Low-fat dietary pattern intervention and health-related quality of life: The WHI 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 (WHI) 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, depressive symptoms, cognitive functioning, and sleep quality.

Design—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, medical conditions with predicted survival less than three 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—RAND 36-Item Health Survey was used to assess HRQoL at baseline, year 1, and close-out (about 8 years post randomization), and estimate differential HRQoL subscale change scores.

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

Results—At one year, there was a differential change between intervention and comparison group of 1.7 units (1.5, 2.0) in general health associated with the intervention. DM intervention improved physical functioning by 2.0 units (1.7, 2.3), vitality by 1.9 units (1.6, 2.2), and global QOL by 0.09 units (0.07, 0.12). With the exception of global QOL, these effects were significantly modified by BMI at baseline.

Conclusions—DM intervention was associated with small, but significant improvements in three health related quality of life subscales: general health, physical functioning, and vitality at one year follow-up, with the largest improvements seen in the women with the greatest baseline BMI.

Keywords

INTRODUCTION

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). Additionally, 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 while 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 percent of the 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 behavioral intervention was associated with large initial changes in dietary fat intake that persisted for an average of eight 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 in the first year of the intervention when very large dietary behavior changes were being made. In earlier published analyses, we have shown that, in spite of efforts to deliver the intervention in a calorie neutral fashion, women in the intervention group lost more weight than those in the comparison group at one year, although the weight difference between the groups decreased over the eight years of follow-up.[23] It seems reasonable to assume, therefore, that while the diet tested in the WHI did not reduce the morbidity and mortality from certain chronic diseases,[21,24,25] it might favorably affect health-related quality of life at one 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] This paper proposes to study changes in quality of life measures among women enrolled in the DM trial of the Women's Health Initiative. Because of the large dietary behavior changes attributable to the intervention at one year follow-up, our specific hypotheses include intervention-associated positive changes in global QOL, eight subscales of HRQoL, overall self-reported health, depressive 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 U.S., 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 one or two years). About 16% of the women in the DM trial also participated in the HT trial (8050 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 32% of total calories as evaluated by the WHI food frequency questionnaire (FFQ).[26] Major exclusions at screening included prior colorectal cancer or breast cancer, other cancers in the last 10 years, type-1 diabetes, medical conditions with predicted survival less than three 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, so as 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 a day and increasing grain servings to at least 6 servings a 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 nutritional and behavioral 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 one year.[22,23] In the first year of the intervention, the reduction in percent energy from fat in the intervention compared to the comparison group was 10.9% (compared to 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 prior to their 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", 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;

(1) general health perceptions (general health); (2) physical functioning; (3) vitality (energy and fatigue);; (4) role limitations due to physical health (role physical); (5) bodily pain; (6) social functioning; (7) role limitations due to emotional problems (role emotional); and (8) 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* included information on vigorous activities, bending, kneeling, stooping and walking one block, and were asked in terms of health limiting these functions. *Vitality* questions included such things as feeling full of pep, worn out, or having a lot of energy. *Role physical* consisted of items which 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 in the last 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 (during the past 4 weeks). *Role emotional* consisted of questions which assessed how often emotional problems affected the respondent's work or other activities of daily living. *Mental health* was assessed by asking questions about how often the participant had felt blue or "down in the dumps", calm and happy, or nervous.

Self-Reported Health was a single item addressing a self-rating of health, that has been used commonly over the past 40 years, with five response options from excellent (coded as 5) to poor (coded as 1).[35-37] It is also one of the questions that makes up the general health subscale of the RAND36, described above.

Depressive symptoms were assessed by a six-item scale described by Smoller and colleagues.[38] This scale characterizes current depressive mood and is composed of six items from the Center for Epidemiological Studies Depressio*n Scale (CES-D).*

3MSE—Cognitive functioning was assessed in participants 65 years or older by the Modified Mini-Mental State Examination (3MSE) [41], a scale used in the Cardiovascular Health Study.[42] The 3MSE consists of 15 parts that contain 46 separately scored items. For some items the maximum score was 1 while for others the maximum score was 8. The functions tested included orientation to time, place and person, short-term memory, reading, writing, naming, verbal fluency, praxis, and graphomotor skill. The 3MSE was not administered at close-out.

Sleep disturbance—Sleep quality *was assessed by the 5-item Wo*men's Health Initiative Insomnia Rating Scale,[39,40] which was developed and validated for use in the WHI. Items in this instrument referenced sleep during the "past 4 weeks." Four items assessed sleep initiation and maintenance using a 5-point response scale (No, not in past four weeks; yes, less than once a week; 1- 2 times a week; 3 or 4 times a week; 5 or more times a week) and a fifth item assessed sleep quality, also using a 5-point scale (very sound or restful, sound or restful, average quality, restless, very restless).

