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A Comparison of Live Counseling with a Web-Based Lifestyle and Medication Intervention to Reduce Coronary Risk A Randomized Clinical Trial

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Abstract

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Importance—Most primary care clinicians lack the skills and resources to offer effective lifestyle and medication counseling to reduce coronary heart disease (CHD) risk. Thus, effective and feasible CHD prevention programs are needed for typical practice settings.

Objective—To assess the effectiveness, acceptability, and cost-effectiveness of a combined lifestyle and medication intervention to reduce CHD risk offered in counselor-delivered and web-based formats.

Design—Comparative effectiveness trial.

Setting—Five diverse family medicine practices in North Carolina.

Participants—Established patients, age 35–79, with no known cardiovascular disease, and at moderate to high risk for CHD -- 10 year Framingham Risk Score (FRS) ≥ 10%.

Intervention—Participants were randomized to counselor-delivered or web-based format, each including 4 intensive and 3 maintenance sessions. After randomization, both formats utilized a web-based decision aid showing potential CHD risk reduction associated with lifestyle and medication risk reducing strategies. Participants chose the risk reducing strategies they wished to follow.

Main Outcome and Measures—Outcomes were assessed at 4 and 12 months; the primary outcome was within group change in FRS at 4 month follow-up. Other measures included standardized assessments of blood pressure, blood lipids, lifestyle behaviors, and medication adherence. Acceptability and cost-effectiveness were also assessed.

Results—Of 2,274 screened patients, 385 were randomized (192 counselor; 193 web): mean age 62 years, 24% African American, and mean FRS 16.9%. Follow-up at 4 and 12 months was 91% and 87%, respectively. There was a sustained reduction in FRS at both 4 (primary outcome) and 12 month follow-up: for counselor, −2.3% (95% CI: −3.0% to −1.6%) and −1.9% (−2.8% to −1.1%) and for web, −1.5% (−2.2% to −0.9%) and −1.7%, (−2.6% to −0.8%) respectively. At 4 month follow-up, the adjusted difference in FRS between groups was −1.0% (95% CI −1.8% to −0.1%, p = 0.03) at 12 month follow-up, it was −0.6% (95% CI, −1.7% to 0.5%, p = 0.30). The 12 month costs from the payer perspective were $207 and $110 per person for the counselor and web interventions respectively.

Conclusions and Relevance—Both intervention formats reduced CHD risk through 12 month follow-up. The web format was less expensive.

Introduction

A healthy lifestyle[1,2] and appropriate medications[3–5] can substantially reduce the risk for coronary heart disease (CHD), yet getting patients to change their lifestyle and initiate and adhere to risk reducing medication can be difficult to achieve in clinical practice. In particular, most primary care clinicians lack the skills[6,7] and resources[8] to offer effective lifestyle and medication counseling to reduce CHD risk. Thus, to improve CHD prevention in primary care practices, where half of Americans are seen annually,[9] clinicians need access to effective and feasible CHD prevention programs that could be implemented in their practice settings.

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While many primary-care based programs to reduce CHD risk have been previously tested, these programs have limitations.[10,11] Most have not jointly addressed lifestyle change and medication optimization and few have taken a patient-centered approach that informs patients about the relative merits of strategies to reduce CHD risk and encourages them to select their preferred risk reducing strategies. Further, few have been evaluated in comparative effectiveness studies[12,13] that: 1) compare clinically relevant implementation strategies, 2) include a diverse population of participants, 3) include a heterogeneous selection of practices, and 4) collect data on a broad range of outcomes.

Given increasing evidence that supports the effectiveness of web-based interventions,[14,15] we developed a combined lifestyle and medication intervention to reduce CHD risk and tested it in two formats: counselor-delivered and web-based. While the counselor intervention provides human interaction and the potential for a higher degree of tailoring, the web intervention offers greater reach, flexibility to patients in the timing and delivery of the intervention, and minimizes clinic staff demands and costs.[16] In this paper, we report the results of a comparative effectiveness trial conducted to assess the effectiveness, acceptability, and cost-effectiveness of the intervention when offered in alternative formats.

METHODS

Study Overview

We conducted this study at 5 diverse family medicine practices located in central North Carolina. Our primary intent was to determine the comparative effectiveness of the two intervention formats on reducing CHD risk as assessed by the Framingham Risk Score (FRS).[17] Participants were randomized to receive interventions similar in contact time, educational content, and individually tailored counseling, but different in format (Figure 1). Study outcomes were assessed at 4 and 12 months. Details of the study design, study practices, participant enrollment, and intervention components are described elsewhere.[17] The University of North Carolina at Chapel Hill's Institutional Review Board (IRB) approved and monitored this study, with data collected between January 31, 2011 and November 26, 2012.

Participants, Enrollment, and Randomization

Participants were established patients (i.e., had at least one office visit in the last 2 years), age 35–79, with no known cardiovascular disease (CVD), who were at moderate to high risk for CHD (≥ 10% 10-year risk of angina, myocardial infarction, or CHD death) based on their FRS. Participants were identified by chart reviews of patients scheduled for routine office visits, supplemented by referrals from clinicians and self-referrals based on word-of-mouth or in response to waiting room flyers. As an initial eligibility screen, the FRS was calculated using risk factors assessed by chart review (age, blood pressure, total cholesterol, high density lipoprotein cholesterol (HDL-C), diabetes, smoking, aspirin use, and left ventricular hypertrophy).[17] Diabetes was included in the FRS and was not considered a CVD equivalent. Because aspirin was not accounted for by the Framingham risk equation, we modelled its effect on CHD risk using a 23% risk reduction for men and 0% reduction for women.[3] Those with a FRS ≥ 10% were further evaluated by their primary care

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clinicians who 1) determined if the patient should be excluded for a variety of previously described[17] medical conditions and 2) approved participation in the overall and physical activity component of the study.

