or physical activity components, or both, designed to prevent obesity in children.	**Size:** 153 RCTs **Inclusion Criteria**: Randomised controlled trials (RCTs) of diet or physical activity interventions, or combined diet and physical activity interventions, for preventing overweight or obesity in children (0-17 years) that reported outcomes at a minimum of 12 weeks from baseline.	**Type:** Systematic Review	**Results:** **Children aged 0-5 years:** There is moderate-certainty evidence from 16 RCTs (n = 6261) that diet combined with physical activity interventions, compared with control, reduced BMI (mean difference (MD) −0.07 kg/m2, 95% confidence interval (CI) −0.14 to −0.01), and had a similar effect (11 RCTs, n = 5536) on zBMI (MD −0.11, 95% CI −0.21 to 0.01). Neither diet (moderate-certainty evidence) nor physical activity interventions alone (high-certainty evidence) compared with control reduced BMI (physical activity alone: MD −0.22 kg/m2, 95% CI −0.44 to 0.01) or zBMI (diet alone: MD −0.14, 95% CI −0.32 to 0.04; physical activity alone: MD 0.01, 95% CI −0.10 to 0.13) in children aged 0-5 years. **Children aged 6 to 12 years:** There is moderate-certainty evidence from 14 RCTs (n = 16,410) that physical activity interventions, compared with control, reduced BMI (MD −0.10 kg/m2, 95% CI −0.14 to −0.05). However, there is moderate-certainty evidence that they had little or no effect on zBMI (MD −0.02,	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				95% CI −0.06 to 0.02). There is low-certainty evidence from 20 RCTs (n = 24,043) that diet combined with physical activity interventions, compared with control, reduced zBMI (MD −0.05 kg/m2, 95% CI −0.10 to −0.01). There is high-certainty evidence that diet interventions, compared with control, had little impact on zBMI (MD −0.03, 95% CI −0.06 to 0.01) or BMI (−0.02 kg/m2, 95% CI −0.11 to 0.06). **Children aged 13 to 18 years**: There is very low-certainty evidence that physical activity interventions, compared with control reduced BMI (MD −1.53 kg/m2, 95% CI −2.67 to −0.39; 4 RCTs; n = 720); and low-certainty evidence for a reduction in zBMI (MD -0.2, 95% CI −0.3 to -0.1; 1 RCT; n = 100). There is low-certainty evidence from eight RCTs (n = 16,583) that diet combined with physical activity interventions, compared with control, had no effect on BMI (MD −0.02 kg/m2, 95% CI −0.10 to 0.05); or zBMI (MD 0.01, 95% CI −0.05 to 0.07; 6 RCTs; n = 16,543). Evidence from two RCTs (low-certainty evidence;	

				n = 294) found no effect of diet interventions on BMI.	

References:

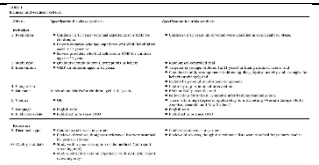
1. Brown, T., et al. (2019). "Interventions for preventing obesity in children." Cochrane Database of Systematic Reviews(7).
2. Al-Khudairy, L., et al. (2017). "Diet, physical activity and behavioural interventions for the treatment of overweight or obese adolescents aged 12 to 17 years." Cochrane Database of Systematic Reviews(6).

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Pico Question: What is the optimal lifestyle intervention for improving health, well-being, and weight loss?
Population: Overweight children (0-11years)
Modality: Lifestyle weight management programs
Outcome: Critical pathways

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*- **Unknown**	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Burchett, H.E.D., et al. Year Published: 2018 Location: London School of Hygiene and Tropical Medicine, London, UK Journal: *Preventive Medicine*	To identify critical features of successful lifestyle weight management interventions for overweight children (0-11 years).	**Size:** 11 studies in the views synthesis and 30 in the evaluation synthesis **Inclusion and Exclusion Criteria:**	**Type:** Systematic Review Using a mixed method evidence synthesis of UK-based qualitative research with children, parents and providers to identify programme components to explore in an –evaluation synthesis" using Qualitative Comparative Analysis (QCA).	**Results:** Three important mechanisms were present in all the most effective interventions but absent in all the least effective: 1/ showing families how to change: a) providing child physical activity sessions, b) delivering practical behaviour change strategy sessions, c) providing calorie intake	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

			The evaluation synthesis QCA explored differences in the programme characteristics of those interventions found to be most and least effective, in terms of reductions in body mass index (BMI) z scores at 12 months.	advice; 2/ ensuring all the family are on board: a) delivering discussion/ education sessions for both children and parents, b) delivering child-friendly sessions, c) aiming to change behaviours across the whole family; 3/ enabling social support for both parents and children by delivering both child group sessions and parent group sessions.	

References:

1. Burchett, H. E. D., et al. (2018). "Lifestyle weight management programmes for children: A systematic review using Qualitative Comparative Analysis to identify critical pathways to effectiveness." Preventive Medicine **106**: 1-12.

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

Adults: Guideline Recommendations

In 2018 the **US Preventive Services Task Force (USPSTF)** recommended:

- The USPSTF recommends that clinicians offer or refer adults with a body mass index (BMI) of 30 or higher (calculated as weight in kilograms divided by height in meters squared) to intensive, multicomponent behavioral interventions (**B recommendation**).

The 2016 **American Academy of Family Physicians (AAFP)** stated:

- The AAFP supports the U.S. Preventive Services Task Force (USPSTF) clinical preventive service recommendations on this topic.

In 2016 the **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

- A structured lifestyle intervention program designed for weight loss (lifestyle therapy) and consisting of a healthy meal plan, physical activity, and behavioral interventions should be available to patients who are being treated for overweight or obesity (**Grade A; BEL1**).

Figure 4. Lifestyle Therapy

Evidence-based lifestyle therapy for treatment of obesity should include 3 components
Recommendations: R64 through R75

Meal Plan (R64, R65, R66)	Physical Activity (R64, R67, R68, R69, R70, R71)	Behavior (R64, R72, R73, R74, R75)
• Reduced-calorie healthy meal plan • ~500–750 kcal daily deficit • Individualize based on personal and cultural preferences • Meal plans can include: Mediterranean, DASH, low-carb, low-fat, volumetric, high protein, vegetarian • Meal replacements • Very low-calorie diet is an option in selected patients and requires medical supervision Team member or expertise: dietitian, health educator	• Voluntary aerobic physical activity progressing to >150 minutes/week performed on 3–5 separate days per week • Resistance exercise: single-set repetitions involving major muscle groups, 2–3 times per week • Reduce sedentary behavior • Individualize program based on preferences and take into account physical limitations Team member or expertise: exercise trainer, physical activity coach, physical/occupational therapist	An interventional package that includes any number of the following: • Self-monitoring (food intake, exercise, weight) • Goal setting • Education (face-to-face meetings, group sessions, remote technologies) • Problem-solving strategies • Stimulus control • Behavioral contracting • Stress reduction • Psychological evaluation, counseling, and treatment when needed • Cognitive restructuring • Motivational interviewing • Mobilization of social support structures Team member or expertise: health educator, behaviorist, clinical psychologist, psychiatrist

In 2015 the **Canadian Task Force on Preventive Health Care** recommended:

- For adults who are obese (BMI 30–39.9) and are at high risk of diabetes, we recommend that practitioners offer or refer to structured behavioural interventions aimed at weight loss. Structured interventions are intensive behavioural modification programs involving several sessions over weeks to months. Recommended interventions include behaviourally based interventions focused on diet, exercise or lifestyle changes, alone or in combination. Lifestyle changes include counselling, education or support, and/or environmental changes in addition to changes in exercise and/or diet. *(Strong recommendation; moderate-quality evidence)*
- For adults who are overweight or obese, we recommend that practitioners offer or refer to structured behavioural interventions aimed at weight loss. *(Weak recommendation; moderate-quality evidence)*

In 2015 the **European Guidelines** stated:

- Significant clinical benefits may be achieved even by modest weight loss (i.e. 5–10% of initial body weight), and lifestyle modification (improved nutritional content of the diet and modest increases in physical activity and fitness) {**level 1**}.
    - **Figure 2. Algorithm for management of overweight and obese adults.** Nutrition: Reduce energy intake by 500-1,000 kcal/day.
    - Physical activity: Initially at least 150 min/week moderate aerobic exercise combined with 1-3 sessions/week resistance exercise.

- Cognitive behavior therapy
- Pharmacotherapy: BMI ≥30 kg/m^2 or ≥27 kg/m^2 with comorbidities, adjunct to lifestyle modification
- Bariatric/metabolic surgery: BMI ≥40 kg/m^2 or BMI between 35.0-39.9 kg/m^2 + comorbidities or BMI between 30.0-34.9 kg/m^2 with type 2 diabetes on individual basis. Consider if other weight loss attempts fail; requires lifelong medical monitoring.
- Prevention and treatment of comorbidities.

In 2014 the **National Institute for Health and Care Excellence (NICE)** stated:

- Multicomponent interventions are the treatment of choice. Ensure weight management programmes include behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake.
- People should have relevant information on realistic targets for weight loss (5-10% of original weight)
- To prevent obesity, most people may need to do 45-60 minutes of moderate intensity activity a day, particularly if they do not reduce their energy intake. Advise people who have been obese and have lost weight that they may need to do 60-90 minutes of activity a day to avoid regaining weight
- The main requirement of a dietary approach is that total energy intake should be less than energy expenditure
- Diets with 600 kcal/day deficit (600 kcal fewer than is needed to stay the same weight; 1 kcal=4.18 kJ) or that reduce energy intake by reducing fat content in combination with expert support and intensive follow-up are recommended for sustainable weight loss

In 2014 the **Department of Veterans Affairs and Department of Defense (VA/DOD)** recommended:

- Offer obese patients comprehensive lifestyle intervention for weight loss to improve lipid levels, blood pressure, and/or glucose control. (A)
- Offer obese patients comprehensive lifestyle intervention for weight loss to reduce harms of obstructive sleep apnea. (B)
- Consider offering obese patients comprehensive lifestyle intervention for weight loss to reduce harms of degenerative joint disease. (C)
- Current evidence is insufficient to support weight loss through comprehensive lifestyle intervention for reducing harms of non-alcoholic fatty liver disease. (I)
- Offer comprehensive lifestyle interventions for weight loss, in either individual or group setting. (B)
    - Comprehensive lifestyle intervention: at least 12 contacts within 12 months of an intervention that combines dietary, physical activity, and behavioral strategies. (B)
    - Plan a net deficit of 500 to 1,000 kcal/day addressing both diet and physical activity to achieve a weight loss of 0.5 to 2 pounds per week, resulting in a 5-10% reduction in body weight over 6 months. (A)
- Offer telephone-based comprehensive lifestyle intervention for weight loss, either as an alternative or an adjunct to face-to-face intervention. (B)
- There is insufficient evidence for or against offering internet-based comprehensive lifestyle intervention for weight loss, as an alternate or adjunct to face-to-face intervention. (I)

In 2013 the **Academy of Nutrition and Dietetics** recommended:

- For weight loss and weight maintenance, the RDN should include the following components as part of a comprehensive weight-management program: reduced-calorie diet, increasing physical activity, use of behavioral strategies. (**Rating: Strong, Imperative**)
- For weight loss, the RDN should prescribe at least 14 MNT encounters (either individual or group) over a period of at least 6 months. (**Rating: Strong, Imperative**)
- For weight maintenance, the RDN should prescribe at least monthly MNT encounters over a period of at least 1 year. (**Rating: Strong, Imperative**)

In 2013 the **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** recommended:

- Advise overweight and obese individuals who would benefit from weight loss to participate for ≥6 months in a *comprehensive lifestyle program* that assists participants in adhering to a lower-calorie diet and in increasing physical activity through the use of behavioral strategies. **Grade: A (Strong)**
    - **Box 10: Weight Loss Option—Comprehensive Lifestyle Intervention Alone or With Adjunctive Therapies** All patients for whom weight loss is recommended should be offered or referred for comprehensive lifestyle intervention (Box 11a and 11b). Comprehensive lifestyle intervention, preferably with a trained interventionist† or nutrition professional, is foundational to weight loss (Box 11a) regardless of augmentation by medications or bariatric surgery. By expert opinion, if the weight and lifestyle history indicates that the patient has never participated in a comprehensive lifestyle intervention program as defined in CQ4 and in Box 11a, it is recommended that he or she be encouraged to undertake such a program before the addition of adjunctive therapies since a substantial proportion of patients will lose sufficient weight to improve health with comprehensive lifestyle treatment alone. This recommendation may be modified by the availability of comprehensive lifestyle intervention or by patient factors, such as medical conditions that warrant earlier initiation of more intensive treatment. If the patient has been unable to lose weight or sustain weight loss with comprehensive lifestyle intervention and he or she has a BMI ≥30 kg/m2 or BMI ≥27 kg/m2 with comorbidity, adjunctive therapies may be considered. Patients who are otherwise appropriate candidates for obesity drug treatment or bariatric surgery, whose weight and lifestyle history indicate a history of inability to achieve or sustain weight loss and who have previously participated in a comprehensive lifestyle intervention, may be offered the option to add pharmacotherapy at the time of initiation of a lifestyle intervention program (BMI ≥30 kg/m2 or BMI ≥27 kg/m2 with comorbidity) or to be referred for evaluation for bariatric surgery (BMI ≥40 kg/m2 or BMI ≥35 kg/m2 with comorbidity) (**expert opinion**).
    - **Box 11a. Offer or Refer for High-Intensity Comprehensive Lifestyle Intervention** The most effective behavioral weight loss treatment is an in-person, high-intensity (ie, ≥14 sessions in 6 months) comprehensive weight loss intervention provided in individual or group sessions by a trained interventionist. The principal components of an effective highintensity, on-site comprehensive lifestyle intervention include 1) prescription of a moderately reduced-calorie diet, 2) a program of increased physical activity, and 3) the use of behavioral strategies to facilitate adherence to diet and activity recommendations. As shown in CQ4, comprehensive lifestyle intervention consisting of diet, physical activity, and behavior therapy produces average weight losses of approximately 8 kg in a 6-month period of frequent, in-person treatment. This approximates losses of 5%-10% of initial weight. The observed average weight loss of approximately 8 kg includes people who have variable weight loss (ie, some more

and some less than average), so accurate prediction of individual weight loss is not possible. After 6 months, most patients will equilibrate (caloric intake balancing energy expenditure) and will require adjustment of energy balance if they are to lose additional weight. As demonstrated in CQ4, continued intervention contact after initial weight loss treatment is associated with better maintenance of lost weight.

- **Box 11b. Options for Alternative Modes of Delivery of Lifestyle Intervention** In primary care offices where frequent, in-person individual or group sessions led by a trained interventionist or a nutrition professional are not possible or available by referral, the physician may consider alternative modes of delivery. As found in CQ4, emerging evidence supports the efficacy, albeit with less weight loss, of electronically delivered interventions (eg, by Internet or telephone) that provide personalized feedback by a trained interventionist and of some commercial programs that provide counseling (face-to-face or telephonic) with or without prepackaged meals. The Expert Panel recommends, by expert opinion, that physicians may refer to these alternative sources provided their outcomes are supported by scientific evidence of safety and efficacy. An additional option if a highintensity comprehensive lifestyle intervention program is not available or feasible is referral to a nutrition professional for dietary counseling.

Adult: Primary Literature

BODY OF EVIDENCE APPRAISAL TABLE FOR: COMPARATIVE EFFECTIVENESS OF LIFESTYLE INTERVENTIONS
Population: Adult
Modality: Lifestyle interventions
Outcome: Weight loss and weight loss maintenance

Quality (certainty) of evidence for: weight loss and weight-loss maintenance
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations

Author: LeBlanc, E., et al. Year Published: 2018 Location: Evidence-based Practice Center, Kaiser Permanente Journal: *Journal of the American Medical Association*	To systematically review evidence on benefits and harms of weight loss and weight loss maintenance interventions in adults.	**Size:** 122 RCTs (N=62,533) and 2 observational studies (N=209,993) **Inclusion Criteria:** RCTs that investigated the effects of weight loss or weight loss maintenance in adults 18 years or older who were candidates for weight loss or weight loss maintenance interventions. Comparators included only no or minimal intervention or attention control for behavioral studies and placebo for pharmacologic studies. Studies had to report a health outcome, intermediate outcome, or adverse event. **Exclusion Criteria:** Studies of adults with chronic diseases for which weight loss or maintenance is part of disease management, chronic diseases not generalizable to the primary care population, secondary causes of obesity, pregnant women, and institutionalized adults.	**Type:** Systematic Review, USPSTF Quality Criteria	**Results:** Participants in behavior-based intervention groups lost more weight than controls. Mean weight change was significantly lower in intervention groups versus controls at 12-18 months (k=67; mean difference -2.39 kg, 95% CI -2.86 to -1.93, I^2=90%) and at 24 months (k=21; mean difference -1.45 kg, 95% CI -2.03 to -0.87, I^2=67.9%) (moderate evidence). At 12-18 months, mean absolute changes in intervention participants ranged from -0.5 kg to -9.3 kg and 1.4 kg to -5.6 kg in controls (moderate evidence). Intervention participants had a 1.94 times greater probability of losing 5% of their body weight compared with controls (k=38; RR 1.94, 95% CI 1.7 to 2.2, I^2=67.2%, NNT 8) (moderate evidence). Participants in behavior-based intervention groups had greater weight loss maintenance than controls at 12 to 18 months (pooled results, k=8; mean difference -1.59 kg, 95% CI -2.38 to -0.79, I^2=26.8%) (moderate evidence).	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis
Author: Ma, C., et al. Year Published: 2017 Location: University of Aberdeen, Scotland Journal: *British Medical Journal*	Conduct a systematic review and meta-analysis of RCTs of dietary interventions with or without exercise advice or programs for adults with obesity.	**Size:** 54 RCTs (N=30,206) **Inclusion Criteria:** RCTs that investigated the effects of long term (≥1 year) weight loss interventions with a weight reducing diet, with or without advice for increasing physical	**Type:** Systematic Review, GRADE	**Results:** Participants in dietary interventions lost more weight than controls (k=49; mean difference -2.85 kg, 95% CI -3.34 to -2.36, I^2=86%). The effect differed significantly based on whether physical activity was	**Study Limitations:** ☐ None ***Systematic Review*** ☒ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised

		activity and/or provision of a physical activity program to attend, compared to a control intervention, in adults mean ≥18 years and mean BMI ≥30. **Exclusion Criteria**: Pregnant or postpartum women.		not included, only recommended, or a program was provided (p=0.02). Weight loss was greatest for interventions providing a program (mean difference -3.61 kg, 95% CI -4.43 to -2.79, p<0.001) or a recommendation for physical activity (mean difference -2.23 kg, 95% CI -2.76 to 1.69, p<0.001), versus interventions not including a physical activity component (mean difference -2.82 kg, -5.40 to -0.24, p=0.03).	☐ Inappropriate pooled analysis
Author: Johns, D.J., et al. Year Published: 2014 Location: Medical Research Council, UK Journal: *Journal of the Academy of Nutrition and Dietetics*	To examine the clinical effectiveness of combined behavioral weight management programs versus single component programs.	**Size:** 8 RCTs (N=1,022) **Inclusion Criteria:** RCTs of weight loss interventions in adults aged ≥18 years with overweight or obesity (or BMI ≥23 in Asian populations). Had to include both diet and physical activity components, multiple contacts, and report weight change at ≥12 months. **Exclusion Criteria:** Pregnant women, people with eating disorders, diseases where weight loss is part of medical treatment, interventions with surgery or medication, other lifestyle changes such as smoking cessation or alcohol intake.	**Type:** Systematic Review, Risk of Bias	**Results:** Participants in combined intervention groups lost more weight than diet or physical activity alone at 12 months. Mean weight loss was higher in combined versus diet only interventions (mean difference -1.72 kg, 95% CI -2.80 vs. -0.64, p=0.002, I^2=3%), and in combined versus physical activity only interventions (mean difference -6.29 kg, 95% CI -7.33 to -5.26, p<0.001, I^2=9%).	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

1. LeBlanc, E., et al. (2018). "Behavioral and Pharmacotherapy Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force." JAMA **320**(11): 1172-1191.
2. Ma, C., et al. (2017). "Effects of weight loss interventions for adults who are obese on mortality, cardiovascular disease, and cancer: systematic review and meta-analysis." BMJ **359**:j4849.
3. Johns, D.J., et al., (2014). "Diet or Exercise Interventions vs Combined Behavioral Weight Management Programs: A Systematic review and Meta-Analysis of Direct Comparisons." J Acad Nutr Diet 114(10):1557-1568.

Question #7: What is the comparative harms and benefits of different pharmacological therapies (Orlistat, Phentermine, Topiramate, Phentermine/Topiramate, Lorcaserin, Buproprion, Bupropion/Naltrexone, Liraglutide, Diethylproprion, Metformin, Pramlintide, Zonisamide) for achieving weight loss and improving health and well-being? What is the optimal dose, duration and combination of pharmacological therapies?

General consensus from literature and external guidelines for pediatrics

Considerations

- Orlistat is only pharmacologic therapy approved for adolescents (≥12 years)
    - Consider after 1 year dietary and lifestyle treatment in peds with no comorbidities?
- No pharmacologics approved for pediatrics <12 years
- Long term use of some rx for comorbidities associated with weight gain (e.g., insulin, antipsychotics, prednisone)

Consensus

- Pediatric overweight defined as BMI ≥85th and <95th percentile for age and sex
    - Racial and ethnic differences in pediatric percentage of body fat at given BMI (e.g., higher CV risk at lower BMI thresholds for Asians)
- Pediatric obesity age ≥2 years defined as BMI ≥95th percentile for age and sex, or BMI ≥30 kg/m^2, whichever is lower
    - Obesity age <2 years defined as weight for recumbent length ≥95th percentile of growth standards
- As with adults, comprehensive lifestyle and behavioral modification is first line; advance to more intensive intervention if weight or BMI percentile does not improve after 3-6 months (in context of longitudinal growth)
- Orlistat (120 mg capsule tid with meals) plus reduced-calorie diet, behavioral modification program, and exercise counseling had average absolute BMI decrease of 0.55 kg/m^2 over 54 weeks in peds age 12-16 years
    - ITT population after 52 weeks: 19% lost ≥5% body weight; 9.5% lost ≥10% body weight
    - Poor absorption of dietary nutrients during treatment, requiring daily fat-soluble vitamins ≥2 hours before or after orlistat and reduced-fat diet (<30% daily calories from fat)
    - Significant GI side effects
    - Warnings and precautions include rare but potential risk of liver injury, increase in urinary oxalate levels, increased risk of cholelithiasis

General consensus from literature and external guidelines for adults

Considerations

- Labels stop at BMI 27 kg/m^2, vs. 25 kg/m^2 – how to manage those with BMI 25-26 kg/m^2?
- Goal should be long-term weight reduction and improvement in overall health; want to consider benefits and harms for each patient based on comorbidities, and clearly present expected outcomes of treatment (TABLE 1)
- For treating specific comorbidities, use weight-centric approach to chronic disease management – i.e., treat hypertension with a drug that may produce weight loss, not weight gain, especially diabetes, depression, autoimmune disorders
- Approved medications are active vs placebo, limited head to head options
- Initiate as monotherapy
- Rx may have significant monitoring requirements

Consensus

- Use after trying, and in conjunction with, lifestyle and behavioral modification, as medicine alone is largely not effective.
- Rx candidates: BMI 30+, or BMI 27 kg/m^2 with weight-related comorbidities, who have not had loss of at least 5% after 3-6 months comprehensive lifestyle intervention
- Goal should be long-term weight reduction and improvement in overall health; want to consider benefits and harms for each patient based on comorbidities, and clearly present expected outcomes of treatment (TABLE 1)
    - Physician communication with patient may incorporate the following:
        - Achieving / maintaining weight loss is really hard – long term needed to change set point
        - Not every drug works for every patient, and individual responses vary greatly
        - You'll hit a plateau, and you might gain weight as your body readjusts
        - Short term: during first month, probably 1 lb/wk (2 kg); loss of 4-5% by 3-6 months, and 4-8% by 6-12 months
        - Can also think about success as improvement in physical function, comorbidities, sense of well-being
        - Want to maintain healthy lifestyle and weight loss, because 5-10% substantially reduce risk of diabetes (if prediabetic), BP and risk of CVD (in patients w/ risk factors)
- Carefully consider potential risks versus reality of potential benefits (TABLE 1) and note limited long term safety data (longest was orlistat, ~4 years)
    - When treating specific comorbidities, use weight-centric approach to chronic disease management – i.e., treat hypertension with a drug that may produce weight loss, not weight gain, esp diabetes, depression, autoimmune
- General guidelines for treatment consideration
    - No diabetes: locaserin 1L (instead of liraglutide; weak / low), followed by liraglutide

  - Diabetes: liraglutide 1L (weak / moderate), followed by locaserin
  - Orlistat for those who don't respond to / tolerate above two, but comes with significant side effects
- Comparison versus placebo (FIGURE 1)
  - Locaserin: similar efficacy but better AEs than orlistat; may be beneficial for glycemia and renal function; can be used in patients with / at risk for CVD
  - Liraglutide: second only to phentermine-topiramate in weight loss; preferred 1L for diabetics but can be used in non, beneficial for glycemia, CVD; but injection and have to consider cost/coverage
  - Orlistat: On par efficacy with locaserin; benefits for glycemia, lipids, and blood pressure, but often not tolerated
  - Combination phentermine-topiramate (XR): highest weight loss but more AEs, can't use in patients with CVD/HTN, teratogenic so conception requirements – consider using only in men / postmenopausal
  - Combination bupropion-naltrexone (SR): on par with orlistat / locaserin, but more AEs and contraindications
  - Use of sympathomimetics (phentermine, diethylpropion) generally not recommended, although phentermine is popular and often used off label
- Monitor weight, vital signs (BP / HR) every 6 weeks, as well as for signs and symptoms of other issues specific to individual drugs – consider tapering and discontinuing if no response, or switch to another option if patient and physician believe benefits outweigh risks
  - For patients with diabetes, especially those on insulin or secretagogues – want patients to check blood glucose daily during initiation / titration; for those who are well-controlled, may want to reduce doses of insulin secretegogues during first month and then adjust as needed

Table 1. Pharmacologic management of obesity, in conjunction with diet, exercise, and behavior modification