Statistical analyses

All primary analyses focused on changes in HRQoL scores from baseline to Year 1 in relation to DM randomization assignment. For all HRQoL measures, an unadjusted linear

model was used to test whether DM had a significant treatment effect on HRQoL change score (year 1 minus baseline). Statistical significance of the effect of DM on HRQoL was judged by a nominal alpha =0.05. We expected to obtain one statistically significant effect by chance. For the subgroup analyses, a nominal alpha of 0.05 was used to judge whether the DM effect was moderated by a baseline characteristic. This p-value corresponded to the interaction term, between DM and a baseline characteristic, from a linear model that also contains the main effects. Baseline characteristics, for which a differential effect of the intervention on HRQoL might be expected, included age, body mass index, physical activity, and dietary fat intake. Additional baseline characteristics other than the four mentioned were also examined and included ethnicity, income, education, geographic region, alcohol, smoking, multivitamin use, use of supplements with vitamin E, use of supplements with vitamin C, total dietary energy, total dietary fat, percent energy from fat, fruit and vegetable intake, total dietary fiber, conjugated equine estrogen (CEE) use (from HT trial), and CEE+ medroxyprogesterone acetate (MPA) use (from the HT trial). Considering all outcome measures and baseline characteristics equally, we count 247 linear models (13 HRQoL measures $\times$ 19 baseline characteristics). Twelve statistically significant subgroups would be expected by chance, of which three subgroups would be expected by chance among our endpoints and four baseline characteristics of interest. Similar analyses of the main effects were performed on data available at end of follow-up. All analyses were based on the intention-to-treat principle using SAS (version 9.1, 2002, SAS Institute Inc).[43]

Effect size (ES) was used to assess the clinical significance of statistically significant findings.[44] ES is a distribution based approach to judge clinical significance and was defined as $d = \dfrac{M_{\text{Intervention}} - M_{\text{control}}}{S}$, where M is the average difference in quality of life measure and S the standard deviation of the difference.[45] Effect sizes of 0.2 to 0.5 are generally regarded as small, 0.5 to 0.8 as medium, and 0.8 and above as large.[45]

RESULTS

Overall, 19,541 women were randomized into the intervention group and 29,294 into the comparison group. The mean length of follow-up was 8.1 (SD 1.7) years, with a maximum of 11.2 years. Less than one percent of women in each group did not participate in the Year 1 follow-up visit because they died or were lost to follow-up. Adherence to the study protocol was good (women in the intervention attended 78% of sessions, provided 87% of fat self-monitoring scores and reduced their percent energy from fat to 25.1%). Table 1 shows selected baseline characteristics of the DM participants in the intervention and comparison groups. The most represented group is age 60 to 69 years, nearly half the women in the DM trial. More than 80% are white, and many women are in the middle family income category of $20,000 to $50,000 per year. About 38% of participants were obese, and a further 36% were overweight. Less than 10% of participants consumed alcohol at a frequency of more than one drink per day, approximately 7% were current smokers, and 36% took multivitamin supplements. As a direct result of eligibility criteria for the DM trial, women reported consuming approximately 38% calories from fat (from the FFQ), and just under four servings daily of vegetables and fruit, and about 15 grams of dietary fiber (Table 1). Their baseline physical activity averaged 10 METs per week.

Baseline scores of women in the intervention and comparison groups were comparable. For example, mean physical functioning scores at baseline were 81.1 and 80.9 for the intervention and comparison groups, respectively (Table 2). At one year, each of these scores had improved by a small but statistically significant amount in the intervention group women relative to the comparison group. The comparison group scores declined (or, in the cases of vitality and sleep disturbance, stayed the same). Figure 1 shows the small shift in the two distributions of change in five of these measures at one year for illustrative purposes. The differential change in all the scores with its 95% confidence interval is shown in Table 2. All the intervention effects were statistically significant at the < 0.001 level except social functioning (P<0.01), depressive symptoms (p=0.009), and role emotional (p=0.53, 3MSE (p=0.69) but effect sizes were small (< 0.20) and did not meet the general criteria of clinical significance. A forest plot of effect sizes are presented in Figure 2.

In subgroup analyses, we found significant modification of the intervention effect on physical functioning according to baseline age (p=0.02), with the greatest benefit experienced by the oldest age group at 2.3 units of change (95% CI 1.7, 3.0); baseline body mass index (p<0.001), with the greatest benefit experienced by very obese women (BMI > 35) at 2.7 (95% CI 2.0, 3.4); and baseline physical activity (p<0.001), with the greatest benefit experienced by women who were inactive 2.6 (95% CI 2.0, 3.3). We failed to find similar effect modification for the differential change in vitality, with the possible exception of baseline BMI (p=0.02), where the largest benefit in the highest BMI group: 2.7 (95% CI 1.9, 3.5). A consistent moderating effect of BMI was also found with respect to general health perceptions (p=0.004), with the greatest benefit in very obese women: 2.3 (95% CI 1.6, 2.9). The interaction with age (p=0.04) was significant even after adjusting for BMI and appeared to be in the opposite direction, with younger women experiencing a larger change in general health perceptions. There was also evidence of an interaction with dietary fat intake at baseline, with largest changes in perception of general health occurring in the group consuming the highest dietary fat (2.0 95% CI (1.5, 2.4) p<0.05). Baseline physical activity did not significantly modify the intervention effect on general health perceptions. Similar interaction effects were found with self-reported health. No additional interactions with age, BMI, physical activity and dietary fat beyond those presented in Table 3 were found. Forest plots of effect sizes for all thirteen HRQoL measures by these select subgroups are displayed in Supplemental Material 1, 2, 3 and 4. Other significant interactions between the intervention and race/ethnicity, smoking status, percent energy from fat, and CEE+MPA trial arm were seen for role-emotional (p=0.05; Hispanic women were most favorably affected), sleep disturbance (p=0.02; current smokers were most favorably affected), depressive symptoms (p=0.03; women that consumed the most fat were most favorably affected) and global QOL (p=0.005; those randomized to CEE+MPA were most favorably affected), respectively. Regardless of whether the effect of the dietary intervention was modified by baseline characteristics or due to chance, the effect sizes remained small across subgroups (ES < 0.20).

