RESEARCH
Original Research

Low-Fat Dietary Pattern Intervention and Health-Related Quality of Life: The Women's Health Initiative Randomized Controlled Dietary Modification Trial

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ABSTRACT

Background Intensive dietary intervention programs may lead to benefits in vitality and other components of health quality. The Women's Health Initiative Dietary Modification (DM) intervention includes a large randomized controlled trial of an intensive intervention.

Objective To evaluate whether the intervention is associated with improved health-related quality of life (HRQoL) subscales, overall self-reported health, depression symptoms, cognitive functioning, and sleep quality.

Design This randomized controlled trial was analyzed as intent to treat.

Participants Between 1993 and 1998, 48,835 women aged 50 to 79 years were recruited by 40 clinical centers across the United States. Eligibility included having fat intake at baseline ≥32% of total calories, and excluded women with any prior colorectal or breast cancer, recent other cancers, type 1 diabetes, or medical conditions with predicted survival <3 years.

Intervention Goals were to reduce calories from fat to 20%, increase vegetables and fruit to 5+ servings, and increase grain servings to 6+ servings a day. During the first year, 18 group sessions were held, with quarterly sessions thereafter.

Main outcome measures The RAND 36-Item Health Survey was used to assess HRQoL at baseline, Year 1, and close-out (about 8 years postrandomization), and estimate differential HRQoL subscale change scores.

Statistical analyses performed Mean change in HRQoL scores (Year 1 minus baseline) were compared by randomization group using linear models.

Results At 1 year, there was a differential change between intervention and comparison group of 1.7 units (95% CI 1.5, 2.0) in general health associated with the intervention. DM intervention improved physical functioning by 2.0 units (95% CI 1.7, 2.3), vitality by 1.9 units (95% CI 1.6, 2.2), and global quality of life by 0.09 units (95% CI 0.07, 0.12). With the exception of global quality of life, these effects were significantly modified by body mass index at baseline.

Conclusions DM intervention was associated with small, but significant improvements in three HRQoL subscales: general health, physical functioning, and vitality at 1 year follow-up, with the largest improvements seen in the women with the greatest baseline body mass index.

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CROSS-SECTIONAL LITERATURE HAS SHOWN THAT lifestyle factors such as higher physical activity[1,2] as well as normal weight status compared with overweight or obesity[3] are associated with indicators of higher health-related quality of life (HRQoL). In addition, changes in diet[4-11] and weight status are associated with changes in quality of life: weight gain is associated with lower measures of quality of life, whereas weight loss is associated with improvements.[4,12-20] Because of its focus on dietary change and its size, the dietary modification (DM) trial of the Women's Health Initiative (WHI) may be able to contribute to the question of whether or not making healthy diet changes is associated with improved HRQoL, both overall and within subgroups of women. The DM trial in the WHI was a randomized controlled trial designed to test the hypothesis that a reduction of fat intake to 20% of total daily calories and an increase in the intake of fruit, vegetables, and whole grains would reduce the risk of breast cancer and of colorectal cancer and, as a secondary outcome, the risk of heart disease in postmenopausal women.[21] The

group-based behavior intervention was associated with large initial changes in dietary fat intake that persisted for a mean of 8 years.[22] It is important to evaluate the extent to which the intervention affected the overall perceived health and well-being of the participants, especially during the first year of the intervention when very large dietary behavior changes were being made. In earlier published analyses, we have shown that, despite efforts to deliver the intervention in a calorie-neutral fashion, women in the intervention group lose more weight than those in the comparison group at 1 year, although the weight difference between the groups decreases over 8 years of follow-up.[23] It seems reasonable to assume that although the diet tested in the WHI did not reduce the morbidity and mortality from certain chronic diseases,[21,24,25] it might favorably affect HRQoL at 1 year follow-up.

Relatively few studies have examined the effect of long-term dietary interventions on quality of life or functional health status.[8,11] We proposed to study changes in quality-of-life measures among women enrolled in the DM trial of the WHI. Because of the large dietary behavior changes attributable to the intervention at 1-year follow-up, our specific hypotheses include intervention-associated positive changes in global quality of life, eight subscales of HRQoL, overall self-reported health, depression symptoms, sleep quality, and cognitive functioning at Year 1.

