Reviewer’s report

Title: The 40-something randomized controlled trial to prevent weight gain in mid-age women

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Reviewer: Catherine Carpenter

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Authors describe their protocol for conducting a randomized controlled prevention trial for weight gain in mid-age women who are at risk for weight gain due to menopausal transition. Much evidence exists for the relationship between weight gain and transition into menopause, and their study proposes to test a weight gain prevention strategy that could be easily translated into already existing clinical care.

Weight gain is a multi-factorial physiologic change which requires varied and extensive measurement of different parameters. Authors are to be acknowledged for developing a thorough protocol that appears to cover most of the important parameters that are necessary.

The following are suggestions for improvement:

1. Biological markers measured in blood

Authors propose collecting blood to measure metabolic syndrome markers. However there are many other markers that are important to measure most notably hormones such as estrogen and progesterone as well as FSH to characterize menopausal status. If funding is insufficient, specimens can be stored. In addition there are other important markers such as leptin and insulin that are associated with obesity and important in relationship to weight gain.

2. Measurement of menopause

Authors did not describe whether they would ask women questions about their menopausal symptoms, hot flashes, anxiety, insomnia, cravings, and so forth, at the various measurement assessment periods. Menopausal symptoms are known to influence weight gain and ought to be measured in relationship to whether symptoms may confound intervention effectiveness.

3. Change in body composition status

Authors did not mention how participants would be treated if they transitioned into another body composition category. For instance, if women started out in the healthy weight category but experienced weight gain during the course of the study and became overweight, would they be given the intervention recommendations for the overweight condition. And, vice versa. Would overweight women who lost weight and became normal weighted be given the
weight maintenance recommendations. It is important to spell this out.