In additional analyses, the differential gains in physical functioning and vitality remained significant after adjusting for age, ethnicity, and weight at year 1 and baseline, suggesting an independent effect of the intervention from weight loss.

The analyses at study close-out demonstrated some continuing benefit of the intervention on physical functioning, vitality and general health perceptions at an average of 8.1 years of follow-up, but the intervention effect estimates were smaller (see Figure 2), with differential change average scores of 0.8, 1.0 and 0.6 respectively (see table 4).

DISCUSSION

The WHI DM intervention was associated with small, statistically significant, improvements in the HRQoL subscales of general health, physical functioning, and vitality, consistent with our hypothesis. Improvements in vitality and physical functioning associated with the intervention persisted after adjusting for age, ethnicity, and weight at year 1 and baseline, suggesting that not all the effects of the intervention are mediated by weight change. In other words, some effects of the intervention are likely directly attributable to the large dietary changes made by the DM intervention group.

These findings are consistent with other research, which has shown improvements in HRQoL among studies that emphasized lower intake of fat, calories or both. Most of these studies, like ours, have not used a study design to specify a dietary component responsible for the observed changes. Increases in physical and mental health were noted with a Mediterranean dietary intervention as measured by the Medical Outcomes Survey short form.[10] A calorie reduction diet coupled with increased physical activity resulted in increases in physical functioning, role physical, vitality and mental health, which compared to increased vitality for diet alone, and no changes in HRQoL for physical activity alone.[4] Also, a low fat intervention to induce weight loss and decrease lipid levels demonstrated improvements in HRQoL including general health, vitality, physical functioning, and mental health.[9] The same scales were markedly increased at the end of a 6 month weight loss intervention that included decreased dietary fat and calories as well as increases in physical activity.[14,46] Another weight loss study with modest caloric reduction comparing self help versus a commercial program demonstrated no difference between groups, but improvement in general health and vitality with weight loss in both groups.[18] As in our findings, changes in HRQoL scales physical functioning, general health, mental health, vitality and role-physical were found after a 13 week intervention, but in contrast only general health and vitality persisted after a year.[17]

In many studies the effects of dietary change are intertwined with those of weight loss, or increased fitness, although some reports reported separate associations. The Nurses' Health Study demonstrated that while weight loss was associated with physical functioning and vitality dimensions of HRQoL, any weight change was more associated with physical rather than mental health.[16] Consistent with those conclusions, a cross sectional study of mildly hypertensive adults by Stewart found that weight and BMI were associated with different HRQoL measures (pain) than those associated with fitness (vitality).[3] In contrast, intervention induced weight loss among obese participants was associated with improvements in overall psychological health, decreases in anxiety and depression, and increases in positive well-being, self-control and vitality.[12] Similarly, weight loss through diet or diet and physical activity interventions among overweight or obese postmenopausal women was strongly associated with improvements in physical functioning, role-physical,

vitality and mental health, as were the psychosocial measures of depression, stress and social support.[4] Though the aspects of HRQoL affected by changes in diet, fitness and weight may be somewhat distinct, Blissmer, et al. determined that sustained weight loss was not necessary to maintain changes in HRQoL.[14] Additionally, the changes in general health, physical functioning, vitality, and mental health identified at one year in our study, though small in magnitude, persisted to the close-out measurement. To our knowledge, longer term follow-up of HRQoL measures have not been demonstrated in other research.

Our research identified significant changes in HRQoL scales, though the average magnitude of change was small. The size of change attributable to the intervention was smaller than is typically considered clinically significant,[44,45] but may nonetheless be important at the population level.[47] Previous studies that found larger effects were focused on overweight and obese participants.[414,17,18] and individuals with pre-existing coronary heart disease.[9] On the other hand, the Nurses' Health Study observed small changes, similar to our findings, among overweight or obese women who lost weight over the four years of observation.[16]

Intervention-associated increases in measures of HRQoL were found among women who were older, and women who at baseline were obese, or who reported minimal activity. The moderating effects in our research have not been identified by others: older women and obese women have not previously been identified as more likely to benefit in physical functioning and general health from a dietary change intervention.

