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Gender, Age and Race/Ethnicity do not Modify the Effectiveness of a Diet Intervention among Family Members of Hospitalized Cardiovascular Disease Patients

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INTRODUCTION

Over the past half-century, cardiovascular disease (CVD) mortality rates have declined more than 60% in the United States (1). This dramatic reduction has largely been attributed to smoking cessation, improvements in medical technology and medications, and also to lower blood cholesterol levels produced by the significant reduction in dietary saturated fat and cholesterol intake achieved by Americans during this period (1–4). Despite these documented improvements, mean intake of saturated fat remains above the Healthy People goal of less than 10% in both men and women (5–6) and more than one in three Americans (36.9%) have CVD (7).

For over fifty years, programs designed to reduce CVD risk through lifestyle modifications including diet have been tested for effectiveness. Effectiveness of these programs to improve diet has been mixed and it has been suggested that heterogeneity in program effectiveness may be related to participant characteristics (8). For example, documented barriers to healthy eating in men include rejection of healthy foods based on poor taste and inability to satisfy (9). In contrast, top barriers to diet change in women include confusion related to media messages and family obligations (10). Barriers to diet change among older adults include low family or social support for diet changes (11). Barriers to diet change among younger adults include not perceiving one's self at risk of heart disease and not wanting to change one's lifestyle (12). Differences such as these among population subgroups may modify the effectiveness of an intervention to improve diet.

Meta-analyses of primary prevention trials suggest that differential program effectiveness may also be related to risk level of the target population (8). Interventions aimed at lower-risk populations may not yield as dramatic risk factor changes compared to those directed at higher-risk groups (8). One population known to be at increased CVD risk is family members of persons with CVD. Few intervention trials for CVD primary prevention have been completed in this population; however studies recently completed in Europe (13) and

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the United States (14) support the claim that family-based intervention programs can improve diet in CVD patient family members.

The hospitalization of a family member with CVD may represent a unique “motivational moment” for encouraging individuals to recognize their own risk and take personal action to improve lifestyle and lower their own CVD risk. In the United States, the Family Heart Health Intervention Trial (FIT Heart) recently demonstrated that a special screening and education intervention for family members of patients hospitalized with CVD was effective to improve diet (14–15). The purpose of this study is to conduct more detailed analysis of the effect of the FIT Heart intervention on diet change that includes subgroup analysis by gender, race/ethnicity, and age to determine if effectiveness of the intervention to promote desirable diet change differs by subgroup. Differences in the effectiveness of the intervention by subgroup may indicate the need improve the intervention to overcome barriers to diet change that may uniquely effect each subgroup.

METHODS

FIT Heart was a one year single site randomized controlled trial designed to evaluate the effectiveness of a special intervention (SI) with personalized risk factor screening, therapeutic lifestyle change counseling, and progress reports to physicians versus a control intervention (CI) to reduce clinical and lifestyle risk factors for CVD among individuals eligible for the primary prevention of CVD (14). The 501 participants were English and Spanish speaking family members (blood relative or cohabitant) of atherosclerotic cardiovascular disease patients admitted to a large university medical center. To avoid non-independence of observations, only one family member per family was enrolled in the trial and randomized. Enrollment was conducted between January 2005 and June 2007. One-year follow-up visits were completed in June 2008.

Exclusion criteria included established CVD (or CVD equivalent such as diabetes, active liver disease, or chronic kidney disease), life expectancy < 5 years, current or planned pregnancy, prescription of a diet non-compatible with National Cholesterol Education Program Adult Treatment Panel III Therapeutic Lifestyle Changes (TLC) Diet recommendations (16), or participation in a clinical study within three months of randomization. Participants were required to complete informed consent to enroll in the trial. The study was approved by the Medical Center Institutional Review Board.

Randomization was completed using a web based application with a MySQL database system (version 12.22, 2002, Sun Microsystems, Inc., Santa Clara, CA) that generated group assignment after enrollment was completed at the baseline visit. Randomization was blocked based on gender and race/ethnicity. Participants were randomized to receive either the SI or the CI.

INTERVENTION

Both SI and CI participants received a standardized baseline and one-year follow up evaluation and brief education at baseline about heart healthy lifestyle based on the United States Department of Health and Human Services messages to avoid tobacco, choose good nutrition and maintain a healthy body weight, and be more active. In addition, the SI arm received a special intervention consisting of a CVD risk factor and lifestyle screening, education, and follow-up both in person and over the telephone. The SI was based on the ‘Five As’ construct (i.e. assess, advise, agree, assist, and arrange) recommended by the Counseling and Behavioral Interventions Work Group of the United States Preventive Services Task Force (17). SI participants were informed how their results compared to prevention goals based on national guidelines (16,18).