Patients screened as eligible attended an enrollment visit, during which study staff obtained written informed consent, confirmed inclusion criteria, screened participants for potential bleeding risk associated with aspirin, re-assessed smoking status, assessed blood pressure using a standard protocol, and obtained a blood sample for study lab assessments. Participants' FRS were re-calculated based on this standardized assessment and, if ≥ 10%, they were contacted for the baseline telephone survey. Those completing this survey were invited to the first intervention visit, where they were randomized, as previously described.[17]

Intervention

Both intervention formats began with a web-based decision aid, followed by the counseling program. As described elsewhere,[17] the intervention was based on previously developed and tested lifestyle and medication interventions revised to be consistent with the latest evidence on CHD risk reduction.

Decision Aid—The decision aid 1) calculated participants' 10-year FRS, 2) educated participants about their CHD risk factors and the pros and cons of risk-reducing strategies, and 3) showed participants how much their CHD risk might be reduced by one or more of the following: changes in diet, increased physical activity, smoking cessation, initiation of aspirin (for men only), or initiation or intensification of statins or hypertension medication. The following risk reduction estimates were used: 20–40% for diet,[1,17–21] 10–20% for physical activity,[22,23] 50% for smoking cessation, and 20–30% depending on type of medication (statins, blood pressure medication, and aspirin for men).[24] For women who indicated an interest in aspirin, the decision aid provided information on stroke risk and the potential reduction in stroke with aspirin of 23%. Participants navigated the decision aid with the assistance of the health counselor and were encouraged to choose the risk reducing strategies they wished to focus on as part of this program.

Counseling—Both formats included 7 counseling sessions: 4 during a 4 month intensive phase (each about 45–60 minutes at monthly intervals) followed by 3 during an 8 month maintenance phase (each about 15–30 minutes at 2 month intervals). Counseling was tailored to choice of risk reducing strategy; diet, physical activity, medications, or any combination. To standardize counseling, the sequence, educational content, and tailoring of the counselor and web formats was the same. Specifically, both formats used the same set of questions to assess baseline habits and barriers. Additionally, counseling sessions included identical educational content (including graphics) that were presented in a 3 ring binder for counselor format and on a sequence of web pages for web format. Finally, the counselor and interactive web progam used the same process to select tailored goals and list first steps. For the counselor format, these goals were checked on a sheet; for the web format, they were printed.

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Dietary counseling focused on improving carbohydrate and fat quality; physical activity counseling focused on walking 7,500 steps or 30 minutes on 5 days each week; and medication counseling focused on understanding medication instructions, planning ahead for refills, and encouragement to partner with clinician to make good decisions about medications to reduce CHD risk. All participants received a cook book, a pedometer for self-monitoring, and a guide with information on local resources promoting healthy eating and physical activity.. The initial visit was conducted at the clinic, where the counselor could assist participants with the web program, if needed. Subsequent visits were conducted at the clinic or remotely (by phone for counseling arm or computer for web arm). Counseling was conducted by trained health counselors, as previously described.[17] Requests for medication initiation or intensification were routed to participants' providers for approval.

Outcomes and Measures

Study measures addressed effectiveness, acceptability, and cost-effectiveness and were assessed by trained research staff at participating practices and by phone. The primary effectiveness measure was within group change in FRS at 4 month follow-up. The FRS was calculated using a well-validated Framingham risk equation[25] with input of relevant risk factor data measured in a standardized fashion and baseline age used for follow-up assessments. Pre-specified secondary effectiveness outcomes included between group changes in FRS and change in dietary intake, physical activity, smoking, medication adherence, blood pressure, blood lipids, and health related quality of life. In addition, an analysis of moderators of outcomes was also planned.

Weight, blood pressure, total cholesterol, HDL-C, directly measured low density lipoprotein cholesterol (LDL-C), hemoglobin A1c (A1c), high sensitivity C reactive protein (hsCRP), alanine aminotransferase (ALT), creatinine, and plasma carotenoids[26] were assessed at baseline, 4 and 12 months as previously described.[17] At the first counseling visit, numeracy,[27] literacy,[28] and medication adherence[29] were assessed using validated instruments. At follow-up visits, aspirin use was assessed by serum thromboxane level and smoking by NicAlert urine test, as previously described.[17]

The following measures were assessed by telephone at baseline and in-person at 4 and 12 month follow-up: medication use, fruit and vegetable intake,[30] dietary fat quality,[31] physical activity,[32,33] and quality of life (SF-12, Quality Metric, Inc., Lincoln, RI). Medication adherence[29] and acceptability of the interventions were assessed in-person at 4 and 12-month follow-up.

Process measures were collected at intervention sessions, by counselor or the web-program. Participants were advised to wear an Omron HJ-720ITC pedometer (Omron Healthcare, Bannockburn, IL) during the week before study measurement visits. Steps were assessed by averaging at least 3 days of 500 or more steps/day during the week prior to the visit. Assessment of costs for the cost-effective analysis are described in the Appendix.

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Sample size

Sample size was based on the hypothesis that both interventions would reduce the FRS by at least 1.5 percentage points (absolute risk reduction of 1.5%). Using a one-sided test, a standard deviation of 3.1 units,[24] an $\alpha = 0.05$, and an expected 10% attrition, a sample of 225 participants in each arm would provide > 99% power to detect a within group reduction in FRS of 1.5 percentage points. This sample size would additionally provide 85% power to detect a 0.9 percentage point difference in FRS between the counselor and web arms (two-sided test).

