



Current Menopause Myths: Aligning Practice with Evidence

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Housekeeping

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 - Disclosures:
 - ECHO Menopause Course Lead
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Objectives

- Review 3 en vogue myths about menopausal hormone therapy (MHT)
 - MHT prevents dementia!
 - MHT prevents CVD!
 - The black box warning on estrogen should have been gone long ago!
 - For each, we'll review
 - What's out there in the social-media-verse
 - What we know
 - What we don't know
 - Latest evidence
 - How this should translate into patient counseling
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Setting the Stage: WHI Basics

- Women's Health Initiative
 - Years: 1991-2002 (combined therapy trial halted)
 - 2004 (CEE alone terminated)
 - Study Type: RCT (NIH funded)
 - Population: 27,000+ (10739 s/p hyst + 16608 with uterus), healthy, postmenopausal women ranging 50-79yo.
 - Goal: Evaluate the anticipated benefit (reduced CHD) and risk (increased breast ca) of the most commonly prescribed HT of the time
 - Regimen: CEE 0.625mg + 2.5mg MPA (if uterus)
 - Key Findings:
 - EPT: Increased risk (breast ca, CVA,PE) exceeded benefits (reduction of fractures and colon ca)
 - Estrogen only: lack of CHD benefit, increased risk of CVA
 - Huge ramifications
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Setting the Stage: WHI vs Now

	WHI	Now	Rationale
Estrogen	Oral CEE (Premarin)	Transdermal Estradiol*	Transdermal administration decreases clot risk
		Oral Estradiol	
Progestogen	Oral MPA (Provera)	Oral Micronized Prog *	Lower dose, more physiologic progestogen may limit impact to the breast
		LNG-IUS (Mirena)	
		Lower dose NETA	
Age @ Initiation	Any! (avg 63)	60 or less	Goal of estrogen treatment is alleviating sx
Time from Menopause	Any!	10y or less	Timing hypothesis

* most commonly used formulation

Myth 1: MHT Prevents Dementia!


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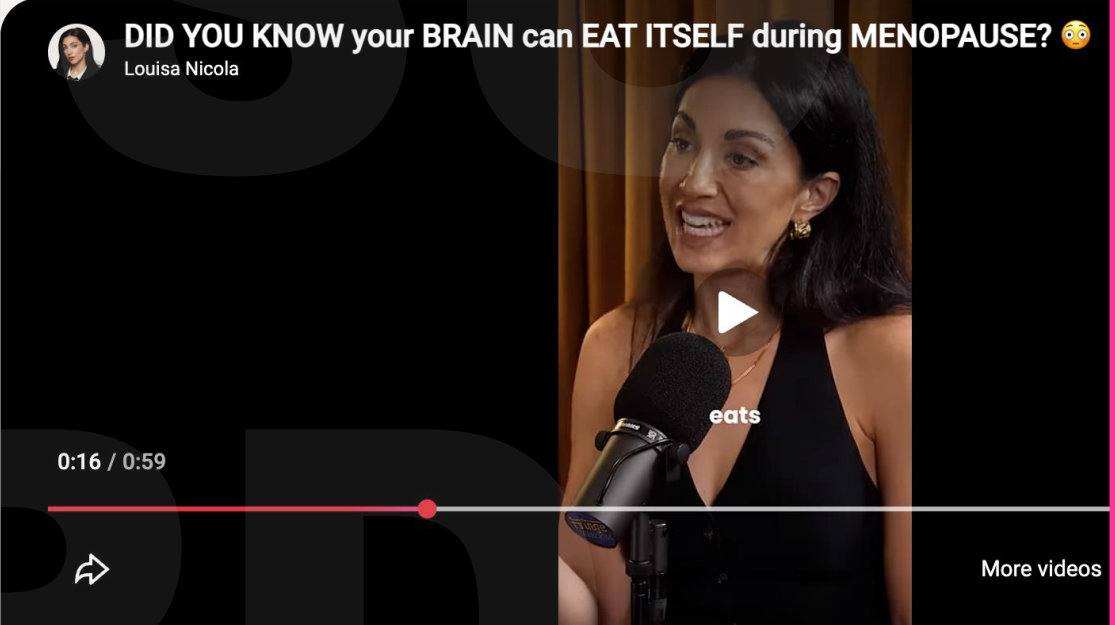
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Ask about hormone replacement therapy

If you've started to experience **menopause** symptoms such as hot flashes and night sweats, talk to your doctor about whether hormone replacement therapy (**HRT**) is right for you. It may be protective against dementia if it's taken in perimenopause or early postmenopause, per a

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MHT Prevents Dementia: Knowns & Unknowns

Knowns

- Dementia disproportionately impacts women
- Estrogen has a role in brain chemistry
- Menopause <45yo increases the risk of dementia
- Starting MHT* after 65yo increases the risk of developing dementia

* PO CEE + MPA

Unknowns

- Why dementia disproportionately impacts women
- What role (if any) estrogen has in this difference
- Impact of modern MHT**