Diet education was based on National Cholesterol Education Program Adult Treatment Panel III, *Therapeutic Lifestyle Change* (TLC) diet recommendations (16). The Transtheoretical Model was the driving theory behind the intervention, which was primarily built on the stage of change construct (19–20). Personally tailored diet counseling matched to stage of change to reduce dietary saturated fat was provided (21–24). Additionally, the processes of change, increasing self-efficacy, and weighing the pros and cons of current dietary behaviors were constructs emphasized in counseling. Motivational interviewing techniques were used to deliver education messages to the SI (25–26). Prevention counselors were master's level health educators with formal training in motivational interviewing acquired through academic coursework and structured workshops provided by a doctoral level certified health education specialist.

Upon completion of the baseline visit, prevention counselors sent risk factor screening results to the SI participant's primary physician using a standardized form. Prevention counselors conducted five pre-scheduled follow up phone calls at 2 weeks, 6 weeks, 3 months, 6 months and 9 months after enrollment with special intervention participants. Standardized scripts were used to reinforce goals, assess barriers to adherence, answer questions, and assist participants. Phone calls lasted approximately 10 to 20 minutes, depending on the extent of patient questions or needs. An invitation to return to the medical center up to three times (at 3, 6, and 9 months) for the purpose of follow-up blood lipid assessment was provided to SI participants if their low-density lipoprotein cholesterol level was above optimal at baseline (≥100 mg/dL).

Baseline measurements were repeated at the 1-year follow-up evaluation in both the SI and CI arms. At the end of 1-year, both SI and CI participants received screening results, counseling, and referral for medical follow up where indicated.

BASELINE AND 1-YEAR MEASUREMENTS

Diet Assessment—Participant diet was assessed by trained interviewer-assisted questionnaire at baseline and one-year using the MEDFICTS questionnaire (**M**eats, **E**ggs, **D**airy, **F**ried foods, fat **I**n baked goods, **C**onvenience foods, fats added at the **T**able and **S**nacks) (16). MEDFICTS focuses on foods that are major sources of fat, saturated fat, and dietary cholesterol and provides a quick way to record intake, frequency, and portion size. The questionnaire yields a continuous score ranging from 0 to 216 points that has been significantly correlated with dietary saturated fat and cholesterol intake in several studies (27–29). The questionnaire has been shown to have over 85% sensitivity to correctly categorize adherence to the TLC diet (29).

Participant diet was also assessed by the Block 98 Food Frequency Questionnaire (FFQ) at baseline and one-year (30–36). Reliability of the Block 98 FFQ has been demonstrated as high, with Pearson correlation coefficients having a median of 0.75 for macronutrients (30). Validity of the Block 98 FFQ to assess macronutrients has also been shown to be moderate to high with deattenuated Pearson correlation coefficients having a median of 0.59 (30). Saturated fat (g), dietary cholesterol (mg), and caloric intake were extracted from the Block 98 FFQ. Percent of daily calories from saturated fat was calculated using the equation: [(grams saturated fat/day) (9 calories/gram)]/(calories/day). Adherence to Step I diet was defined as consuming < 10 % of calories from saturated fat and < 300 mg dietary cholesterol per day. Adherence to TLC diet was defined as consuming < 7 % of calories from saturated fat and < 200 mg dietary cholesterol per day.

Risk Factor Measurements—Demographics, medical and family history, education level, and other characteristics were obtained from participants at baseline and one-year by standardized questionnaire. Anthropometric measurements were conducted at baseline and one-year by trained examiners and assessed using standard methods and research grade scales (37). All study forms were available in both English and Spanish and research staff was bilingual English/Spanish speaking.

Subgroups—Participants were categorized by gender, race/ethnicity and age group. Race/ethnicity was categorized by United States census definitions then dichotomized as racial/ethnic minority versus white; dichotomous definition was selected over categorization for each race/ethnic group, based on small sample size within African American (6%) and Asian (4%) racial/ethnic subgroups relative to Whites (64%) and Hispanics (26%). Age group was defined as having age as a CVD risk factor (≥ 45 years for males and ≥ 55 years for females) versus not having age as a risk factor (< 45 years for males and < 55 years for females) based on national guidelines (16).

DATA ANALYSIS

Data were double entered and ranges and distributions were evaluated for outliers. Participants with extreme caloric intake values (defined as <500 or >3,500 kcals/day in women/<800 or >4,000 kcals/day in men) were excluded from analysis (n=16) (38). Participant characteristics are presented using means for continuous variables and proportions for categorical variables.

For the primary outcome, change in MEDFICTS score from baseline to one-year, stratified analysis was conducted using the t-test to determine the difference in mean change in MEDFICTS score from baseline to one-year in the SI versus CI within subgroups. This procedure was repeated for secondary diet outcomes 1) change in saturated fat and 2) change in dietary cholesterol (the two major dietary targets of the TLC diet) from baseline to one-year. Chi square statistics were used to determine whether there was a significant difference in proportion adherent to categorical outcome measures 1) Step I Diet and 2) TLC Diet, by group assignment at one-year.