Analysis

We summarized baseline sample characteristics using descriptive statistics and compared groups using chi-square and t-tests. The primary outcome analysis was conducted using an intention-to-treat approach with a paired t-test (1-sided) for changes in FRS within each intervention arm. Additionally, for the primary outcome, we used multiple approaches for imputing missing data including last observations carried forward and multiple imputation methods.[17]

Secondary outcomes were examined using paired t-tests or McNemar's tests for within group comparisons (2-sided tests). Additional analyses were conducted to compare the mean changes in FRS and other outcomes between arms using a simple t-test and a multivariable analysis of covariance model (ANCOVA) adjusting for the baseline value of the outcome, practice, and additional variables deemed relevant to behavior change *a priori* (age, race, educational achievement, and BMI) or that differed between intervention groups at baseline ($p < 0.10$). In addition, we conducted longitudinal analyses with FRS data from all 3 time points using generalized linear mixed models that included time, study groups, and time by study group interaction as fixed and participants as random effects along with site and the full set of covariates as fixed effects. To assess potential moderators of change in FRS, we used linear regression models that included the baseline FRS, the potential moderator of interest, and study arm by potential moderator interaction term.

For cost-effectiveness, we assessed the incremental cost effectiveness ratio (ICER) of each intervention from the payer, participant, and societal perspectives, as described in the Appendix. We calculate the ICER per 1 absolute percentage point reduction in CHD risk and per quality adjusted life year (QALY) gained at 12 months. We calculate QALY gained in one year by converting SF-12 scores into a health related quality of life weight using a well-defined algorithm.[34] Because our analysis considers only a one year time horizon, this weight is equivalent to QALYs saved over this time period. We then report incremental cost-effectiveness per QALY gained and compare these ratios to common thresholds of cost-effectiveness. All analyses were conducted using SAS version 9.3 (SAS Institute, Cary, NC) and Stata version 12 (StataCorp, College Station, TX) with $p \leq .05$ considered significant.

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RESULTS

Enrollment and Baseline Characteristics of Participants

As depicted in Figure 1, of 2274 patients eligible to be screened for the study, 633 agreed to participate. Of these, 114 were ineligible because their FRS calculated using standardized measures was less than 10%, 111 took part in another intervention for those with known CVD as described elsewhere,[17] 23 were lost to follow-up or declined participation and 385 participants took part in this study.

Table 1 reports baseline characteristics of study participants. The mean age was 62 years, 24% were African American, 32% were employed full time, and 88% had health insurance. Overall, the sample was at high risk for CHD: 86% had current or previous high blood pressure, 85% had current or previous high blood cholesterol, 61% had diabetes, and the mean FRS was 16.9%. Also, two-thirds of participants reported they were comfortable or very comfortable using a computer.

Participants Choice of Risk Reducing Strategies, Intervention Participation, and Follow-up Rates

As noted in Figure 1, after viewing the decision aid, 366 (95%) participants elected to work on improving their diet, 256 (66%) chose to work on increasing their physical activity, 71 (18%) decided to work on smoking cessation, and 142 (37%), chose to start or increase blood pressure or cholesterol medication or start aspirin.. Follow-up rates at 4 and 12 months were 91% and 87%, respectively Those who did not return for follow-up at 4 months were more likely to be white, younger, walk fewer minutes each week and at 12 months, consume less fruit and vegetables and be less adherent to medications ($p < 0.05$ for comparisons).

Study Outcomes

Change in study outcomes from baseline to follow-up, by treatment arm, are shown in Table 2. For the FRS, there was a statistically significant and sustained reduction at both 4 (primary outcome) and 12 month follow-up for participants in both study groups. For the counselor group, the change was −2.3% and −1.9% at 4 and 12 months, respectively. For the web group, it was −1.5% and −1.7%, respectively. When values of no change and multiple imputations methods were used to impute missing FRS scores, results did not change appreciably.

In both groups, all components of the FRS changed in the direction of decreased risk and the majority of changes were statistically significant and maintained from 4 to 12 month follow-up. Likewise, most changes in diet and physical activity were in the direction of decreased risk and sustained over time. Moreover, there were substantial increases in appropriate use of and adherence with medication to reduce CHD risk. Other statistically significant outcomes of note include slight weight loss at 12 months, a reduction in A1c in the counselor group, and a sustained improvement in the physical component measure of quality of life in both groups.

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Self-reported results for tobacco cessation and aspirin use at follow-up were confirmed by biomarkers. Of 23 smokers who reported cessation, 18 (78%) were confirmed by urine cotinine testing and of 425 participants who reported aspirin use, 319 (75%) had serum thromboxane levels consistent with aspirin use.

The difference in study outcomes between treatment arms are shown in Table 3. At 4 month follow-up, the adjusted change (SE) in FRS was −2.4% (0.3) for counselor and −1.4% (0.3) for web, difference −1.0% (95% CI −1.8% to −0.1%, p = 0.03). At 12 month follow-up, the adjusted change (SE) in FRS −2.1% (0.4) for counselor and −1.5% (0.4) for web, difference −0.6% (95% CI, −1.7% to 0.5%, p = 0.30). When change in FRS was assessed by longitudinal analysis, there was no significant time by group interaction (p = 0.27) and within and between group comparisons were similar to analyses at each time point.