Name MOA Population	Dosing and Monitoring	AEs	Precautions and Notes
Liraglutide 3.0 • GLP-1 agonist • BMI ≥30 kg/m^2, or BMI ≥27 kg/m^2 with ≥1 weight-related comorbidity	• Initial: 0.6 mg subQ qd • Titrate: increase dose at weekly intervals (1.2, 1.8, 2.4 mg) until 3 mg qd • Re-evaluate after 16 weeks; if weight loss ≤4% after 16 weeks, or 3 mg/week is not tolerated, discontinue use • May need to reduce dosage of insulin or oral hypoglycemics	• Common: Nausea, vomiting, diarrhea, constipation, hypoglycemia (in T2D patients using sulphonylureas or insulin), headache, dyspepsia, injection site reactions, increased lipase, increased heart rate • Less common: Gallbladder disease, renal impairment,	• Contraindicated during pregnancy, patients with personal/family history of medullary thyroid cancer, multiple endocrine neoplasia 2A or 2B, patients using other GLP-1 agonists or insulin • Monitor for signs of medullary thyroid cancer, pancreatitis, gall bladder

		suicidal behavioral and ideation	disease, hypersensitivity reactions, suicidal behavior and ideation • Delays gastric emptying; may impact absorption of other oral meds
Locaserin • 5HT-2_C receptor agonist • BMI ≥30 kg/m^2, or BMI ≥27 kg/m^2 with ≥1 weight-related comorbidity	• 10 mg bid (XR: 20 mg qd) • Re-evaluate after 12 weeks; if weight loss ≤5% after 12 weeks, discontinue drug. • May need to reduce dosage of insulin or oral hypoglycemics	• Diabetes: Hypoglycemia in T2D patients using sulphonylureas or insulin, headache, back pain, cough • No-diabetes: Headache, dizziness, fatigue, nausea, dry mouth, constipation	• Contraindicated in pregnancy • Avoid in patients with severe hepatic or renal insufficiency (CrCl <30 mL/min); patients using 5HT agents to reduce risk of serotonin syndrome • Monitor for signs of valvular heart disease, cognitive impairment • DEA schedule C-IV, as low abuse potential for psychic dependence and/or euphoria at higher than recommended doses
Orlistat • Pancreatic lipase inhibitor • BMI ≥30 kg/m^2, or BMI ≥27 kg/m^2 with ≥1 weight-related comorbidity	• Prescription and OTC • 120 mg tid with fat-containing meals • 60 mg tid for those not tolerating 120 mg dose • Should take daily multivitamin with A, D, E, K, and beta-carotene 2 hours before/after orlistat • May need to reduce dosage of insulin or oral hypoglycemics	• Common: cramps, flatulence, oily spotting, fecal incontinence • Less common: hepatic or renal injury	• Contraindicated during pregnancy, in patients with chronic malabsorption syndrome or cholestatis • May reduce absorption of fat-soluble vitamins, cyclosporine • Monitor patients on levothyroxine for changes in thyroid function (take 4 hrs apart), warfarin for coagulation (3 hrs apart),

			and anti-epileptics for convulsions
Phentermine • Centrally-acting adrenergic agonist • BMI ≥30 kg/m^2, or BMI ≥27 kg/m^2 with ≥1 weight-related comorbidity	• Immediate release: 8 mg tablets (Lomaira) up to TID, 37.5 mg tablets (Adipex-P) qd or divided 18.75 mg BID; 15 mg and 30 mg capsules • Orally disintegrating tablets: 15, 30, or 37.5 mg qd in morning • May need to reduce dosage of insulin or oral hypoglycemics	• Increase in heart rate or blood pressure, insomnia, dry mouth, constipation, nervousness, impaired ability to engage in operating machinery or drive	• Contraindicated during pregnancy or nursing; in patients with history of CVD (CAD, stroke, arrhythmia, CHF, un- or poorly controlled HTN), untreated hyperthyroidism, MAOI use, glaucoma, agitation • Current FDA approval limited to short term use (<12 weeks), although approved for longer-term use in combination tablet with topiramate (see below) • Avoid in patients <16 years and >65, and patients with pulmonary HTN, history of substance addiction or abuse, renal impairment • May counteract efficacy of BP medications • DEA schedule C-IV, low abuse potential as amphetamine derivative
Phentermine-topiramate • 5HT-2C receptor agonist	• Initial 3.75 mg phentermine / 23 mg topiramate qd in am for 2 weeks, then increase to 7.5mg/46 mg T qd for 12 weeks • If ≤3% weight loss after 12 weeks on 7.5 mg/46 mg,	• Dry mouth, constipation, paraesthesias, depression, anxiety, taste disturbance, elevated heart rate or blood pressure, cognitive	• Contraindicated in pregnancy or during nursing, patients using ergot derivatives or MAOIs, patients with hyperthyroidism, severe

• BMI ≥30 kg/m^2, or BMI ≥27 kg/m^2 with ≥1 weight-related comorbidity	escalate dose to 11.25 mg/69 mg for 14 days, followed by 15mg/92mg for 12 weeks, or discontinue • If ≤5% weight loss after 12 weeks on maximum dose of 15 mg/95 mg qd, discontinue • To discontinue: taper dose over minimum 1 week, every other day dosing, to reduce risk of seizure • If moderate hepatic (C-P score 7-9) or moderate to severe renal impairment (CrCl <50 mL/min), max dose 7.5 mg/46 mg • May need to reduce dosage of insulin or oral hypoglycemics	disturbances, insomnia (at higher doses) • Potential for metabolic acidosis and kidney stones from renal bicarbonate loss (topiramate) • Teratogenic (increased risk of oral cleft defects) (topiramate)	hepatic impairment, glaucoma • Women of childbearing potential: negative pregnancy test prior to/during treatment and 2 forms of contraception required • Monitor for increased heart rate, suicidal behavior and ideation, glaucoma, mood or sleep disorders, metabolic acidosis, elevated creatinine • Caution with CNS depressants, non-potassium sparing diruetics • DEA schedule C-IV, low abuse potential of phentermine as amphetamine derivative
Bupropion-naltrexone • Opioid antagonist + aminoketone antidepressant (POMC neuron activator) • BMI ≥30 kg/m^2, or BMI ≥27 kg/m^2 with ≥1	• Week 1: 8 mg naltrexone / 90 mg bupropion qd in am • Week 2: 8 mg/90 mg in am and pm • Week 3: 2x 8 mg/90 mg in am, 1x in pm • Week 4 and beyond: 2x in am, 2x in pm • Do not take with high-fat meal • In mod to severe renal impairment, max dose 1 tablet	• Nausea, constipation, headache, vomiting, insomnia, dry mouth, dizziness, diarrhea, elevated heart rate or blood pressure • Siezures in those with a history of these • Renders narcotics ineffective	• Contraindicated in pregnancy, uncontrolled HTN, chronic opioid use, seizure disorders, anorexia or bulimia, MAOI use, using other products with bupropion, abrupt withdrawal of alcohol, benzos, or antiepileptics • If patient in smoking cessation, caution re: neuropsychiatric events

weight-related comorbidity	2x daily; not recommended in ESRD • In hepatic impairment, max dose is 1 tab daily. • May need to reduce dosage of insulin or oral hypoglycemics		• Monitor for suicidal ideation or behavior, BP and HR, hepatotoxicity, glaucoma, hypoglycemia in patients taking antidiabetics • May increase effects of SSRIs, TCAs, antipsychotics, beta-blockers, antiarrhythmics • May decrease effects of digoxin • Efficacy of B-N may be reduced by CYP2B6 inducers (e.g., ritonavir, lopinavir, efavirenz, phenobarbital) • Concentration of B-N may be increased by CYP2B6 inhibitors (e.g., ticlopidine, clopidogrel) • Consider avoiding in patients using drugs to lower seizure threshold, dopaminergic drugs, or in patients taking drug tests for amphetamines

Notes: Weight-related comorbidities include hypertension, dyslipidemia, type 2 diabetes; serotoninergic agents include SSRIs, SNRIs, MAOIs, triptans, bupropion, tramadol, TCAs, lithium, dextromethorphan, St. John's Wort; orlistat 60 mg (Alli) available OTC

Figure 1. Meta-analysis of weight loss medications versus placebo (from Khera et al., 2016)

Meta-analysis of weight loss medications versus placebo[1]

Medication	Dose	No. of trials	No. of patients	>5% Weight loss			>10% Weight loss		
				OR	95% CI	NNT	OR	95% CI	NNT
Phentermine-topiramate	15 mg/92 mg daily	2	2,956	9.1	7.7–10.8	3	11.4	9.1–14.1	3
Liraglutide	3 mg SQ daily	3	4,424	5.1	4.1–6.4	3	4.4	3.6–5.3	5
Naltrexone-bupropion	32 mg/360 mg 2× daily	4	3,363	3.9	2.9–5.2	4	4.1	2.8–6.1	5
Lorcaserin	10 mg 2× daily	3	6,638	3.1	2.5–3.8	5	3.2	2.5–4.0	8
Orlistat	120 mg 3× daily	16	10,009	2.7	2.4–3.1	5	—	—	—
Orlistat	120 mg 3× daily	14	9,108	—	—	—	2.1	2.1–2.8	7

CI=confidence interval; NNT=number needed to treat; OR=odds ratio; SQ=subcutaneously.

Surgical Questions:

- Question #8: What are the harms and benefits of surgical procedures (metabolic and bariatric procedures such as roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, sleeve gastrectomy, biliopancreatic diversion with duodenal switch) to treat obesity, weight-related complications?

- Question #9: What are the harms and benefits of endoscopic procedures (space-occupying devices, gastric capacity reduction methods, endoluminal devices, endoluminal ablation) to treat obesity and weight-related complications?

- Question #10: What are the thresholds for considering surgical or endoscopic approaches to weight loss and management of obesity-related comorbidities?

- Question #11: What are the long-term outcomes of bariatric and metabolic interventions in children and young people with obesity?

General consensus from literature and external guidelines

Adults:

- The evidence base for recommending bariatric surgery for patients with BMI >/=40 kg/m2 without coexisting medical problems demonstrated benefit for: mortality, weight loss, diabetes remission; improved beta-cell function; and improved pulmonary function.
- Currently, the WHO classification scheme for obesity, based on BMI, determines diagnostic and therapeutic management. However, BMI is confounded by ethnic differences and body composition, and future improved risk stratification strategies may incorporate other anthropometric measurements, such as waist circumference or waist-to-hip ratio, co-morbidity and functional status assessments, and body composition technologies.
- Factors found to be associated with poor outcome include open procedures, male gender, older age, congestive heart failure, peripheral vascular disease, deep venous thrombosis, PE, obstructive sleep apnea, impaired functional status, and chronic kidney disease. Therefore, further studies are needed that utilize new clinical risk-stratification systems to optimize patient selection criteria and consequently, patient outcomes.
- Many recent studies demonstrate benefit for bariatric surgery patients with BMI <35kg/m2 in terms of weight loss, diabetes remission, and cardiovascular risk reduction.
- This evidence base is supported by additional, though not as strong, studies and post hoc analyses from diverse ethnicities on weight loss andT2D improvement. As a result, the United States Food and Drug Administration (FDA) approved the LAP-BAND for patients with a BMI of 30–34.9kg/m2 with an obesity-related co-morbidity.
- Moreover, the recent comparative effectiveness, randomized, non-blinded, single-center trial, with 34% of patients with BMI <35 kg/m2, represents a highly relevant study, even though it cannot yet be generalizable. A companion paper by Mingroneetal. Randomized patients with BMI >/=35 kg/m2 and does not apply to this CPG recommendation. Future, well- designed clinical trials that incorporate longer follow-up periods with demonstration of safety

in the surgical group, relevant CVD outcomes, and an intensive medical therapy comparator group associated with weight loss, will clarify this CPG recommendation for patients with BMI o35 kg/m2.

- Endoscopic procedures can be used in patients with severe obesity as a bridge to traditional bariatric surgery. They also can be used as a bridge to allow unrelated interventions that are unable to be performed because of weight limits (ie, orthopedic surgery, organ transplantation).
- Scientific evidence demonstrating the high propensity of severely obese adolescents to become severely obese adults and the greater associated risk among adults with "juvenile-onset" obesity (i.e. obese adults who become obese during childhood; approximately 25%) combined with evidence demonstrating improvement in obesity-related co-morbid disease after weight loss induced by bariatric surgery support the concept of "early" intervention in carefully selected adolescents patients.
- Although current evidence is not sufficiently robust to allow a precise discrimination or recommendation among specific bariatric procedures, an increasing body of data demonstrating evidence of safety and efficacy exists for two of the more commonly performed bariatric procedures for this age group (i.e. Roux-en-Y gastric bypass [RYGB] and adjustable gastric band [AGB].

Question #8: What are the harms and benefits of surgical procedures (metabolic and bariatric procedures such as roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, sleeve gastrectomy, biliopancreatic diversion with duodenal switch) to treat obesity, weight-related complications?

Guideline Recommendations:

ASMBS Guidelines/Statements – Part 2 of 2: scientific statement from the American Society for Metabolic and Bariatric Surgery (ASMBS), the National Lipid Association (NLA), and Obesity Medicine Association (OMA), 2016

Table 1
Bariatric procedure effects on hormones affecting nutrient metabolism and lipid blood levels.

Gut hormones (most are peptide hormones)	Description	Lipid effects of bariatric procedures	References
Stomach			
Ghrelin	Stomach ghrelin (name is derived from growth hormone releasing peptide) stimulates pituitary growth hormone release, increases gastric motility, and acts on the feeding center of the hypothalamus to stimulate hunger. Ghrelin may have direct cardiovascular effects, such as coronary artery constriction, and yet protective effects against myocardial ischemia, decreased peripheral vascular resistance with vasodilation, increased cardiac output, decreased blood pressure, increased cardiac contractility, increased exercise capacity, and inhibition of apoptosis of endothelial cells and cardiomyocytes. Conversely, stimulation of eating behavior with ghrelin may increase cardiovascular disease risk factors such as obesity, adiposopathy, and increased risk for insulin resistance, hyperglycemia, nonalcoholic fatty liver disease, high blood pressure, and mixed dyslipidemia. Ghrelin may be influenced by the gut microbiome (see Part 1 of this Scientific Statement) and is among the few gut hormones that is orexigenic. As opposed to most other gut hormones, ghrelin increases with fasting and decreases with eating.	Bariatric surgery has variable effects on ghrelin, depending on the type of surgery, timing of postoperative ghrelin measurements, and the size of the remaining remnant gastric pouch. In general, gastric bypass and sleeve gastrectomy decrease ghrelin levels, which may decrease food intake, improve insulin sensitivity, reduce the risk of nonalcoholic fatty liver disease, and potentially improve dyslipidemia.	[3,11–17]
Gastrin	Gastrin is structurally similar to cholecystokinin and stimulates stomach exocrine cells to secrete hydrochloric acid and pepsinogen (which is activated to pepsin by the hydrochloric acid). Pepsin assists with protein digestion. Gastrin increases with eating.	Bariatric surgery has variable effect on postoperative gastrin levels, depending on the type of surgery. Sleeve gastrectomy appears to most consistently increase gastrin levels. It is unclear that alterations in gastrin secretion affect lipid levels.	[12,13,15]
Pancreas			
Insulin	Insulin binds to insulin receptors of tissues such as adipose tissue and skeletal muscle, stimulates cellular glucose uptake, reduces glucose blood levels, increases lipoprotein lipase activity, and increases lipogenesis. Insulin increases with eating and, when not associated with hypoglycemia, increased central nervous system insulin may promote satiety.	Bariatric procedures may improve postoperative β-cell function, insulin release, and insulin sensitivity, especially procedures such as gastric bypass and sleeve gastrectomy. Improvement in glucose metabolism via enhanced insulin sensitivity may improve mixed dyslipidemia.	[3,11,12,20]
Glucagon	Glucagon is produced by pancreatic α-cells and converts stored liver glycogen to glucose, thus raising glucose levels. Glucagon may increase adipose tissue lipolysis. Glucagon increases with eating and may promote satiety.	Bariatric surgery (e.g., gastric bypass) may result in a transient rise in postoperative glucagon. To the extent that increased postoperative glucagon may promote satiety, this could conceivably help account for improved dyslipidemia with bariatric surgery.	[19,21–24]
Pancreatic polypeptide	Pancreatic polypeptide inhibits pancreatic exocrine secretion. It increases with eating and may promote satiety.	Bariatric surgery has variable reported effects on postoperative pancreatic polypeptide. To the extent that increased postoperative pancreatic polypeptide may promote satiety, this could conceivably help account for improved mixed dyslipidemia with bariatric surgery.	[12,23,25–27]
Amylin	Amylin is co-secreted with insulin from the pancreatic β-cells, delays gastric emptying, and inhibits glucagon release. Increased amylin levels are associated with hypertriglyceridemia. Amylin increases with eating and may promote satiety.	Bariatric surgery may decrease postoperative amylin levels, with gastric bypass more so than gastric banding. Although unclear that reducing amylin levels per se reduce triglyceride levels, weight reduction reduces both amylin and triglyceride levels.	[28–30]

Table 1
Continued.

Gut hormones (most are peptide hormones)	Description	Lipid effects of bariatric procedures	References
Duodenum			
Somatostatin	Somatostatin is produced in the pyloric antrum and duodenum and inhibits growth hormone secretion. Somatostatin also inhibits the release of gastrin and hydrochloric acid from the stomach, inhibits the release of secretin and cholecystokinin from the duodenum, inhibits insulin and glucagon from the pancreas, and decreases gut motility. Somatostatin may decrease hepatic bile excretion, which may affect lipid levels (see Part 1 of this Scientific Statement). Somatostatin increases with eating and may promote satiety.	Bariatric surgery may not change postoperative somatostatin levels; lipid levels are unlikely altered by this mechanism.	[12,18,19]
Cholecystokinin (CCK)	CCK stimulates the gallbladder to contract and force bile into the intestine, stimulates pancreatic digestive enzyme secretion, inhibits gastric acid secretion, and slows gastric emptying. CCK increases with eating and may promote satiety.	Although the data is inconsistent, bariatric surgery may increase postoperative CCK levels, especially after a meal stimulus. The potential effect of increased CCK on lipid levels is mixed.[7]	[12,13,15,31]
Secretin	Secretin stimulates pancreatic bicarbonate secretion to neutralize acidity of gastric contents, stimulates hepatic bile secretion, inhibits gastric secretion, and increases lipolysis in adipocytes. Secretin increases with eating.	The effect of bariatric surgery on postoperative secretin is unclear and is likely dependent on the type of bariatric surgery.	[12,32]
Gastric inhibitory peptide, also known as glucose-dependent insulinotropic peptide (GIP)	GIP is an incretin that increases pancreatic insulin secretion, increases lipoprotein lipase in adipose tissue, increases fatty acid uptake by adipocytes, inhibits gastric secretion, and delays intestinal motility. GIP increases with eating.	Preoperatively, GIP levels may be increased in patients with obesity and diabetes mellitus. To the extent that increased GIP increases insulin and lipoprotein lipase, and facilitates fatty acid uptake by adipocytes, then increased GIP would improve dyslipidemia. Although reports are variable, bariatric surgery (e.g., gastric bypass) may reduce GIP levels, which may reflect improvements in glucose and lipid metabolism by other mechanisms.	[12,33,34]
Motilin	Motilin stimulates gallbladder contraction, promotes enzyme secretion from the stomach and pancreas, and stimulates gastric motility. Motilin may increase adipocyte proliferation, differentiation, fatty acid storage, and lipogenesis. Motilin is released during fasting and after eating and may serve to clear the stomach an intestine from undigested material. Some reports suggest motilin may promote satiety.	Bariatric surgery (jejunoileal bypass) may increase postoperative basal and postprandial motilin secretion. Increased energy storage in adipocytes may improve mixed dyslipidemia.	[35–38]
Ileum and large intestine			
Fibroblast growth factor (FGF19)	FGF19 is expressed upon activation of farnesoid X receptors (FXR) by intestinal bile acids. FGF19 reduces the activity of cytochrome P7 A1 (CYP7 A1), the rate-limiting step of bile acid synthesis, and thus decreases hepatic bile acid production. FGF19 also increases insulin sensitivity, inhibits glucose production, stimulates hepatic glycogen synthesis, may increase fatty acid β-oxidation, and may decrease lipid blood levels. FGF19 increases with eating, and may promote satiety.	Bariatric surgery (e.g., gastric bypass) may alter postoperative bile acid metabolism, increase bile acid blood levels, and increase FGF19. In addition to the improvement in lipid levels with favorable bile acid metabolism (see Part 1 of this Scientific Statement), FGF19 mediated satiety may improve dyslipidemia.	[39–41]
Glucagon like peptide-1 (GLP-1)	Incretin GLP-1 is produced by L-cells located in the ileum and large intestine and stimulates pancreatic insulin secretion, inhibits pancreatic glucagon secretion, inhibits gastric secretion,	Bariatric surgery may increase postoperative GLP-1 activity, especially after a meal stimulus. GLP-1 agonists improve glucose metabolism, decrease secretion of apolipoprotein B48	[11,12,19,25,29,42]

Table 1
Continued.

Gut hormones (most are peptide hormones)	Description	Lipid effects of bariatric procedures	References
	and inhibits gastric emptying. GLP-1 may be influenced by the gut microbiome (see Part 1 of this Scientific Review). GPL-1 may also mediate secretion of apolipoprotein B48 chylomicron secretion from the intestine. GLP-1 increases after meals and may promote satiety.	chylomicron secretion from the intestine, and promote satiety, all of which may contribute to their reduction in low-density lipoprotein cholesterol and triglycerides; high-density lipoprotein cholesterol may not be significantly changed.	
Glucagon like peptide-2 (GLP-2)	Incretin GLP-2 is produced by L-cells and inhibits gastric secretion, promotes intestinal mucosal growth, and promotes tissue repair. GPL-2 analogues may therapeutically improve the dependence on parenteral nutrition or intravenous fluid among those with short bowl syndrome. GLP-2 enhances intestinal digestive and absorptive capacities, including increases in chylomicron release into the circulation. GLP-2 increases after meals.	Bariatric surgery (e.g., gastric bypass) may increase postoperative GLP-2 levels, especially after a meal stimulus. Although administration of GLP-2 may increase postprandial triglyceride-rich lipoproteins in the form of stored apoB-48 chylomicrons, this effect is transient and unlikely a long-term effect found with bariatric surgery. To the extent GLP-2 promotes satiety and facilitates weight loss, this would be expected to improve dyslipidemia.	[12,15,43–45]
Oxyntomodulin	Oxyntomodulin is produced by L-cells and inhibits gastric acid production, reduces gastric motility, and may improve glucose metabolism. Oxyntomodulin increases with eating and may promote satiety.	Bariatric surgery (e.g., gastric bypass) may increase postnutrient ingestion oxyntomodulin levels. Improved glucose metabolism and promotion of satiety may facilitate decrease triglyceride levels.	[12,46,47]
Peptide YY 3-36 (PYY)	PYY is produced by L-cells and inhibits gallbladder and pancreatic secretion and reduces gut motility. PYY may be influenced by the gut microbiome (see Part 1 of this Scientific Review). PYY may also reduce the expression of intestinal Niemann-Pick C1-Like-1 (NPC1 L1) resulting in reduced intestinal cell cholesterol absorption. PYY increases with eating, and may promote satiety.	Although the data are not always consistent, bariatric surgery (e.g., gastric bypass) may increase postoperative PYY, especially after a meal stimulus. PYY-mediated inhibition of intestinal cholesterol absorption would be expected to reduce cholesterol levels. This is similar to ezetimibe, which also inhibits cholesterol uptake through the NPC1 L1 intestinal receptor. Promotion of satiety would also be expected to improve dyslipidemia.	[11,12,15,25,29,48,49]
Throughout gastrointestinal tract			
Neuropeptide Y (NPY)	NPY is produced in the central and peripheral nervous system, including the sympathetic nerves of the gut (co-released with norepinephrine). NPY is involved with inflammatory processes, pain, emotion, mood, cognition, and stress resilience, as well as energy homeostasis and hunger. NPY may increase hepatic VLDL secretion from the liver. NPY may be influenced by the gut microbiome (see Part 1 of this Scientific Review). NPY is orexigenic and increases with fasting and decreases with eating.	Bariatric surgery may not change postoperative basal NPY levels, but gastric bypass may reduce postprandial NPY secretion. Reducing NPY activity, and thus diminishing VLDL secretion and NPY's orexigenic effects, would be expected to improve mixed dyslipidemia.	[33,50–53]

VLDL = very low density lipoprotein.
*Although not confirmed, some older reports suggest glucagon may modestly improve lipid levels.
†An increase in bile secretion may improve cholesterol and triglyceride absorption from the intestine, which may promote hyperlipidemia. Decreased caloric intake from increased satiety may decrease cholesterol and triglyceride intake, thus decreasing hyperlipidemia.

The Diabetes Surgery Summit II Guidelines: a Disease-Based Clinical Recommendation, 2016

- Introduce metabolic surgery in the armamentarium to treat T2D for patients whose BMI is > 35 kg/m2.

- Adding this potent therapeutic option to treat patients with type I obesity and uncontrolled T2D patients may lead to better glycemic control in these patients, eventually decreasing long-term micro- and macrovascular complications, while eventuating a return on investment compared with best medical treatment

Guideline Systematic Reviews

Source, Year	Summary of Findings
American Society for Metabolic and Bariatric Surgical Weight Loss, 2016	**Harms of WLS include micronutrient deficiencies:** Thiamin: Prevalence of TD post-WLS ranges from 1% to 49% and varies by type of WLS and post-WLS time frame. Vitamin B12: Prevalence of B12 deficiency post-WLS at 2–5 yr is 20% in RYGB and 4–20% in SG. Zinc Prevalence of zinc deficiency occurs in: up to 70% post-BPD/DS 40% post-RYGB 19% post-SG 34% post-AGB Folate: Prevalence of folate deficiency is reported in up to 65% patients post-WLS. Iron: Prevalence of iron deficiency is reported to occur in post-WLS patients from 3 mo to10 yr: AGB 14% SG 18% RYGB 20–55% BPD 13–62% DS 8–50% Vitamin D: Prevalence of vitamin D deficiency is reported to occur in up to 100% of post-WLS patients. Vitamins A, E, K Prevalence of vitamin A deficiency is reported to occur in up to 70%of patients with RYGB and BPD/DS within 4 years post-WLS. Deficiencies of vitamins E and K are uncommon after WLS.

	Copper: Prevalence of copper deficiency is reported to be as high as 90% of patients post-BPD/DS and 10–20% post-RYGB. Only 1 case report noted for post-SG copper deficiency; no data reported for post-AGB patients.
HERC, 2016	**Benefits:** • Reduction in all-cause mortality (OR 0.48; 95% CL 0.35-064). Crude event rates 3.6% with surgery and 11.4% without surgery. NNT 13. (low certainty based on consistent but indirect observational studies) • Reduction in major adverse CV events. Odds ratio: 0.54 (95% CI 0.41 to 0.70) Crude event rates 2.4% with surgery and 4.0% without surgery. Number needed to treat = 62. (low certainty based on consistent but indirect observational studies) • Type 2 DM remission/resolution. Odds ratio: 3.6 to 52.4 (favoring surgery). Number needed to treat: 1 to 5. (moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects) • Hypertension remission/resolution. Odds ratio: 2.99 to 3.12 (favoring surgery). Number needed to treat: 4. (moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects) • Change in BMI. Mean difference at 1 year: -5.5 to 33.35 kg/m2 (favoring surgery). Pooled mean difference: -7.4 kg/m2 (favoring surgery). (moderate certainty based on a mix of RCTs and observational studies with consistent but imprecise effects) Harms of bariatric surgery include a perioperative mortality rate that probably ranges from 0.10 to 2%, and an overall complication rate that is probably on the order of 8 to 25%. The estimated reoperation rate is likely between 2 and 13%. There is limited evidence from a single study that comorbid congestive heart failure, cardiac arrhythmias, and peripheral vascular disease are associated with higher rates of complications after bariatric surgery. **Harms** Mortality < 30 days post op 0.08% in RTCs 0.22% in OSs Mortality in > 30 days or not specified 0.31% in RCTs 0.35% in OSs 1% for bypass 0.2% for banding BPD: 0%-2.9%, 1.4% LAGB: 0%-2.0%, 0.15% RYGB: 0%-4.3%, 1.94% VSG: 0%-3.9%, 0.07 Complication rate 17% in RCTs 10% in OSs

	BPD: 8%-83%, 26.9% LAGB: 0%-53%, 10.1% RYGB: 0%-78%, 9.2% VSG: 0%- 80%, 8.8% Reoperation rate 7% in RCTs 6% in OSs 2%-13% BPD: 0%-30%, 3.6% LAGB: 0%-44%, 7.4% RYGB: 0%-22%, 5.8% Serious adverse event rate 0-37% in surgical groups 0-25% in nonsurgical groups These are taken directly from Systematic Reviews so perhaps those articles and this info should be included in the primary literature instead of as a part of this guideline?
NICE, 2016	• Surgical intervention is more clinically effective than non-surgical management at: ○ Increasing percentage weight loss from baseline (5 studies, n=417; very low quality) ○ Reduction in use of diabetic medication (4 studies, n=306; moderate quality) ○ Increasing remission of diabetes (6 studies, n=503; very low quality) ○ Improving glycaemic control (5 studies, n=370; low quality) ○ Reducing weight as measured by BMI (4 studies, n=303; low quality) or kg (5 studies, n=398; low quality) • These changes were considered to be clinically important differences. ○ Mortality rates did not appear to differ between groups (6 studies, n=503; very low quality). ○ One study reported improvement in quality of life across 5 domains in the gastric bypass procedure and 2 domains in the gastric sleeve procedure using a RAND 36 questionnaire. Economic • Two cost-utility analyses found that LAGB was cost effective compared to non-surgical management for treating obese patients with early onset type 2 diabetes (ICERs: £3602 per QALY gained, £1634 per QALY gained). These studies were assessed as directly applicable with potentially serious limitations. ○ One cost-utility analysis found that LAGB was dominant (less costly and more effective) compared to non-surgical management for treating obesity in obese patients with early onset type 2 diabetes. This analysis was assessed as partially applicable with potentially serious limitations. ○ One cost-utility analysis found that gastric bypass was cost effective compared to non-surgical management for treating obese patients with early onset type 2 diabetes (ICER: £4472 per QALY gained). This study was assessed as partially applicable with potentially serious limitations.