Linear regression was used to 1) evaluate the potential interactions between subgroup and group assignment (SI versus CI) on change in diet from baseline to one-year, and 2) assess potential confounding of the effect of group assignment on diet change by subgroup, education level (≤ high school versus > high school), health insurance status (yes versus no), baseline BMI, blood relation to the hospitalized CVD patient (yes versus no), or baseline diet.

Power calculations completed prior to study initiation indicate we had 80% power to detect a difference of .63 in mean individual change in percent of calories from saturated fat from baseline to one year between the SI and CI groups given a two-sided alpha of .05. We had 80% power to detect a difference of .77 in mean individual change in percent of calories from saturated fat from baseline to one year between SI and CI groups among female participants alone and 80% power to detect a difference of 1.0 among racial/ethnic minority participants alone. All analyses were performed using SAS statistical software (version 9.1, 2002–2003, SAS Institute, Cary, NC). Significance was set at p<0.05.

RESULTS

Of the 501 participants randomized, 419 (84%) had complete diet data at baseline and one-year. Among those with compete diet data, 403 (96%) had baseline and one-year calorie levels that fell within the acceptable range and were included in the analysis. These participants did not materially differ from those with incomplete or outlier diet data based on baseline characteristics, including diet, therefore results from these participants are presented below.

The characteristics of study participants are shown in Table 1. There were no significant differences in baseline characteristics by group assignment. Over 60% of participants were overweight or obese. Baseline diet did not differ by group assignment and is presented in Table 2. On average, participants were exceeding TLC diet and Step I diet recommendations at baseline by consuming over 10% of calories from saturated fat and more than 200 mg dietary cholesterol/day.

Unadjusted mean changes in MEDFICTS score, saturated fat, and dietary cholesterol are presented in Table 3. Mean individual reduction in MEDFICTS score was significantly greater in the SI versus CI at one-year. SI participants reduced their saturated fat and dietary cholesterol intakes approximately two times as much as CI participants from baseline to one-year.

Analyses of mean changes in diet from baseline to one-year were conducted by gender, race/ethnicity and age subgroups and are presented in Table 4.

GENDER

At baseline, MEDFICTS score, saturated fat, and dietary cholesterol intake were significantly lower among female versus male participants (41 versus 58 MEDFICTS points; $p<.0001$, 10.5 versus 11% kcals from saturated fat; $p=.06$; 210 versus 289 mg/day cholesterol; $p<.0001$). Males were less likely to be adherent to a Step I diet at baseline compared to females (OR=0.6; 95%CI=0.38–0.94).

From baseline to one-year, female SI participants experienced significantly greater reductions in MEDFICTS score compared to female CI participants (Table 4). There was no significant additive interaction between gender and group assignment on change in MEDFICTS score ($\beta_{MALExSIinteraction}=0.9$; $p=0.84$). In multivariable regression analysis of the association between SI group assignment and change in MEDFICTS score from baseline to one-year, adjusted for gender, race/ethnicity, age group, and baseline MEDFICTS score, female gender was an independent predictor of greater reductions in MEDFICTS score from baseline to one-year ($\beta_{MALEvs.FEMALE}=4.6$; $p=0.02$). Education level, health insurance status, baseline BMI, and blood relation to the hospitalized CVD patient were not associated with change in MEDFICTS score from baseline to 1-year.

Reduction in saturated fat and dietary cholesterol over one year was also greater among female SI participants versus female CI participants (Table 4). There was no interaction between the SI and gender on change in saturated fat ($\beta_{MALExSIinteraction}=0.4$; $p=0.48$) or dietary cholesterol ($\beta_{MALExSIinteraction}=10.7$; $p=0.65$) intake over one year. In multivariable analysis adjusted for gender, race/ethnicity, age group and baseline cholesterol intake, female gender was a significant predictor of greater reduction in dietary cholesterol intake from baseline to one-year ($\beta_{MALEvs.FEMALE}=32.2$; $p<.001$). Education level, health insurance status, baseline BMI, and blood relation to the hospitalized CVD patient were not associated with change in saturated fat or change in dietary cholesterol intake from baseline to 1-year.

Adherence to Step I and TLC diet patterns were assessed among men and women at one-year. The intervention was effective to promote Step I diet adherence in both male and female participants. Women adherent to Step I diet at baseline were significantly more likely to maintain adherence to a Step I diet at one-year if they were assigned to the SI versus the CI (83% versus 67%). And men who were non-adherent to a Step I diet at baseline were significantly more likely to achieve adherence to the Step I diet over one year if assigned to the SI group versus the CI group (29% versus 11%).