Sub-group analysis

Figure 2 shows the change in FRS at 4 and 12 month follow-up stratified on selected baseline variables. Assessing change in FRS by subgroups, without regard to treatment arm, the intervention was significantly more effective at 4 and 12 months among younger participants (*P* = .05 and <.001). In addition, at 4 month follow-up, the intervention was more effective among males (*P* = .04), those without diabetes (*P* = .02), and those choosing lifestyle and medication (*P* = .01). We noted little difference in the effectiveness of the counselor-delivered vs. web-based interventions when change in FRS was assessed by treatment arm and subgroups. At 4 month follow-up, there were a larger improvement in FRS among participants with diabetes in the counselor group (*P* for interaction = 0.03).

Adverse Outcomes

There were no reported adverse side effects related to dietary change or increased physical activity. Deaths due to CHD and newly diagnosed CHD are noted in Figure 1. There were no other deaths during follow-up. In addition, there was no material change in ALT or creatinine from baseline to follow-up.

Acceptability

Both counselor and web formats were well received. At 4 month follow-up, among 177 counselor participants completing the acceptability survey, 137 (77%) strongly agreed and 36 (20%) agreed that they would recommend this program to others. Similarly, among 173 web participants, 128 (74%) strongly agreed and 42 24%) agreed with this statement. At 12 month follow-up, among 170 counselor and 166 web participants completing the survey, 166 (98%) counselor and 161 (97%) web participants would recommend or strongly recommend this program to others.

Cost Effectiveness

At 12 months, the costs per participant from the payer perspective were $207 (SE 3.4) and $110 (SE: 3.5) for the Counselor and Web interventions respectively (p<0.001). From the payer perspective, the incremental cost-effectiveness ratio for the less expensive Web intervention, compared to no intervention, was $73 per percentage point reduction in CHD

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risk and $2,973 per QALY gained, which is considered very cost-effective based on common benchmarks[35]. Additional results are reported in the Appendix.

Sensitivity Analysis

A limited sensitivity analysis was conducted (Table 4) to assess change in 10-year risk for CHD as calculated with the Adult Treatment Panel (ATP) III risk calculator[36] (which calculates MI and CHD death) and the Framingham risk calculator used for this study[25] without including a term for aspirin. Overall, results were similar, with significant reductions in estimated CHD risk in both groups at 4 and 12 month follow-up.

Discussion

In this comparative effectiveness trial, a combined lifestyle and medication intervention lowered predicted 10-year CHD risk within each treatment arm (pre-post change) at 4 and 12 months. This risk reduction was achieved by improvements in lifestyle, medication use, or both and mediated through improvements in blood pressure, blood lipids, cigarette smoking, and aspirin use. The intervention was highly acceptable to participants, and the web format was cost effective based on established benchmarks.

These findings reinforce increasing evidence suggesting web-based interventions can have an important role in clinical practice.[14,37,38] In this study, the web-based intervention was equally effective to the counselor-delivered intervention at 12 month follow-up. This suggests web interventions could be used to fill important gaps in counselor availability and, where counselors are available, allow counselors to focus their efforts on harder to change behaviors, such as refractory lifestyle behaviors.[37] Web interventions might also be used to reach populations who have limited access to the clinic.

This study has several limitations. It was designed as a comparative effectiveness trial, without a no-intervention control group. Thus, observed changes could be due in part to regression to the mean (though baseline screening included two sequential assessments of FRS), secular trends, or other factors. Though non-intervention factors may account for some of the observed change, we believe much of the change was due to intervention effects as the components of the current intervention have previously been compared to no-intervention control groups and have been shown to be effective.[17] In a previous trial of a similar web-delivered medication intervention,[24] the additional reduction in FRS between intervention and control groups at 3 month follow-up was 1.1 percentage points overall and 1.4 percentage points among a pre-specified subgroup of participants with a 10-year predicted risk >10%. In a previous trial of a similar counselor-delivered dietary intervention,[39] there was a substantial increase in fruit and vegetable intake, confirmed by blood carotenoids.

Additional limitations include many secondary outcomes that were self-reported behaviors, which may be exaggerated due to social desirability reporting bias, though we did measure biomarker change for fruit and vegetable intake, aspirin use, and smoking cessation. Also, we present many comparisons in our secondary analysis, and some p-values may be significant by chance. Our follow-up interval was 12 months, and the intervention effects

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may attenuate over time. Further, our achieved sample size was somewhat less than our goal, decreasing power to detect between group differences. The generalizability of our findings may be limited to established, older patients who are at high risk for CHD. Finally, as lifestyle change may have beneficial effects on CHD risk independent of traditional risk factors,[1,40] calculated change in FRS may underestimate intervention benefit.