There are several limitations to this study. Dietary interventions designed for weight loss may have different results from those reported in this study, since the diet intervention did not include energy reduction or weight loss goals although both occurred in the first year of the intervention.[26] This was not a blinded trial, so participant's perception of the benefits of the intervention, and perceived lack of benefit for the control group, may have biased the results in these self-reported outcomes. The social support offered to participants in the group sessions, an important part of the intervention, could also have played a role not only in their weight loss but in change in measures of HRQoL (improved vitality, general health, and physical functioning) as well. It is difficult to separate the social benefits from the dietary benefits of the intervention, though the intervention appeared to provide increased benefit for very obese women, indicating that the effect was higher for heavier women. Women who did not complete the first year follow-up had lower baseline physical functioning and global QOL scores compared to women who participated in follow-up measures. However, since the proportion of women who did not complete follow up in both groups was very low, the likelihood of these differences influencing the results observed is minimal. The Role Physical scale measures problems with work or other daily activities that are the result of physical health. It is not inconceivable that those who are successful in changing their dietary habits improve their overall health in a way that would affect their ability to perform their daily activities or work. Change in diet may result in mood changes, some weight loss, or even some increase in physical activity which can, in turn, be associated with less difficulty performing work or daily activities. On the other hand, the changes may be largely perceptual: those deciding to make healthy changes may perceive greater differences in this particular scale once they notice they have made dietary behavior changes.

There were a large number of statistical tests of significance performed and some may be due to chance. The reader should be particularly cautious in interpreting associations within subgroups (e.g., CEE+MPA randomization group) that appear to modify the effect of DM on only one HRQoL measure. In contrast, DM effects varied among levels of BMI for several HRQoL measures, so these significant interactions are more plausible, although the effect sizes remained small. In interpreting the findings, it should be borne in mind that the women in the DM trial (both experimental groups) were by design those who were consuming a high proportion of calories from fat at baseline, and likely had a high fat dietary pattern for many years prior to the study.

Though the changes in HRQoL achieved were small for the full group, it is important to place those changes in the context of an intervention study that did not aim to change HRQoL, and did not even aim to change weight. [23, 33] The intervention asked participants to make many changes in their diets. Investigators were concerned that the magnitude of these changes would be burdensome to participants. The results of this paper demonstrate that not only were the changes not excessively burdensome, but may in fact have contributed to an overall increase in HRQoL attributable to the DM intervention.