RACE/ETHNICITY

At baseline, there was no significant difference in mean MEDFICTS score or dietary cholesterol intake between white and racial/ethnic minority participants (46 versus 47 MEDFICTS points; p=.77 and 235 versus 237 mg/day dietary cholesterol; p=.19). Racial/ ethnic minority participants consumed significantly less saturated fat (10.2 vs. 10.9 % kcals/ day; p=.005) compared to white participants.

Both white and racial/ethnic minority participants achieved reductions in MEDFICTS score from baseline to one-year that were greater in the SI vs. CI arms (Table 4). There was no additive interaction between SI group assignment and race/ethnic group on change in MEDFICTS score from baseline to one-year ($\beta_{\text{RACIAL/ETHNIC MINORITYxSIinteraction}}=-1.1$; p=0.81).

At one-year, racial/ethnic minority participants had reductions in saturated fat intake that were more than five times greater in the SI versus CI arm (−1.0 vs. −0.14% kcals from saturated fat; p=.04). There was no additive interaction between race/ethnic group and SI on change in saturated fat intake from baseline to one-year ($\beta_{\text{RACIAL/ETHNICMINORITYxSIinteraction}}=-0.8$; p=0.08). In multivariable regression models adjusted for gender, race/ethnic group, age group, and baseline saturated fat intake, racial/ ethnic minority status was an independent predictor of reduction in saturated fat intake from baseline to one-year ($\beta_{\text{RACIAL/ETHNICMINORITYvs.WHITE}}=-0.5$; p=0.04). There was no difference in new adherence to or maintenance of a Step I or TLC diet between the SI and the CI among white or racial/ethnic minority participants.

AGE GROUP

At baseline, older participants had significantly lower MEDFICTS score, saturated fat intakes, and dietary cholesterol intakes relative to younger participants (37 versus 47 MEDFICTS points; p=.0007, 10.3 versus 10.9% kcals from saturated fat; p=.03, 222 vs. 247 mg/day dietary cholesterol; p=.04). Older participants were also more likely to be adherent to a Step I diet at baseline compared to younger participants (45 vs. 33%; p=.01).

Among older participants, those assigned to the SI had larger reductions in MEDFICTS diet score from baseline to one-year compared to CI (Table 4). A similar trend was observed among younger participants, but the between group difference in change in MEDFICTS score did not reach statistical significance (−15.2 vs. −9.9 points; p=.10). There was no significant additive interaction was identified between age group and SI group assignment on change in MEDFICTS score ($\beta_{\text{OLDERAGExSIinteraction}}=-0.6$; p=0.89).

Among older participants, the SI also experienced significantly greater reductions in dietary cholesterol compared to the CI (Table 4). No additive interaction between group assignment and age group on change in dietary cholesterol from baseline to one- year was identified ($\beta_{\text{OLDERAGExSIinteraction}}=-16.3$; p=0.46). In multivariable models adjusted for gender, race/ ethnicity, age group, and baseline dietary cholesterol intake, older age was an independent predictor of reduction in dietary cholesterol from baseline to one-year ($\beta_{\text{OLDERvs.YOUNGER}}=-21.2$; p=0.02).

The SI was not associated with greater proportions of new adherence to, or maintenance of, Step I diet or TLC diet patterns from baseline to one-year relative to the CI among older or younger participants.

DISCUSSION

The effectiveness of the FIT Heart intervention to reduce MEDFICTS score, saturated fat, or dietary cholesterol intake from baseline to one year was not modified by gender, race/ethnicity, or age group. Although stratified analysis showed effectiveness of the SI among females and older participants compared to the CI, multivariable analysis indicated that these differences were driven by the independent effect of the subgroup itself, and not by interaction with the SI. These results are encouraging, because they suggest that subgroup did not alter the effectiveness of the SI to promote diet change among participants.

Female gender was an independent predictor of desirable diet changes in this study and in others (39–40). Females in this study were more likely than males to be spouses of the hospitalized patient and may have had more incentive to improve their diets if they were preparing meals with or for the CVD patient, independent of group assignment. The effect of the SI to reduce MEDFICTS score over one-year was highly significant after adjustment for gender which underscores the effectiveness of the intervention to improve diet in both men and women. Poorer adherence to diet protocols among racial/ethnic minority participants compared to whites has been reported in lifestyle intervention trials, but was not observed in this trial (40–41). In this study, both white and racial/ethnic minority participants assigned to the SI had greater reductions in MEDFICTS score, saturated fat, and/or dietary cholesterol compared to CI over one year. Effectiveness of the SI among both white and racial/ethnic minority participants to promote desirable diet changes may be attributable in part to the bilingual English/Spanish speaking prevention counselors and the translation of all study materials into Spanish. Additionally formal education level was higher among participants in this study compared to in others that have assessed cardiovascular disease related knowledge in the New York Metropolitan area and nationally (10,42). Knowledge is a known antecedent to preventive actions such as diet change which might explain why there was no observed disparity in effectiveness of the intervention to promote reduced saturated fat and cholesterol intake by race/ethnic group (10).