Primary Literature:

Outcome: Cardiac Structure and Function				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Aggarwal, 2016	Systematic Review **Sample:** 40 studies met inclusion criteria with a pooled data set of 1486 patients. 26 non-randomized prospective observational studies and 14 were retrospective cohort studies. **Inclusion and Exclusion Criteria:** All studies reporting echocardiographic or magnetic resonance cardiac parameters of structure and function were included. Studies were excluded from analysis if inconsistency of data did not allow valid extraction and studies did not report both pre-operative and post-operative data. A minimum follow-up of 3 months post-surgery was required for inclusion, and quality scoring was performed utilizing the Newcastle-Ottawa scale.	Bariatric surgery is associated with significant improvements in the weighted incidence of a number of cardiac indices including a decrease in left ventricular mass index (11.2 %, 95 % confidence intervals (CI) 8.2–14.1 %), left ventricular end-diastolic volume (13.28 ml, 95 % CI 5.22–21.34 ml), and left atrium diameter (1.967 mm, 95 % CI 0.980–2.954). There were beneficial increases in left ventricular ejection fraction (1.198 %, 95 %CI −0.050–2.347) and E/A ratio (0.189 %, 95 %CI −0.113–0.265).	None	Low
Zhou, 2016	Systematic Review **Sample:** 11 RCTs, 4 non-randomized trials, and 17 cohort studies. **Inclusion Criteria**: An eligible study should meet all of the following criteria: enrolled patients aged 18 years	The randomized evidence suggested substantial uncertainty regarding the effects on all-cause mortality (0/382 vs. 1/287; 7 studies), cancer (OR 0.77, 95 % CI 0.22 to 2.71; 4 studies), and cardiovascular events (no data). The pooled adjusted estimates from non-randomized studies suggested that, compared to the control, the surgical group had lower risk of all-cause	Quality of Studies was not appraised	Moderate

	or older who had BMI greater than 30 kg/m2; compared surgical strategies versus non-surgical treatment; reported data on all-cause mortality, cancer of any type, or cardiovascular events; followed up patients for at least 1 year; explicitly reported outcome data; and was a randomized controlled trial (RCT) or a non-randomized controlled study (including non-randomized controlled trial [non-RCT], cohort study, and case-control study).	mortality (OR 0.55, 95 % CI 0.46 to 0.65; 10 studies), cancer (OR 0.74, 95 % CI 0.65 to 0.85; 2 studies), and cardiovascular events (MI: OR 0.71, 95 % CI 0.54 to 0.94; stroke: OR 0.66, 95 % CI 0.49 to 0.89; and their composite: OR 0.67, 95 % CI 0.54 to 0.83; 1 study).		

Outcome: Type 1 Diabetes

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Ashrafian, 2016	Systematic Review **Sample:** 27 studies, 142 patients **Inclusion and Exclusion Criteria:** All studies reporting pre-operative and post-operative liver biochemistry or liver histology (or both) were included. Studies were excluded for data inconsistency or overlapping data from other studies (for example, two studies used data from the same patients.	Bariatric surgery in obese T1DM patients is associated with a significant reduction in insulin requirement (−48.95 units, 95 % CI of −56.27, −41.62), insulin requirement per kilogram (−0.391, 95 % CI of −0.51, −0.27), HbA1c (−0.933, 95 % CI of −1.604, −0.262) and BMI (−11.04 kg/m2, 95 % CI of −13.49, −8.59). Surgery is also associated with a statistically significant reduction in systolic and diastolic blood pressure and a significant beneficial rise in HDL. Heterogeneity in these results was high, and study quality was low overall.	None	Low
Chow, 2016	Systematic Review **Sample:**	There was a marked reduction in BMI postoperatively at 12 months and at study endpoint to 29.55 ± 1.76 kg/m^2 ($P < 0.00001$)	Quality of studies was not appraised	Moderate

	13 studies, 86 subjects **Inclusion and Exclusion Criteria:** Inclusion criteria included human adult subjects with BMI ≥35 kg/m^2 and a confirmed diagnosis of type 1 diabetes who underwent a bariatric surgical procedure.	and 30.63 ± 2.09 kg/m^2 ($P < 0.00001$), respectively. Preoperative weighted mean total daily insulin requirement was 98 ± 26 IU/d, which decreased significantly to 36 ± 15 IU/d ($P < 0.00001$) and 42 ± 11 IU/d ($P < 0.00001$) at 12 months and at study endpoint, respectively. An improvement in *HbA1c* was also seen from 8.46 ± 0.78% preoperatively to 7.95 ± 0.55% ($P = 0.01$) and 8.13 ± 0.86% ($P = 0.03$) at 12 months and at study endpoint, respectively.		

Population: Type 2 Diabetes				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Wu, 2016	Systematic Review **Sample:** 8 RCTs, 619 T2DM patients **Inclusion Criteria:** Studies looking at bariatric surgery techniques included Roux-en-Y gastric bypass, sleeve gastrectomy, laparoscopic adjustable gastric banding, and biliopancreatic diversion in T2DM patient populations	Compared with non-surgical treatment group, bariatric surgery group was associated with higher rate T2DM remission (RR = 5.76, 95%CI:3.15-10.55, $P < 0.00001$), more reduction HbA1C (MD = 1.29, 95%CI: -1.70 to -0.87, $P < 0.00001$), more decrease fasting plasma glucose (MD = -36.38, 95%CI: -51.76 to -21.01, $P < 0.00001$), greater loss body weight (MD = -16.93, 95%CI: 19.78 to -14.08, $P < 0.00001$), more reduction body mass index (MD = -5.80, 95%CI: -6.95 to -4.64, $P < 0.00001$), more decrease triglyceride concentrations (MD = -51.27, 95%CI: -74.13 to -28.41, $P < 0.0001$), and higher increase density lipoprotein cholesterol (MD = 9.10, 95%CI: 7.99 to 10.21; $P < 0.00001$).	None	Low

		But total and low density lipoprotein cholesterol were no significant changes.		
Yan, 2016	Systematic Review **Sample:** 6 RCTs, 410 T2DM patients **Inclusion Criteria**: RCTs evaluated RYGB surgery in patients with T2DM and investigated medical treatment as comparator were included in the meta-analysis if each treatment group included patients with BMI of 30 kg/m2 or more and the mean BMI of each treatment group was 30 kg/m2 or more. The RYGB procedure performed in order to improve metabolic conditions in patients with T2DM and obesity regardless of laparoscopic or open way. The rate of diabetes remission, HbA1c, FPG, BMI, waist circumference, serum lipid level, blood pressure, medication use, and adverse events were reported. Case reports, prospective studies, letters, comments, reviews, and animal studies were excluded.	RYGB surgery was associated with a higher T2DM remission rate (OR: 76.37, 95% CI: 20.70–281.73, P<0.001) and serum level of high-density lipoprotein cholesterol (MD: 0.24 mmol/L, 95% CI 0.18–0.30 mmol/L, P<0.001) than medical treatment alone. HbA1c (MD: –1.25%, 95% CI: 1.88% to –0.63%, P<0.001), BMI (MD: –6.54 kg/m2, 95% CI: –9.28 to –3.80 kg/m2, P<0.001), waist circumference (MD: –15.60 cm, 95% CI: –18.21 to –13.00 cm, P<0.001), triglyceride (MD: –0.87 mmol/L, 95% CI: –1.17 to –0.57 mmol/L, P<0.001), low-density lipoprotein cholesterol (MD: –0.32 mmol/L, 95% CI: –0.62 to –0.02 mmol/L, P=0.04), systolic blood pressure (MD: –2.83 mm Hg, 95% CI: –4.88 to –0.78 mm Hg, P<0.01) were lower after RYGB surgery. However, FPG (MD: –1.58 mmol/L, 95% CI: –3.58 to 0.41 mmol/L, P=0.12), total cholesterol (MD: –0.40 mmol/L, 95% CI: –0.92 to 0.12 mmol/L, P¼0.13), and diastolic blood pressure (MD: 0.28mmHg, 95% CI: –1.89 to 2.45mmHg, P¼0.80) were not significantly different between the 2 treatment groups.	None	Low
Zhou, 2016	Systematic Review **Sample:** 29 studies, 18,172 T2DM patients	Analyses of changes before and after surgeries suggested a significantly lower proportion of albuminuria (difference –21.2%, 95% confidence interval [CI] –28.8% to –13.5%), 24-hour urine album in excretion rate (weighted mean difference –48.78 mg/24hr, 95%CI –75.32	None	Moderate

	Inclusion Criteria: Randomized controlled trials (RCTs), non- randomized controlled trials, cohort studies, and case- control studies comparing bariatric surgery with nonsurgical treatment (controlled studies), as well as single-arm before-and-after studies (i.e., uncontrolled longitudinal studies) that enrolled patients with T2D receiving bariatric surgery	to –22.24) and urine albumin-to- creatinine ratio (uACR) (weighted mean difference –16.10 mg/g, 95%CI –22.26 to –9.94) after surgery. Compared with nonsurgical treatment, bariatric surgery was associated with a statistically lower level of uACR and lower risk of new-onset albuminuria (odds ratio .18, 95% CI .03–.99 from randomized controlled trials). The effects on glomerular filtration rate, serum creatinine, creatinine clearance, and risk of end-stage renal disease were not statistically significant.		
Switzer, 2016	Systematic Review **Sample:** 11 studies, 1354 subjects **Inclusion Criteria:** All human randomized controlled trials, non-randomized comparison students, case series, abstracts and those published in languages other than English. **Exclusion Criteria:** Case reports, expert's opinions and reviews	T2DM patients (n = 402) encompassed 29.7 % of patients. Diabetes prevalence decreased post-operatively to 20.5 % at 5 years, with diabetes resolution occurring in 60.8 % of patients. Mean plasma glucose levels and haemoglobin A1c values fell from 170.3 to 112.0 mg/dL and 8.3 to 6.7 % respectively at the 5-year mark.	Quality of studies was not appraised	Moderate

Outcome: Quality of Life				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Kroes, 2016	Systematic Review	Although study design and outcomes were heterogeneous, improvements in HRQoL were	Inconsistency on how	Moderate

	Sample: 32 studies **Inclusion and Exclusion Criteria:** Table 1. Inclusion and exclusion criteria. BMI: body mass index; HRQoL: quality of life.	generally observed with weight loss. Bariatric surgery studies provided the most evidence (12 publications) and demonstrated dramatic (_20%) weight loss and associated HRQoL improvements. Sustained weight loss was associated with maintenance of HRQoL improvements out to 6 years in some studies. In lifestyle and pharmaceutical intervention studies showing weight loss of 5%–10%, some aspects of HRQoL improved, although the association with weight was not typically explored. Across the 20 publications, physical versus mental HRQoL improvements were more commonly statistically significant. In long-term bariatric surgery studies weight loss was associated with improvements in HRQoL using the SF-36 and weight-specific HRQoL using the IWQOL-Lite, with greater improvements typically observed for physical, rather than mental components of HRQoL.	outcomes were measured	

	Inclusion criteria	Exclusion criteria
HRQoL systematic review criteria (subset of a larger systematic review)		
Participants	Adults (≥18 years) who are overweight or have obesity (any definition)	Studies with <90% of study population meeting the inclusion criteria (mixed populations) were excluded, unless results for such populations were reported separately
Interventions and comparators	Not restricted	
Outcomes	HRQoL impact associated with weight/BMI change	Studies reporting weight/BMI change without explicitly quantifying the weight/BMI change
Study design	Any study reporting original HRQoL data (i.e. not from other sources) in relation to weight change	Reviews, letters, editorials and case studies (i.e. defined by the paper as case series or case study)
Country	Only US studies	Studies conducted in multiple countries not reporting results separately for a US population
Publication date	2008 onwards	–
Study duration/follow-up	Only studies with follow-up HRQoL results of ≥1 year	–
Additional criteria for inclusion in the manuscript		
Data	Included sufficient HRQoL data	Insufficient data (e.g. lack of methodological details)
Comorbidities	If comorbidities were present they had to be specifically described as obesity-related or were known to be commonly related to obesity	Obesity not described as the cause of the comorbidity
Instrument	Data presented for the two most commonly used instruments in the identified publications (SF-36 and IWQOL-Lite)	–

Outcome: Performance

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Li, 2016	Systematic Review **Sample:** 62 studies, 18449 patients. 10498 underwent LRYGB and 7951 underwent LSG	**Percent Excess Weight loss (%EWL)** • Patients receiving LRYGB had a significantly higher %EWL compared with those receiving LSG (weighted mean difference= 7.24, 95 % CI 3.81–10.67, P<0.0001)	Quality of Studies was not appraised	Low

	Inclusion criteria: (1) randomized controlled trials, controlled clinical trials, and cohort studies or retrospective observational studies regardless of publication date; (2) surgical treatment with LRYGB or LSG; and (3) adult populations only (>18 years of age) and BMI ≥35 kg/m2. **Exclusion criteria:** Studies with the following conditions were excluded: (1) non-human studies, (2) non-surgical interventions, (3) letters and comments, and (4) unreliable design or obvious statistical errors as evaluated by two independent investigators.	**Comorbidities** • T2DM resolved more often after LRYGB than after LSG, but the difference was not significant (OR=1.27, 95 % CI 0.95–1.69, P=0.10). • Hypertension resolved significantly more often after LRYGB compared with LSG (OR=1.43, 95 % CI 1.15–1.77, P=0.001). • Dyslipidemia resolved significantly more often after LRYGB compared with LSG (OR=2.40, 95 % CI 1.89–3.05, P<0.00001). • GERD resolved significantly more often after LRYGB compared with LSG (OR=8.99, 95 % CI 4.77–16.95, P<0.00001). • Arthritis resolved significantly more often after LRYGB compared with after LSG (OR=2.28, 95 % CI 1.23–4.22, P=0.009) • Apnea resolved more often after LRYGB than after LSG, but the difference was not significant (OR=2.25, 95 % CI 0.96–5.28, P=0.06)		
Ahluwalia, 2016	Retrospective Study **Sample**: 139 patients. 42 underwent laparoscopic adjustable gastric banded plication (LAGBP) and 97 underwent laparoscopic sleeve gastrectomy **Inclusion and Exclusion Criteria:**	The operating time for LAGBP was significantly longer: 105.39±39 vs. 59±29.56 min. The postoperative hospital stay was not statistically different between the two procedures. The mean percent excess weight loss (%EWL) was significantly lower for LAGBP at 1 year but became insignificant at 2 years. Both groups had two postoperative complications, but the rate	Failure to adequately control confounding	Moderate

	The inclusion criterion for both groups was BMI between 30 and 35 with or without comorbidity. Patients with type 2 diabetes of recent onset (<5 years) and C-peptide >3 ng/ml were offered these restrictive surgeries.	was not statistically different. The comorbidity resolution data did not show any significant difference between the two groups.		

Outcome: Death

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Rausa, 2016	Systematic Review **Sample:** 17 studies **Inclusion and Exclusion Criteria:** studies including major surgical complications and the 30-day rate of mortality between laparoscopic and open Roux-en-Y gastric bypass (LRYGB and RYGB)	When looking at surgical techniques separately, a higher rate of mortality was observed for open surgery (death rate 0.82 %, 95 % CI = 0.49-1.23) compared to laparoscopic surgery (death rate 0.22 %, 95 % CI = 0.09-0.40). This difference resulted highly significant when the two techniques were formally compared ($p < 0.001$). The improving of surgery technique resulted in a mean rate of mortality reduction of 0.069 %. Laparoscopy represents the approach of choice for bariatric surgery. Contemporary reports of LRYGB show low mortality rates and progressive decline in postoperative complications.	Quality of studies was not appraised	Moderate

Outcome: Stone Formation

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Upala, 2016	Systematic Review **Sample:** 12 studies	There was significantly higher risk of stone formation after Roux-en-Y gastric bypass surgery with pooled relative risk = 1.79 (95% CI: 1.54–2.10). In the analysis of urine chemistry profiles, there was significantly higher calcium oxalate	Quality of studies not appraised	Moderate

	Inclusion Criteria: (1) published randomized, controlled trials or observational studies including cross-sectional, prospective cohort, retrospective cohort, and case-control studies assessing the effect of bariatric surgery and the change in urinary chemistry profiles or the risk of nephrolithiasis; (2) participants aged 18 years or older; (3) all or part of participants in the included studies underwent bariatric procedures that included RYGB, gastric banding, vertical banded gastroplasty, sleeve gastrectomy (SG), duodenal switch, or biliopancreatic diversion; (4) relative risks (RR), odds ratios (OR), hazard ratios (HR), standardized incidence ratios with 95% confidence intervals (CI) of the risk of nephrolithiasis or the values of urine chemistry profiles including brushite supersaturation (SS), uric acid SS, calcium oxalate (CaOx) SS, 24-hour measurement of urine calcium, oxalate, phosphorus, citrate, volume, and pH were provided; (5) participants who did not have bariatric surgery (control) or preoperative baseline data were used as reference groups.	supersaturation, lower citrate, and lower volume postoperatively compared with preoperatively. There was also higher urine oxalate in patients who had bariatric surgery compared with nonsurgery controls.		

Population: Elderly

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Wang, 2016	Systematic Review **Sample:** 11 studies	Old patients had a worse outcome in percentage of excess weight loss than the young ones (SMD −0.39, 95 % CI −0.55 to −0.24). No significant differences were recorded in resolution of co-morbidities: type 2 diabetes mellitus (OR 1.60, 95 % CI 0.84–3.05), hypertension (OR 1.05, 95 %	Quality of studies not appraised	Low

	Inclusion Criteria: Cohort studies that reported the effectiveness and safety of SG in the obese elderly patients and compared with the young ones.	CI 0.65–1.68), dyslipidemia (OR 1.38, 95 % CI 0.68–2.80), OSAS (OR 0.64, 95 % CI 0.30–1.34), or postoperative complications (OR 0.89, 95 % CI 0.51–1.55) between the elderly and the young who had undergone SG.		

Question #9: What are the harms and benefits of endoscopic procedures (space-occupying devices, gastric capacity reduction methods, endoluminal devices, endoluminal ablation) to treat obesity and weight-related complications?

Guideline Systematic Reviews

Source, Year	Summary of Findings
American Society for Metabolic and Bariatric Surgery position statement on intragastric balloon therapy, 2016	1. Level 1 data regarding the clinical utility, efficacy, and safety of intragastric balloon therapy for obesity are derived from randomized clinical studies. 2. Implantation of intragastric balloons can result in not able weight loss during treatment. A few studies, representing lower-level evidence, have suggested that the weight loss effect can be maintained after balloon retrieval for some finite time in to the future. 3. Although utilization of intragastric balloons results in notable weight loss, separating the effect of the balloon alone from those of supervised diet and lifestyle changes may be challenging. Of note, recent FDA pivotal trials demonstrated a benefit to balloon use compared with diet alone in their study populations. In general, any obesity treatment, including intragastric balloon therapy, would benefit from a multidisciplinary team that is skilled and experienced in providing in-person medical, nutritional, psychological, and exercise counseling. 4. The safety profiles for intragastric balloons indicate a safe intervention, with serious complications being rare. Early postoperative tolerance challenges can be significant but can be controlled with pharmacotherapy in the majority of patients, thereby minimizing voluntary balloon removals. These early symptoms should be discussed with the patient before the procedure. 5. Although therapy with prolonged balloon in situ time and the use of sequential treatments with multiple balloons have been studied, awareness and adherence to absolute and relative contraindications of use and timely removal optimize device safety. Based on current evidence, balloon therapy is FDA approved as an endoscopic, temporary (maximum 6 months) tool for the management of obesity. Further review will evaluate the impact of diet, lifestyle changes, and pharmacotherapy during and after balloon removal.

	6. The ability to perform appropriate follow-up is essential when intragastric balloons are used for weight loss to enhance their safety and avoid complications related to spontaneous deflation and bowel obstruction.
AGA Clinical Practice Update: Expert Review	*Best Practice Advice 1*: EBTs should be considered in patients with obesity who have been unsuccessful in losing or maintaining weight loss with lifestyle interventions. *Best Practice Advice 2*: EBTs can be used in patients with severe obesity as a bridge to traditional bariatric surgery. They also can be used as a bridge to allow unrelated interventions that are unable to be performed because of weight limits (i.e., orthopedic surgery, organ transplantation). *Best Practice Advice 3*: Clinicians should use EBTs as part of a structured weight loss program that includes dietary intervention, exercise therapy, and behavior modification, in both the active weight loss phase and the long-term maintenance phase. *Best Practice Advice 4*: Clinicians should screen all potential EBT candidates with a comprehensive evaluation for medical conditions, comorbidities, and psychosocial or behavioral patterns that contribute to their condition before enrolling patients in a weight loss program that includes EBTs. *Best Practice Advice 5*: Clinicians incorporating EBTs into their clinical practice should follow up patients prospectively to capture the impact of the EBT program on weight and weight-related comorbidities, and all related adverse outcomes. Poor responders should be identified and offered a detailed evaluation and alternative therapy. *Best Practice Advice 6*: Clinicians embarking on incorporating EBTs into their clinical practice should have a comprehensive knowledge of the indications, contraindications, risks, benefits, and outcomes of individual EBTs, as well as a practical knowledge of the risks and benefits of alternative therapies for obesity. *Best Practice Advice 7*: Institutions should establish specific guidelines that are applied consistently across disciplines for granting privileges in EBTs that reflect the necessary knowledge and technical skill a clinician must achieve before being granted privileges to perform these procedures.

Primary Literature:

Outcome: Liver Enzymes				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Popov, 2016	Systematic Review	ALT decreased by −10.02 U/l (95 % CI, −13.2, −6.8), GGT decreased by −9.82 U/l (95 % CI,	None	Low

	Sample: 9 observational studies and one randomized trial **Inclusion Criteria:** *Study type* was any observational or randomized studies with ≥5 adult patients in the intervention arm. *Population* was obese or overweight adult patients. *Intervention* was endoscopic IGB balloon therapy. *Comparator* was the patient at baseline before IGB placement; in randomized controlled trials the outcomes for the IGB and control groups were also compared. *Outcomes* were liver tests [alanine aminotransferase (ALT) or gamma-glutamyl transpeptidase (GGT)] or measures of NAFLD (e.g., ultrasound, magnetic resonance imaging (MRI), histological examination of biopsy) reported before IGB insertion and after IGB removal.	−12.9, −6.8), and BMI decreased by −4.98 kg/m2 (−5.6, −4.4) with IGB therapy. Hepatic steatosis improved from baseline after 6 months of balloon therapy by magnetic resonance imaging (fat fraction, 16.7 ± 10.9–7.6 ± 9.8, $p = 0.003$), ultrasound (severe liver steatosis, 52–4 %, $p < 0.0001$). Histological NAFLD activity score was lower after 6 months of IGB versus control with sham endoscopy and diet (2 ± 0.75 vs. 4 ± 2.25, $p = 0.03$).		

Outcome: Performance of Intragastric Balloon				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Yorke, 2016	Systematic Review **Sample:** 26 studies **Inclusion and Exclusion Criteria:** English speaking studies, with >25 patients, where IGB was a primary weight-loss agent and patients had not had previous bariatric interventions. Any study that required patients to have placement of more than one IGB simultaneously	At balloon removal, mean change in weight and BMI were 15.7 ± 5.3 kg and 5.9 ± 1.0 kg/m2. The most common complications were nausea/vomiting (23.3 %) and abdominal pain (19.9 %). Serious complications were rare: mortality (0.05 %) and gastric perforation (0.1 %). IGBs are associated with marked short-term weight loss with limited serious complications.	Quality of studies was not appraised	Moderate

	during the initial 6-month treatment duration was excluded.			

Outcome: Type 2 Diabetes				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Jirapinyo, 2018	Systematic Review **Sample:** 17 studies **Inclusion and Exclusion Criteria:** RCTs, observational cohort studies, and case series that were published and peer reviewed were included. Reviews, editorials, case-control studies, case reports, conference abstracts, and studies using nonhuman subjects were excluded, as were articles without full text availability or English translation.	At explant, HbA_{1c} decreased by 1.3% [95% CI 1.0, 1.6] and HOMA-IR decreased by 4.6 [2.9, 6.3]. Compared with control subjects, DJBL subjects had greater HbA_{1c} reduction by 0.9% [0.5, 1.3]. Six months after explant, HbA_{1c} remained lower than baseline by 0.9% [0.6, 1.2]. At explant, patients lost 11.3 kg [10.3, 12.2], corresponding to a BMI reduction of 4.1 kg/m^2 [3.4, 4.9], total weight loss of 18.9% [7.2, 30.6], and excess weight loss of 36.9% [29.2, 44.6]. The amount of weight loss remained significant at 1 year postexplantation. After DJBL, GIP decreased, whereas GLP-1, PYY, and ghrelin increased.	None	Moderate

Question #10: What are the thresholds for considering surgical or endoscopic approaches to weight loss and management of obesity-related comorbidities?

Guideline Recommendations:

The 2016 **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

- Patients with a BMI of ≥40 kg/m2 without coexisting medical problems and for whom the procedure would not be associated with excessive risk should be eligible for bariatric surgery **(Grade A; BEL 1)**.
- Patients with a BMI of ≥35 kg/m2 and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m2 with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.
    - BMI ≥35 kg/m2 and therapeutic target of weight control and improved biochemical markers of CVD risk **(Grade A; BEL 1)**.
    - BMI ≥30 kg/m2 and therapeutic target of weight control and improved biochemical markers of CVD risk **(Grade B; BEL 2)**.
    - BMI ≥30 kg/m2 and therapeutic target of glycemic control in type 2 diabetes and improved biochemical markers of CVD risk **(Grade C; BEL 3)**.
- Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or CVD risk reduction alone **(Grade D)**.
- All patients should undergo preoperative evaluation for weight-related complications and causes of obesity, with special attention directed to factors that could affect a recommendation for bariatric surgery or be ameliorated by weight loss resulting from the procedure **(Grade A; BEL 1)**.

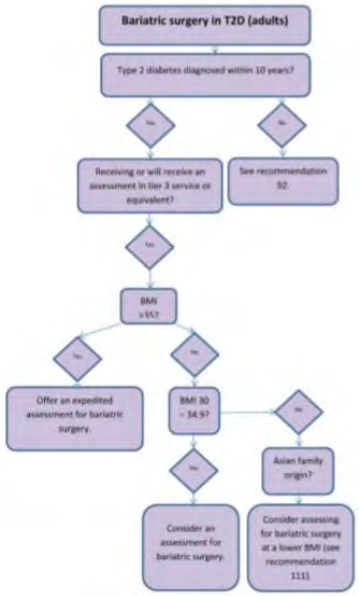
The 2016 **American Academy of Family Physicians (AAFP)** recommended:

- Patients with a BMI of 40 kg per m2 or greater and those with a BMI greater than 35 kg per m2 who also have obesity-related comorbidities should be referred for consideration of bariatric surgery. Patients with a BMI greater than 30 kg per m2 who also have obesity-related comorbidities may be candidates for adjustable gastric banding. **(Evidence rating: B)**

NICE, 2014

- Bariatric surgery is a treatment option for people with obesity if all of the following criteria are fulfilled:
    - They have a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.
    - All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.