CONCLUSIONS

The WHI DM intervention was associated with small, but significant improvements in three health related quality of life subscales: general health, physical functioning, and vitality at one year follow-up, with the largest improvements seen in the women with the greatest baseline BMI. Intervention-associated increases in measures of HRQoL were found among women who were older, and women who at baseline were obese, or who reported minimal activity. Obese women might ordinarily be targeted for intervention due to the clear health benefits of even modest weight loss, but our research suggests that older women could also be targeted for weight loss interventions given the likely benefits reported by this study: benefits over and above those directly associated with diet improvement or weight loss. Additionally, dietitians might consider emphasizing improved HRQoL as an outcome expectation among all diet improvement and weight loss candidates. The study may have implications for beneficial changes in quality of life associated with dietary changes in later life more generally.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.
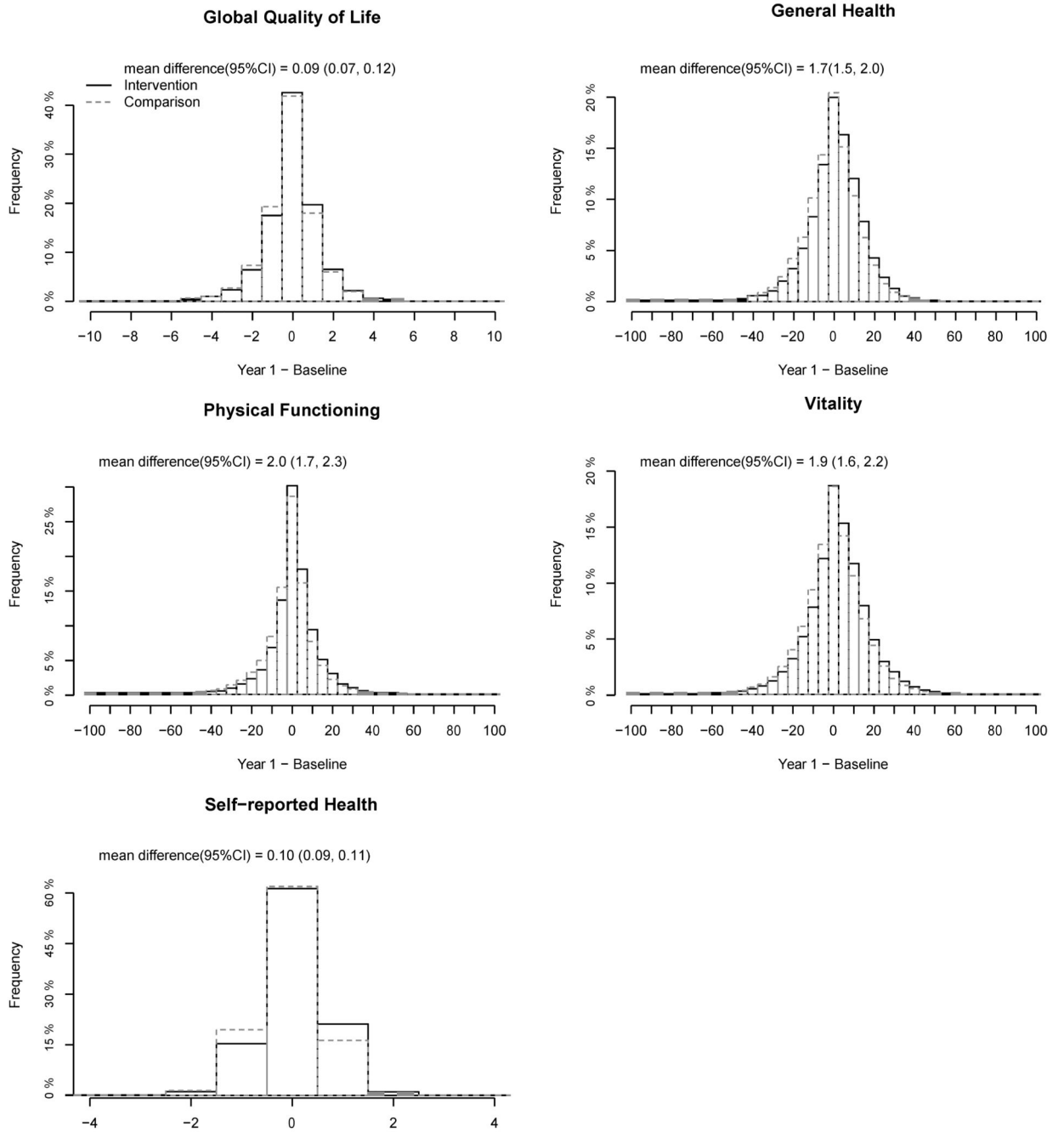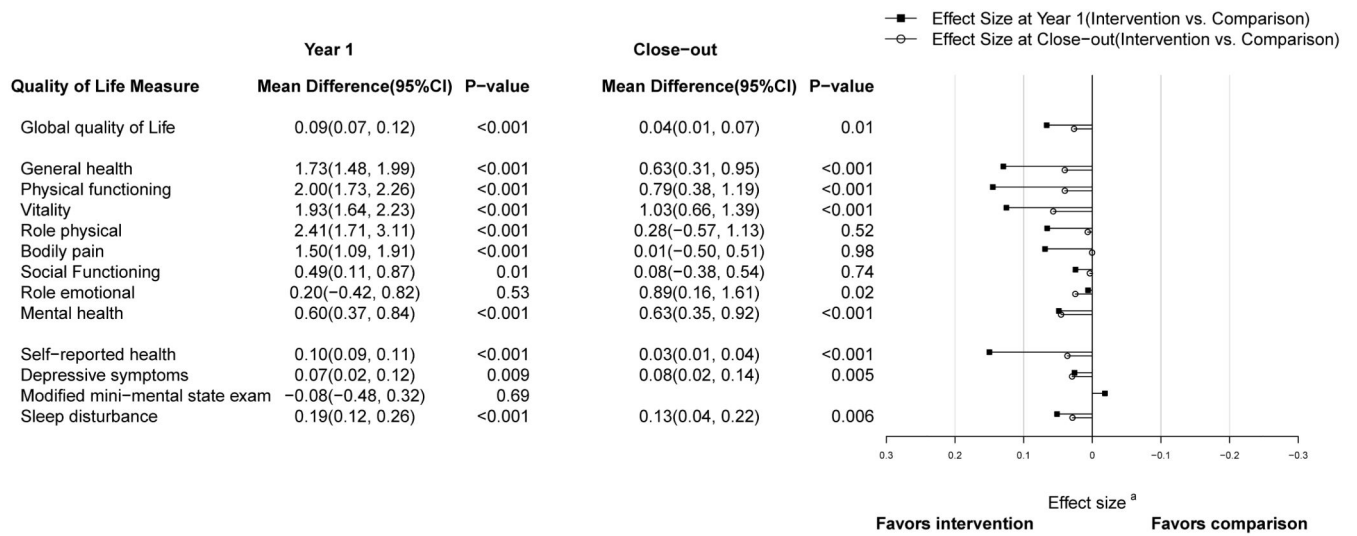
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Global Quality of Life

mean difference(95%CI) = 0.09 (0.07, 0.12)

— Intervention
--- Comparison

General Health

mean difference(95%CI) = 1.7(1.5, 2.0)

Physical Functioning

mean difference(95%CI) = 2.0 (1.7, 2.3)

Vitality

mean difference(95%CI) = 1.9 (1.6, 2.2)

Self−reported Health

mean difference(95%CI) = 0.10 (0.09, 0.11)

Figure 1.
Histograms of change scores (year 1 minus baseline) for select quality of life scores by randomization assignment in the Women's Health Initiative Dietary Modification Trial.