In this study, stratified analysis showed significant reductions in MEDFICTS score and cholesterol intakes among older SI participants compared to older CI participants. But this within group difference did not translate into an interaction between age group and assignment to the SI. It can be attributed to the independent association between older age group and reductions in MEDFICTS score and cholesterol intake over one year illustrated in final multivariable models. Age is an established predictor of diet adherence in clinical trials with older persons generally more adherent to recommendations compared to younger (40–41). One barrier to low-fat diet adherence reported by persons 55 and over is concern for negative responses from others (43). However older FIT Heart participants were more likely than younger participants to cohabitate with patients with CVD. It is possible that the independent effect of older age group on desirable diet changes could be attributed to social support for diet change at home from the CVD patient who is also making diet changes (11,44).

MEDFICTS score is a conglomerate measure of saturated fat and cholesterol rich food intake. Therefore, it is not surprising that changes in MEDFICTS score were consistent with changes in saturated fat and cholesterol in this study. Baseline saturated fat and cholesterol intakes in this study population are comparable to national averages suggesting results from this study may be generalizable to family members of CVD patients in the United States (2).

Almost half of the decline in CVD mortality over the past several decades can be attributed to improvement in CVD risk factors such serum cholesterol levels (4). Although greater use of lipid-lowering drugs has been cited as a primary reason for favorable trends in serum lipids among United States adults over the past 30 years (45), medication is not indicated for all individuals with elevated serum cholesterol levels (16). Heart healthy diet strategies such as reduction in saturated fat intake are recommended for most individuals, independent of CVD risk level, and can reduce CVD risk (16,46). For example, mean reduction in percent of calories from saturated fat achieved in the SI from baseline to one-year was as great as −1.0 within the subgroups. A reduction in saturated fat of 1 percent of calories per day is estimated to reduce total serum cholesterol by approximately 0.08mmol/L (3.1mg/dL), or approximately 1.5% in a person with total cholesterol of 200mg/dL (47). The effect of cholesterol reduction of this magnitude is not unimportant. It is estimated that each 1% reduction in plasma cholesterol confers a 2% decrease in CVD incidence (48–49). Because CVD is the number one cause of mortality in the United States, a nationally disseminated intervention for CVD patient family members that effectively reduces blood cholesterol levels through improved diet adherence could significantly impact CVD risk (16,18).

Strengths of the study include the sample size and a gender and race blocked randomized controlled design, which allowed for subgroup analysis with equal distribution of gender and race groups within each study arm. The randomized design also minimized potential confounding of the effect of group assignment on diet change. Fixed sample size may have limited power to test for significance of smaller differences in diet change between groups, even though smaller effects may be biologically important in relation to reduction in blood cholesterol levels. Small sample sizes within select racial/ethnic subgroups led to an inability to categorize for each racial/ethnic minority individually therefore we cannot rule out the possibility that SI responses varied within the non-white subgroup. Widespread dissemination of this intervention would likely require prioritization of CVD risk in families as a national target for health promotion. However, demonstrated cost effectiveness of this intervention in a diverse population suggests feasibility (50).

IMPLICATIONS FOR RESEARCH AND PRACTICE

Effectiveness of a special intervention to improve diet at one-year was not modified by participant gender, race/ethnicity, or age group, despite potential barriers to diet change that may uniquely affect each of these subgroups. These results support the potential for a hospital-based screening and education program to improve diet in diverse populations of CVD patient family members.

References

1. Achievements in public health, 1990–1999: decline in deaths from heart disease and stroke – United States, 1990–1999. MMWR Weekly. August 6.1999 48:649–656.
2. Wright, JD.; Wang, CY.; Kennedy-Stephenson, J.; Ervin, RB. Advance data from vital and health statistics; no 334. Hyattsville, Maryland: National Centre for Health Statistics; 2003. Dietary intake of ten key nutrients for public health, United States: 1999–2000.
3. Ernst ND, Sempos CT, Briefel RR, Clark MB. Consistency between US dietary fat intake and serum cholesterol concentrations: the National Health and Nutrition Examination Surveys. Am J Clin Nutr. 1997; 66:965S–972S. [PubMed: 9322575]
4. Ford ES, Ajani UA, Croft JB, Critchley JA, Labarthe DR, et al. Explaining the decrease in U.S. deaths from coronary disease, 1980–2000. N Engl J Med. 2007; 356:2388–2398. [PubMed: 17554120]
5. Trends in intake of energy and macronutrients—United States, 1971–2000. MMWR Weekly. 2004; 53:80–82.
6. Healthy People. National Health Promotion and Disease Prevention Objectives Final Review. Department of Health and Human Services; Centers for Disease Control and Prevention; National Center for Health Statistics; 2000.