In conclusion, the combined lifestyle and medication intervention tested in alternative formats yielded a substantial and sustained reduction in predicted 10-year CHD risk. Risk reduction was similar in both intervention formats at 12 month follow-up, though the web was less expensive to implement. Future research should assess the implementation and maintenance of high-quality evidence-based interventions in a broad selection of clinical settings. In addition, the lifestyle component of the interventions could be used, and should be studied, in non-clinical health promotion settings.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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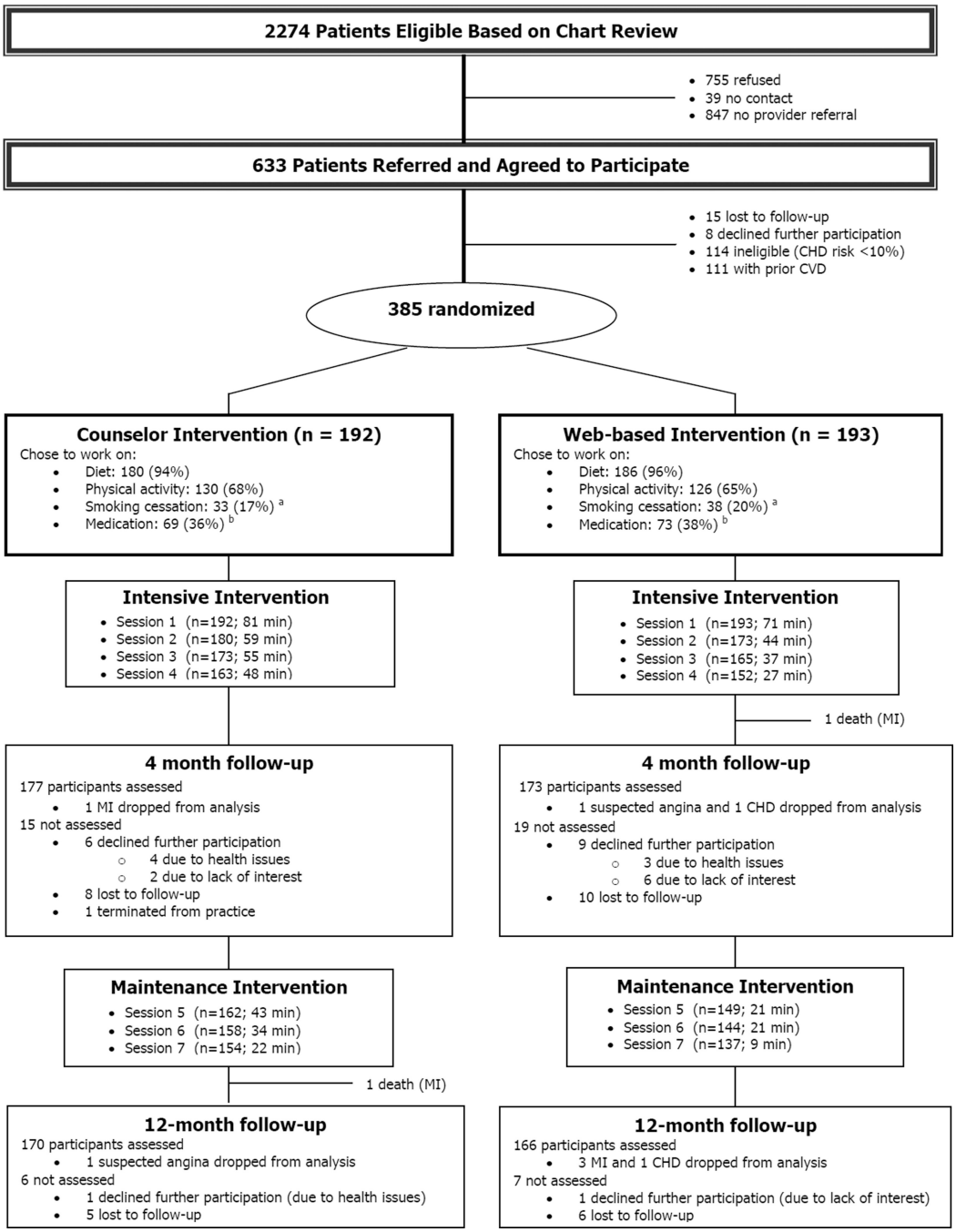

Figure 1. Study flow diagram

[a]Number of smokers at baseline: 55 (counselor intervention) and 58 (web-based intervention)

[b]Includes intent to start or increase blood pressure or cholesterol medication or start aspirin

Abbreviations: MI, myocardial infarction; CHD, coronary heart disease.

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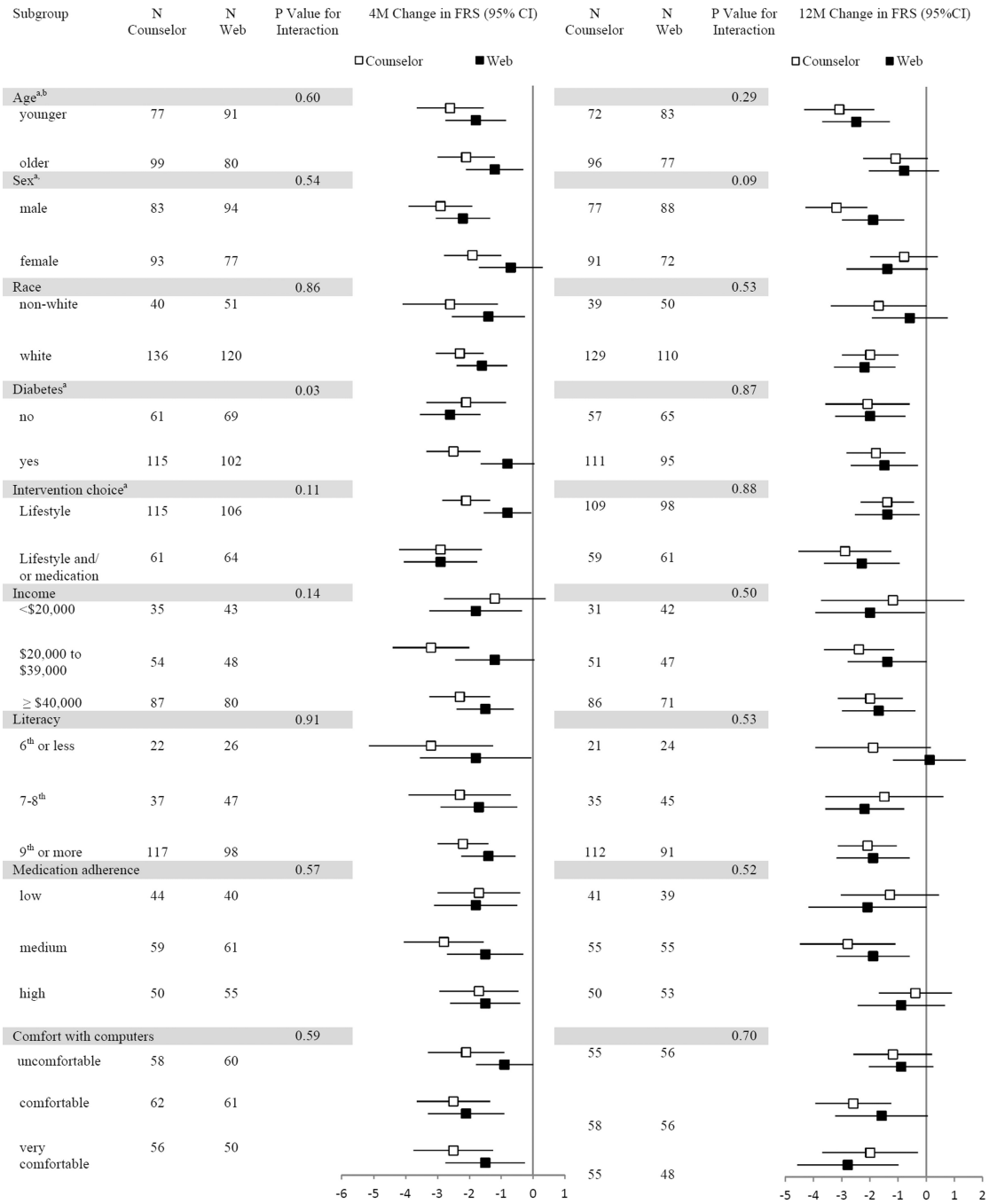