Quality of Life Measure	Year 1		Close-out	
	Mean Difference(95%CI)	P−value	Mean Difference(95%CI)	P−value
Global quality of Life	0.09(0.07, 0.12)	<0.001	0.04(0.01, 0.07)	0.01
General health	1.73(1.48, 1.99)	<0.001	0.63(0.31, 0.95)	<0.001
Physical functioning	2.00(1.73, 2.26)	<0.001	0.79(0.38, 1.19)	<0.001
Vitality	1.93(1.64, 2.23)	<0.001	1.03(0.66, 1.39)	<0.001
Role physical	2.41(1.71, 3.11)	<0.001	0.28(−0.57, 1.13)	0.52
Bodily pain	1.50(1.09, 1.91)	<0.001	0.01(−0.50, 0.51)	0.98
Social Functioning	0.49(0.11, 0.87)	0.01	0.08(−0.38, 0.54)	0.74
Role emotional	0.20(−0.42, 0.82)	0.53	0.89(0.16, 1.61)	0.02
Mental health	0.60(0.37, 0.84)	<0.001	0.63(0.35, 0.92)	<0.001
Self−reported health	0.10(0.09, 0.11)	<0.001	0.03(0.01, 0.04)	<0.001
Depressive symptoms	0.07(0.02, 0.12)	0.009	0.08(0.02, 0.14)	0.005
Modified mini−mental state exam	−0.08(−0.48, 0.32)	0.69		
Sleep disturbance	0.19(0.12, 0.26)	<0.001	0.13(0.04, 0.22)	0.006

Figure 2. close–out (minus baseline), and the corresponding Effect Size for Health Related Quality of Life Scores in the Women's Health Initiative Dietary Modification Trial

[a] Effect size is the estimated mean difference at year 1 or close–out, divided by the respective root–mean–square error. For all measures, the sign of the effect size has been flipped (if necessary) so that adverse effects (favors comparison) extend to the right and favorable effects (favors intervention) extend to the left.

Table 1

Baseline Characteristics of the Women's Health Initiative Dietary Modification Trial Participants (N = 48,835) by Randomization Assignment

	Comparison (n=29294)		Intervention (n=19541)		
	n	(%)	n	%	P-Value[a]
Age group at screening, years					> 0.99
50-54	4178	(14.3)	2783	(14.2)	
55-59	6619	(22.6)	4423	(22.6)	
60-69	13626	(46.5)	9086	(46.5)	
70-79	4871	(16.6)	3249	(16.6)	
Ethnicity					0.76
White	23890	(81.6)	15869	(81.2)	
Black	3129	(10.7)	2137	(10.9)	
Hispanic	1099	(3.8)	755	(3.9)	
American Indian	115	(0.4)	88	(0.5)	
Asian/Pacific Islander	674	(2.3)	433	(2.2)	
Unknown	387	(1.3)	259	(1.3)	
Family income					0.24
<$20K	4303	(15.6)	2774	(15.1)	
$20-$50K	12682	(46.0)	8455	(45.9)	
$50K	10610	(38.4)	7180	(39.0)	
More than high school education	22639	(77.8)	15156	(78.0)	0.52
Body mass index					0.69
<25	7585	(26.0)	5072	(26.1)	
25-29	10446	(35.8)	6940	(35.7)	
30-34	6748	(23.1)	4450	(22.9)	
35	4378	(15.0)	2992	(15.4)	
U.S. region					> 0.99
Northeast	6855	(23.4)	4561	(23.3)	
South	7640	(26.1)	5105	(26.1)	
Midwest	5978	(20.4)	3984	(20.4)	
West	8821	(30.1)	5891	(30.1)	
Alcohol servings					0.62
Non Drinker	12323	(42.2)	8134	(41.8)	
1 drink/day	14121	(48.3)	9449	(48.5)	
> 1 drink/day	2769	(9.5)	1881	(9.7)	
Smoking					0.24

	Comparison (n=29294)		Intervention (n=19541)		
	n	(%)	n	%	P-Value[a]
Never smoked	15029	(51.8)	9918	(51.4)	
Past smoker	11980	(41.3)	8121	(42.1)	
Current smoker	1977	(6.8)	1273	(6.6)	
Multivitamin (with or without minerals)	10398	(35.5)	6939	(35.5)	0.97
Use of supplements containing vitamin E	15032	(51.3)	10039	(51.4)	0.89
Use of supplements containing vitamin C	14852	(50.7)	9894	(50.6)	0.89
Menopausal hormone therapy trial arm					
CEE[b]-Alone	1039	(3.5)	615	(3.1)	0.41[c]
CEE-Alone Placebo	1068	(3.6)	670	(3.4)	
CEE+MPA[d]	1457	(5.0)	972	(5.0)	0.30[e]
CEE+MPA Placebo	1304	(4.5)	925	(4.7)	
Not randomized	24426	(83.4)	16359	(83.7)	

	n	Mean	SD	n	Mean	SD	P-Value
Total energy expended from recreational physical activity (MET[f]-hours/week)	26254	10.1	(12.0)	17507	10.0	(11.7)	0.45
Dietary energy (kcal)	29216	1789.4	(703.0)	19470	1790.2	(710.1)	0.90
Dietary total fat (g)	29216	75.7	(33.6)	19470	75.7	(34.1)	0.83
Percent calories from fat	29216	37.8	(5.0)	19470	37.8	(5.1)	0.84
Vegetable and fruit (servings/day)	29216	3.6	(1.8)	19470	3.6	(1.8)	0.52
Dietary fiber (g)	29216	15.4	(6.4)	19470	15.4	(6.4)	0.63

[a]Test of association, based on chi-squared (categorical variables) or t-test (continuous variables), between baseline characteristic and randomization assignment.