7. Lloyd-Jones D, Adams RJ, Brown TM, Carnethon M, Dai S, et al. Heart Disease and Stroke Statistics 2010 Update: A Report From the American Heart Association. Circulation. 2010; 121:e46–e215. [PubMed: 20019324]

8. Ebrahim S, Beswick A, Burke M, Davey Smith G. Multiple risk factor interventions for primary prevention of coronary heart disease. Cochrane Database Syst Rev. 2006; (4):CD001561. [PubMed: 17054138]

9. Gough B, Conner MT. Barriers to healthy eating amongst men: A qualitative analysis. Soc Sci Med. 2006; 62:387–395. [PubMed: 16011867]

10. National study of women's awareness, preventive action, and barriers to cardiovascular health. Circulation. 2006; 113:525–534. [PubMed: 16449732]

11. Wen LK, Parchman ML, Shepherd MD. Family support and diet barriers among older Hispanic adults with type 2 diabetes. Fam Med. 2004; 36:423–430. [PubMed: 15181555]

12. Twelve-year follow up of American women's awareness of cardiovascular disease risk and barriers to heart health. Circ Cardiovasc Qual Outcomes. 2010; 3:120–127. [PubMed: 20147489]

13. Wood DA, Kotseva K, Connolly S, Jennings C, Mead A, Jones J, Holden A, De Bacquer D, Collier T, De Backer G, Faergeman O. on behalf of EUROACTION Study Group. Nurse-coordinated multidisciplinary, family-based cardiovascular disease prevention programme (EUROACTION) for patients with coronary heart disease and asymptomatic individuals at high risk of cardiovascular disease: a paired, cluster-randomised controlled trial. Lancet. 2008; 371:1999–2012. [PubMed: 18555911]

14. A novel family-based intervention trial to improve heart health: FIT Heart. Results from a randomized controlled trial. Circ Cardiovasc Qual Ooutcomes. 2008; 1:98–106.

15. Does Stage of Change Modify the Effectiveness of an Educational Intervention to Improve Diet among Family Members of Hospitalized Cardiovascular Disease Patients? J Am Diet Assoc. 2010; 110:1027–1035. [PubMed: 20630159]

16. Third report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III) final report. Circulation. 2002 Dec 17; 106(25):3143–421. [PubMed: 12485966]

17. Whitlock EP, Orleans CT, Pender N, Allan J. Evaluating primary care behavioral counseling interventions: an evidence-based approach. Am J Prev Med. 2002; 22:267–284. [PubMed: 11988383]

18. Evidence-based guidelines for cardiovascular disease prevention in women: 2007 update. Circulation. 2007; 115:1481–1501. [PubMed: 17309915]

19. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot. 1997 Sep-Oct; 12(1):38–48. [PubMed: 10170434]

20. Bridle C, Riemsma RP, Pattenden J, Sowden AJ, Mather L, Watt IS, Walker A. A systematic review of the effectiveness of health behavior interventions based on the transtheoretical model. Psychol Health. 2005; 20:283–301.

21. Curry SJ, Kristal AR, Bowen DJ. An application of the stage model of behavior change to dietary fat reduction. Health Ed Res. 1992; 7:97–105.

22. Greene GW, Rossi SR. Stages of change for reducing dietary fat over 18 months. J Am Diet Assoc. 1998; 98:529–34. [PubMed: 9597025]

23. Greene GW, Rossi SR, Reed G, Wiley C, Prochaska JO. Stages of change for dietary fat reduction to 30% of energy or less. J Am Diet Assoc. 1994; 94:1105–10. [PubMed: 7930314]

24. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change: applications to addictive behaviors. Am Pyshcol. 1992; 47:1102–14.

25. Miller, WR.; Rollnick, S. Motivational Interviewing: Preparing People for Change. New York, NY: The Guilford Press; 2002.

26. Shinitzky H, Kub J. The art of motivating behavior change: The use of motivational interviewing to promote health. Public Health Nurs. 2001; 18:178–185. [PubMed: 11359619]

27. National Cholesterol Education Program. Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). Circulation. 1994; 89(3):1333–445. [PubMed: 8124825]