Figure 2. Change in Framingham Risk Score, stratified on selected baseline variables, shown by treatment arm at 4 and 12 month follow-up

[a]At 4 month follow-up, *P*-value ≤ .05 for comparison of FRS between sub-groups with web and counselor groups combined; [b]at 12 month follow-up, *P*-value ≤ .05 for same comparison.

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Table 1

Baseline Participant Characteristics

Characteristic	Total Sample (n=385)	Counselor Group (n =192)	Web Group (n =193)	*P*-value
Demographics				
Age, mean (SE)	62 (0.4)	63 (0.5)	62 (0.6)	0.09
Female sex, No. (%)	186 (48)	102 (53)	84 (43)	0.06
Race, No. (%)				0.49
African American	92 (24)	43 (22)	49 (25)	
White	292 (76)	150 (78)	142 (74)	
Total household income, No. (%)				0.68
< $20,000	87 (23)	39 (20)	48 (25)	
$20–39,999	112 (29)	61 (32)	51 (26)	
$40–69,999	70 (18)	33 (17)	37 (19)	
$70–99,999	37 (10)	19 (10)	18 (9)	
$100,000 or more	28 (7)	12 (6)	16 (8)	
Currently employed full time, No. (%)	125 (32)	63 (33)	62 (32)	0.88
Health insurance, No. (%)[a]				0.24
Commercial	248 (64)	125 (65)	123 (64)	
Medicare	62 (16)	35 (18)	27 (14)	
Medicaid	29 (7)	15 (8)	14 (7)	
No insurance	46 (12)	17 (9)	29 (15)	
Education, No. (%)				0.68
Less than high school	68 (18)	37 (19)	31 (16)	
High school	144 (37)	69 (36)	75 (39)	
College graduate or advanced degree	173 (45)	86 (45)	87 (45)	
Less than 7–8th grade reading level, No. (%)	53 (14)	23 (12)	30 (15)	0.31
Risk factors for CHD, No. (%)				
High blood pressure	332 (86)	166 (86)	166 (86)	0.90
High blood cholesterol	326 (85)	162 (84)	164 (85)	0.87
Current smoker	113 (29)	55 (29)	58 (30)	0.76
Diabetes	236 (61)	124 (65)	112 (58)	0.19
Medication use relevant to CHD risk reduction, No. (%)				
Taking blood pressure medicine	289 (75)	144 (75)	145 (75)	0.85
Taking cholesterol medicine	236 (61)	119 (62)	117 (61)	0.78
Taking aspirin (limited to males)	84 (42)	38 (42)	46 (42)	0.99
Factors affecting medication and lifestyle adherence, No. (%)				
Prescription drug plan	335 (87)	173 (90)	162 (84)	0.07
Number of medications per day				0.27

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Characteristic	Total Sample (n=385)	Counselor Group (n =192)	Web Group (n =193)	*P*-value
None	10 (3)	6 (3)	4 (2)	
1–2	42 (11)	18 (9)	24 (12)	
3–5	144 (37)	69 (35)	75 (39)	
6–9	130 (34)	74 (38)	56 (29)	
10 or more	60 (16)	26 (13)	34 (18)	
Living with spouse or someone like spouse	263 (68)	124 (65)	139 (72)	0.12
Comfort with computer	255 (66)	128 (67)	127 (66)	0.86
Other outcomes, mean (SE)				
Framingham Risk Score[b]	16.9 (0.3)	16.9 (0.4)	16.9 (0.4)	0.60
Weight in kg	96 (1.1)	95 (1.6)	97 (1.5)	0.26
BMI, kg/m^2	33 (0.4)	33 (0.5)	34 (0.5)	0.71
Systolic blood pressure	134 (0.9)	134 (1.2)	134 (1.3)	0.68
Diastolic blood pressure	79 (0.6)	78 (0.7)	80 (0.9)	0.10
Total cholesterol	194 (2.4)	197 (3.4)	190 (3.3)	0.14
HDL-C	41 (0.5)	42 (0.8)	39 (0.7)	0.03
LDL-C	122 (2.0)	125 (2.9)	119 (2.8)	0.26
Hgb A1c	6.9 (0.1)	7.0 (0.1)	6.8 (0.1)	0.07
hsCRP	4.7 (0.5)	4.9 (0.6)	4.6 (0.8)	0.29
Fruit and vegetables servings/day	4.1 (0.1)	4.1 (0.1)	4.1 (0.1)	0.56
Minutes of walking per week	77 (8.3)	74 (11.3)	79 (12.0)	0.63
Steps per day (pedometer, n = 253)	4691 (168.4)	4604 (225.6)	4776 (250.0)	0.71
Morisky medication adherence scale, No. (%)			0.75	
Low adherence	94 (27)	49 (29)	45 (26)	
Medium adherence	136 (39)	65 (39)	71 (40)	
High adherence	114 (33)	54 (32)	60 (34)	