[b]CEE, conjugated equine estrogens

[c]P-value corresponds to test of association between dietary modification trial group and CEE alone trial group.

[d]MPA, medroxyprogesterone acetate

[e]P-value corresponds to test of association between dietary modification trial group and CEE+MPA trial group.

[f]MET, metabolic equivalent of task

Table 2

Mean Health Related Quality of Life Scores at Baseline, Year 1, and Change Scores (Year 1 minus Baseline) by Randomization Assignment in the Women's Health Initiative Dietary Modification Trial

Quality of Life Measure	Intervention				Comparison				Difference[a]		P-Value[c]
	n	Baseline	Means Year1	Change score[b]	n	Baseline	Means Year1	Change score	Mean	(95%CI)	
Global quality of life (0 worst to 10 best)	17780	8.20	8.19	−0.01	26407	8.18	8.11	−0.10	0.09	(0.07, 0.12)	<0.001
General Health [d] (0 worst to 100 best)	17518	74.5	75.8	1.1	25985	74.3	73.9	−0.7	1.7	(1.5, 2.0)	<0.001
Physical Functioning [d] (0 worst to 100 best)	17329	81.1	81.9	0.6	25716	80.9	79.8	−1.4	2.0	(1.7, 2.3)	<0.001
Vitality [d] (0 worst to 100 best)	17559	62.6	64.7	2.0	25997	62.8	63.1	0.0	1.9	(1.6, 2.2)	<0.001
Role Physical [d] (0 worst to 100 best)	17592	75.0	75.7	0.4	26054	74.5	72.9	−2.0	2.4	(1.7, 3.1)	<0.001
Bodily Pain [d] (0 worst to 100 best)	17808	74.8	74.9	−0.2	26410	74.5	73.1	−1.7	1.5	(1.1, 1.9)	<0.001
Social Functioning [d] (0 worst to 100 best)	17713	90.2	88.9	−1.5	26253	90.0	88.3	−2.0	0.5	(0.1, 0.9)	0.01
Role Emotional [d] (0 worst to 100 best)	17612	84.3	84.1	−0.7	26129	84.2	83.8	−0.9	0.2	(−0.4, 0.8)	0.53
Mental Health [d] (0 worst to 100 best)	17472	79.0	80.4	1.1	25905	79.1	79.8	0.5	0.6	(0.4, 0.8)	<0.001
Self-Reported Health (1 worst to 5 best)	17815	3.64	3.72	0.06	26456	3.64	3.61	−0.05	0.10	(0.09, 0.11)	<0.001
Depressive Symptoms (0 worst to 18 best)	17335	15.72	15.71	−0.05	25698	15.69	15.61	−0.12	0.07	(0.02, 0.12)	0.009
3MSE[e] (0 worst to 100 best)	762	95.1	95.6	0.5	1155	95.0	95.3	0.6	−0.1	(−0.5, 0.3)	0.69
Sleep disturbance (0 worst to 20 best)	17242	13.44	13.65	0.18	25583	13.43	13.44	−0.01	0.19	(0.12, 0.26)	<0.001

[a] Mean difference of change scores (intervention minus comparison).

[b] Missing data, at either baseline or Year 1, account for mean change scores not equal to Year 1 mean minus baseline mean.

[c] Based on statistical significance of randomization assignment from linear model.

[d] RAND-36 subscales

[e] 3MSE, modified mini-mental state examination

Table 3

Mean Difference (Intervention vs. Comparison) of Health Related Quality of Life Change Score (Year 1 minus Baseline) by Subgroup in the Women's Health Initiative Dietary Modification Trial