28. Kris-Etherton P, Eissenstat B, Jaax S, Srinath U, Scott L, Rader J, Pearson T. Validation for MEDFICTS, a dietary assessment instrument for evaluating adherence to total and saturated fat recommendations of the National Cholesterol Education Program Step 1 and Step 2 diets. J Am Diet Assoc. 2001; 101(1):81–6. [PubMed: 11209589]
29. Validation of the MEDFICTS Dietary Assessment Questionnaire in a diverse population. J Am Diet Assn. 2008; 108:817–822.
30. Boucher B, Cotterchio M, Kreiger N, Nadalin V, Block T, Block G. Validity and Reliability of the Block98 Food-Frequency Questionnaire in a Sample of Canadian Women. Public Health Nutrition. 2006; 9(1):84–93. [PubMed: 16480538]
31. Block G, Hartman AM, Dresser CM, Carroll MD, Gannon J, Gardner L. A databased approach to diet questionnaire design and testing. Am J Epidemiol. 1986; 124:453–469. [PubMed: 3740045]
32. Block G, Coyle LM, Hartman AM, Scoppa SM. Revision of dietary analysis software for the Health Habits and History Questionnaire. Am J Epidemiol. 1994; 139:1190–1196. [PubMed: 8209877]
33. Mares-Perlman JA, Klein BEK, Klein R, Ritter LL, Fisher MR, Freudenheim JL. A diet history questionnaire ranks nutrient intakes in middle-aged and older men and women similarly to multiple food records. J Nutr. 1993; 123:489–501. [PubMed: 8463852]
34. Block G, Woods M, Potosky A, Clifford C. Validation of a self-administered diet history questionnaire using multiple diet records. Clin Epidemiol. 1990; 43(12):1327–35.
35. Nutritionquest. Development and Validation of Block FFQs and Screeners. [(accessed 16 July 2010)]. Internet: http://www.nutritionquest.com/company/our-research-questionnaires/
36. Nutritionquest. Questionnaires and Screeners. Block Questionnaire - 1998 FFQ. [(accessed 16 July 2010)]. Internet: http://www.nutritionquest.com/assessment/list-of-questionnaires-and-screeners/
37. Lohman, TC.; Roche, AF.; Martorell, R., editors. Anthropometric Standardization Reference Manual. Human Kinetics Books; Champaign, IL: 1988.
38. Willett, W. Nutritional Epidemiology. 2. New York: Oxford University Press; 1998.
39. Kristal AR, Hedderson MM, Patterson RE, Neuhauser ML. Predictors of self-initiated, healthful dietary change. J Am Diet Assoc. 2001; 101:762–766. [PubMed: 11478472]
40. Bosworth, HB.; Oddone, EZ.; Weinberger, M. Patient treatment adherence. New Jersey: Lawrence Erlbaum Associates Inc; 2006.
41. Van Horn LV, Dolecek TA, Grandits GA, Skweres L. Chapter 8: Adherence to dietary recommendations in the special intervention group in the Multiple Risk Factor Intervention Trial. Am J Clin Nutr. 1997; 65:289A–304S.
42. Kaplan RC, Bhalodkar NC, Brown DL, White J, Brown EJ. Differences by age and race/ethnicity in knowledge about hypercholesterolemia. Cardiol Rev. 2006; 14:1–6. [PubMed: 16371759]
43. Kearney MH, Rosal MC, Ockene JK, Churchill LC. Influences on older women’s adherence to a low-fat diet in the Women’s Health Initiative. Psychometric Medicine. 2002; 64:450–457.
44. Low Social Support Level is Associated with Non-Adherence to Diet at 1-Year in the Family Intervention Trial for Heart Health (FIT Heart). J Nutr Educ Behav. 2010; 42:380–388. [PubMed: 20696617]
45. Cohen JD, Cziraky MJ, Cai Q, et al. 30-year trends in serum lipids among United States adults: Results from the National Health and Nutrition Examination Surveys II, III, and 1999–2006. Am J Cardiol. 2010; 106:969–975. [PubMed: 20854959]
46. van Dam RM, Willett WC. Unmet potential for cardiovascular disease prevention in the United States. Circulation. 2009; 120:1171–1173. [PubMed: 19752318]
47. Oster G, Thompson D. Estimated effects of reducing dietary saturated fat intake on the incidence and costs of coronary heart disease in the United States. J Am Diet Assoc. 1996; 96:127–131. [PubMed: 8557937]
48. Law MR, Wald NJ, Wu T, Hackshaw A, Bailey A. Systematic underestimation of association between serum cholesterol concentration and ischaemic heart disease in observational studies: data from the BUPA study. BMJ. 1994; 308:363–366. [PubMed: 8124143]
49. Rifkind BM. Diet cholesterol and coronary heart disease: the Lipid Research Clinics Program. Proceedings of the Nutrition Society. 1987; 46:367–372. [PubMed: 3324096]

50. Nawathe AC, Glied SA, Weintraub WS, et al. The effect of a cardiovascular educational intervention on health utilization and costs. Am J Manag Care. 2010; 16:339–346. [PubMed: 20469954]