  - The person has been receiving or will receive intensive management in a tier 3 service.
  - The person is generally fit for anesthesia and surgery.
  - The person commits to the need for long-term follow-up.
- Children
  - Surgical intervention is not generally recommended in children or young people.
  - Bariatric surgery may be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity.
- People with recent onset type 2 diabetes
  - Offered an expedited assessment for bariatric surgery to people who with a BMI of 35 or over who have recent-onset type 2 diabetes as long as they are receiving or will receive assessment in a tier 3 service (or equivalent).
  - Consider an assessment for bariatric surgery in people with a BMI of 30-34.9 who have recent-onset type 2 diabetes as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent)
  - Consider an assessment for bariatric surgery in people of Asian family origin who have recent-onset type 2 diabetes at a lower BMI than other populations as long as they are also receiving or will receive assessment in a tier 3 service.



Oregon's Health Evidence Review Commission (HERC) provided the following coverage guidance in 2016:

- Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, and sleeve gastrectomy) is recommended for:
  - Adult obese patients (BMI ≥ 35) with
    - Type 2 diabetes **(strong recommendation)** OR
    - at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea **(weak recommendation)**
  - Adult obese patients (BMI ≥ 40) **(strong recommendation)**

- Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program **(weak recommendation)**.
- Metabolic and bariatric surgery is not recommended for coverage in:
  - Patients with BMI <35, or 35-40 without the defined comorbid conditions above **(weak recommendation)**
  - Children and adolescents **(weak recommendation)**

The 2015 **ASGE Bariatric Endoscopy Task Force** recommended:
Endoscopic Bariatric Therapy (EBT)

- Failed weight loss or weight maintenance with lifestyle intervention alone, unless medical conditions exist that require earlier addition of adjunctive therapy
- BMI criteria for primary EBT (this may vary with individual EBTs)
- Medical conditions that require weight loss for additional therapy but may exceed BMI criteria for primary EBT (bridge therapy)

The 2015 **European Guidelines** for Obesity Management in Adults recommended the following:

- Surgery should be considered for patients aged 18–60 years with a BMI ≥ 40.0 kg/m 2 or with BMI between 35.0 and 39.9 kg/m 2 and co-morbidities, in whom surgically induced weight loss is expected to improve the disorder (such as type 2 diabetes and other metabolic disorders, cardiorespiratory disease, severe joint disease and obesity-related severe psychological problems). BMI criterion may be the current BMI or a documented previous BMI of this severity.
- Patients with BMI >30 and <35 kg/m 2 with type 2 diabetes may also be considered for bariatric surgery on an individual basis, as there is evidence-based data supporting bariatric surgery benefits in regards to type 2 diabetes mellitus remission or improvement in this group.
- A laparoscopic technique should be considered as the first treatment choice in bariatric surgery. In all situations the bariatric surgeon's experience is a key issue for an immediate successful outcome. It is not advisable to perform bariatric techniques on an occasional basis {level 1}.

The 2015 **American Academy of Pediatrics Institute for Health Childhood Weight** released the following assessment and management algorithm for childhood obesity:

- **Where/By Whom:** Pediatric Weight Management Center/Providers with expertise in treating childhood obesity
- **What:** Recommended for children with BMI > 95% and significant comorbidities if unsuccessful with Stages 1 - 3. Also recommended for children > 99% who have shown no improvement under Stage 3. Intensive diet and activity counseling with consideration of the use of medications and surgery.
- **Goals**: Positive behavior change. Decrease in BMI.
- **Follow-up:** Determine based upon patient's motivation and medical status.

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

- Offer bariatric surgery, as an adjunct to comprehensive lifestyle intervention, for weight loss in adult patients with a body mass index (BMI) >40 kg/m^2 or those with BMI 35.0-39.9 kg/m^2 with one or more obesity-associated conditions. **(A)**
- Offer bariatric surgery, as an adjunct to comprehensive lifestyle intervention, to improve some obesity-associated conditions in adult patients with a body mass index (BMI) >35.0 kg/m^2. **(A)**
- Current evidence is insufficient to assess the balance of benefits and harms of offering bariatric surgery as an adjunct to comprehensive lifestyle intervention, for weight loss or to improve some obesity-associated conditions, to patients over age 65 or with a body mass index (BMI) <35 kg/m^2. **(I)**
- Engage all patients who are candidates for bariatric surgery in a general discussion of the benefits and potential risks. If more detailed information is requested by the patient to assist in the decision-making process, a consultation with a bariatric surgical team should occur. **(EO)**
- Provide lifelong follow-up after bariatric surgery to monitor adverse effects and complications, dietary restrictions, adherence to weight management behaviors and psychological health. **(EO)**

The **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** in 2013 recommended:

- Selecting patients for bariatric surgical treatment for obesity (bariatric surgical treatment for obesity)
    - Advise adults with a BMI >/= 40kg/m2 or BMI >/= 35kg/m2 with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation. **(Strong Recommendation, Moderate Quality Evidence)**
    - For individuals with a BMI <35 kg/m2, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. **(No Recommendation)**

- Advise patients that choice of a specific bariatric surgical procedure may be affected by patient factors, including age, severity of obesity/BMI, obesity-related comorbid conditions, other operative risk factors, risk of short- and long-term complications, behavioral and psychosocial factors, and patient tolerance for risk, as well as provider factors (surgeon and facility). **(Expert Opinion)**

American Society for Metabolic and Bariatric Surgery pediatric committee best practice guidelines, 2012

- Adolescents
  - BMI of >/= 35 kg/m^2 with major co-morbidities (i.e. type 2 diabetes mellitus, moderate to severe sleep apnea [apnea-hypopnea index >15], pseudotumor cerebri, or severe NASH) or a BMI of >/= 40 kg/m^2 with other co-morbidities (e.g. hypertension, insulin resistance, glucose intolerance, substantially impaired quality of life or activities of daily living, dyslipidemia, sleep apnea with apnea-hypopnea index >5). The associated risk/benefit should also include the consideration of the potential long-term health risks of untreated or inadequately treated obesity for the individual candidate.

2007 **AAP Expert Committee Recommendations** Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity:

- Selection criteria proposed by Inge et al include BMI of >/=40 kg/m2 with a medical condition or >/=50 kg/m2; physical maturity (generally 13 years of age for girls and >/=15 years of age for boys); emotional and cognitive maturity; and weight loss efforts for >/=6 months in a behavior-based treatment program. Those investigators also recommended strongly that bariatric surgery centers maintain databases, so that these criteria can be modified as appropriate on the basis of outcomes. Furthermore, adolescents who undergo such procedures need careful evaluation before surgery and prolonged nutritional and psychological support after surgery, and many youths who might otherwise qualify live too far from an adolescent bariatric center.

AACE/TOS/ASMBS

- The evidence base for recommending bariatric surgery for patients with BMI >/=40 kg/m2 without coexisting medical problems demonstrated benefit for: mortality, weight loss, diabetes remission; improved beta-cell function; and improved pulmonary function. Currently, the WHO classification scheme for obesity, based on BMI, determines diagnostic and therapeutic management. However, BMI is confounded by ethnic differences and body composition, and future improved risk stratification strategies may incorporate other anthropometric measurements, such as waist circumference or waist-to-hip ratio, co-morbidity and functional status assessments, and body composition technologies. Factors found to be associated with poor outcome include open procedures, male gender, older age, congestive heart failure, peripheral vascular disease, deep venous thrombosis, PE, obstructive sleep apnea, impaired functional status, and chronic kidney disease. Therefore, further studies are needed that utilize new clinical risk-stratification systems to optimize patient selection criteria and consequently, patient outcomes.
- Many recent studies demonstrate benefit for bariatric surgery patients with BMI <35kg/m2 in terms of weight loss, diabetes remission, and cardiovascular risk reduction. This evidence base is supported by additional, though not as strong, studies and post hoc analyses from diverse ethnicities on weight loss andT2D improvement. As a result, the United States Food and Drug Administration (FDA) approved the LAP-BAND for patients with a BMI of 30–34.9kg/m2 with an obesity-related co-morbidity. Moreover, the recent comparative effectiveness, randomized, non-blinded, single-center trial,

with 34% of patients with BMI <35 kg/m2, represents a highly relevant study, even though it cannot yet be generalizable. A companion paper by Mingroneetal. Randomized patients with BMI >/=35 kg/m2 and does not apply to this CPG recommendation. Future, well- designed clinical trials that incorporate longer follow-up periods with demonstration of safety in the surgical group, relevant CVD outcomes, and an intensive medical therapy comparator group associated with weight loss, will clarify this CPG recommendation for patients with BMI o35 kg/m2.

Primary Literature:

Source, Year	Summary of Findings
HERC, 2016	Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, and sleeve gastrectomy) is recommended for: 1. Adult obese patients (BMI ≥ 35) with a. o Type 2 diabetes (strong recommendation) OR o at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea (weak recommendation) □ 2. Adult obese patients (BMI ≥ 40) (strong recommendation) 3. Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (weak recommendation). 4. Bariatric surgery is not recommended for coverage in children and adolescents (weak recommendation). 5. There is no evidence-based minimum age recommendation for pediatric bariatric surgery. Patients as young as five years old were included in the studies reported in the summary literature.
NICE, 2014	Randomized trials comparing the effectiveness of surgical interventions versus nonsurgical management for people with recent-onset T2D and obesity were found. Recent-onset T2D was defined as within 10 years of diagnosis. Six studies were included in the review. • Three studies included people with a mean duration of T2D that was less than 10 years but with very large standard deviations which shows that there were a large proportion of patients who had T2D for longer than 10 years. These studies were considered to have indirect populations since they included a large proportion of people without recent-onset diabetes. • All outcomes were reported in at least 1 study. However, only 1 study reported health related quality of life after at least 1 year of follow-up. The study reported results from the RAND-36 questionnaire before and after treatment for each of the individual domains, but the study did not report composite scores across all domains. The study reports that there were significant improvements over conventional therapy in 5 of the 8 mental and physical domains among people treated with gastric bypass and 2 of the domains among people treated with sleeve gastrectomy. • The way diabetic medication usage was reported in the studies varied. Two studies reported the proportion of participants who were still taking diabetic medication at follow-up (dichotomous) and 2 other studies reported the number of diabetic medications being taken at follow-up (continuous). Consequently, both dichotomous and continuous outcomes were

	presented separately. Two of the other papers reported this outcome in the surgery group only so it was not possible to include the results from these studies. • 'Remission' of type 2 diabetes is often used as an outcome but there is controversy over the term as it is defined by hyperglycemia which may change over time. The American Diabetes Association has defined partial and complete remission. Complete remission is defined as a return to normal glycemic measures (HbA1C in the normal range, fasting glucose less than 100 mg/dl [5.6mmol/l]) of at least 1 year's duration in the absence of active pharmacological therapy or on-going procedures. Partial remission is sub-diabetic hyperglycemia (HbA1C not diagnostic of diabetes [less than 6.5%], fasting glucose 100-125 mg/dl [5.6-6.9 mmol/l]) of at least 1 year's duration in the absence of active pharmacologic therapy or on-going procedures. • Normal range of HbA1c is typically defined as less 6% [less than 43mmol/mol]. Remission of T2D was reported in a number of studies but the definition was different across the included studies.

Question #11: What are the long-term outcomes of bariatric and metabolic interventions in children and young people with obesity?

Endocrine Society Clinical Practice Guideline, 2017

- Suggest bariatric surgery only under the following conditions:
  - the patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height, the patient has a BMI of >40 kg/m2 or has a BMI of >35 kg/m2 and significant, extreme comorbidities
  - extreme obesity and comorbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy
  - psychological evaluation confirms the stability and competence of the family unit [psychological distress due to impaired quality of live (QOL) from obesity may be present, but the patient does not have an underlying untreated psychiatric illness]
  - the patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits
  - there is access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family. (2|⊕⊕○○)
- Suggest against bariatric surgery in preadolescent children, pregnant or breast-feeding adolescents (and those planning to become pregnant within 2 years of surgery), and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has an unresolved substance abuse, eating disorder, or untreated psychiatric disorder. (2|⊕○○○)

American Society for Metabolic and Bariatric Surgery pediatric committee best practice guidelines, 2012

- Scientific evidence demonstrating the high propensity of severely obese adolescents to become severely obese adults and the greater associated risk among adults with "juvenile-onset" obesity (i.e. obese adults who become obese during childhood; approximately 25%) combined with evidence demonstrating improvement in obesity-related co-morbid disease after weight loss induced by bariatric surgery support the concept of "early" intervention in carefully selected adolescents patients.
- Although current evidence is not sufficiently robust to allow a precise discrimination or recommendation among specific bariatric procedures, an increasing body of data demonstrating evidence of safety and efficacy exists for two of the more commonly performed bariatric procedures for this age group (i.e. Roux-en-Y gastric bypass [RYGB] and adjustable gastric band [AGB].
- Indications for bariatric surgery:
  - Type 2 diabetes mellitus
  - Moderate or severe obstructive sleep apnea
  - Nonalcoholic fatty liver disease and nonalcoholic steatohepatitis
  - Pseudotumor cerebri
  - Diagnosis of metabolic syndrome

Health Evidence Review Commission (HERC), 2016

- Metabolic and bariatric surgery is not recommended for coverage in children and adolescents (**weak recommendation**)

Guideline Systematic Reviews:

Source, Year	Summary of Findings
HERC, 2016	Bariatric surgery is associated with significant reductions in BMI in children and adolescents, despite a short-term increased risk of perioperative mortality and complications (based on low certainty evidence primarily from small, non-comparative observational trials of bariatric surgery for pediatric obesity). Bariatric surgery is associated with remission or resolution of T2DM and hypertension in children or adolescents, despite a short term increased risk of perioperative mortality and complications (based on very low certainty evidence from a small number of trials). **Benefits:** **1.** All-cause mortality. Insufficient evidence in this population **2.** Major Adverse CV event. Insufficient evidence in this population 3. Type 2 DM remission. Rates of remission of T2DM ranged from 50 to 100%. (very low certainty based on mostly small observational trials with imprecise effects) 4. Hypertension remission. Rates of remission of hypertension ranged from 50 to 100%. (very low certainty based on mostly small observational trials with imprecise effects) 5. Change in BMI. Mean weighted difference in BMI at 1 year (from baseline): -10.5 to -17.2 kg/m2. (low certainty based on mostly small observational trials)
ASMBS 2016 & 2012	2016 • Metabolic and bariatric surgery is a proven, effective treatment for severe obesity disease in adolescents and should be considered standard of care. Pediatricians and primary care providers should recognize that children with severe obesity require tertiary care and refer early to a MBS center with advanced treatments and support. • Adolescents with severe obesity have significant risk factors for CVD, including, hyperlipidemia, elevated inflammatory markers, HTN, and insulin resistance. MBS significantly improves these risk factors, and therefore would be expected to decrease morbidity and mortality from CVD long term. CVD risk factors should be considered a strong indicator for MBS. • Childhood-onsetT2Dfails medical therapy in >50% of cases and has a poor outcome with respect to end organ damage and early mortality. Insulin resistance in adolescents is more severe than in adults. Both the RYGB and VSG produce remission of insulin resistance and T2D in at least 90% of adolescents and should be considered as a primary therapy for children with T2D and severe obesity. Childhood-onset T2D and insulin resistance should be considered strong indications for MBS. • OSA has been shown to cause significantly decreased health-related quality of life (HRQoL) with increased risk of morbidity and mortality in adolescents. MBS in adolescents results in significant improvement or resolution of OSA. Thus, OSA should be considered a strong indication for MBS.

	• NAFLD may be present in at least 59% of adolescent patients referred for MBS. Given complete resolution of NASH in approximately 85% of patients who undergo VSG or RYGB, NAFLD should be considered a strong indication for MBS in adolescents with severe obesity. • Patients who suffer from severe obesity complicated by SCFE or Blount's disease should be considered for MBS to potentially improve outcomes surrounding orthopedic operations and to reduce the risk of developing bilateral or recurrent disease. • Adolescents who suffer from severe obesity and have failed medical management of IIH should be considered for MBS. There is little published data, however expert opinion supports MBS as effective and safe in treating IIH associated with severe obesity. • GERD should be considered a strong indication for MBS in adolescents. RYGB is highly effective at treating GERD and should be considered the most effective treatment for patients with severe obesity and GERD. It is unclear if VSG may also be a reasonable approach to patients with GERD and obesity (as long as there is no evidence of Barrett's esophagus), as weight loss alone may resolve GERD in some of these patients. Fundoplication surgery should be avoided in patients who may require MBS in their lifetime. • Adolescents with severe obesity report significant impairment in quality of life, with marked and sustained improvements in relation to surgically induced weight loss beyond 5 years. Therefore, reduced HRQoL should be considered a significant indication for MBS. • With the exception of active psychosis, suicidality, or substance abuse, mental health disorders are not a contraindication to MBS in adolescents. As with any subspecialty clinic, patients who present with mental health disorders should be carefully monitored after surgery to promote positive mental health and reduce the potential risk of further mental health complications (i.e., new substance abuse or suicidality). • Family dysfunction is not uncommon, yet there is not strong evidence suggesting it impacts adolescent weight loss after MBS, at least in the short term, and therefore should not be considered a contraindication to MBS in adolescents. • Adolescents with a history of maltreatment may present with greater psychosocial challenges in general, but there are no data to suggest a history of child maltreatment is a contraindication for MBS. • Initial evidence suggests adolescents increase alcohol use after MBS, largely due to age-related trends. With this in mind, binge drinking and alcohol-related harm might signal increased risks for this patient population. All adolescent patients undergoing MBS should be routinely screened and counseled on the risks of alcohol misuse and abuse. Smoking or vaping with nicotine should be strongly discouraged after MBS, specifically RYGB. • LOC eating is the most common type of disordered eating in the adolescent patient presenting for MBS (~1 in4patients). LOC eating should be routinely assessed, treated, and closely monitored before and after MBS. However, given that it is treatable, LOC eating should not be considered a contraindication to MBS. • A BMI ≥120% of the 95th percentile with a co-morbidity or a BMI ≥140%ofthe 95th percentile should be used when determining weight cut offs for adolescents to undergo MBS. Tanner stage and linear growth should not be used to determine readiness for adolescent MBS. Adolescents are defined by the World Health Organization's definition of 10-to 19-years old, but younger children who meet the other criteria could be considered when benefit outweighs risk.

- VSG and RYGB can be considered both safe and effective treatments for severe obesity in adolescents. When deciding which operation to use in adolescents, consideration of complications associated with vitamin deficiencies, durability, and reoperation must take high priority. The risk of reoperation is significantly higher in BPD and AGB than in the other 2operations, making these less desirable choices.
- Years of exposure to the obese state likely contributes to early mortality in patients with childhood onset obesity; therefore, early intervention may decrease mortality in adolescents undergoing MBS.
- When there is inadequate weight loss or failure of resolution of certain co-morbidities, then conversion of an AGB or VSG to a RYGB is recommended; however, it may be reasonable to try the addition of weight loss medications as well.
- Adolescents are more likely to stop taking nutritional supplements. Therefore, annual follow-up with vitamin level monitoring is strongly recommended. All efforts should be made to help adolescents remember and become accustomed to taking supplements daily.
- There is significant morbidity and mortality associated with pregnancy in women with obesity. Pregnancy after MBS confers a significant health benefit for both mother and infant; however, infants are likely to be small for gestational age and vitamin supplementation is imperative. Adolescent pregnancy carries its own risks and MBS can increase fertility. Therefore, all female MBS patients should be counseled on birth control surrounding MBS.

Table 1
Indications and contraindications for adolescent metabolic and bariatric surgery (MBS)

Indications for adolescent MBS include
• BMI ≥35 kg/m^2 or 120% of the 95th percentile with clinically significant co-morbid conditions such as obstructive sleep apnea (AHI >5), T2D, IIH, NASH, Blount's disease, SCFE, GERD, or hypertension; or BMI ≥40 kg/m^2 or 140% of the 95th percentile (whichever is lower). • A multidisciplinary team must also consider whether the patient and family have the ability and motivation to adhere to recommended treatments pre- and postoperatively, including consistent use of micronutrient supplements.
Contraindications for adolescent MBS include
• A medically correctable cause of obesity • An ongoing substance abuse problem (within the preceding yr) • A medical, psychiatric, psychosocial, or cognitive condition that prevents adherence to postoperative dietary and medication regimens. • Current or planned pregnancy within 12 to 18 mo of the procedure

BMI = body mass index; AHI = apnea-hypopnia index; T2D = type 2 diabetes; IIH = idiopathic intracranial hypertension; NASH = nonalcoholic steatohepatitis; SCFE = slipped capital femoral epiphysis; GERD = gastroesophageal reflux disease.

2012

- Data suggests that diabetes can go into complete remission in adolescents who undergo RYGB. Thus, established type 2 diabetes is a strong indication for bariatric surgery in morbidly obese adolescents.

	• Demonstrated substantial improvement and/or resolution after bariatric surgery in adolescents consistent with the outcomes in adults. Thus, moderate or severe obstructive sleep apnea is a strong indication for early bariatric surgery in adolescents. • Nonalcoholic fatty liver disease and nonalcoholic steatohepatitis should be considered as a strong indication for early bariatric surgery in adolescent patient compared with steatosis alone • Pseudotumor cerebri is a strong indication for bariatric surgery in morbidly obese adolescents • Evidence of short-term morbidity from long-term risk of cardiovascular disease (CVD) is lacking. Thus, CVD risk factors are less strong indications for early bariatric interventions in adolescents. • Bariatric surgery can result in improvement of the metabolic and inflammatory parameters of the metabolic syndrome, including hyperinsulinemia, insulin resistance, and abnormal lipid metabolism. Diagnosis of a metabolic syndrome in obese adolescents is a relative indication for bariatric surgery. • Important benefits to the emotional health and quality of life in extremely overweight adolescents. • Available data indicate that the presence of depression before bariatric surgery does not adversely affect the rate of anticipated weight loss after bariatric surgery. Current data demonstrate that depression improve markedly in adolescents after bariatric surgery. Thus, depression is not an exclusion criterion for bariatric surgery. However, suicide can be a risk after bariatric surgery in adults, and it is important that adolescents with preoperative depression be monitored for recurrence of depression postoperatively. • Presence of easting disturbances before bariatric surgery does not appear to affect weight loss outcome after bariatric surgery in adult cohorts, at least in the short term. If an eating disorder is identified, treatment should be initiated and the patient should be considered stable before bariatric surgery. • Psychosocial outcomes after bariatric surgery have not been adequately studied, particularly in adolescents. • Consistent attendance and compliance with medical interventions is an important measure of whether a patients and family are likely to comply with care postoperatively. Low levels of iron, vitamin B_{12}, vitamin D, and calcium are common problems after RYGB. • Female adolescents should be informed about increased fertility after weight loss and that pregnancy during the first 18 months after bariatric surgery has possible risks. These patients should be considered to avoid pregnancy during this period and offered contraception. • A review of current data indicated that patient safety and weight loss outcomes for extremely obese adolescents undergoing bariatric surgery are comparable or better than those seen in adults. • A meta-analysis that reviewed the outcomes of 6 RYGB studies, including 131 adolescent patients (mean BMI of 51.8 kg/m^2) reported a significant and sustained decrease in BMI after surgery. Severe complications, such as anastomotic leak, sepsis, bleeding, complications, and thromboembolic events, are rare but have been reported. No deaths have been reported in the perioperative period, with 3 long-term deaths reported (occurring 9 mo and 2 and 6 yr after RYGB).

	• The preliminary results from ongoing studies are required, the preliminary results from ongoing studies of adolescents undergoing sleeve gastrectomy appear to demonstrate excellent weight reduction, reversal of associated co-morbid diseases, and morbidity outcomes similar to those of the adult population. Long-term adolescent outcomes data are still required. • Reports describing the outcomes related to biliopancreatic diversion and duodenal switch exist but currently are not robust. Concerns regarding associated fat-soluble vitamin deficiencies and long-term protein malnutrition limit the ability to offer specific recommendations at present.

Outcome: Weight Loss				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Pedroso, 2018	Systematic Review **Sample:** 24 studies, 1928 patients **Inclusion Criteria:** Both prospective and retrospective observational studies as well as 1 randomized controlled trial were included. Studies were limited to adolescent patients, as defined by the World Health Organization (10–19 years of age). To capture the greatest number of adolescent patients, additional studies with an expanded adolescent age group, inclusive of patients up to 21 years of age, where a majority of the patients were of adolescent age, were also assessed in one of our sensitivity analyses. Included studies were limited to those evaluating gastric band, gastric sleeve, or gastric bypass in at least 5 patients, and those that evaluated weight loss at the specified follow-up times (6, 12, 24, and 36 mo).	Mean preoperative BMI (kg/m2) was 45.5 (95% confidence interval [CI]: 44.7, 46.3) in gastric band, 48.8 (95%CI: 44.9, 52.8) in gastric sleeve, and 53.3 (95%CI: 50.2, 56.4) in gastric bypass patients. The short-term weight loss, measured as mean (95%CI) absolute change in BMI (kg/m2) at 6 months, was –5.4 (−3.0, −7.8) after gastric band, −11.5 (−8.8, −14.2) after gastric sleeve, and −18.8 (−10.9, −26.6) after gastric bypass. Weight loss at 36 months, measured as mean (95%CI) absolute change in BMI (kg/m2) was −10.3 (−7.0, −13.7) after gastric band, −13.0 (−11.0, −15.0) after gastric sleeve, and −15.0 (−13.5, −16.5) after gastric bypass.	None	Low

Outcome: Health Outcomes				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Qi, 2017	Systematic Review **Sample:** 49 studies, 3007 patients **Inclusion Criteria:** 1. The patients in the studies were under the age of 21 (and less than 10% were >21 years) at study entry. 2. The studies reported either pre- and postoperative data on BMI, glycemic, and lipid parameters (glycosylated hemoglobin A1C [HbA1C], fasting blood insulin, fasting blood glucose [FBG], total cholesterol [TC] level, triglyceride [TG] level, high-density lipoprotein cholesterol [HDL-C], and low-density lipoprotein cholesterol [LDL-C]), or the remission of related co-morbidities including prediabetes, T2D, dyslipidemia, or hypertriglyceridemia after surgery; 3. Outcomes were reported with mean follow-up>12 months in the studies; 4. Studies with ≥5 specific individuals; 5. The language of the studies was English.	Roux-en-Y gastric bypass (n = 1216), laparoscopic adjustable gastric banding (n = 1028), and laparoscopic sleeve gastrectomy (n = 665) were the most common bariatric surgeries performed. At the longest follow-up (range, 12–120 mo), bariatric surgery led to an overall 16.43 kg/m2 (95% confidence interval [CI]: 14.84–18.01) and 31% (95% CI: 28%–34%) reduction in body mass index. There were significant improvements in glycemic and lipid profiles including glycosylated hemoglobin A1C, fasting blood insulin, fasting blood glucose, total cholesterol, triglyceride, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol, postoperatively at 12 months. The remission rate of dyslipidemia was 55% (95% CI: 34%–76%), 70% (95% CI: 55%–82%), and 95% (95% CI: 80%–100%) at 1, 3, and>5 years after surgery. Roux-en-Y gastric bypass produced better improvements than other surgical procedures.	None	Low

Outcome:				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Inge, 2019	Retrospective Study	There was no significant difference in percent weight change between adolescents (-26%; 95%	Failure to adequately	Moderate

	Methods: Two cohorts of adolescents and adults were evaluated after Roux-en-Y gastric bypass. The two cohorts were participants in two related but independent studies. Linear mixed and Poisson mixed models were used to compare outcomes with regard to weight and coexisting conditions between cohorts 5 years after surgery. The rates of death and subsequent abdominal operations and selected micronutrient levels were also compared between cohorts. **Sample:** 161 adolescents, 396 adults.	CI -29 to -23) and adults (-29; 95% CI, -31 to -27) 5 years after surgery (*P* = 0.08). After surgery, adolescents were significantly more likely than adults to have remission of type 2 diabetes (85% vs. 53%; risk ration, 1.27; 95% CI 1.03 to 1.57) and of hypertension (68% vs. 41%; risk ration, 1.51; 95% CI, 1.21 to 1.88). Three adolescents (1.9%) and seven adults (1.8%) died in the 5 years after surgery. The rate of abdominal reoperations was significantly higher among adolescents than among adults (19 vs. 10 reoperations per 500 person-years, *P* = 0.003). More adolescents than adults had low ferritin levels (72 of 132 patients [48%] vs. 54 of 179 patients [29%], *P* = 0.004).	control confounding	

Question #12: What is the best approach for managing co-morbidities? (diabetes risk, type 2 diabetes, hypertension, cardiovascular disease, congestive heart failure, nonalcoholic fatty liver disease, polycystic ovary syndrome, infertility, male hypogonadism, obstructive sleep apnea, asthma, osteoarthritis, depression)

Weight loss and behavior change through multicomponent lifestyle interventions is the cornerstone of managing comorbidities in patients with overweight and obesity. The benefits of weight loss include reduction in risks and rates of weight-related comorbidities, including type 2 diabetes, hypertension, cardiovascular disease, non-alcoholic fatty liver disease, polycystic ovary syndrome, depression, and others. Regardless of comorbidity, all patients should be referred to a multicomponent lifestyle intervention to address overweight and obesity as first line therapy, or in conjunction with management of other diseases.