**Formulation, age group

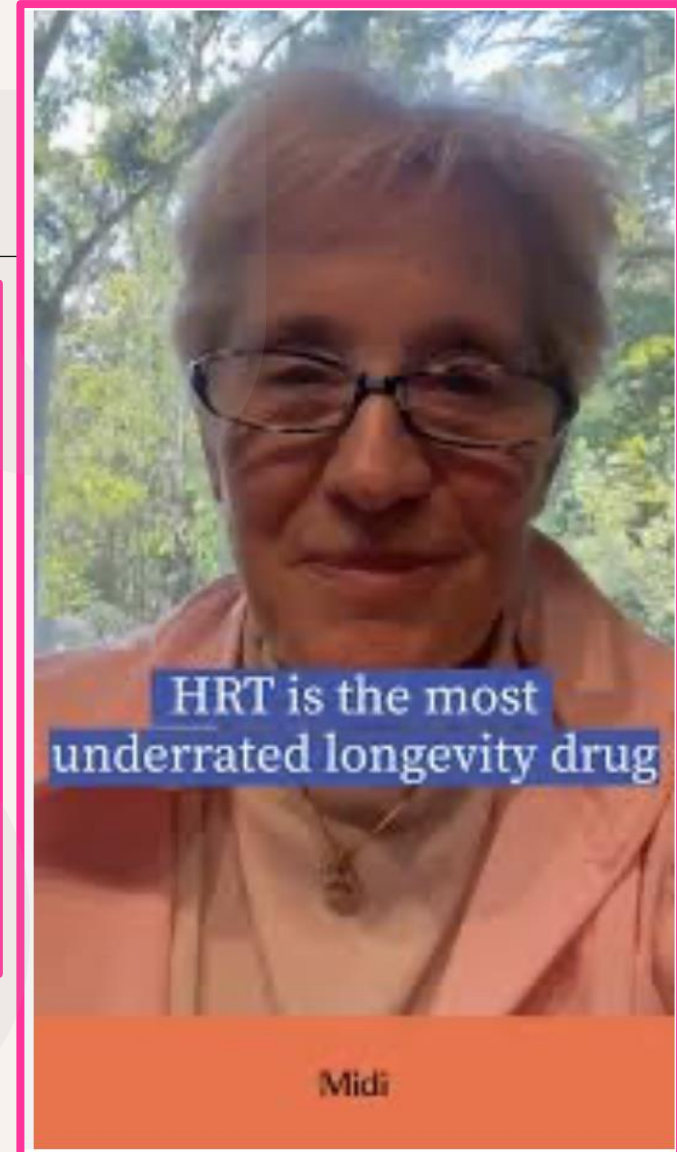
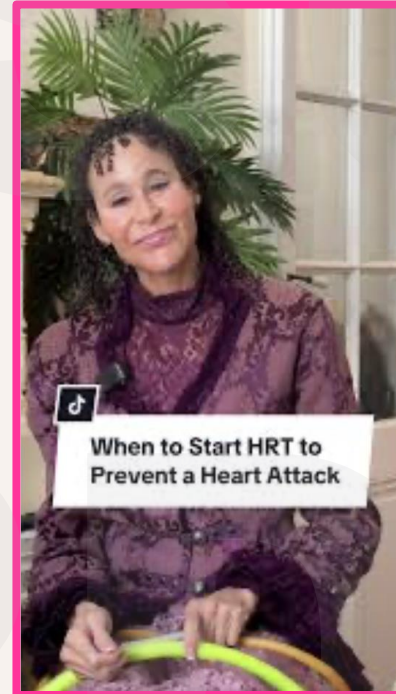
MHT Prevents Dementia: Latest Evidence

- Best quality evidence: Lancet Longevity 2025
 - Questions
 - Does MHT or no MHT affect the risk of MCI or dementia in peri- or post-menopausal women?
 - Does MHT type, duration, or age at initiation influence this risk?
 - Meta-analysis
 - 1 RCT (WHIMS) + 9 observational studies
 - 1 million women
 - **"No significant association was found between MHT use and the risk of MCI or dementia."**
 - Not significant, : suggestion that ET conferred a very small risk reduction for Alzheimers (RR 0.95)
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MHT Prevents Dementia: Counseling

- We don't have evidence that menopausal hormone therapy prevents dementia.
 - If this is the reason you want to start MHT, I wouldn't recommend that.
 - If you're over 65yo, we're concerned that starting MHT actually may increase your risk of developing dementia.
 - Modifiable factors that we know increase the risk of dementia:
 - Physical inactivity
 - Excessive alcohol consumption.
 - Social isolation
 - Depression
 - Untreated hearing or vision loss
 - Smoking
 - Poor CV health
 - Chronic Sleep Deprivation
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Myth 2: MHT Prevents CVD!