Subgroup	Global Quality of Life			General Health			Physical Functioning			Vitality			Self-reported Health		
	Mean	(95% CI)	P[a]	Mean	(95% CI)	P	Mean	(95% CI)	P	Mean	(95% CI)	P	Mean	(95% CI)	P
All	0.09	(0.07, 0.12)	<0.001	1.7	(1.5, 2.0)	<0.001	2.0	(1.7, 2.3)	<0.001	1.9	(1.6, 2.2)	<0.001	0.10	(0.09, 0.11)	<0.001
Age (years)			0.62			0.04			0.02			0.76			0.03
50-54	0.07	(0.00, 0.14)		1.7	(1.0, 2.4)		1.5	(0.8, 2.2)		1.8	(1.0, 2.6)		0.12	(0.09, 0.16)	
55-59	0.11	(0.05, 0.17)		2.2	(1.6, 2.7)		1.6	(1.1, 2.2)		1.8	(1.1, 2.4)		0.11	(0.08, 0.14)	
60-69	0.10	(0.06, 0.13)		1.6	(1.2, 2.0)		2.2	(1.8, 2.6)		2.0	(1.6, 2.5)		0.09	(0.07, 0.11)	
70-79	0.08	(0.01, 0.14)		1.5	(0.8, 2.1)		2.3	(1.7, 3.0)		2.0	(1.3, 2.7)		0.09	(0.06, 0.12)	
Body Mass Index			0.61			0.004			<0.001			0.02			0.003
<25	0.10	(0.04, 0.15)		1.2	(0.7, 1.7)		1.3	(0.8, 1.8)		1.6	(1.1, 2.2)		0.08	(0.05, 0.10)	
25 – 29	0.11	(0.06, 0.15)		1.7	(1.3, 2.1)		1.9	(1.4, 2.3)		1.8	(1.3, 2.3)		0.10	(0.08, 0.12)	
30 – 34	0.09	(0.03, 0.14)		2.0	(1.5, 2.5)		2.6	(2.1, 3.2)		1.9	(1.3, 2.5)		0.11	(0.08, 0.14)	
>35	0.06	(−0.01, 0.13)		2.3	(1.6, 2.9)		2.7	(2.0, 3.4)		2.7	(1.9, 3.5)		0.13	(0.10, 0.17)	
Physical Activity (MET-hours/week)[b]			0.46			0.67			<0.001			0.70			0.25
Inactive	0.07	(0.01, 0.13)		1.9	(1.3, 2.5)		2.6	(2.0, 3.3)		1.7	(0.9, 2.4)		0.10	(0.07, 0.14)	
< 5	0.06	(0.00, 0.11)		1.7	(1.2, 2.3)		2.3	(1.7, 2.9)		1.9	(1.3, 2.6)		0.09	(0.06, 0.11)	
5-12	0.13	(0.08, 0.19)		1.5	(0.9, 2.0)		2.2	(1.6, 2.8)		2.2	(1.5, 2.8)		0.12	(0.09, 0.14)	
> 12	0.09	(0.04, 0.14)		1.8	(1.4, 2.3)		1.3	(0.8, 1.8)		1.8	(1.3, 2.4)		0.09	(0.06, 0.11)	
Dietary total Fat (g)			0.56			0.05			0.07			0.34			0.10
<57.6	0.08	(0.03, 0.12)		1.4	(0.9, 1.8)		1.7	(1.2, 2.1)		1.8	(1.3, 2.3)		0.08	(0.06, 0.10)	
57.6 - 82.8	0.08	(0.04, 0.13)		1.8	(1.4, 2.3)		2.0	(1.6, 2.5)		1.8	(1.3, 2.3)		0.11	(0.09, 0.13)	
82.8	0.11	(0.06, 0.16)		2.0	(1.5, 2.4)		2.3	(1.9, 2.8)		2.2	(1.6, 2.7)		0.11	(0.09, 0.13)	

[a] P-value based on a test of interaction between baseline characteristic and randomization assignment.

[b] Total energy expended from recreational physical activity; MET, metabolic equivalent of task. Participants with 0 MET-hours/week

Table 4

Mean Health Related Quality of Life Change Scores at Close-out (Close-out minus Baseline) by Randomization Assignment in the Women's Health Initiative Dietary Modification Trial

Quality of Life Measure	Intervention			Comparison			Difference [a]		
	n	Mean	S.D.	n	Mean	S.D.	Mean	(95%CI)	P-Value [b]
Global quality of life (0 worst to 10 best)	15788	0.07	(1.41)	24342	0.03	(1.44)	0.04	(0.01, 0.07)	0.01
General Health [c] (0 worst to 100 best)	15504	−5.2	(15.9)	23912	−5.8	(15.8)	0.6	(0.3, 1.0)	<0.001
Physical Functioning [c] (0 worst to 100 best)	15132	−9.7	(19.8)	23365	−10.5	(19.7)	0.8	(0.4, 1.2)	<0.001
Vitality [c] (0 worst to 100 best)	15501	−2.5	(18.0)	23917	−3.5	(18.1)	1.0	(0.7, 1.4)	<0.001
Role Physical [c] (0 worst to 100 best)	15620	−14.3	(42.0)	24089	−14.6	(42.3)	0.3	(−0.6, 1.1)	0.52
Bodily Pain [c] (0 worst to 100 best)	15833	−7.8	(25.3)	24414	−7.8	(25.2)	0.0	(−0.5, 0.5)	0.98
Social Functioning [c] (0 worst to 100 best)	15709	−5.2	(22.9)	24217	−5.2	(23.2)	0.1	(−0.4, 0.5)	0.74
Role Emotional [c] (0 worst to 100 best)	15664	−4.4	(35.3)	24129	−5.3	(36.4)	0.9	(0.2, 1.6)	0.02
Mental Health [c] (0 worst to 100 best)	15506	0.7	(13.9)	23873	0.0	(14.0)	0.6	(0.4, 0.9)	<0.001
Self-Reported Health (1 worst to 5 best)	15795	−0.20	(0.81)	24374	−0.23	(0.79)	0.03	(0.01, 0.04)	<0.001
Depressive Symptoms (0 worst to 18 best)	15285	−0.11	(2.71)	23549	−0.19	(2.79)	0.08	(0.02, 0.14)	0.005
Sleep disturbance (0 worst to 20 best)	15190	−0.53	(4.33)	23435	−0.66	(4.43)	0.13	(0.04, 0.22)	0.006

[a] Intervention minus comparison.

[b] P-value based on statistical significance of randomization assignment from linear model.

[c] RAND-36 subscales