References: Durrer Schutz 2019, Perreault 2019, Semlitsch 2019

When treating specific comorbidities, consider effects of medications on weight when determining approach to chronic disease management (i.e., choosing therapies that are weight neutral or result in weight loss rather than weight gain, especially for hypertension, diabetes, depression, and autoimmune disorders; see *Pharmacologic Therapy* section for additional details).

Specific considerations for patients not able to manage comorbidities through lifestyle modification alone are discussed below.

Pediatrics

The primary treatment for weight-related comorbidities in the pediatric population is weight loss through multicomponent lifestyle interventions. Management of comorbidities through pharmacologic or surgical means in addition to lifestyle modification may be considered.

Hypertension

Consider pharmacologic agents with favorable metabolic profiles such as ACEis and ARBs. Beta-blockers and diuretics are not recommended in this population.

References: Appel 2018, Binka 2019, Cuda 2019

Polycystic ovary syndrome

Oral contraceptives are considered first line therapy, with progestin monotherapy as an alternative for those in whom OCs are contraindicated. Metformin may be effective in combination with weight loss.

References: Cuda 2019, Ibáñez 2017

Type 2 diabetes

Consider metformin for children ages 10 years and older.

References: Cuda 2019

Adults

Management of comorbidities through pharmacologic or surgical means should be in conjunction with lifestyle modification. Weight loss of 10-15% is the general target across comorbidities to minimize symptoms; the long-term goal is to reduce or eliminate the need for pharmacologic management.

References: Durrer Schutz 2019

Chronic inflammatory conditions

Consider NSAIDs and DMARDs when possible, as corticosteroids are commonly associated with weight gain.

References: Andrew 2019

Hypertension

Consider anti-obesity agents lorcaserin or orlistat, type 2 diabetes agent liraglutide, ACEis, ARBs, and CCBs. While phentermine is a commonly prescribed anti-obesity medication, most guidelines recommend against using sympathomimetics such as phentermine in this population, as they may raise blood pressure. In addition, beta-blockers are not recommended in this population as they may cause weight gain.

References: Andrew 2019, Apovian 2015, Cohen 2019

Mental health

Consider antidepressants (SSRIs fluoxetine, sertraline) and antipsychotics (ziprasidone, lurasidone) with a lower probability of weight gain, or those with weight-loss effects (NDRI bupropion), and employ shared decision-making with the patient regarding estimates of potential weight effects of medications. Agents most likely to cause the greatest weight gain from baseline include antipsychotics clozapine, olanzapine, and risperidone, and antidepressants mirtazapine and paroxetine.

References: Apovian 2015, Alonso-Perdrero 2019, Dayabandara 2017, Hasnain 2012, Spertun 2019

Polycystic ovary syndrome

Lifestyle modification is a cornerstone in therapy for PCOS, with a goal of reducing circulating androgens, insulin resistance, and improving hirsutism and ovulation. Consider liraglutide to increase weight loss potential; adding metformin to liraglutide has synergistic effects on weight loss. Thiazolidinedones may increase body weight in this population.

References: Glueck 2019

Type 2 diabetes

If metformin does not produce sufficient results or is contraindicated, consider adding antidiabetic medications that promote weight loss, such as GLP-1 agonists (e.g., liraglutide, exenatide, dulaglutide) or SGLT-2 inhibitors (e.g., dapagliflozin, canagliflozin, empagliflozin) in addition to metformin. In patients requiring insulin, consider basal insulin as first line therapy, prior to combination or premixed insulin, and consider adding metformin or GLP-1 agonists to moderate insulin-associated weight gain.

References: Apovian 2015, Huang 2016

Question #13: What is the optimal combination of lifestyle interventions (nutritional interventions, physical activity, behavioral interventions, pharmacological therapies, surgical procedures, endoscopic procedures) for improving health and well-being?

A multicomponent, comprehensive, and long-term program is recommended for all patients with overweight and obesity. A program should be tailored to the patient's preferences, needs, and contexts; components should cover diet (reduced caloric intake, nutritional counseling), physical activity (increased exercise, reduced sedentary behavior), and behavior change (structured modification of maladaptive patterns, controlling cues and stimuli in the environment) for at least 12 months, followed by long-term support for weight maintenance in accordance with a chronic care model. Refer to *Behavioral Interventions*, *Nutritional Interventions*, and *Physical Activity* sections for additional details.

References: Al-Khudairy 2017, APA 2018, Mead 2017, Semlitsch 2019, USPSTF 2018, Zolotarjova 2018

Pediatrics

The primary goals in treating adolescents with overweight and obesity are decreasing BMI velocity and minimizing or preventing development of further weight-related complications in adolescence and adulthood. Lifestyle interventions for children and adolescents should incorporate the family for optimal adherence and maintenance.

References: Al-Khudairy 2017, Cardell 2019, Whitlock 2010, Zolotarjova 2018

- Diet programs may include counseling on consumption of healthy meals and snacks, reduction in prepared and processed foods and sugar-sweetened beverages, and other topics in line with family cultural beliefs and preferences.
- Physical activity programs should be based on the age and ability of the child and adolescent.
- Behavioral interventions may include techniques for helping patients modify behavior that contributes to excess weight and facilitate adherence to prescriptions for healthy behavior, such as motivational interviewing, goal-setting, stress reduction, self-monitoring, and others.

Pharmacologic and surgical interventions are appropriate only as adjuncts to lifestyle interventions, and should be considered carefully through shared decision-making with patient, families, and medical and surgical providers (see Pharmacologic Therapy and Surgical Interventions for additional details).

References: Armstrong 2019, Binka 2019, Chao 2018, Mead 2016, Polfuss 2020

Adults

The primary goal of treatment of obesity in adults is long-term weight reduction and improvement in overall health, including reducing risk of or minimizing effects of weight-related comorbidities (e.g., DPP, Look AHEAD).

References: Garvey 2016, Khandelwal 2020, Perreault 2020, USPSTF 2018, Wadden 2012, Wadden 2020

- Diet programs may include counseling on reduced caloric intake, consumption of healthy meals and snacks, reduction in prepared and processed foods and sugar-sweetened beverages, specific dietary plans informed by comorbidities (e.g., Mediterranean Diet, DASH, low-glycemic, etc.), and other topics in line with patient cultural beliefs and preferences.
- Physical activity programs should be based on the age, current fitness level, goals, and physical capabilities of the patient.
- Behavioral interventions may include techniques for helping patients modify behavior that contributes to excess weight and facilitate adherence to prescriptions for healthy behavior, such as motivational interviewing, goal-setting, stress reduction, self-monitoring, and others.

Pharmacologic and surgical interventions are appropriate only as adjuncts to lifestyle interventions, and should be considered carefully through shared decision-making with patient, medical, and surgical providers (see Pharmacologic Therapy and Surgical Interventions for additional details).

Question #14: What is the optimal approach to integrate community resources into obesity management services? What is the effectiveness of community resources amongst different ethnicities?

General consensus from literature and external guidelines

Evidence supported the combination of strategies targeted at the individual and community in terms effectiveness at influencing public health. However, research was limited on evaluating how health care systems involve and partner with community resources.

Pediatrics

For the community-level interventions, evidence was inconclusive with some studies suggesting that community-based group-based programs were effective in reducing obesity while others did not. One systematic review found that home visits delivered by professional staff were more efficacious than those delivered by paraprofessional or community-based staff. Another systematic review found community health workers demonstrated a small but significant impact on BMIz and BMI percentile (BMIz [7 studies]: -0.08, 95% CI: -0.15, -0.01, p= 0.03, I^2= 39.4%; BMI percentile [2 studies]: -0.25, 95% CI: -0.38, -0.11, p<0.01, I^2= 0%). One RCT found no difference was observed in BMI z score in the intervention group receiving clinical care plus community-based programming, but intervention group had significantly greater improvements in physical activity (P = 0.010) and quality of life (P = .008).

Evidence suggests that combined interventions implemented in multiple setting may be more effective at preventing weight gain in children than single-component interventions located in the community only. Tailoring community resources was shown to be effective in the Connect to Health geographic information system study.

Moderate Quality Evidence

Patients with low socioeconomic position

Interventions involving community-based strategies or policies were more effective than individual-level behavior change interventions for patients with low socioeconomic position. One systematic review found that whole-of-community (WOC) interventions were more effective for lower socioeconomic positions populations than higher socioeconomic position populations. These interventions included incorporating structural changes to the environment, included community engagement and community-based weight management programs.

Moderate Quality Evidence

Minority Populations

Studies evaluating community interventions effectiveness in minority populations found statistical significant improvements to health related behaviors, such as increase consumption of fruit and vegetables, reduced daily consumption of sugary drinks, increase of physical activity. One quasi-experimental study found

children in intervention group had statistically significant improvements in systolic BP, diastolic BP, nutrition knowledge, and nutrition self-efficacy. Studies were inconsistent regarding change in BMI, with some showing an improvement and some showing no change.

Notes:

- Positive outlier study, Connect for Health, results have not yet been published. Researching novel approach to care delivery that leverages clinical and community resources and addresses socio-contextual factors to improve obesity-related outcomes.
- Inconsistent evidence for school-based and child-care based studies at improving obesity-related outcomes when utilizing community partners.

Guideline Recommendations:

The 2018 **Physical Activity Guidelines for Americans** recommends:

- Health care systems can partner with other sectors to promote access to community-based physical activity programs.

In 2016, the **Academy of Nutrition and Dietetics** recommended the following in the position paper on interventions for the treatment of overweight and obesity in adults.

- The RDN should recommend use of community resources, such as local food sources, food assistance programs, support systems, and recreational facilities (**Rating: Strong, Imperative**)

The 2015 **Dietary Guidelines for Americans 2015-2020**

Multi-Component Versus Multi-Level Strategies To Influence Food & Physical Activity Choices

Evidence demonstrates that both multi-component and multi-level changes must be implemented to effectively influence public health. Multi-component changes are those that use a *combination of strategies* to promote behavior change. These strategies can be employed across or within different settings. For example, a multi-component obesity prevention program at an early care and education center could target classroom education around nutrition and physical activity, ensure the continued nutritional quality of meals and snacks served, make improvements to the mealtime setting, increase opportunities for active play, and initiate active outreach to parents about making positive changes at home.

Multi-level changes are those that *target change at the individual level as well as additional levels*, such as in community, school, and retail settings. For example, strategies to reduce sodium intake could include providing individual education on how to interpret sodium information on food labels or restaurant menus (e.g., sodium versus salt), reformulating foods and meals to reduce sodium content in retail and food service establishments, and conducting public health campaigns to promote the importance of reducing sodium intake.

Many strategies for implementing these types of multi-component and multi-level actions have shown promise to positively influence food and physical activity choices. For example, moderate evidence indicates that multi-component school-based programs can improve dietary intake and weight status of school-aged children. Fundamental to the success of such actions is tailoring programs to meet the needs of the individual, the community, and/or the organization so as to increase the chances of affecting social and cultural norms and values over time.

- Strategies for Action
  Sectors:
  - **Foster partnerships** with food producers, suppliers, and retailers to increase access to foods that align with the *Dietary Guidelines*.
  - Promote the development and availability of food products that align with the *Dietary Guidelines* in food retail and food service establishments.
  - **Identify and support policies and/or programs that promote healthy eating and physical activity patterns**.
  - **Encourage participation in physical activity programs offered in various settings.**

2007 AAP Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity:

- Practice- and Community-Level Interventions
  - The expert committee recommends that physicians, allied health care professionals, and professional organizations (a) advocate for the federal government to increase physical activity at schools through intervention programs from grade 1 through the end of high school and college and through the creation of school environments that support physical activity in general and (b) support efforts to preserve and to enhance parks as areas for physical activity, inform local development initiatives regarding the inclusion of walking and bicycle paths, and promote families' use of local physical options by making information and suggestions about physical activity alternatives available in doctors' offices.
  - The expert committee recommends the use of the following techniques to aid physicians and allied health care providers who may wish to support obesity prevention in clinical, school, and community settings: (a) actively engaging families with parental obesity or maternal diabetes, because these children are at increased risk for developing obesity even if they currently have normal BMI; (b) encouraging an authoritative parenting style in support of increased physical activity and reduced sedentary behavior (authoritative parents are both demanding and responsive, providing tangible and motivational support for children); (c) discouraging a restrictive parenting style (restrictive parenting involves heavy monitoring and controlling of a child's behavior) regarding child eating; (d) encouraging parents to model healthy diets and portions sizes, physical activity, and limited television time; and (e) promoting physical activity at school and in child care settings (including afterschool programs) by asking children and parents about activity in these settings during routine office visits.

Primary Literature:

Population: Pediatrics **Outcome:** Efficacy				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Appelhans, 2016	**Design:** Systematic Review **Sample:** 15 studies	**Interventions in which professional staff (e.g. dietitians and exercise trainers) conducted home visits tended to be more**	Did not assess quality of studies	Low to moderate

	Inclusion and Exclusion Criteria: Studies (1) reported original research data with human subjects, (2) involved an intervention that was at least partly delivered in the home of the index child/adolescent (studies in which only research assessments were conducted in the home were excluded), (3) included objective assessments of adiposity (weight, body mass index [BMI] or BMI derivative, waist girth, percentage body fat and skin fold thickness) at baseline and as an outcome, (4) included a comparison condition, (5) involved at least 10 subjects in the condition receiving home visits, (6) had a follow-up duration of at least 2 months, (7) reported outcomes for youth ages 2-18 years, (8) were conducted in a 'very high human development' country based on the United Nations' Human Development Index, (9) involved a population that was not defined by a specific disease, biomedical condition or syndromal cause of obesity, (10) did not combine a home-based behavioral intervention with pharmacologic or surgical intervention and (11) were available in English	**efficacious than those delivered by paraprofessional or community-based staff, as were interventions with more frequent contact.** As most studies compared interventions with home visits with less intensive and qualitatively different approaches, it remains unclear whether home visitation per se enhances weight loss efficacy. **Overall, pediatric weight management interventions that feature home visitation are promising, but the incremental benefit of the home visitation treatment modality remains to be rigorously evaluated.**	Unable to conduct meta-analysis due to variations between studies	
Hillier-Brown, 2014	**Design:** Systematic Review **Aim:** To systematically review studies of the effectiveness of interventions (individual, community and societal) operating via different approaches (targeted or universal) in reducing socio-economic inequalities in obesity-related outcomes amongst children	**For the community level interventions (n = 17), evidence was inconclusive - with some studies suggesting that school-based health promotion activities and community-based group-based programs were effective in reducing obesity - others not.** Societal level evaluations were few (n = 1). However, there was no evidence to	Unable to conduct meta-analysis due to variations between studies	Low

	Sample: 23 studies **Inclusion and Exclusion Criteria:** Included interventions at the individual, community and societal (environment and macro policy) level that might reduce inequalities in obesity-related outcomes amongst children 0-18 years. Individual level interventions were defined as those that included individualized/one-to-one health promotion, education, advice, counselling or subsidy and were conducted in a health care or research setting, or in participant's homes. Community level interventions were defined as group-based health promotion, education, advice, counselling or subsidy only interventions, or interventions conducted in a community setting (for example a school, community center, sports center and shop).	suggest that any of these intervention types increase inequalities and several studies found that interventions could at least prevent the widening of inequalities in obesity.		
Hoffman, 2018	**Design**: RCT Randomized participants to clinical care or clinical care plus community-based programming at a local parks and recreation facility. Primary outcomes were the change in child BMI at 6 months and the intensity of the program in treatment hours. Secondary outcomes included health behaviors, fitness, attrition, and quality of life. **Sample:** 97 children	Intervention participants achieved more treatment hours than controls (11.4 vs 4.4, SD: 15.3 and 1.6, respectively). **No difference was observed in child BMI z score or percent of the 95th percentile at 6 months. Intervention participants had significantly greater improvements in physical activity (P = .010) and quality of life (P = .008).**	Large loss to follow-up	Moderate

	Inclusion Criteria: Patients aged 5 to 11 with a BMI ≥95th percentile, referred by their primary care provider to the Healthy Lifestyles clinic, along with each child's adult primary caregiver ("parent") aged 18 or older. **Exclusion Criteria:** Children with a medical cause for obesity (hypothyroidism, Cushing's syndrome, etc), those who lived more than 30 miles from the clinic or planned to move out of the area, and those whose parents could not speak or read English or Spanish.			
Schroeder, 2018	**Design:** Systematic Review **Sample:** 11 studies, 9 studies included in meta-analysis **Inclusion Criteria:** Quasi-experimental or experimental design, sample included children (0–18 years), implemented in developed nation as defined by the United Nations, intervention focused on childhood obesity prevention or treatment, interventionists included CHW, results reported change in adiposity (e.g. BMI percentile, BMI z-score, percent over-weight or any other relevant metric). **Exclusion Criteria:** Non-intervention design (e.g. report of study protocol, cross-sectional), adult population (>18 years), implemented in developing or transitioning nation as defined by the United	**Community health workers:** Meta-analytic findings demonstrated a small but significant impact on BMIz and BMI percentile (BMIz [7 studies]: -0.08, 95% CI: -0.15, -0.01, p= 0.03, I^2= 39.4%; BMI percentile [2 studies]: -0.25, 95% CI: -0.38, -0.11, p<0.01, I^2= 0%).	None	Low

	Nations, no inclusion of CHW, no reported change in adiposity (e.g. only changes in health behavior), not published in English.			
Bleich, 2013	**Design:** Systematic Review **Sample:** 9 studies **Inclusion and Exclusion Criteria:** (1) were primarily located in the community setting; (2) targeted at the pediatric population (ages 2–18); (3) had at >/=1 year of follow-up after baseline; (4) compared results from an intervention to a comparison group (eg, usual care, another different intervention, or no intervention); (5) reported differences in weight between the intervention and control groups (eg, BMI, BMI z-score and percentile, waist circumference, percent body fat, skinfold thickness, prevalence of obesity and overweight); (6) described results from RCTs, quasi experimental studies, and natural experiments, such as those that described outcomes from a community that had a food policy change; or (7) were published in English but reviewed the abstracts of non–English language articles to assess agreement with the results published in English.	Four of the studies, which used combined diet and physical activity approaches, reported significant reduction in adiposity and weight related outcomes as a result of the intervention. One of the studies reported significant improvements in intermediate weight-related outcome (physical activity) as a result of the intervention. **The evidence suggests that combination interventions implemented in multiple settings may be more effective at preventing weight gain in children than single-component interventions located in the community only.**	Heterogeneity across the study designs Inconsistent findings	Moderate
Fiechtner, 2017	**Design:** RCT (Part of the intervention arm in Connect to Health study) By using semi-structured interviews with parents and community partners and geographic	Parents, community partners, and experts identified several resources to be included in the map, including farmers markets, supermarkets, parks, and fitness centers. Parents expressed the need for affordable	Lack of blinding Lack of allocation concealment	Medium to High

	information systems (GIS), a community resource map was created and validated for childhood obesity. Semi-structured interviews were conducted with 11 parents and stakeholder feedback was received from 5 community partners, 2 pediatricians, and 3 obesity-built environment experts to identify community resources that could support behavior change. GIS databases were used to identify the location of resources. After the resources were validated, an online, interactive searchable map was created. Parent resource empowerment was evaluated at baseline and follow-up, by examining if the participant families went to new locations for physical activity and food shopping, and evaluated how satisfied the families were with the information they received. **Sample:** Parent interviews – 11 participants 657 families competed follow-up survey on interactive map (360 in intervention arm) **Inclusion Criteria:** Child was aged 2 to 12.9 years, had a BMI at or above the 85th percentile, and received their routine health care at the 6 practices	activities. **Parent resource empowerment increased by 0.25 units (95% confidence interval, 0.21-0.30) over the 1-year intervention period; 76.2% of participants were physically active at new places, 57.1% of participant families shopped at new locations; and 71.8% reported they were very satisfied with the information they received.**	Incorrect analysis of ITT	

References

1. Appelhans, B. M., et al. (2016). "Systematic review of paediatric weight management interventions delivered in the home setting." Obesity Reviews **17**(10): 977-988.
2. Bleich, S. N., et al. (2013). "Systematic review of community-based childhood obesity prevention studies." Pediatrics **132**(1): e201-210.
3. Fiechtner, L., et al. (2017). "A Community Resource Map to Support Clinical-Community Linkages in a Randomized Controlled Trial of Childhood Obesity, Eastern Massachusetts, 2014-2016." Preventing Chronic Disease **14**: E53.
4. Hillier-Brown, F. C., et al. (2014). "A systematic review of the effectiveness of individual, community and societal level interventions at reducing socioeconomic inequalities in obesity amongst children." BMC Public Health **14**: 834.
5. Hoffman, J., et al. (2018). "An Integrated Clinic-Community Partnership for Child Obesity Treatment: A Randomized Pilot Trial." Pediatrics **141**(1): 01.

6. Schroeder, K., et al. (2018). "The role and impact of community health workers in childhood obesity interventions: a systematic review and meta-analysis." Obesity Reviews **19**(10): 1371-1384.

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Inconsistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Population: Lower socioeconomic position
Outcome: Efficacy

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Beauchamp, 2014	**Design:** Systematic Review **Sample:** 14 studies **Inclusion and Exclusion Criteria:** English language studies, studies with results derived from public health interventions that utilized any type of study design to report changes in anthropometric outcomes stratified by a measure of socio-economic position (SEP), or that reported an interaction term between SEP and an anthropometric outcome, studies including primary prevention strategies that potentially address everyone across the socioeconomic gradient, rather than selective interventions that specifically target lower SEP groups.	Three studies were shown to have no effect on anthropometric outcomes and were not further analyzed. Interventions shown to be ineffective in lower SEP participants were primarily based on information provision directed at individual behavior change. **Studies that were shown to be effective in lower SEP participants primarily included community-based strategies or policies aimed at structural changes to the environment.** Interventions targeting individual-level behavior change may be less successful in lower SEP populations. Systematic Review Critical Appraisal Of the 11 studies demonstrating an effect on anthropometric outcomes, five were rated as being of weak quality. This rating was most commonly given because of probable	Unable to conduct meta-analysis due to variations between studies	Low to Moderate

		selection bias due to either the sampling method used or a low response rate. Other reasons were a high attrition rate from observational studies and limited description of control for potential confounders during analysis. Of the remaining six studies, two were rated as strong. The three studies showing no effect on anthropometric outcomes received moderate to strong ratings in terms of study quality.		
Boelsen-Robinson, 2015	**Design**: Systematic Review **Aim**: To summarize evidence of differential effectiveness of whole-of-community (WOC) interventions by socioeconomic position (SEP) **Sample:** 10 studies **Inclusion and Exclusion Criteria:** WOC intervention on behavioral change indicators, energy balance behaviors or anthropometric outcomes according to any measure of SEP. As changes in BMI can occur at a slow rate, a 2-year intervention may not have impacted on this anthropometric outcome yet, and thus measures of energy balance behaviors and behavioral change indicators, such as the psychological readiness of individuals to engage in healthy behaviors, were included to fully capture the potential impact of the intervention. All study designs were included.	**Nine of the 10 WOC interventions included in this review were found to be more or equally effective for lower socioeconomic groups compared with their higher socioeconomic counterparts.** These studies commonly featured **interventions that incorporated structural changes to the environment, acted across more than three settings and/or employed community engagement**. Conclusions did not change when excluding low-quality studies (n=4). WOC interventions represent an effective and equitable approach for the reduction of population weight. Structural components, a larger number of settings and community engagement were common inequitable WOC interventions.	Unable to conduct meta-analysis due to variations between studies	Low

	Characteristic of WOC interventions include the presence of components in more than three settings within a community. These were common in school settings, within the community, as well as social marketing promoting healthy behaviors.			
Hillier-Brown, 2014	**Design:** Systematic Review **Aim:** To systematically review studies of the effectiveness of individual, community and societal interventions in reducing socio-economic inequalities in obesity among adults. **Sample:** 20 studies **Inclusion and Exclusion Criteria:** Included interventions at the individual, community and societal (environment and macro policy) level that might reduce inequalities in obesity-related outcomes among adults (aged 18 years or older). Individual level interventions were defined as those that included individualized/one-to-one health promotion, education, advice, counselling or subsidy and were conducted in a health care or research setting, or in participant's homes. Community level interventions were defined as group-based health promotion, education, advice, counselling or subsidy only interventions, or interventions conducted in a community setting (for example a school, community center, sports center and shop).	At the individual level, there was evidence of the effectiveness of primary care delivered tailored weight loss programs among deprived groups. **Community based behavioral weight loss interventions and community diet clubs (including workplace ones) also had some evidence of effectiveness-at least in the short term.** Societal level evaluations were few, low quality and inconclusive. Further, there was little evidence of long term effectiveness, and few studies of men or outside the USA. However, there was no evidence to suggest that interventions increase inequalities.	Unable to conduct meta-analysis due to variations between studies	Low

References:

1. Beauchamp, A., et al. (2014). "The effect of obesity prevention interventions according to socioeconomic position: a systematic review." Obesity Reviews **15**(7): 541-554.

2. Boelsen-Robinson, T., et al. (2015). "A systematic review of the effectiveness of whole-of-community interventions by socioeconomic position." Obesity Reviews **16**(9): 806-816.
3. Hillier-Brown, F. C., et al. (2014). "A systematic review of the effectiveness of individual, community and societal level interventions at reducing socioeconomic inequalities in obesity amongst children." BMC Public Health **14**: 834.

