

## The role of Vitamin D in menopause: Relationship to menopausal symptoms and body composition

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### Abstract

We propose a pilot randomized placebo-controlled clinical trial (RCT) to evaluate the treatment effect of Vitamin D on menopause-related symptoms and body composition in women who are transitioning through menopause or are in early postmenopause. Several lines of research and public health trends are converging to suggest that Vitamin D deficiency could have important health effects, e.g., worsening quality of life and increasing obesity, in the transition through menopause—when there is an epidemic prevalence (>75%) of Vitamin D deficiency according to the latest National Health and Nutrition Examination Survey (NHANES).<sup>1</sup>

**Specific Aim 1:** To compare effects of Vitamin D supplementation to usual care on symptoms in women transitioning to early postmenopause and determine the associated effect size in order to conduct a power analysis for a future RCT. *Hypothesis: Vitamin D insufficient women in early postmenopause who are randomized to supplementation, titrated to achieve sufficiency for 2 months, will have fewer symptoms including hot flashes, mood, and musculoskeletal complaints than women randomized to usual care.*

**Specific Aim 2:** To compare effects of Vitamin D supplementation to usual care on body composition (by dual-energy x-ray absorptiometry [DXA] and by weight, BMI, waist to hip ratio) in overweight/obese women transitioning to early postmenopause and determine the associated effect size for a power analysis for a future RCT. *Hypothesis: Vitamin D insufficient women in the menopausal transition randomized to supplementation, titrated to achieve sufficiency for 9 months, will improve DXA body composition (less total body and abdominal fat), compared to women in usual care, who will have increased body weight, including total and abdominal fat.*

**Specific Aim 3:** To estimate the proportion of overweight/obese middle-aged women who achieve sufficiency by 1 month versus 2 or more months and to determine if achieving sufficiency by 1 month varies by baseline characteristics. *Hypothesis: About 80% of participants will achieve sufficient Vitamin D level by 1 month. Those who need more than 1 month for sufficiency will have lower baseline levels and higher initial BMI.*