MHT Prevents CVD: Knowns & Unknowns

Knowns

- CVD is leading cause of death in women
- Menopause is a time of accelerated CVD risk
- Observational studies demonstrated
 - MHT use > lower risk of CVD
 - More intense VMS > Increased risk of CVD
- RCT level data are more complicated

Unknowns

- Impact of particular MHT regimens on the heart
 - Translation of outcomes studied in RCTs into clinical events
 - General dearth of knowledge about CV health in women
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MHT Prevents CVD: Latest Evidence (kind of)

- WHI = Double blinded RCT designed to answer this exact question!
 - 50-59yo
 - EPT: Increased risk CVA and MI during study, back to baseline after 13y
 - ET: Decreased risk during trial, statistically significant decrease in CAD after 13y (11 cases/10k women)
 - 60yo or 10y+ from menopause
 - MHT had null effect on CHD, all cause mortality but increased risk of CVA and VTE
 - ELITE:
 - PO E2 close to menopause decreases CIMT progression and LDL (6-10 points)
 - No impact on coronary calcium
 - KEEPS:
 - Transdermal E2 + PO Prog didn't change coronary calcium or LDL
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MHT Prevents CVD: Summarizing Evidence

- Oral CEE (Premarin) without Progestin decreases CAD, but the numbers are small and therapy is associated with risk of CVA, DVT.
 - Oral estradiol may decrease CIMT, but the clinical impact of this is unknown.
 - Oral estradiol decreases LDL, but this effect is dwarfed by the impact of statins
 - Transdermal estradiol doesn't impact lipids or improve coronary calcium.
 - The Timing Hypothesis is a hypothesis—and may only extend to oral estrogen.
 - MHT doesn't appear to negatively effect the heart in people starting it close to menopause at low risk of CVD.
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MHT Prevents CVD: Counseling

- We don't have evidence that MHT prevents cardiac disease.
 - If this is the reason you want to start MHT, I wouldn't recommend that.
 - We do have evidence that MHT is safe for people
 - at average risk of cardiac disease
 - who are going through menopause
 - who have recently gone through menopause.
 - If MHT is needed to help manage VMS or mitigate bone loss, it's appropriate to use
 - Don't forego the things we know decrease the risk of CVD.
 - Diet, exercise, statins!
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Myth 3: The black box was nonsense!

FDA NEWS RELEASE

HHS Advances Women's Health, Removes Misleading FDA Warnings on Hormone Replacement Therapy



WARNING: CARDIOVASCULAR DISORDERS, BREAST CANCER and PROBABLE DEMENTIA FOR ESTROGEN PLUS PROGESTIN THERAPY

Cardiovascular Disorders and Probable Dementia

Estrogens plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia. (See **CLINICAL STUDIES** and **WARNINGS, Cardiovascular disorders and Probable dementia.**)

The Women's Health Initiative (WHI) estrogen plus progestin substudy reported increased risks of deep vein thrombosis, pulmonary embolism, stroke and myocardial infarction in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with daily oral conjugated estrogens (CE) [0.625 mg] combined with medroxyprogesterone acetate (MPA) [2.5 mg], relative to placebo. (See **CLINICAL STUDIES** and **WARNINGS, Cardiovascular disorders.**)

The WHI Memory Study (WHIMS) estrogen plus progestin ancillary study of the WHI reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with daily CE (0.625 mg) combined with MPA (2.5 mg), relative to placebo. It is unknown whether this finding applies to younger postmenopausal women. (See **CLINICAL STUDIES** and **WARNINGS, Probable dementia and PRECAUTIONS, Geriatric Use.**)

Breast Cancer

The WHI estrogen plus progestin substudy also demonstrated an increased risk of invasive breast cancer. (See **CLINICAL STUDIES** and **WARNINGS, Malignant neoplasms, Breast Cancer.**)

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and MPA, and other combinations and dosage forms of estrogens and progestins.

Progestins with estrogens should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

The black box was nonsense: Knowns & Unknowns

Knowns

- Vaginal estrogen is safe in almost all people
 - Points of caution:
 - Unexplained vaginal bleeding
 - H/o estrogen-sensitive malignancy
- The findings of the WHI have limited MHT use for 1-2 generations of women
- Systemic estrogen is very effective therapy
 - Mgmt of VMS
 - Prevention of bone loss

Unknowns

- Impact of alternative regimens on risks of
 - CVD
 - CVA, VTE
 - Malignancy

The black box was nonsense: Latest Evidence

- Lack of new, high quality evidence
- Lack of commitment to getting this evidence

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The black box was nonsense: Counseling

- Vaginal estrogen is safe for basically everyone.
 - Systemic estrogen is very good at 2 things:
 - Treating VMS
 - Decreasing the risk of bone loss
 - Systemic estrogen is safe for the majority of people but does carry risk
 - CVA, VTE
 - Likely mitigated with transdermal E2, but no definitive data on this
 - Breast cancer
 - Best estimates of this are from WHI, lack of data regarding most commonly used therapies now
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Takeaways

- Commonly held or widely advertised “truths” about MHT are more complex
 - No definitive data to suggest MHT prevents disease
 - Best data around long term risk of MHT comes from the WHI
 - New studies need to determine the impact of new Rx
 - Not a reason to withhold therapy
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Thank you!

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References

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