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Low to Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Population: Minority Populations
Outcome: Efficacy

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Laws, 2014	**Design:** Systematic Review **Aim**: To systematically review the literature to examine the effectiveness of interventions to prevent obesity or improve obesity related behaviors in children 0-5 years from socioeconomically disadvantaged or Indigenous families **Sample:** 32 studies **Inclusion Criteria:** Studies including healthy young children ages zero to five years from socioeconomically disadvantaged or Indigenous families targeting: 1) prevention of unhealthy weight gain and/or 2) obesity related behaviors including child diet, physical activity levels, sedentary behaviors and parental feeding	**Mean differences between intervention and control groups ranged from -0.29 kg/m(2) to -0.54 kg/m(2) for body mass index (BMI) and -2.9 to -25.6% for the prevalence of overweight/obesity.** Interventions initiated in infancy (under two years) had a positive impact on obesity related behaviors (e.g. diet quality) but few measured the longer-term impact on healthy weight gain. Findings amongst pre-schoolers (3-5 years) were mixed, with the more successful interventions requiring high levels of parental engagement, use of behavior change techniques, a focus on skill building and links to community resources.	Studies included in meta-analysis were of low quality	Low

	practices associated with obesity (e.g. breastfeeding and early introduction of solids).			
Anderson, 2015	**Design:** Quasi-experimental Study Families were referred to Taking Steps Together (TST) by their primary care provider if at least one child had a body mass index >=85%. The TST intervention comprised 16 weekly 2-hour classes including educational activities, group cooking/eating, and physical activities for parents and children. TST's approach emphasized building self-efficacy, targeting both children and parents for healthy change, and fostering intrinsic motivation for healthier living. Pre-post intervention data were collected on health-related behaviors using a survey, and trained staff measured weight and height. **Sample**: Adults (n = 33) and children (n = 62) **Inclusion Criteria:** Families with at least one child between the ages 7 and 17 with a BMI% ≥85% and fluency in English or Spanish	**Among adults, there was a statistically significant increase in reported average daily servings of fruits (1.8 to 2.6 servings per day, p = .001); average daily servings of vegetables (1.9 to 2.8 servings per day, p < .001); and average number of days per week with at least 30 minutes of physical activity (2.6 to 3.9 days per week, p = .001). A statistically significant decrease was reported in average daily consumption of sugared drinks (1.3 to 0.7 servings per day, p = .002) and the average number of hours of TV and/or computer screen time per day (2.7 to 2.0 hours per day, p = .041).** **Among children, there was a statistically significant increase in reported average daily servings of fruits (2.6 to 3.3 servings per day, p = .006); average daily servings of vegetables (1.9 to 2.7 servings per day, p < .001); and average number of days per week with at least 30 minutes of physical activity (4 to 4.9 days per week, p = .001).** **For both adult and child participants, mean BMI did not significantly change from pre- to post-intervention.**	Large loss to follow-up Failure to adequately control confounding	High
Chen, 2013	**Design:** Quasi-experimental Study	**Children in the intervention group had statistically significant**	Failure to adequately	High

	8-week play-based childhood obesity intervention at a neighboring community center. A historical comparison group was used to explore the feasibility of an obesity intervention for overweight Chinese American children, ages 7-12. Data were collected on weight, height, blood pressure, waist circumference, physical activity, food intake, knowledge, and self-efficacy about diet and physical activity at baseline, 2 months, and 6 months post-baseline. **Sample:** 21 in intervention group and 20 in comparison group **Inclusion Criteria:** Chinese American children who were 7–12 years old and overweight or obese and their parents were eligible for enrollment if they met the following criteria: (1) The adult and child self-identified ethnicity as Chinese or of Chinese origin, and they reside in the same household. (2) The child was able to speak and read English. (3) The child was in good health, defined as free of an acute or life-threatening disease. (4) Parents were able to speak English, Mandarin, or Cantonese and were able to read in English or Chinese.	**improvements in BMI, BMI percentile, systolic BP, diastolic BP, nutrition knowledge, and nutrition self-efficacy after the intervention.** Mixed models also revealed that children in the intervention group significantly reduced their BMI compared to children in the control group ($F = 8.65$, $p = .004$) from baseline to 6 months post-baseline. No significant differences in BP were found between the intervention and control groups. Table 1 Study variables Variables | Intervention | | | Control | | | | T0 | T1 | T2 | T0 | T1 | T2 | BMI | 25.53 (3.65) | 25.16 (3.91) | 24.53 (4.20) | 23.17 (1.22) | 23.18 (1.28) | 23.20 (1.31) | SBP (mmHg) | 106.9 (5.25) | 95.52 (14.40) | 99.71 (10.87) | 101.33 (4.56) | 99.64 (2.80) | 98.80 (4.73) | DBP (mmHg) | 62.73 (7.11) | 52.86 (9.83) | 57.81 (12.02) | 59.92 (11.20) | 59.27 (10.51) | 58.80 (11.94) | Waist circumference (inches) | 32.53 (4.43) | 32.02 (4.24) | 32.2 (4.38) | | | | Moderate-to-vigorous activity (min/day) | 72.96 (83.53) | 109.01 (62.62) | 118.3 (75.53) | | | | Sedentary time (min/day) | 83.07 (55.29) | 66.46 (54.08) | 57.52 (52.53) | | | | Veg and fruit intake (serving/day) | 2.9 (1.22) | 3.39 (1.14) | 3.84 (1.58) | | | | Nutrition knowledge | 8.04 (3.26) | 9.54 (2.33) | 9.83 (1.82) | | | | Physical activity knowledge | 3.13 (1.2) | 3.56 (.63) | 3.69 (1.14) | | | | Nutrition self-efficacy | 2.19 (.54) | 2.47 (.40) | 2.57 (.37) | | | | Physical activity self-efficacy | 2.14 (.41) | 2.25 (.57) | 2.42 (.37) | | | | T0—baseline assessment T1—2 months post baseline assessment T2—6 months post baseline assessment	control confounding	

References:

1. Anderson, J. D., et al. (2015). "Taking steps together: a family- and community-based obesity intervention for urban, multiethnic children." Health Education & Behavior **42**(2): 194-201.
2. Chen, J. L., et al. (2013). "iStart smart: a primary-care based and community partnered childhood obesity management program for Chinese-American children: feasibility study." Journal of Immigrant & Minority Health **15**(6): 1125-1128.
3. Laws, R., et al. (2014). "The impact of interventions to prevent obesity or improve obesity related behaviours in children (0-5 years) from socioeconomically disadvantaged and/or indigenous families: a systematic review." BMC Public Health **14**: 779.

Quality of evidence (GRADE) –

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate to High	Precise	Inconsistent	Direct	No	**Low**

Note: Low suggests future research very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Question #15: What is the optimal approach to addressing the social determinants of health (lack of fresh produce in corner stores, food deserts, lack of stable housing, wage/income equality) in obesity management services?

General consensus from literature and external guidelines

Research studies demonstrated that the social determinants of health play an important role is the development of overweight/obesity, and the cost of participating in weight management programs may be a barrier. Although, no research was found evaluating how to approach addressing the social determinants of health within the health care setting.

Takeaway: Incorporate community into the assessment and action planning, by utilizing the Rapid, Assessment, Response, and Evaluation (RARE) project model. This will provide the community the opportunity to provide their voice in the design and increase engagement with the organization. OHSU Health should consider a similar model to assist in addressing some of the social determinants of health within the health care setting.

Question #16: How are obesity management interventions determined to be successful? Or, how is weight loss determined to be successful?

Guideline Recommendations

External Guidelines

Endocrine Society Clinical Practice Guideline (2017)[7]

- We recommend that clinicians prescribe and support intensive, age-appropriate, culturally sensitive, family-centered lifestyle modifications (dietary, physical activity, behavioral) to promote a decrease in BMI. (Strong recommendation, moderate quality.
- Although a BMI decrease of 1.5 kg/m^2 may seem small, if maintained for the long term, overweight or obese children and adolescents may benefit by maintaining weight as they grow; BMI will decline as linear growth proceeds, and lifestyle modification may reduce fat mass, increase lean body mass, and improve cardiovascular fitness.

American Association of Clinical Endocrinologists / American College of Endocrinology (2016)[9]

- Patients with overweight or obesity and with either metabolic syndrome or prediabetes, or patients identified to be at high risk of T2DM based on validated risk-staging paradigms, should be treated with lifestyle therapy that includes a reduced-calorie healthy meal plan and a physical activity program incorporating both aerobic and resistance exercise to prevent progression to diabetes. (**Strong recommendation, strong evidence**). The weight-loss goal should be 10%. (**Intermediate recommendation, intermediate evidence**).
- Patients with overweight or obesity and comorbidities should be treated with lifestyle therapy to achieve 5 to 15% weight loss or more as needed to achieve therapeutic targets. (**Strong recommendation, strong evidence**).

European Guidelines for Obesity Management in Adults (2015)[14]

- Appropriate goals of weight management emphasise realistic weight loss to achieve a reduction in health risks and should include promotion of weight loss, maintenance and prevention of weight regain. (**Recommended Best Practice**). Patients should understand that, since obesity is a chronic disease, weight management will need to be continued lifelong.
- Set goals and propose realistic, individualised, and sustainable lifestyle changes at the long term (5-15% of body weight or 0.5-1 kg/week).
    - A 5–15% weight loss over a period of 6 months is realistic and of proven health benefit. (**Level 1**) A greater (20% or more) weight loss may be considered for those with greater degrees of obesity (BMI ≥ 35 kg/m^2) (**Recommended Best Practice**). Maintenance of weight loss and prevention and treatment of co-morbidities are the two main criteria for success. (**Level 1**).

Department of Veterans Affairs / Department of Defense (2014)[13]

- Comprehensive lifestyle intervention is central to successful and sustained weight loss. Tangible intermediate and long-term weight loss goals are critical to weight loss success.
    - Convey the importance of weight loss and maintenance as a lifelong commitment rather than a brief episode of treatment. (**Expert Opinion**)
    - Offer patients at least 12 contacts within 12 months of a comprehensive lifestyle intervention that combines dietary, physical activity and behavioral strategies. (**Moderate recommendation**).
    - Plan a net deficit of 500 to 1,000 kcal/day addressing both diet and physical activity to achieve a weight loss of 0.5 to 2 pounds per week, resulting in a 5-10% reduction in body weight over 6 months. (**Strong recommendation**).

American College of Cardiology / American Heart Association Task Force / The Obesity Society (2013)[10]

- Counsel overweight and obese adults with cardiovascular risk factors (high BP, hyperlipidemia, and hyperglycemia) that lifestyle changes that produce even modest, sustained weight loss of 3%–5% produce clinically meaningful health benefits, and greater weight losses produce greater benefits. (**Strong recommendation, strong evidence**).
    - Sustained weight loss of 3%–5% is likely to result in clinically meaningful reductions in triglycerides, blood glucose, hemoglobin A1c, and the risk of developing type 2 diabetes. (**Strong recommendation, strong evidence**).
    - Greater amounts of weight loss will reduce BP, improve LDL–C and HDL–C, and reduce the need for medications to control BP, blood glucose, and lipids as well as further reduce triglycerides and blood glucose. (**Strong recommendation, strong evidence**).

Childhood Obesity Task Force of the European Association for the Study of Obesity (2010)[1]

- Setting realistic goals and expectations can help avoid unnecessary frustrations along the road. For growing children who are overweight or mildly obese, weight maintenance (and not weight loss) is sufficient to improve well-being and the metabolic profile.
- In adolescents, a weight loss of 1–2 kg per month is achievable for a limited time in some and may be sustainable.

American Academy of Pediatrics (2007)[2]

- The establishment of permanent healthy lifestyle habits is a good outcome, regardless of weight change, because of the long-term health benefits of these behaviors. Improvement in medical conditions is also an important sign of long-term health benefits. The metric for improved weight is BMI percentile, generally to <85th percentile, although some children are healthy in the overweight category (85th–94th percentile).

Summary

Pediatrics

The primary goals in treating adolescents with overweight and obesity are decreasing BMI velocity and minimizing or reducing risk of long-term weight-related comorbidities. Goals of reducing BMI or zBMI to age-appropriate levels as described by the WHO, followed by weight maintenance, are realistic and clinically meaningful.[1-8] Weight loss should not exceed 0.5 kg per month for children ages 2 to 11 years or 1-2 kg per month for adolescents and teenagers.[1]

Adults

The primary goal of treatment of obesity in adults is long-term weight reduction and improvement in overall health, as well as minimizing or reducing risks of comorbidities. Goals of 2.5% weight loss after 1 month and 5-10% weight loss after 6 months, followed by sustained weight loss and maintenance beyond 1 year, are realistic and clinically meaningful.[9-12] Weight loss of 10-15% is the general target across comorbidities to minimize symptoms; the long-term goal is to reduce or eliminate the need for pharmacologic management.[10] Weight loss and weight maintenance are lifelong commitments, as overweight and obesity is a chronic disease.[13]

Question #17: For patients who have successfully made obesity-related lifestyle changes, what intervention are effective for maintenance of health?

Guideline Recommendations:

Children and Adults

The UK's **National Institute for Health and Care Excellence (NICE) in 2014** recommended the following

- Pharmacological treatment may be used to maintain weight loss rather than to continue to lose weight.
- Offer support to help maintain weight loss to people whose drug treatment is being withdrawn; if they did not reach their target weight, their self-confidence and belief in their ability to make changes may be low.

Adults

The **American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society (AHA/ACC/TOS)** in 2013 recommended:

Box 15: Weight Loss Maintenance

Typically, obesity is a chronic condition that develops over an individual's lifetime. The prevalence of obesity has greatly increased over the past 30 years, most likely because of environmental changes that promote increased consumption of high-calorie palatable foods, decreased physical activity, and more sedentary behavior. In this environment, it is difficult to maintain a healthy weight and prevent weight gain. Long-term research has shown that continuing weight loss maintenance interventions produce better long-term results than limited term intervention programs. Clinicians must acknowledge the lifelong challenge that patients experience with obesity, provide support and encouragement, be prepared to assist patients with addressing small weight gains before they become larger ones, and reinstitute weight management efforts as early as possible in the course of regain.

The usual pattern of weight loss in patients undergoing a lifestyle intervention is that maximum weight loss is achieved at 6 months, followed by plateau and gradual regain over time. This is also true for medication-assisted weight loss, although weight regain may be slower with continued medication use. For bariatric surgery patients, it may take much longer for weight to plateau (CQ3, CQ4, and CQ5).

The strategies for weight maintenance after successful loss differ from the strategies for achieving weight loss. Flexibility and willingness to try different approaches are recommended. Patients should be advised that participation in a long-term (≥1 y) comprehensive weight loss maintenance program with monthly or more frequent contact, in person or by telephone, can improve successful weight maintenance. Strategies such as frequent self-weighing (at least weekly), consumption of a reduced-calorie diet, and high levels of physical activity (>200 min/wk) are associated with better weight maintenance over time.

The 2015 **European Guidelines** for Obesity Management in Adults recommended the following:
Assess effect on co-morbidities, weight maintenance and weight regain

- Regular monitoring of weight, BMI, and WC
- Reinforce lifestyle modification
- Address other risk factors

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

- Obesity is a chronic disease requiring lifelong commitment to treatment and long-term maintenance
- Offer patients who have met their weight loss goals a comprehensive maintenance program consisting of behavioral components and ongoing support

Primary Literature:

Interventions: Behavioral, physical activity and pharmacologic **Outcome: Weight loss maintenance**				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Dombrowski, 2014	**Design:** Systematic Review **Sample:** 45 trials; 7788 individuals **Inclusion and Exclusion Criteria:** *Types of studies*—Randomized controlled trials or cluster randomized controlled trials with participants randomized to a weight maintenance intervention compared with a control condition or another intervention, or both, and ≥12 months' follow-up of weight outcomes from inception of the maintenance intervention.	Behavioral interventions focusing on both food intake and physical activity resulted in an average difference of -1.56 kg (95% confidence interval -2.27 to -0.86 kg; 25 comparisons, 2949 participants) in weight regain compared with controls at 12 months. Orlistat combined with behavioral interventions resulted in a -1.80 kg (-2.54 to -1.06; eight comparisons, 1738 participants) difference compared with placebo at 12 months. All orlistat studies reported higher frequencies of adverse gastrointestinal events in the experimental compared with placebo control groups. A	None	Low

	Types of participants—Participants were adults (aged ≥18, no upper age limit) who had, or had had, an average BMI of ≥30 and lost ≥5% of their body weight/mass within 24 months before weight loss maintenance treatment. Studies that recruited participants with established mental health conditions, including eating disorders, and conditions requiring treatment with antipsychotic drugs were excluded. **Type of interventions**—Any behavioral/lifestyle, pharmacological (with European Medicines Agency approval for weight loss), food replacement/supplement, or alternative interventions, singly or in combination were included. Surgical interventions were excluded. *Types of outcomes*—Primary outcome was weight at 12 months from randomization to the weight loss maintenance intervention. Weight could be reported as absolute weight change during the trial including the weight loss phase, weight change during the maintenance treatment period, or final weight values. Types of reports—Full text reports in any language from 1946 to January 2014.	dose-response relation for orlistat treatment was found, with 120 mg doses three times a day leading to greater weight loss maintenance (-2.34 kg, -3.03 to -1.65) compared with 60 mg and 30 mg three times a day (-0.70 kg, 95% confidence interval -1.92 to 0.52), P=0.02.		

1. Dombrowski, S. U., et al. (2014). "Long term maintenance of weight loss with non-surgical interventions in obese adults: systematic review and meta-analyses of randomised controlled trials." BMJ (Clinical research ed.) **348**: g2646.

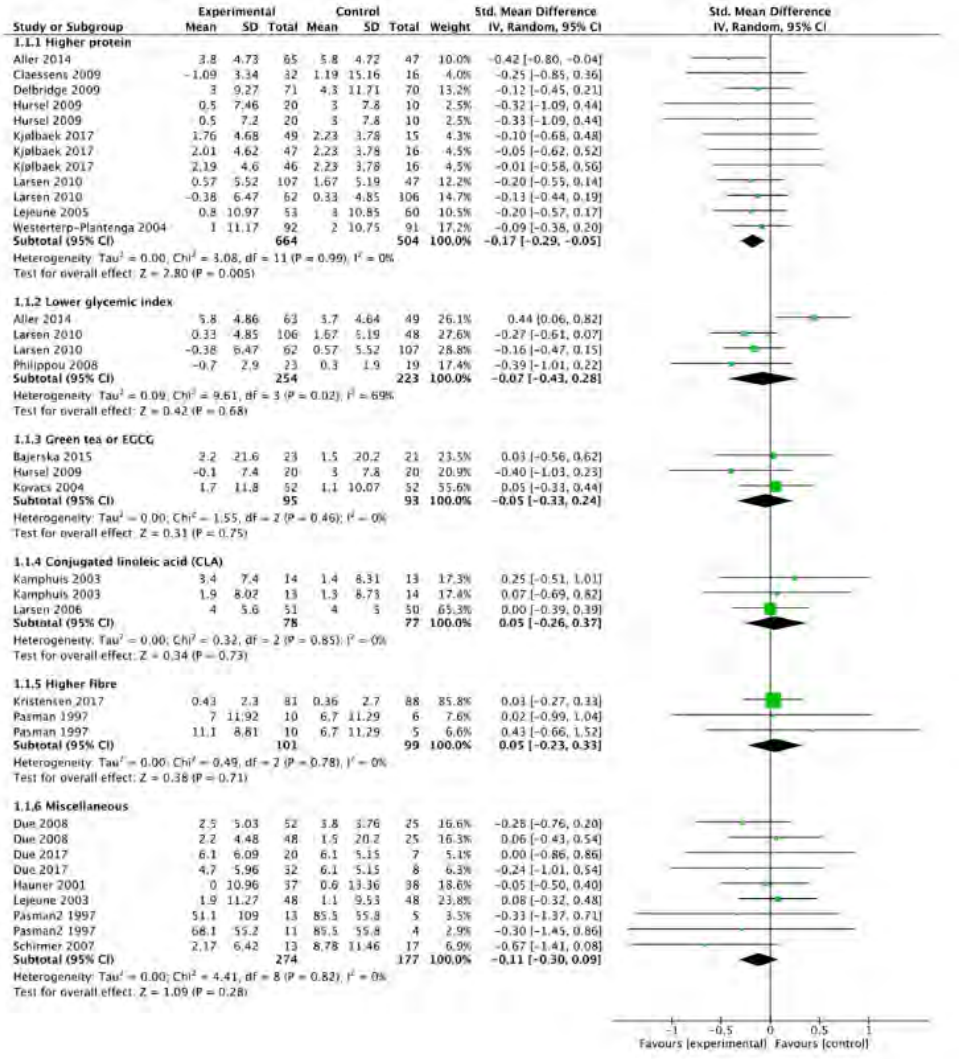
Population: Pharmacologic Interventions **Outcome: Maintenance of Health**				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**

Johansson, 2014	**Design:** Systematic Review **Sample:** 20 studies; 3017 participants **Inclusion Criteria:** Randomized controlled trials of adults (age >/=18 y), and consisted of an initial weight loss period with a very low calorie diet (VLCD) or low calorie diet (LCD) (<1000 kcal/d) followed by randomization to a maintenance strategy (anti-obesity drug, diet, and/or exercise) or control. No restrictions regarding study duration were imposed. **Exclusion Criteria:** Studies evaluated anti-obesity drugs that never reached approval by regulatory agencies or if the weight-loss period did not include a VLCD or LCD.	Compared with controls, anti-obesity drugs improved weight-loss maintenance by 3.5 kg [95% CI: 1.5, 5.5 kg; median duration: 18 mo (12-36 mo)], meal replacements by 3.9 kg [95% CI: 2.8, 5.0 kg; median duration: 12 mo (10-26 mo)], and high-protein diets by 1.5 kg [95% CI: 0.8, 2.1 kg; median duration: 5 mo (3-12 mo)]. Exercise [0.8 kg; 95% CI: -1.2, 2.8 kg; median duration: 10 mo (6-12 mo)] and dietary supplements [0.0 kg; 95% CI: -1.4, 1.4 kg; median duration: 3 mo (3-14 mo)] did not significantly improve weight-loss maintenance compared with control.	Synthesized data from different dietary interventions Variations between included study protocols (included length of phases and interventions)	Low to moderate

References:

1. Johansson, K., et al. (2014). "Effects of anti-obesity drugs, diet, and exercise on weight-loss maintenance after a very-low-calorie diet or low-calorie diet: a systematic review and meta-analysis of randomized controlled trials." The American journal of clinical nutrition **99**(1): 14-23.

van Baak 2019 Meta-analysis



Intervention: Nutrition **Outcome: Weight Maintenance**				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
van Baak, 2019	**Design:** Systematic Review **Sample:** 21 studies; 2875 participants **Inclusion Criteria:** Studies with adult participants, were overweight or obese at baseline, and had been randomized to different diets after following the same energy-restricted diet to attain weight loss, and if the randomized diets were ad libitum and the study design was a randomized controlled trial. Outcome was the weight change over the experimental period.	The meta-analysis shows a significant beneficial effect of higher protein intake on the prevention of weight regain (SMD (standardized mean difference) -0.17 (95% CI -0.29, -0.05), z = 2.80, p = 0.005), without evidence for heterogeneity among the included studies. No significant effect of the other strategies is detected.	None	Low

References:
1. van Baak, M. A. and E. C. M. Mariman (2019). "Dietary Strategies for Weight Loss Maintenance." Nutrients **11**(8).

Intervention: Nutritional

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Intervention: Behavioral and Physical Activity

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Intervention: Pharmacologic

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Question #18: What is the appropriate follow-up (length, interventions, etc.) with patients who are actively attending to lifestyle changes for obesity management?

External Guidelines

United States Preventive Services Task Force (2017)[8]

- Lifestyle-based weight loss programs (including those aiming to minimize weight gain with growth in height) with an estimated 26 or more contact hours consistently demonstrated small average reductions in excess weight in children and adolescents who were overweight or had obesity compared with usual care or other control groups, with no evidence of causing harm.
- Interventions offering 52 or more contact hours showed fairly consistent improvements in blood pressure; benefits in cardiometabolic outcomes were not observed in trials with fewer than 52 estimated contact hours and were sparely reported.

American Association of Clinical Endocrinologists / American College of Endocrinology (2016)[16]

- Behavioral lifestyle intervention and support should be intensified if patients do not achieve a 2.5% weight loss in the first month of treatment, as early weight reduction is a key predictor of long term weight-loss success (**Strong recommendation, strong evidence**).

Department of Veterans Affairs / Department of Defense (2014)[19]

- Assess adherence to the weight loss program one-to-two times per month by measuring the patient's weight and providing feedback and ongoing support. Re-evaluate the treatment plan for patients who have lost an average of less than 0.5 pound per week. Offer patients who have met their weight loss goals a comprehensive maintenance program consisting of behavioral components and ongoing support. (**Expert Opinion**).

American Academy of Pediatrics (2007)[18]

- When a patient's weight or BMI percentile does not improve as desired over 3 to 6 months of planned treatment, the provider and family should consider advancing to the next, more-intensive stage of treatment.
- Weight goals to improve BMI percentile include weight velocity maintenance and weight maintenance through a staged approach, based on age and BMI percentile. Weight loss of up to 0.5 kg per month is acceptable for children ages 2-11 years and up to 1 kg per week for adolescents and teenagers ages 12-18 years.

Summary

A multicomponent, comprehensive, and long-term intervention is recommended for all patients with overweight and obesity. There is a dose response between contact and duration of lifestyle interventions and weight loss, with more intense interventions resulting in greater and sustained weight loss and improvement in weight-related health outcomes.[1-4]

Interventions with at least 12 sessions over 6 months or minimum 26 contact hours over 12 months, followed by long-term support for weight maintenance in accordance with a chronic care model, are recommended.[1-12] Moderate- and high-intensity interventions demonstrate significantly greater weight loss and improvement in weight-related comorbidities versus low intensity interventions, especially when paired with extended maintenance sessions by a trained professional (including minimum monthly follow-ups).[1-4,13-15]

Pediatrics

Family-based multicomponent lifestyle interventions are recommended, with initiation at the earliest stage possible.[4,8,11] If there is no improvement in BMI or weight status after 3-6 months, escalate intervention intensity or refer to specialty centers (*see Behavioral Interventions, Lifestyle Interventions, Nutritional Interventions, Physical Activity, and Pharmacologic Therapy, and Surgical Interventions sections*).

Adults

Multicomponent lifestyle interventions are recommended consisting of nutritional, physical activity and behavioral components. Clinicians should support intensive, culturally sensitive, patient-centered lifestyle modifications. If there is no improvement in BMI or weight status after 3 months, consider escalating intensity, adding pharmacotherapy, or refer to specialty centers (*see Behavioral Interventions, Lifestyle Interventions, Nutritional Interventions, Physical Activity, and Pharmacologic Therapy, and Surgical Interventions sections*).[5,16-17]

Population: Adults
Outcome: Intervention Intensity

Source, Year	Study Design and Methods	Summary of Findings	Design Limitations	Quality or risk of bias
Singh, 2019	**Design**: Meta-analysis **Purpose:** To evaluate the importance of the frequency and duration of lifestyle interventions for	• Median 28 contacts in first year (IQR 12-37), with median 18 (IQR 10-24) during first 6 months.	Adherence, specific intervention characteristics not consistently reported in studies	Moderate to high quality

	achieving weight loss over ≥1 year and associations with all-cause mortality. **Sample:** 31 RCTs (20,816) **Inclusion Criteria**: RCTs ≥1 year, N≥100 overweight and obese adults (BMI ≥25 kg/m^2) participants, lifestyle intervention vs. usual care control. **Exclusion Criteria:** Studies with pharmacotherapy, surgery, 'self-help' controls, <1 contact, >5% attrition.	• Mean difference in weight loss at 1 year vs. controls: -3.63 kg (95% CI -4.67 to -2.58), p<0.001, I^2=97% • Greater weight loss in obese vs. overweight participants (not significant) • Greater weight loss in interventions with >28 interventions vs. ≤28: -4.5 kg (95% CI -5.97 to -3.03) vs. -2.4 kg (95% CI -3.98 to -0.78) • Estimated 0.6 kg lost for every additional 10 contacts		

1. Singh N, Stewart RAH, Benatar JR. Intensity and duration of lifestyle interventions for long-term weight loss and association with mortality: a meta-analysis of randomised trials. BMJ Open. 2019;9:e029966. doi:10.1136/bmjopen-2019-029966

Question #19: In patients who have undergone bariatric surgery, what post-operative lifestyle intervention programs (exercise, behavioral, dietary or long-term pharmacologic therapy) improve long-term weight loss and weight-loss maintenance?