[a]Categorized as commercial if participant had commercial and other insurance

[b]Framingham risk scores calculated as percent chance of developing angina, myocardial infarction, or coronary heart disease death over a 10 year time frame

Abbreviations: CHD, coronary heart disease; BMI, body mass index; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; Hgb A1c, hemoglobin A1c; hsCRP, high sensitivity C-reactive protein.

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Table 2

Study outcomes: change from baseline by study group at 4 and 12 month follow-up. Data are for returnees, except as noted.

	4 months					12 months				
Outcome	**n**	**Baseline**	**4 months**	**Change (4 months minus baseline, 95% CI)**	***P*-value**	**n**	**Baseline**	**12 months**	**Change (12 months minus baseline, 95% CI)**	***P*-value**
Framingham Risk Score[a]: primary study outcome is change in risk score at 4 month follow-up -- mean (SE)										
Counselor	176	17.0 (0.5)	14.7 (0.4)	−2.3 (–3.0 to −1.6)	<.001	168	17.1 (0.5)	15.1 (0.5)	−1.9 (−2.8 to −1.1)	<.001
Web	171	16.8 (0.4)	15.2 (0.5)	−1.5 (−2.2 to −0.9)	<.001	160	16.7 (0.4)	15.0 (0.5)	−1.7 (−2.6 to −0.8)	<.001
Framingham Risk Score: no change from baseline imputed for those lost to follow-up - - mean (SE)										
Counselor	191	17.0 (0.4)	14.8 (0.4)	−2.1 (−2.7 to −1.5)	<.001	189	16.9 (0.4)	15.2 (0.5)	−1.7 (−2.5 to −1.0)	<.001
Web	190	16.9 (0.4)	15.6 (0.4)	−1.4 (−1.9 to −0.8)	<.001	186	16.8 (0.4)	15.4 (0.4)	−1.5 (−2.2 to −0.7)	<.001
Components of the Framingham Risk Score Assessed at Follow-up										
Systolic blood pressure -- mean (SE)										
Counselor	176	134 (1.2)	131 (1.2)	−3.0 (−5.5 to −0.5)	.02	169	134 (1.3)	131 (1.4)	−3.2 (−6.0 to −0.4)	.02
Web	170	134 (1.4)	133 (1.3)	−1.2 (−4.0 to 1.6)	.39	164	134 (1.4)	133 (1.5)	−0.9 (−3.9 to 2.0)	.53
Total cholesterol, mg/dL, -- mean (SE)										
Counselor	177	196 (3.5)	188 (3.5)	−8.4 (−13.3 to −3.5)	<.001	170	196 (3.6)	188 (3.6)	−7.6 (−12.6 to −2.6)	.003
Web	173	191 (3.6)	187 (2.9)	−4.1 (−9.4 to 1.3)	.13	166	190 (3.6)	187 (3.2)	−3.6 (−10.1 to 3.0)	.28
HDL-C, mg/dL -- mean (SE)										
Counselor	177	41 (0.8)	43 (0.8)	1.4 (0.4 to 2.3)	.004	170	41 (0.8)	42 (0.8)	0.4 (−0.6 to 1.5)	.42
Web	173	40 (0.8)	42 (0.8)	1.8 (0.7 to 2.8)	.001	166	40 (0.8)	42 (0.9)	2.2 (1.0 to 3.3)	<.001
Smoking -- no. (%)										
Counselor	177	48 (27%)	39 (22%)	−5% (−9% to −1%)	.01	170	45 (26%)	33(19%)	−7% (−11% to −3%)	.001
Web	173	50 (29%)	43(25%)	−4% (−8% to −.3%)	..03	166	48 (29%)	39 (23%)	−5% (−10% to −1%)	.01
Dietary intake										
Fat quality screener score[b] -- mean (SE)										
Counselor	177	4.8 (0.2)	4.1 (0.1)	−0.8 (−1.1 to −0.4)	<.001	170	4.9 (0.2)	4.3 (0.1)	−0.6 (−1.0 to −0.2)	.001
Web	173	5.1 (0.2)	4.2 (0.1)	−0.9 (−1.3 to −0.6)	<.001	166	5.1 (0.2)	4.3 (0.1)	−0.8 (−1.1 to −0.4)	<.001
Fruit and vegetable servings per day -- mean (SE)										