Table 1

Baseline Characteristics of FIT Heart Study Participants (n=403)*

Characteristic	Special Intervention (n=198) n (%)	Control Intervention (n=205) n (%)
Age (≥55 years (F)/≥45 years (M))	91 (46)	91 (44)
Female	135 (68)	140 (68)
Racial/ethnic minority	75 (38)	73 (36)
Blood relative of CVD patient	137 (69)	135 (66)
Spouse of CVD patient	60 (31)	70 (34)
Single/Widowed/Divorced	69 (35)	64 (31)
Education ≤ high school	45 (23)	39 (19)
No health insurance	29 (15)	27 (13)
Family history of premature CHD	106 (54)	103 (50)
Framingham risk ≥10%	17 (9)	18 (9)
BMI ≥ 25kg/M^2	121 (61)	130 (63)
Saturated fat ≥10% of kcals/day	112 (57)	122 (60)
Statin therapy	28 (14)	33 (16)

*No statistically significant baseline differences by group assignment

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Table 2

Baseline Diet by Group Assignment among FIT Heart Participants

	Special Intervention n=198 mean (SD)	Control Intervention n=205 mean (SD)	p
MEDFICTS Score	45.0 (26.3)	47.7 (28.7)	.33
Saturated fat (%kcals)	10.6 (2.4)	10.7 (2.7)	.80
Cholesterol (mg/day)	238.2 (116.8)	233.1 (131.0)	.68
	number (%)	**number (%)**	
Step I Diet Adherence	77 (39)	78 (38)	.86
TLC Diet Adherence	11 (6)	10 (5)	.76

Table 3

T-tests for Difference in Mean within Individual Change in Diet from Baseline to 1-Year by Group Assignment among FIT Heart Participants

	Change in Diet (Baseline to 1-year)		**Between Group Difference in Mean Change**
	Special Intervention n=198 mean (SD)	**Control Intervention n=205 mean (SD)**	**P**
MEDFICTS Score[1]	−13.8 (22.2)	−8.3 (21.0)	**.01**
Saturated fat (%kcals)	−0.7 (2.2)	−0.4 (2.4)	.18
Cholesterol (mg)	−45 (111)	−27 (107)	**.09**

[1]MEDFICTS (**M**eats, **E**ggs, **D**airy, **F**ried foods, fat **I**n baked goods, **C**onvenience foods, fats added at the **T**able and **S**nacks) Score ranges from 0–216 and is correlated with dietary saturated fat and cholesterol intake (12).

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Table 4

T-tests for Change in Diet from Baseline to 1-Year by Group Assignment among FIT Heart Participants: *Stratified by Gender, Race/Ethnicity, Age Group, and Relation to Hospitalized CVD Patient*[1]

	Male			Female		
Diet[2]	**SI n=63 mean (SD)**	**Control n=65 mean (SD)**	**p**	**SI n=135 mean (SD)**	**Control n=140 mean (SD)**	**p**
MEDFICTS Score[3]	−16.3(24.4)	−11.5(26.0)	.28	−12.6(21.1)	−6.8 (18.1)	**.02**
Saturated fat	−0.79 (2.1)	−0.72 (2.0)	.85	−0.64 (2.3)	−0.21 (2.6)	.15
Cholesterol	−51.6 (121)	−40.3 (130)	.61	−42.5 (105)	−20.5 (95)	.07
	Non-White			**White**		
Diet[2]	**SI n=77 mean (SD)**	**Control n=78 mean (SD)**	**p**	**SI n=123 mean (SD)**	**Control n=132 mean (SD)**	**p**
MEDFICTS Score[3]	−14.5(22.7)	−8.3 (17.5)	.07	−13.3(22.0)	−8.3 (22.7)	.07
Saturated fat	−1.0 (2.3)	−0.14 (2.6)	**.04**	−0.51 (2.1)	−0.52 (2.4)	.98
Cholesterol	−43.2 (134)	−30.2(108)	.52	−46.8(94.4)	−24.9(107)	.08
	Age ≥ 45y (M)/≥ 55y (F)			**Age < 45y (M)/<55y (F)**		
Diet[2]	**SI n=91 mean (SD)**	**Control n=91 mean (SD)**	**p**	**SI n=107 mean (SD)**	**Control n=114 mean (SD)**	**p**
MEDFICTS[3] **Score**	−12.1(21.7)	−6.3 (17.2)	**.04**	−15.2(23.4)	−9.9 (23.6)	.10
Saturated fat	−0.7 (2.0)	−0.3 (2.4)	.34	−0.72 (2.4)	−0.40 (2.5)	.33
Cholesterol	−52.1(97.7)	−24.5(86.2)	**.04**	−39.8 (121)	−28.6(122)	.49

[1] Univariable results stratified by demographic sub-group

[2] Diet change from baseline to 1-year: dietary fats (%kcals), dietary cholesterol (mg/day)

[3] MEDFICTS (**M**eats, **E**ggs, **D**airy, **F**ried foods, fat **I**n baked goods, **C**onvenience foods, fats added at the **T**able and **S**nacks) Score ranges from 0–216 and is correlated with dietary saturated fat and cholesterol intake (27).