Guideline Recommendations:

Children and adolescents

The **2019 American Academy of Pediatrics** recommendations on Pediatric Metabolic and Bariatric Surgery: Evidence, Barriers, and Best Practice:

- Coordinate pre- and postoperative care with the patient, family, and multidisciplinary, anesthesia and surgical teams.
- Monitor patients postoperatively for micronutrient deficiencies and consider providing iron, folate, and vitamin B12 supplementation as needed.
- Monitor patients postoperatively for risk-taking behavior and mental health problems.

The **2019 American Society for Metabolic and Bariatric Surgery Pediatric Committee (ASMBS)** best practice guidelines recommendations:

- Consistent attendance and compliance with medical interventions is an important measure of whether a patient and family are likely to comply with care postoperatively.
- Substantial efforts should be made to achieve long-term follow-up after RYGB to limit the associate risks of micronutrient and vitamin deficiencies to maximize postoperative nutritional compliance.
- It is important that adolescents with preoperative depression be monitored for recurrence of depression postoperatively.

Adult

The 2016 **American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE)** Clinical Practice Guidelines for Comprehensive Medical Care of Patients with Obesity stated:

Post-bariatric surgery

- Patients who have undergone bariatric surgery should continue to be treated with an intensive lifestyle intervention (**Grade A; BEL 1**).
- Patients who have regained excess weight (≥25% of the lost weight) and who have not responded to intensive lifestyle intervention and are not candidates for reoperation may be considered for treatment with liraglutide 1.8 to 3.0 mg or phentermine/topiramate ER; the safety and efficacy of other weight-loss medications have not been assessed in these patients (**Grade D; BEL 3, downgraded due to evidence gaps**).

The **2013 American Association of Clinical Endocrinologists, The Obesity Society, and the American Society for Metabolic and Bariatric Surgery (AACE/TOS/ASMBS)** Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patients recommends:

- The frequency of follow up depends on the bariatric procedure performed and the severity of co-morbidities (**Grade D**).
- Following LAGB, frequent nutritional follow-up and/or band adjustments are important for maximal weight loss (**Grade C; Bel 3**).
- Significant weight regain or failure to lose weight should prompt evaluation for (a) decreased patient adherence with lifestyle modification, (b) evaluation of medications associated with weight gain or impairment of weight loss, (c) development of maladaptive eating behaviors, (d) psychological complications, and (e) radiographic or endoscopic evaluation to assess pouch enlargement, anastomotic dilation, formation of a gastrogastric fistula among patients who underwent a RYGB, or inadequate band restriction among patients who underwent a LAGB (**Grade B; Bel 2**).
- Interventions should first include a multidisciplinary approach, including dietary change, physical activity, behavioral modification with frequent follow up; and then if appropriate, pharmacologic therapy and/or surgical revision (**Grade B; Bel 2**).
- In patients with or without complete resolution of their T2D, dyslipidemia or hypertension, continued surveillance and management should be guided by current clinical practice guidelines for those conditions (**Grade D**)
- Routine metabolic and nutritional monitoring is recommended after all bariatric surgical procedures (**Grade A; Bel 1**).
- Patients should be advised to incorporate moderate aerobic physical activity to include a minimum of 150 minutes per week and goal of 300 minutes per week, including strength training 2 to 3 times per week (**Grade A; Bel 1**)
- All patients should be encouraged to participate in ongoing support groups after discharge from the hospital (**Grade B; Bel 1**).

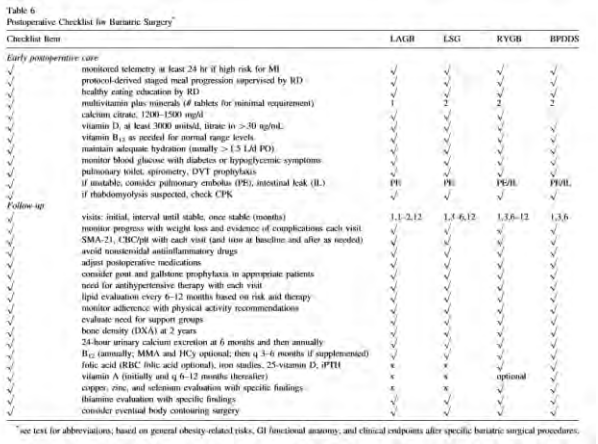


Table 6
Postoperative Checklist for Bariatric Surgery*

Checklist Item		LAGB	LSG	RYGB	BPDDS
Early postoperative care					
√	monitored telemetry at least 24 hr if high risk for MI	√	√	√	√
√	protocol-derived staged meal progression supervised by RD	√	√	√	√
√	healthy eating education by RD	√	√	√	√
√	multivitamin plus minerals (# tablets for minimal requirement)	1	2	2	2
√	calcium citrate, 1200–1500 mg/d	√	√	√	
√	vitamin D, at least 3000 mIU/d, titrate to >30 ng/mL	√	√	√	√
√	vitamin B_{12} as needed for normal range levels	√	√	√	√
√	maintain adequate hydration (usually >1.5 L/d PO)	√	√	√	√
√	monitor blood glucose with diabetes or hypoglycemic symptoms	√	√	√	√
√	pulmonary toilet, spirometry, DVT prophylaxis	√	√	√	√
√	if mutable, consider pulmonary embolus (PE), intestinal leak (IL)	PE	PE	PE/IL	PE/IL
√	if rhabdomyolysis suspected, check CPK	√	√	√	√
Follow-up					
√	visits: initial, interval until stable, once stable (months)	1,1–2,12	1,1–6,12	1,3,6–12	1,3,6
√	monitor progress with weight loss and evidence of complications each visit	√	√	√	√
√	SMA-21, CBC/plt with each visit (and iron at baseline and after as needed)	√	√	√	√
√	avoid nonsteroidal antiinflammatory drugs	√	√	√	√
√	adjust postoperative medications	√	√	√	√
√	consider gout and gallstone prophylaxis in appropriate patients	√	√	√	√
√	need for antihypertensive therapy with each visit	√	√	√	√
√	lipid evaluation every 6–12 months based on risk and therapy	√	√	√	√
√	monitor adherence with physical activity recommendations	√	√	√	√
√	evaluate need for support groups	√	√	√	√
√	bone density (DXA) at 2 years	√	√	√	√
√	24-hour urinary calcium excretion at 6 months and then annually	√	√	√	√
√	B_{12} (annually; MMA and HCy optional; then q 3–6 months if supplemented)	√	√	√	√
√	folic acid (RBC folic acid optional), iron studies, 25-vitamin D, iPTH	x	x	√	√
√	vitamin A (initially and q 6–12 months thereafter)	x	x	optional	√
√	copper, zinc, and selenium evaluation with specific findings	x	x	√	√
√	thiamine evaluation with specific findings	√	√	√	√
√	consider eventual body contouring surgery	√	√	√	√

*see text for abbreviations; based on general obesity-related risks, GI functional anatomy, and clinical endpoints after specific bariatric surgical procedures.

The **American Society for Metabolic and Bariatric Surgery (ASMBS)** Integrated Health Nutritional Guidelines for the Surgical Weight Loss Patient 2016 Update Micronutrients.

- Optimizing postoperative patient outcomes and nutritional status begins preoperatively. Patients should be educated before and after WLS on the expected nutrient deficiencies associated with alternations in physiology, especially those involving nutrient digestion, absorption, metabolism and excretion.

The 2015 **ASGE Bariatric Endoscopy Task Force** recommended:

- Patients should undergo a nutrition assessment that should include a diet history, assessment of eating patterns, and education for postprocedure diet by a registered dietitian or physician trained in obesity medicine.

The UK's **National Institute for Health and Care Excellence (NICE) in 2014** recommended the following

Offer people who have had bariatric surgery a follow-up care package for a minimum of 2 years within the bariatric service. This should include:

- monitoring nutritional intake (including protein and vitamins) and mineral deficiencies
- monitoring for comorbidities
- medication review
- dietary and nutritional assessment, advice and support
- physical activity advice and support

- psychological support tailored to the individual
- information about professionally-led or peer-support groups.

After discharge from bariatric surgery service follow-up, ensure that all people are offered at least annual monitoring of nutritional status and appropriate supplementation according to need following bariatric surgery, as part of a shared care model of chronic disease management.

The 2014 **Department of Veterans Affairs and Department of Defense** (VA/DoD) recommended:

- Provide lifelong follow-up after bariatric surgery to monitor adverse effects and complications, dietary restrictions, adherence to weight management behaviors, and psychological health. [**EO**]

Primary Literature:

Intervention: Physical Activity				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Ren, 2018	**Design:** Systematic Review **Sample:** A total of 8 studies met the inclusion criteria (n=347 participants) **Inclusion and Exclusion Criteria:** Prespecified inclusion criteria were as follows: (1) All of the published RCTs on physical exercise in patients after bariatric surgery were considered for inclusion; (2) Subjects were adults with obesity (age ≥18 years) who had undergone bariatric surgery (all types); (3) For the intervention group(s), modes of exercise regimens were defined as aerobic exercise, resistance training or a combination of both. The control group received only standard care (eg,	Compared with those without exercise intervention after surgery, patients engaging in physical exercise were associated with greater weight loss (weighted mean difference (WMD) -1.94 kg; 95% CI -3.18 to -0.69; n=8) and longer 6 min walk distance (6MWD; WMD29.67 m; 95% CI 25.97 to 33.37; n=2) during follow-up. By subgroup analyses, the additional weight loss in exercise group was related to the starting time and type of exercise: patients engaging in exercise 1 year or more after surgery and patients received aerobic-resistance exercise experienced more weight loss. Besides, patients in	The quality of evidence for body weight and BMI were moderate. And the quality of evidence for other outcomes was downgraded to 'low' or 'very low', mainly due to high risk of performance bias, inconsistency (with a large I2 value or a wide 95% CI around the	Low

	advice to increase physical activity and healthy eating) or no exercise training; (4) At a minimum, the studies must have assessed weight loss or physical function as an outcome and must have reported mean values or the differences between the mean values. The exclusion criteria were as follows: (1) intervention studies comparing only two kinds of exercise prescriptions without control groups and (2) duplicate publications of the included trials.	exercise training group also had lower systolic blood pressure and resting heart rate after surgery.	pooled effect) and imprecision (small sample size).	
da Silva, 2019	**Design:** Systematic Review **Sample:** 7 studies **Inclusion Criteria:** All eligible prospective cohort models, human subjects (adults over 19 years old), written in English language, studies investigating the association between CRF and measured cardiorespiratory variables following BS by cardiopulmonary exercise testing, and studies which included a description of the exercise training protocol. **Exclusion criteria:** Non-original publications (i.e., errata, letters to the editor, reviews), retracted papers, guidelines, qualitative studies, lack of an exercise training intervention (aerobic, resistance, or combined), and studies which did not investigate the effects of exercise training on VO2max.	The pooled results of these studies demonstrate that exercise training leads to a moderate and significant increase of VO2max in post-BS patients (SMD= 0.430, 95% CI 0.157; 0.704, p = 0.002)	Unable to eliminate all confounding	Low

1. da Silva, A. L. G., et al. (2019). "Exercise Training Does Improve Cardiorespiratory Fitness in Post-Bariatric Surgery Patients." Obesity Surgery **29**(4): 1416-1419.

2. Ren, Z.-Q., et al. (2018). "Effect of physical exercise on weight loss and physical function following bariatric surgery: a meta-analysis of randomised controlled trials." BMJ Open **8**(10): e023208.

Physical Activity – Efficacy

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Academy of Nutrition and Dietetics Evidence Review Summary, 2019

Question No.	Question	Conclusion Statement	Grade
1.1. Postoperative MNT[a] on behavior change	What is the effect of postoperative MNT provided by an RDN[b] on behavior change in adults who have undergone bariatric surgery?	Three studies (including gastric bypass, gastric band, and biliopancreatic diversion patients [with the majority of patients having undergone gastric bypass]) reported on the effect of MNT from an RDN on behavior change. One study reported that MNT, provided as 15-min in-person sessions with an RDN every other week for the first 4 mo after surgery, resulted in a significant increase in cognitive restraint (controlled eating) for up to 18 mo compared with standard care. However, two studies reported mixed results regarding the effect of MNT on increasing protein intake and physical activity.	III
1.2. Postoperative MNT on weight loss	What is the effect of postoperative MNT provided by an RDN on weight loss in adults who have undergone bariatric surgery?	Four studies (including gastric bypass, gastric band, sleeve gastrectomy, and biliopancreatic diversion patients [with the majority of patients having undergone gastric bypass]) reported that patients receiving MNT from an RDN for two to six visits during the first year post-surgery had significant excess weight loss, ranging from 60% to 80%, and significant reduction in body mass index, ranging from 5% to 31%, at 12 mo. An MNT session duration of 90 min was reported in one study, which also demonstrated that a higher frequency and duration of MNT visits resulted in the greatest weight loss (80% vs 64% excess body weight loss at 1 y post-surgery) compared to those receiving standard care.	II
2.0. Postoperative energy needs	What is the effect of bariatric surgery on RMR[c] in adults?	A total of 10 studies, including gastric bypass and gastric band (with the majority of patients having undergone gastric bypass) reported a clinically meaningful and statistically significant decrease in RMR after bariatric surgery. Five studies reported a decrease ranging from 12% to 21% during the first 6 mo post-surgery, four studies reported a decrease ranging from 13.5% to 26% at 1 y, and one study reported that an approximately 20% reduction in RMR was sustained at 2 y. Ongoing research is needed regarding the effect of available bariatric surgical options on RMR.	I
3.0. Postoperative energy intake	What is the effect of bariatric surgery on energy intake in adults?	Eight studies (including gastric bypass, gastric band, sleeve gastrectomy, and biliopancreatic diversion patients [with the majority of patients having undergone gastric bypass]) reported a clinically meaningful and statistically significant reduction in self-reported energy intake after bariatric surgery. Six studies reported a	II

(continued on next page)

Figure 2. Conclusion statements for the Academy of Nutrition and Dietetics Evidence Analysis Library evidence-based systematic review of nutrition care in bariatric surgery.

Question No.	Question	Conclusion Statement	Grade
		reduction ranging from 45% to 72% during the first 6 mo post-surgery, five studies reported a reduction ranging from 19% to 50% at 1 y post-surgery, four studies reported a reduction ranging from 30% to 62% at 2 y post-surgery, and one study reported a reduction ranging from 28% to 38% at 4 and 5 y post-surgery when compared with presurgical energy intake. These wide ranges may be due to the variation in methods used to measure energy intake. Ongoing research is needed regarding the effect of available bariatric surgical options on energy intake.	
4.0. Postoperative macronutrient intake	What is the relationship between postoperative macronutrient distribution and weight loss in adults who have undergone bariatric surgery?	Seven studies (including gastric bypass, gastric band, and sleeve gastrectomy, with the majority of patients having undergone gastric bypass) report that postoperative macronutrient distribution based on percentage of energy ranges from 35% to 50% from carbohydrates, 15% to 23% from protein, and 35% to 42% from fat, for a period of up to 5 y. While a particular postoperative macronutrient distribution may be associated with receiving MNT, postoperative dietary adherence and daily caloric intake, there was no statistically significant relationship between postoperative macronutrient distribution and postoperative weight loss. These ranges may be due to the variation in methods used to measure macronutrient distribution. Ongoing research is needed regarding the effect of available bariatric surgical options on macronutrient distribution.	II

[a]MNT=medical nutrition therapy.
[b]RDN=registered dietitian nutritionist.
[c]RMR=resting metabolic rate.

Figure 2. *(continued)* Conclusion statements for the Academy of Nutrition and Dietetics Evidence Analysis Library evidence-based systematic review of nutrition care in bariatric surgery.

Intervention: Nutritional				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Andromalos, 2019	**Design:** Systematic Review **Sample:** 27 research studies **Inclusion and Exclusion Criteria:**	**Summary above* Limited research demonstrates that registered dietitian nutritionists play a role in improving weight loss outcomes after	Inconsistency between methods in research studies	Low

	Only original, peer-reviewed studies, published in the English language, with publication dates from 1980 to 2015, and which had a dropout rate of <20% were included.	bariatric surgery; further research is needed to understand the role of registered dietitian nutritionists in changing behaviors after bariatric surgery. Bariatric surgery results in significant reductions in resting metabolic rate and postoperative energy intake. There is no significant relationship between macronutrient distribution and postoperative weight loss.		
Holderbaum, 2018	**Design:** Systematic Review **Sample:** 9 studies included (849 patients including 250 controls, 196 controls without VLCD) **Inclusion Criteria:** Patients >18 years of age in the preoperative period of any BS technique for the treatment of obesity, who underwent VLCDs (up to 800 kcal/d) for a minimum of 10 days and a maximum of 12 weeks; analyses of 1 or more of the following outcomes after treatment: change in weight, change in liver size, and number of complications in the perioperative period. Randomized clinical trials (RCT) and prospective and retrospective studies with or without control groups were included. **Exclusion Criteria:** Reviews, letters to the editor, and conference abstracts.	VLCD treatment led to weight loss (-2.8 to -14.8 kg) and to liver size reduction by 5% to 20% of the initial volume. VLCD treatment did not significantly reduce perioperative complications. However, 1 study (n = 273) reported a protective effect 30 days after surgery. This systematic review found VLCD treatment led to significant weight loss and liver volume reduction when applied to patients with obesity in BS preoperative period. The effect of VLCD on surgical risks is not clear. Standardization of dietary characteristics is needed, because weight loss and decrease in liver size were not connected to higher caloric restriction.	Lack of blinding in 7 studies including in meta-analysis	Low to moderate

References:

1. Andromalos, L., et al. (2019). "Nutrition Care in Bariatric Surgery: An Academy Evidence Analysis Center Systematic Review." Journal of the Academy of Nutrition and Dietetics **119**(4): 678-686.

2. Holderbaum, M., et al. (2018). "Effects of very low calorie diets on liver size and weight loss in the preoperative period of bariatric surgery: a systematic review." Surg Obes Relat Dis **14**(2): 237-244.

Nutritional – Efficacy

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Intervention: Behavioral				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
David, 2020	**Design:** Systematic Review **Sample:** 44 Studies **Inclusion Criteria:** (a) therapist (health care professional with mental health training, a clinician working in conjunction with a mental health care professional, or a student working under the supervision of such health care professional), (b) psychosocial intervention (treatments with a cognitive or behavioral component; interventions that focused solely on dietary advice, social support, or physical activity were not included), and (c) participants (adult bariatric surgery patients). All study designs except for qualitative studies, case studies, and study protocols without empirical data were considered in this review. Included articles must be written or translated to English.	The current evidence is strongest for the impact of psychosocial interventions, particularly cognitive behavioral therapy, on eating behaviors (eg, binge eating and emotional eating) and psychological functioning (eg, quality of life, depression, and anxiety). The evidence for the impact of psychosocial interventions on weight loss, dietary behaviors (eg, dietary intake), and lifestyle behaviors (eg, physical activity) is relatively weak and mixed. Psychosocial interventions can improve eating pathology and psychosocial functioning among bariatric patients, and the optimal time to initiate treatment appears to be early in the post-operative period before significant problematic eating behaviors and weight regain occur.	Unable to conduct meta-analysis due to variation between the way outcomes were reported	Moderate

Rudolph, 2013	**Design:** Systematic Review **Sample:** 15 studies; 1008 participants **Inclusion Criteria:** Observational studies, treatment studies, and non-randomized and uncontrolled studies investigating the impact of behavioral management on weight loss after bariatric surgery. Furthermore, studies had to include (i) adult patients (age >/= 18 years) who underwent bariatric surgery as defined in the search criteria in the following statements; (ii) post-operative behavioral management that was aimed at post-operative lifestyle change, such as support groups, behavioral weight management or psychotherapy and (iii) outcome variables including any indicator of body weight change after behavioral management, e.g. kilogram, pounds, BMI (kg m2) or percentage of excess weight loss **Exclusion Criteria:** Discussion papers, reviews, comments and case reports were excluded.	The main finding is that behavioral management had a positive effect on weight loss following surgery. In 13 studies, patients receiving behavioral management had greater weight loss than patients receiving usual care or no treatment. A meta-analysis of five randomized controlled trials suggests greater weight loss in patients with behavioral lifestyle interventions compared with control groups. Post-operative behavioral management has the potential to facilitate optimal weight loss following bariatric surgery. A meta-analysis was conducted to examine the overall effect of post-operative behavioral lifestyle interventions for bariatric surgery patients compared with control groups. A significant difference in weight change favoring intervention over no intervention was found with a standardized mean difference of 1.6 (95% CI = 0.8, 2.4), Z = 4.0, P < 0.01.	Small study samples Studies were heterogeneous Quality of studies was not appraised	Moderate
Stewart, 2016	**Design:** Systematic Review **Sample:** 2 studies	Weight change was significantly greater for participants receiving post-operative intervention than controls (mean difference −12.96 kg [95 % CI −21.66 to	Small sample size Quality of studies not appraised	Moderate

	Inclusion Criteria: RCTs or quasi-RCTs, open only to adults (age ≥18 years or any given definition of adult) with BMI ≥35 kg/m2 with significant co-morbidities or BMI ≥40 kg/m2, undergoing any kind of BS. Any behavioral interventions were eligible, with the explicit aim of changing behavior related to diet and/or physical activity, starting within 12 months of surgery, either pre- or post-operatively. A minimum of 6 months' follow-up was specified.	−4.26, p = 0.03]). The direction of effect was strongly in favor of the intervention. Statistical heterogeneity was low (I2 = 0 %). Data relating to % EWC did not reach statistical significance (mean difference −13.97 % EWC [95 % CI −30.53 to 2.58, p = 0.1]) and heterogeneity was high (I2 = 68 %).		

1. David, L. A., et al. (2020). "Preoperative and post-operative psychosocial interventions for bariatric surgery patients: A systematic review." Obesity reviews : an official journal of the International Association for the Study of Obesity **21**(4): e12926
2. Rudolph, A. and A. Hilbert (2013). "Post-operative behavioural management in bariatric surgery: a systematic review and meta-analysis of randomized controlled trials." Obesity reviews : an official journal of the International Association for the Study of Obesity **14**(4): 292-302.
3. Stewart, F. and A. Avenell (2016). "Behavioural Interventions for Severe Obesity Before and/or After Bariatric Surgery: a Systematic Review and Meta-analysis." Obesity Surgery **26**(6): 1203-1214.

Behavioral – Efficacy

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Inconsistent	Direct	No	**Low**

Note: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Karmali, S., et al. 2013, Weight recidivism clinic Algorithm

Intervention: Follow-up				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Karmali, 2013	**Design:** Systematic Review **Sample:** 16 studies **Inclusion Criteria:** English language manuscripts, adult populations (>18 years of age), and human subjects. Randomized controlled trials, meta-analyses, case reports, non-randomized control trials, reviews and retrospective and prospective case series were considered. **Exclusion Criteria:** Studies only reporting surgical/endoscopic techniques or studies without follow-up outcomes.	Weight regain in these patients appeared to be multi-factorial and overlapping. Etiologies were categorized as patient specific (psychiatric, physical inactivity, endocrinopathies/metabolic and dietary non-compliance) and operation specific. **Weight regain following bariatric surgery varies according to duration of follow-up and the bariatric surgical procedure performed.** The underlying causes leading to weight regain are multi-factorial and related to patient- and procedure-specific factors.	No meta-analysis performed Quality of studies not assessed	Moderate
Kim, 2014	**Design:** Systematic Review **Sample:** 4 studies, n=365 **Inclusion Criteria:** The included studies compared weight change variables (kilogram, pounds, BMI, or percentage of excess weight loss)	Meta-analysis of these studies found increase in the percentage of excess weight loss (%EWL) at 1-year post gastric bypass surgery (mean difference 6.38 % %EWL, 95 % CI 1.68-11.15) when patients were compliant with follow-up.	Quality of studies not appraised Review did not address focused clinical question	Moderate

References:

1. Karmali, S., et al. (2013). "Weight recidivism post-bariatric surgery: a systematic review." Obesity Surgery **23**(11): 1922-1933.
2. Kim, H. J., et al. (2014). "Does patient compliance with follow-up influence weight loss after gastric bypass surgery? A systematic review and meta-analysis." Obesity Surgery **24**(4): 647-651.

Follow-up – Efficacy

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Intervention: Multidisciplinary care				
Source, Year	**Study Design and Methods**	**Summary of Findings**	**Design Limitations**	**Quality or risk of bias**
Marshall, 2020	**Design:** Systematic Review **Sample:** 18 studies; N = 1533 participants **Inclusion Criteria:** Any study which prospectively compared a preoperative and/or post-operative intervention delivered by a multidisciplinary team (MDT) against a comparator group that had less engagement with the MDT or had no MDT follow-up in adults (≥18 years) was included if relevant outcomes were measured. Included study designs were randomized controlled trials (RCTs), pseudo-RCTs (ie, allocation by researchers does not follow a truly random sequence generation such as allocation by date of birth), or non-RCTs **Exclusion Criteria:** Review, observational, single-group pre-test post-test, and cross-sectional studies, as were abstracts and non-peer-reviewed	Intensive MDT interventions increased post-operative weight loss (SMD: -0.94; 95% CI: -1.27 to -0.61) if delivered post-operatively. Preoperative and post-operative intensive interventions improved symptoms of depression and anxiety, quality of life, diastolic blood pressure, and resting heart rate but not lipids or glycemic measures. Whilst usual MDT care is important preoperatively, this review conditionally recommends intensive MDT interventions for enhanced post-operative weight loss if delivered in the post-operative period, led by any health professional, based on moderate evidence.	None	Low

	papers. Studies that evaluated a "usual care" MDT service against a comparator group were considered observational or implementation studies.			

References:

1. Marshall, S., et al. (2020). "Does intensive multidisciplinary intervention for adults who elect bariatric surgery improve post-operative weight loss, co-morbidities, and quality of life? A systematic review and meta-analysis." Obesity reviews : an official journal of the International Association for the Study of Obesity.

Multidisciplinary Care – Efficacy

Risk of bias	Imprecision	Inconsistency	Indirectness	Publication bias	Certainty (Overall)
Moderate	Precise	Consistent	Direct	No	**Moderate**

Note: Moderate suggests future research will likely have an important impact on confidence in the estimate of effect and may change the estimate.

Question #20: What interventions targeting health care providers and/or organizations reduce weight bias (less time with patient, less rapport building, patient delaying or avoiding treatment) towards patients living with overweight or obesity?

Guideline Recommendations

2019 **ASMBS** position statement on weight bias and stigma:

1. Education on obesity as a chronic disease; advances in research and management: individuals with obesity must be treated by providers and insurers as other patients with a chronic disease. Obesity medicine should be part of medical training and should focus on increasing knowledge, competency, sensitive communication, and confidence in treating patients with obesity. Providers need greater guidance on how to raise the topic of weight loss in a non-stigmatizing manner and provide recommendations that are relevant, evidence-based, individualized, and realistic;
2. Sensitivity training to increase awareness for and reduce the impact of weight bias: there is a broad need for recognition of weight bias, the challenge of living with obesity, and the difficulty of weight loss. In addition, the emotional and health consequences of being stigmatized must be recognized and appreciated. Providers bear the responsibility for ensuring their provision of care is not, to the best of their ability, affected by biases. Providers must ensure their office and hospital environments are conducive to caring for patients with obesity;

3. Improved knowledge of resources: patients and their providers should be familiar with multimodal management options for obesity and local, community, state, and national resources. Payor policies should be continuously monitored by patients, providers, and advocates to ensure evidence-based, bias-free coverage of the medical and surgical treatment of obesity;
4. Facility resources must be made available: specific accommodations are needed to appropriately treat people affected by obesity. These include, but are not limited to, furniture (e.g., chairs, exam tables, operating room tables, hospital beds, wheelchairs, etc.), equipment (e.g., blood pressure cuffs, scales, sequential compression devices, etc.), and facility changes (e.g., doorways, floormounted toilets, etc.); and
5. Educate the public: education of the public is essential for the meaningful implementation of the above recommendations. Effective use of media and other resources are needed to enhance the public understanding of the chronic disease of obesity and the risks of obesity stigma.