METHODS

Study Population

Recruitment of postmenopausal women aged 50 to 79 years who were interested in one or more components of the WHI clinical trials was conducted between 1993 and 1998 by 40 clinical centers throughout the United States as described previously.[21,24,25] The clinical trials were: hormone therapy (HT), with 27,347 women, DM (48,835 women), and calcium and vitamin D supplementation (36,282 women who had been part of one or both HT or DM for 1 or 2 years). About 16% of the women in the DM trial also participated in the HT trial (8,050 women). Eligibility criteria for the DM trial included being willing to be randomized to the intervention or comparison group and having fat intake at baseline $\geq$32% of total calories as evaluated by the WHI food frequency questionnaire.[26] Major exclusions at screening included prior colorectal cancer or breast cancer, other cancers during the past 10 years, type 1 diabetes, medical conditions with predicted survival $<$3 years, and adherence concerns, including frequent meals away from home. The Fred Hutchinson Cancer Research Center Institutional Review Board approved the study protocol and all participants provided written informed consent. Women were randomized to intervention or comparison group in the ratio of 2:3 to contain trial costs while preserving power, as has been previously described.[22,27-29]

Intervention

The primary nutrition goal of the WHI DM intervention was to reduce total dietary fat intake to 20% of energy. Individualized fat gram goals were set according to the person's height to reduce energy from total fat to 20% if the goals were achieved. The DM intervention was characterized as a low-fat dietary pattern, and included recommendations to increase consumption of vegetables and fruit to at least 5 servings/day and increase grain servings to at least 6 servings/day. It was presumed that reduction of total fat to 20% energy intake would reduce the amount of energy from saturated fat to 7%. The DM intervention was delivered in a group setting by trained nutritionists delivering information and activities that reflect both nutrition and behavior principles. During the first year, 18 group sessions were held, with quarterly sessions thereafter. Later in the intervention period, additional tailored and targeted strategies were added to enhance adherence. Details on the DM intervention are published elsewhere.[25,30-32] The WHI DM intervention changed the dietary fat intake of participants at 1 year.[22,23] During the first year of the intervention, the reduction in percent energy from fat in the intervention compared with the comparison group was 10.9% (compared with the goal of 13%).[2] The differential changes associated with the intervention, in percent energy from fat, percent energy from saturated fat, servings of fruits and vegetables, and servings of grain, were all statistically significant ($P<0.001$).[22] It is clear that, although short of the goal, the dietary changes made by the intervention women were substantial, demonstrating what might be possible on a population basis.[33]

Assessment of Quality of Life-Related Variables

All quality of life-related variables were self-reported via questionnaires completed by the women before the first screening visit and selected follow-up times. Completed HRQoL questionnaires were collected and reviewed for completeness during the screening clinic visit and at previously determined follow-up visits. Women who forgot to bring in their completed questionnaires could complete them in the clinic or mail them back to the clinic with a stamped, addressed envelope provided by the clinic at their visit.

Quality of Life and Functional Status. Global quality of life was assessed by a single item ("Overall, how would you rate your quality of life?") with an 11-point response scale (0="As bad or worse than being dead," and 10="Best quality of life"). Quality of life/functional status was assessed using the RAND 36-Item Health Survey (RAND36).[34] The RAND36 provides eight subscales that include general health perceptions (general health); physical functioning; vitality (energy and fatigue); role limitations due to physical health (role-physical); bodily pain; social functioning; role limitations due to emotional problems (role-emotional); and general mental health or emotional well-being (mental health). General health was assessed by asking questions about perceived health relative to another person or to the expectation of one's health in the near future. Physical functioning assessed the extent to which their health limited their typical day activities, including vigorous activities, bending, kneeling, stooping, and walking one block. Vitality questions included such things as feeling full of pep, worn out, or having a lot of energy. Role-physical consisted of items that measure the extent to which physical health interfered with work or activities of daily living. Bodily pain was determined by asking how much pain the participant had during the past 4 weeks and how much it interfered with her work inside and outside of the house. Social functioning consisted of how much the participant's physical or emotional health interfered with her regular social activities