Primary Literature:

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Population: Adults

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain) - Unknown*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Alberga, A. S., et al. Year Published: 2016 Location: University of Calgary, Alberta Journal: *Clinical Obesity*	To systematically review peer-reviewed published interventions designed to reduce weight bias in health professionals	**Size:** 17 Studies **Inclusion Criteria:** Studies published between 1990 and September 2015 were included if they met the following criteria: (i) published in English or French, (ii) original primary	**Type:** Systematic Review	**Results:** Literature scan highlighted four primary approaches. (1) Emphasized intellectual understanding of weight, overweight, obesity and weight-related bias, stigma and discrimination by providing basic information	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive

		empirical research and (iii) where weight bias was the focus of the intervention identified in students or professionals in a health-related field. Comments, editorials, letters, abstracts and grey literature were excluded. Reference lists of related publications were also examined for further sources not identified in online searches.		for health professions; (2) Focus on empathy with the lived experience of people who are classified as obese by targeting peoples' emotions; (3) emphasizes self-awareness through self-reflection and gaining an understanding of ones' own attitudes and biases; and (4) influence of respected and trusted leaders or peers who can "sway" people to think one way or another can be utilized. To date, there is insufficient evidence as to which approach is more successful for reducing weight bias among health professionals. Learning from other models of discrimination suggests that "any approach must be multi-faceted and multi-level in order to address the many mechanisms that can lead to harm." The results of this systematic review demonstrated a lack of robust interventions that address weight bias reduction amongst students and health professionals. Many included studies had methodological weaknesses, including short-term follow-up periods (<6 months); lack of randomization and control groups; and inconsistency of outcome variables that limited comparability.	☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis – *Unable to conduct meta-analysis*

References:

1. Alberga, A. S., et al. (2016). "Weight bias reduction in health professionals: A systematic review." Clinical Obesity **6**(3): 175-188.

Question #21: In patients living with overweight or obesity, what is the preferred language (obese, elevated weight) and approach for health care professionals to discuss weight and treatment? Do these preferences vary by ethnicity or socio-economic status?

Guideline Recommendations

In 2014, the **Obesity Society** called for people-first language. People-first language has been widely adopted for most chronic diseases and disabilities, but not obesity. Labeling individuals as obese creates negative feelings toward individuals with obesity, perpetuates weight bias, and must be avoided. Health care providers who use respectful communication with their patients, such as people-first language, create positive, productive discussions about weight and health.

BODY OF EVIDENCE APPRAISAL TABLE FOR: (OUTCOME)
Population: Children and adolescents

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Bejarano, C.M., et al. Year Published: 2017 Location: USA Journal: *Children's Health Care*	To present data regarding the proposed relationships between measures of visit satisfaction and treatment alliance with outcomes of clinic visits for pediatric obesity	**Size:** 50 **Inclusion Criteria:** Age ≥ 5 years but < 17 years at baseline; age-adjusted Body Mass Index ≥ 95th percentile; considered developmentally normal by the treating provider; established care at	**Type:** Observational Study **Intervention:** The data was collected over three visits at approximately 3-month intervals in three obesity specialty care clinics.	**Results:** Results suggest that visit satisfaction and treatment alliance contribute positively to parent/youth self-efficacy and self-reported treatment adherence. However, more weight loss was associated with less favorable treatment alliance	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome

		the enrolling site; sufficient English fluency to converse and to complete study questionnaires. **Exclusion Criteria:** Disorder of hearing, language or speech that significantly impeded communication during health care encounters; unlikely to continue to receive medical care for the obesity for the 6 months following study enrollment.		and visit satisfaction. Findings suggest that an optimal approach to weight management may require a balance between maintaining a positive rapport and challenging families to make and sustain meaningful lifestyle changes. Physical Exercise: There was a significant association between Child TAS Total score at baseline and change in Child PESE from Visit 1 to Visit 2 (V1 to V2) after controlling for Child PESE at baseline ($p < 0.001$). Nutrition: There was a significant association between Child TAS Total at baseline and the change in Child NSE from Visit 1 to Visit 2 after controlling for Child NSE at baseline ($p < 0.005$).	☐ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up
Author: Puhl, R.M. and M.S., Himmelstein Year Published: 2018 Location: USA Journal: *Pediatric Obesity*	To conduct a systematic assessment of youth perspectives of weight-based language used by providers	**Size:** 148 **Inclusion Criteria:** Adolescents enrolled in a national weight loss camp	**Type:** Survey Study **Methods:** Adolescents were surveyed about their preferences for words that health providers use to refer to their body weight. Adolescents completed an online survey and responded to a list of 16 words describing excess body weight, as well as questions assessing demographics, body mass index, and experienced as well as internalized weight stigma.	**Results:** Adolescents assigned low ratings to words like 'fat', 'large', 'obese' and 'extremely obese', indicating that they would not want providers to use these words when discussing their body weight. In contrast, words like 'weight problem', 'BMI' and 'plus size' were rated among the most preferred words for providers to use. Word preferences varied across gender, body mass index and extent of internalized weight stigma.	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

References:

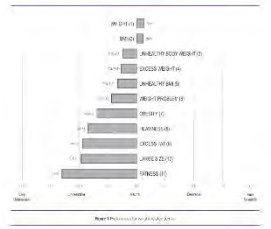
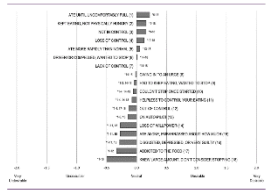
1. Bejarano, C. M., et al. (2017). "Longitudinal associations of visit satisfaction and treatment alliance with outcomes in pediatric obesity clinic visits." Children's Health Care **46**(3): 282-300.
2. Puhl, R. M. and M. S. Himmelstein (2018). "Adolescent preferences for weight terminology used by health care providers." Pediatric Obesity **13**(9): 533-540.

BODY OF EVIDENCE APPRAISAL TABLE FOR: (OUTCOME)
Population: Adults

Quality (certainty) of evidence for: (outcome)
☐ High
☒ Moderate
☐ Low
☐ Very Low

Risk of Bias across studies:	**Low Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Ivezaj, V., et al. Year Published: 2020 Location: USA Journal: *Obesity*	To examine patient preferences for desired weight- and eating-related terms for health care providers among individuals with loss-of-control eating after bariatric surgery	**Size:** 114 **Inclusion Criteria:** Participants underwent bariatric surgery approximately 1.5 years prior at an institution's bariatric center of excellence and were in the follow-up stage of a randomized controlled treatment trial testing treatments following bariatric surgery	**Type:** Cross-sectional study **Methods:** Adults who underwent bariatric surgery approximately 1.5 years prior and were in the follow-up stage of a controlled treatment trial testing behavioral treatments completed language preference measures.	**Results:** Of the 11 terms used to describe weight, only 2 were viewed neutrally, weight and BMI. All other terms, including obesity, were rated negatively, and many were rated extremely negatively. Fatness was the least desirable term. Of the 18 terms used to describe loss-of-control eating, one ("ate until uncomfortably full") was rated positively, and several were rated neutrally. On average, none of the weight or loss-of-control	**Study Limitations:** ☒ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

				eating terms was rated as "desirable" or "very desirable." Analyses revealed few gender and racial differences in language preferences.  	
Author: Volger, S. et al. Year Published: 2012 Location: USA Journal: *Obesity*	To identify terms that obese individuals who were treated in primary care would find the most and least acceptable for describing their excess weight	**Size:** 390 **Inclusion Criteria:** Persons were eligible to participate if they were ≥21 years and had a BMI of 30–50 kg/m², an increased waist circumference (≥40 in for men and >35 in for women), and at least one of the four other criteria for metabolic syndrome	**Type:** Cross-sectional study **Methods:** Obese adult primary care patients in the Philadelphia area were administered the Weight Preferences Questionnaire from January 2008 through February 2009. Ratings of 11 terms used to describe excess weight were transformed to a 5-point scale, ranging from "very desirable" (+2) to neutral (0) to "very undesirable" (-2).	**Results:** The term "fatness" (mean score -1.1 ± 1.3) was rated as significantly more undesirable than all other descriptors (P < 0.001). The terms "excess fat" (-0.6 ± 1.3), "large size" (-0.6 ± 1.3), "obesity" (-0.5 ± 1.4), and "heaviness" (-0.4 ± 1.2) were rated as significantly more undesirable then the remaining terms, which included weight problem, BMI, and excess weight (P < 0.001). In contrast, the term "weight" was viewed as the most desirable term for characterizing excess weight. Patients' preferences for terms were not significantly influenced by gender,	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

				race/ethnicity, or a BMI ≥40 kg/m(2).	
Author: de Heer, H., et al. Year Published: 2019 Location: USA Journal: *Am J Health Promot*	To assess the proportion of people who reported seeking help from their doctor or other health professional to lose weight after a health professional told them to do so	**Size:** 3682 **Inclusion Criteria:** Adults enrolled in National Health and Nutrition Examination Survey (NHANES) who were overweight or obese. Overweight was calculated from reported height and weight and defined as having a body mass index (BMI) equal or greater than 25 kg/m2; obese was defined as a BMI greater or equal to 30 kg/m2	**Type:** Cross-sectional data survey **Methods:** Cross-sectional data from the 2011 to 2012 NHANES. Questionnaires asked whether participants received advice to lose weight, and whether they sought health professional's assistance with weight management. Accounting for NHANES sampling and design, frequency distributions characterized demographics and proportions. Logistic regressions estimated odds of seeking weight loss help by demographics.	**Results:** Of 3682 overweight/obese adults, 1908 were told they were overweight or recommended to lose weight. Of 1908 people, 68% reported weight loss efforts, but only health 10.9% sought a health professional's help (dietician/nutritionist 4.7%, personal trainer 3.0%, doctor 2.8%). Females, people with health insurance and high health-care utilization had 1.5 to 3.5 times greater odds of seeking help; age, ethnicity, and income were not significantly associated with seeking help with weight management.	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up
Author: Croghan, I.T., et al. Year Published: 2018 Location: USA Journal: *Primary health care research & development*	To conducted a needs assessment survey of patient experiences and expectations regarding weight management in the primary care setting to inform weight management in clinical care	**Size:** 471 **Inclusion Criteria:** Patients' presenting to an office visit at a primary care clinic at Mayo Clinic	**Type:** Cross-sectional survey **Methods:** All patients seen for a primary care visit received an anonymous survey, a cover letter explaining the purpose of the study, and a stamped return envelope. Patients either returned the survey to the receptionist or mailed it after the visit. The survey included a subset of validated questions from the National Health and Nutrition Examination Survey and questions (developed by the study team) related to weight management in primary care.	**Results:** Multivariable analysis found that respondents with higher body mass index (BMI) were more likely to report that a physician had told them that they were overweight (OR=3.49, 95% CI 2.06-5.89, P<0.001). However, this conversation was less likely to change their personal view of their weight (OR=0.62 per 5 kg/m2, 95% CI 0.45-0.86, P=0.004), or motivate them to lose weight (OR=0.67 per 5 kg/m2, 95% CI 0.50-0.91, P=0.009). Higher BMI was associated with higher	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

				weight-loss goals (P<0.001), while anticipated time to achieve those goals was increased (P<0.001). Physician involvement in weight management was important, but the patients' needs and experiences differed by BMI.	
Author: Pool, A.C., et al. Year Published: 2014 Location: USA Journal: *Obes Res Clin Pract*	To examine the association of a physician's discussion of patients' weight status with self-reported weight loss	**Size:** 5054 **Inclusion Criteria:** Participants between the ages of 20 and 64 with a measured body mass index (BMI) of ≥ 25 who responded to the question, "Has a doctor or other health professional ever told you that you were overweight?" Participants with a BMI between 25 and 29.9 were classified as overweight whereas participants with a BMI ≥ 30 were classified as obese; in accordance with National Heart, Lung, and Blood Institute guidelines **Exclusion Criteria:** Women who were currently pregnant	**Type:** Cross-sectional survey **Methods:** Data analysis of participants in the National Health and Nutritional Examination Survey (NHANES) in 2005-2008. The main outcome was rates of self-reported weight loss and the association with physicians' discussion of their patients' weight status.	**Results:** Overweight and obese participants were significantly more likely to report a 5% weight loss in the past year if their doctor had told them they were overweight (adjusted OR (AOR) 1.88; 95% CI 1.45-2.44; AOR 1.79; 95% CI 1.30-2.46, respectively).	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up
Author: Year Published: Location: USA Journal:	To assess changes in diet, exercise, and measured weight, both pre-encounter and 3 months post-encounter.	**Size:** **Inclusion Criteria:** **Exclusion Criteria:**	**Type:** Mixed-methods study **Methods:** Used audio-recorded primary care encounters between 40 physicians and 461 of their overweight or obese patients, coded weight-related advice as nonspecifi c, specifi c nutritional, specifi c exercise, or specifi c weight. Physicians and patients were told the study was about preventive health, not weight.	**Results:** When discussing weight, physicians typically provided a combination of specifi c weight, nutrition, and physical activity advice to their patients (34%). Combined advice resulted in patients reducing their dietary fat intake (P=.02). However, when physicians provided physical activity advice only, patients were signifi cantly (P=.02) more likely to gain weight (+1.41 kg) compared	**Study Limitations:** ☒ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

				with those who received no advice.	

References:

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2. Croghan, I. T., et al. (2018). "Patient perception matters in weight management." Primary health care research & development **19**(2): 197-204.
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5. Pool, A. C., et al. (2014). "The impact of physician weight discussion on weight loss in US adults." Obes Res Clin Pract **8**(2): e131-139.
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Question #22: Does weight bias among health care providers and/or organizations lead to adverse health outcomes independent of physiologic and mechanical impact of excess adiposity among persons living with overweight or obesity?

Children and Adolescents

BODY OF EVIDENCE APPRAISAL TABLE FOR: (OUTCOME) Population: Children and Adolescents		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☒ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☐ Medium ☒ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - UNKNOWN ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Wong, M.S., et al. Year Published: 2017 Location: USA Journal: *Patient Education and Counseling*	To examine the association between healthcare provider communication quality and child obesity status, and the role of parent obesity and child race/ethnicity regarding this association	**Size:** 5390 **Inclusion Criteria:** parents with a child aged 6–12 who had at least one visit with their healthcare provider in the past 12 months. Limited study sample to parents of pre-adolescents, as healthcare providers direct more of their communication towards parents of younger children, while they may communicate more directly with adolescent pediatric patients. **Exclusion Criteria:** Excluded parents of underweight children from our analysis due to significant heterogeneity in the underlying reason for their child's weight status (e.g., underweight due to illness)	**Type:** Cross-sectional study **Methods:** Secondary data analysis with the 2011–2013 Medical Expenditures Panel Survey of parents with children ages 6–12 (n = 5390). Multivariable logistic regression was used to examine the association of parent-reported healthcare provider communication quality (explaining well, listening carefully, showing respect, and spending enough time) with child obesity status, and effect modification by parent obesity and child race/ethnicity.	**Results:** Parents of obese children were more likely to report that their child's healthcare provider listened carefully (OR = 1.41, p = 0.002) and spent enough time (OR = 1.33, p = 0.022) than parents of non-obese children. Non-obese parents of obese children experienced better communication in the domains of listening carefully (p < 0.001) and spending enough time (p = 0.007). Parents of obese non-Hispanic Asian children and non-Hispanic Black children were more likely to report that providers explained things well (p = 0.043) and listened carefully (p = 0.012), respectively.	**Study Limitations:** ☒ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

References:

1. Wong, M. S., et al. (2017). "The association between parent-reported provider communication quality and child obesity status: Variation by parent obesity and child race/ethnicity." Patient Education and Counseling **100**(8): 1588-1597.

BODY OF EVIDENCE APPRAISAL TABLE FOR: (OUTCOME) Population: Adults		
Quality (certainty) of evidence for: (outcome) ☐ High ☒ Moderate ☐ Low ☐ Very Low		
Risk of Bias across studies: ☐ High ☒ Medium ☐ Low	**Low Quality Rating if:** ☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect

		☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Phelan, S. M., et al Year Published: 2015 Location: University of Calgary, Canada Journal: *Obesity Reviews*	To conduct a search for all peer-reviewed papers presenting original empirical data relevant to stigma, bias, discrimination, prejudice and medical care.	**Size:** Unknown **Inclusion Criteria:** Search strategies not included **Exclusion Criteria:** Search strategies not included	**Type:** Systematic Review	**Results:** There is evidence that providers' communication is less patient-centered with members of stigmatized racial groups (7 studies), and other stigmatized groups including patients with obesity (1 study), and that provider attitudes contribute to this disparity (3 studies). Implicit attitudes have also been found to be associated with lower patient ratings of care (1 study). In one study involving medical students, virtual patients with shortness of breath were more likely to receive lifestyle change recommendations if they were obese (54% vs. 13%), and more likely to receive medication to manage symptoms if they were normal weight (23% vs. 5%) There is evidence that obese women are less likely to seek recommended screening for some cancers (5 studies) Patients who report feeling judged by their primary care provider are less likely to seek or achieve successful weight loss (2 studies)	Study Limitations: ☐ None Systematic Review ☐ Review did not address focused clinical question ☒ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis – *Unable to conduct meta-analysis*

				Individuals who experience more obesity stigma report less health utility, or place lower value on health (1 study) There is evidence that many providers dislike treating obesity, feel underprepared to do so, and have little hope that their patients will make lifestyle changes (5 studies), which may be detectable in their tone of voice or language.	
Author: Wong, M.S., et al. Year Published: 2015 Location: USA Journal: *Patient Education and Counseling*	To examine the relationship between patient weight and provider communication quality and determine whether patient race/ethnicity modifies this association	**Size:** 25,971 **Inclusion Criteria:** 18 years who had an appointment at a doctor's office or clinic within the previous 12 months **Exclusion Criteria:** Pregnant women and underweight individuals	**Type:** Cross-sectional study **Methods:** Study pooled 2009 and 2010 data from Medical Expenditure Panel Survey's (MEPS) Household Component (MEPS-HC) and supplemental Adult Self-Administered Questionnaire (SAQ) files. Dependent variables were patient report of providers explaining well, listening, showing respect, and spending time. Independent variables were patient weight status and patient weight-race/ethnicity groups. Using survey weights, multivariate logistic regression was performed to examine the adjusted association between patient weight and patient-provider communication measures, and whether patient race/ ethnicity modifies this relationship.	**Results:** Compared to healthy weight whites, obese blacks were less likely to report that their providers explained things well (OR 0.78; p=0.02) or spent enough time with them (OR 0.81; p=0.04), and overweight blacks were also less likely to report that providers spent enough time with them (OR 0.78; p=0.02). Healthy weight Hispanics were also less likely to report adequate provider explanations (OR 0.74; p=0.04).	**Study Limitations:** ☒ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

Author: Hansson, L.M. and F. Rasmussen Year Published: 2014 Location: Sweden Journal: *Obesity Facts*	To examine the association between experiences of health care stigmatization and BMI changes in men and women with normal weight and obesity in Sweden	**Size:** 2628 **Inclusion Criteria:** Random sample of Swedish Survey of Living Conditions (ULF) **Exclusion Criteria:** None	**Type:** Population-based, survey study **Methods:** The participants were drawn from a population-based survey in Sweden (1996–2006), and data on their perceived health care stigmatization were measured in 2008. They were categorized in individuals with normal weight (n = 1,064), moderate obesity (n = 1,273), and severe obesity (n = 291). The main outcome measure was change in BMI.	**Results:** Individuals with severe obesity experiencing any health care stigmatization showed a BMI increase by 1.5 kg/m 2 more than individuals with severe obesity with no such experience. For individuals with moderate obesity, insulting treatment by a physician and avoidance of health care were associated with a relative BMI increase of 0.40 and 0.75 kg/m 2 , respectively, compared with their counterparts who did not experience stigmatization in these areas. No difference in experience of any form of health care stigmatizing associated BMI change was observed for men and women with normal weight.	**Study Limitations:** ☐ None **Non-Randomized Studies** ☒ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up
Author: Kass, A.E., et al. Year Published: 2015 Location: USA Journal: *Eat Behav*	To evaluate the realtion between screen for overweight and eating disorder (ED) risk	**Size:** 548 **Inclusion Criteria:** College-age women, ages 18–25, were recruited for participation as part of a larger randomized controlled trial.	**Type:** Cross-sectional survey **Methods:** college-age women were classified as at-risk or with an ED and were assessed for disordered eating attitudes, behaviors, and relevant history, including, “Has a doctor, nurse, or other medical professional ever told you that you were overweight?” Regression analyses were used to evaluate the relations between being identified as overweight and current disordered eating behaviors, attitudes, and ED diagnosis, without and with covariates (history of weight-related teasing, history of an ED, family history of being	**Results:** 146 (26.6%) women reported being previously identified as overweight by a medical professional. There was no relation between being previously identified as overweight and having an ED. Those identified as overweight were more likely to have weight/shape concerns above a high-risk cutoff, but showed no difference in dietary restraint, binge eating, purging behaviors, or excessive exercise compared to those not identified.	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

			identified as overweight, and current body mass index)		
Author: Kraschnewski, J. L., et al. Year Published: 2012 Location: USA Journal: *Preventive Medicine*	To examine the association between body mass index (BMI) and preventive service receipt, controlling for relevant factors.	**Size:** 1342 **Inclusion Criteria:** Participants from the the Central Pennsylvania Women's Health Study (CePAWHS) longitudinal survey of women ages 18–45	**Type:** Longitudal Survey Study **Methods**: Data from the Central Pennsylvania Women's Health Study (CePAWHS) longitudinal survey of women ages 18-45. The baseline random-digit-dial telephone survey was conducted in 2004-2005 and a second telephone interview two years later; participants comprised the analytic sample. Dependent variables were seven preventive services identified at follow-up. In addition to baseline body mass index (BMI) category, independent variables were selected based on the behavioral model of health services utilization.	**Results:** Forty-six percent of the sample was classified as normal weight, 28% as overweight, and 26% as obese. In adjusted analyses, women who were overweight and obese, compared to women with normal weight, were more likely to receive preventive counseling for diet/nutrition, physical activity, and weight management ($p<0.01$). Overweight and obese women received more cholesterol and diabetes screening ($p<0.05$ and $p<0.01$, respectively). However, there were no differences by BMI category in receipt of Pap testing or reproductive counseling.	**Study Limitations:** ☐ None **Non-Randomized Studies** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

References:

1. Kass, A. E., et al. (2015). "Identification as overweight by medical professionals: relation to eating disorder diagnosis and risk." Eat Behav **17**: 62-68.
2. Kraschnewski, J. L., et al. (2012). "Prospective association between body mass index and receipt of preventive services: results from the Central Pennsylvania Women's Health Study (CePAWHS)." Preventive Medicine **54**(5): 302-305.
3. Wong, M. S., et al. (2015). "Provider communication quality: Influence of patients' weight and race." Patient Education and Counseling **98**(4): 492-4

Appendix A. GRADE criteria for rating a body of evidence on an intervention

Developed by the GRADE Working Group

Grades and interpretations:

High: Further research is very unlikely to change our confidence in the estimate of effect. Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low: Any estimate of effect is very uncertain.

Type of evidence and starting level

Randomized trial–high Observational study–low Any other evidence–very low

Criteria for increasing or decreasing level

Reductions Study quality has serious (–1) or very serious (–2) problems Important inconsistency in evidence (–1) Directness is somewhat (–1) or seriously (–2) uncertain Sparse or imprecise data (–1) Reporting bias highly probable (–1) **Increases** Evidence of association† strong (+1) or very strong (+2) Dose-response gradient evident (+1) All plausible confounders would reduce the effect (+1) †Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders Very strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity.

Appendix B. Trustworthy Guideline rating scale

The University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale is based on the Institute of Medicine's "Standards for Developing Trustworthy Clinical Practice Guidelines" (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guide-line does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). Current quality scales like AGREE emphasize documentation. They are important checklists for developers of new guidelines, but are less useful for grading existing guidelines. These scales also are harder for clinicians and other persons who are not methodology experts to apply, and their length discourages their use outside formal technology assessment reports. This new scale is brief, balanced, and easy and consistent to apply.

We do not attempt to convert the results of this assessment into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. This facilitates qualitative understanding by the reader, who can see for what areas the guideline base as a whole is weak or strong as well as which guidelines are weaker or stronger.

1. Transparency

A	Guideline development methods are fully disclosed.
B	Guideline development methods are partially disclosed.
C	Guideline development methods are not disclosed.

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:
Who wrote the initial draft?
How the committee voted on or otherwise approved recommendations.
Evidence review, external review and methods used for updating are not addressed in this standard.

2. Conflict of interest

A	Funding of the guideline project is disclosed, disclosures are made for each individual panelist, and financial or other conflicts do not apply to key authors of the guideline or to more than 1 in 10 panel members).
B	Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source.
C	Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline project was funded by industry sponsor with no assurance of independence.
NR	Guideline does not report on potential conflict of interests.

For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive. As much as anything, this is a surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

3. Guideline development group

A	Guideline development group includes 1) methodological experts and clinicians and 2) representatives of multiple specialties.
B	Guideline development group includes one of the above, but not both.
C	Guideline developers all from one specialty or organization, and no methodologists.
NR	Affiliations of guideline developers not reported

The purpose of this standard is to ensure that supporters of competing procedures, or clinicians with no vested interest in utilization of one procedure or another, are involved in development of the guideline. Both AGREE II and IOM call for patient or public involvement: very few guideline panels have done so to date, so this is not necessary for guidelines to be rated A. Involvement of methodologists or HTA specialists in the systematic review is sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors are the guideline group.

4. Systematic review

A	Guideline includes a systematic review of the evidence or links to a current review.
B	Guideline is based on a review which may or may not meet systematic review criteria.
C	Guideline is not based on a review of the evidence.

In order to qualify as a systematic review, the review must do all of the following:
Describe itself as systematic or report search strategies using multiple databases
Define the scope of the review (including key questions and the applicable population)
Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: this element does not address the quality of the systematic review: simply whether or not it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.
Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in text of the report.

5. Grading the supporting evidence

A	Specific supporting evidence (or lack thereof) for each recommendation is cited and graded

B	Specific supporting evidence (or lack thereof) for each recommendation is cited but the recommendation is not graded.
C	Recommendations are not supported by specific evidence.

To score a B on this domain there should be specific citations to evidence tables or individual references for each relevant recommendation in the guideline, or an indication that no evidence was available. Any standardized grading system is acceptable for purposes of this rating. If a guideline reports that there is no evidence available despite a thorough literature search, it may be scored B on this domain, or even A if evidence for other recommendations is cited and graded.

6. Recommendations

A	Considerations for each recommendation are documented (i.e. benefits and harms of a particular action, and/or strength of the evidence); and recommendations are presented in an actionable form.
B	Either one or the other of the above criteria is met.
C	Neither of the above criteria are met

In order to be actionable, the guideline should specify the specific population to which the guideline applies, the specific intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like “should” or “should not” for strong recommendations, and passive language like “consider” for weak recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the forthcoming NICE manual (24) for a good discussion of actionability in guidelines.

7. External review

A	Guideline was made available to external groups for review.
B	Guideline was reviewed by members of the sponsoring body only.
C	Guideline was not externally reviewed.
NR	No external review process is described.

8. Updating and currency of guideline

A	Guideline is current and an expiration date or update process is specified.
B	Guideline is current but no expiration date or update process is specified.
C	Guideline is outdated.

A guideline is considered current if it is within the developers’ stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the analyst’s discretion, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered outdated.