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	4 months					12 months				
Outcome	**n**	**Baseline**	**4 months**	**Change (4 months minus baseline, 95% CI)**	***P*-value**	**n**	**Baseline**	**12 months**	**Change (12 months minus baseline, 95% CI)**	***P*-value**
Counselor	177	4.2 (0.1)	4.5 (0.1)	0.3 (0.1 to 0.6)	.001	170	4.2 (0.1)	4.5 (0.1)	0.3 (0.1 to 0.5)	.01
Web	173	4.0 (0.1)	4.2 (0.1)	0.2 (0.0 to 0.5)	.04	166	4.1 (0.1)	4.3 (0.1)	0.3 (0.0 to 0.5)	.02
Carotenoid index, mcg/dL[c] -- mean (SE)										
Counselor	152	35.4 (1.9)	35.6 (1.7)	0.2 (−2.2 to 2.7)	.41	140	34.8 (1.9)	36.8 (1.9)	2.0 (−0.6 to 4.7)	.07
Web	147	34.6 (1.7)	34.4 (1.6)	−0.2 (−2.3 to 1.9)	.74	142	34.4 (1.7)	34.6 (1.7)	0.2 (−2.1 to 2.4)	.99
Physical activity										
Questionnaire—total walk time -- mean (SE)										
Counselor	177	77 (12)	132 (19)	55 (14 to 96)	.009	170	78 (12)	95 (9)	17 (−10 to 45)	.22
Web	173	83 (13)	113(13)	30 (0 to 61)	.06	166	84 (13)	143 (24)	59 (8 to 110)	.02
Pedometer, total steps assessed during prior week -- mean (SE)										
Counselor	59	4767 (292)	5657 (390)	889 (274 to 1505)	.005	62	4619 (317)	5254 (364)	635 (135 to 1135)	.01
Web	62	4783 (344)	5317 (339)	533 (92 to 974)	.02	58	4996 (350)	5176 (365)	180 (−358 to 719)	.50
Medication use										
Morisky questionnaire for medication adherence—high adherence -- no. (%)										
Counselor	152	49 (32%)	69 (45%)	13% (4% to 22%)	.006	145	49 (34%)	80 (55%)	21% (11% to 32%)	<.001
Web	153	57(37%)	86 (56%)	19% (10% to 28%)	<.001	147	55 (37%)	82 (56%)	18% (8% to 28%)	<.001
Taking blood pressure medication- - no. (%)										
Counselor	177	133 (75%)	141 (80%)	5% (0.1% to 9%)	.05	170	127 (75%)	141 (83%)	8% (4% to 13%)	<.001
Web	173	132 (76%)	134 (77%)	1% (−2% to 4%)	.48	166	127 (77%)	131 (79%)	2% (−2% to 6%)	.25
Taking cholesterol medication -- no. (%)										
Counselor	177	110(62%)	119 (67%)	5% (−0.4% to 1%)	.07	170	106 (62%)	113 (66%)	4% (−2% to 10%)	.19
Web	173	105 (61%)	104 (60%)	−0.6% (−6% to 5%)	.84	166	101 (61%)	98 (59%)	−2% (−8% to 5%)	.59
Taking aspirin -- no. (%)										
Counselor	177	76(43%)	104 (59%)	16% (10% to 22%)	<.001	170	72 (42%)	104 (61%)	19% (12% to 26%)	<.001
Web	173	84 (48%)	111 (64%)	16% (9% to 22%)	<.001	166	80 (48%)	105 (63%)	15% (7% to 23%)	<.001
Other outcomes										
Diastolic blood pressure -- mean (SE)										

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	4 months					12 months				
Outcome	**n**	**Baseline**	**4 months**	**Change (4 months minus baseline, 95% CI)**	***P*-value**	**n**	**Baseline**	**12 months**	**Change (12 months minus baseline, 95% CI)**	***P*-value**
Counselor	176	80 (0.7)	77 (0.8)	−1.4 (−2.8 to 0.0)	.06	169	78 (0.8)	77 (0.8)	−1.0 (−2.5 to 0.4)	.17
Web	170	80 (1.0)	79 (0.9)	−0.8 (−2.4 to 0.8)	.34	164	80 (1.0)	79 (1.0)	−0.2 (−1.8 to 1.4)	.81
LDL-C, mg/dL, -- mean (SE)										
Counselor	177	124 (3.0)	120 (3.2)	−4.5 (−9.1 to 0.1)	.05	170	124 (3.1)	119 (3.1)	−4.9 (−9.7 to −0.1)	.04
Web	173	120 (3.0)	118 (2.6)	−1.2 (−5.5 to 3.0)	.57	166	119 (3.0)	117 (2.9)	−2.0 (−7.0 to 3.0)	.43
Weight in kg -- mean (SE)										
Counselor	177	95 (1.7)	95 (1.7)	−0.5 (−1.0 to 0.0)	.04	170	95 (1.7)	94 (1.7)	−1.0 (−1.7 to −0.2)	.01
Web	173	97 (1.6)	96 (1.5)	−1.1 (−1.6 to −0.5)	<.001	166	97 (1.6)	95 (1.6)	−1.5 (−2.3 to −0.8)	<.001
HgbA1c (overall) -- mean (SE)										
Counselor	176	7.0 (0.1)	6.8 (0.1)	−0.3 (−0.4 to −0.1)	.002	170	7.0 (0.1)	6.9 (0.1)	−0.2 (−0.4 to 0.0)	.03
Web	173	6.8 (0.1)	6.7 (0.1)	0.0 (−0.1 to 0.1)	.41	166	6.7 (0.1)	6.8 (0.1)	0.1 (0.0 to 0.2)	.28
HgbA1c for those with diabetes -- mean (SE)										
Counselor	111	7.6 (0.1)	7.3 (0.1)	−0.3 (−0.6 to −0.1)	.01	107	7.6 (0.1)	7.4 (0.1)	−0.2 (−0.5 to 0.0)	.10
Web	98	7.4 (0.1)	7.3 (0.1)	−0.1(−0.3 to 0.1)	.31	96	7.4 (0.1)	7.5 (0.1)	0.1 (−0.1 to 0.3)	.46
hsCRP -- mean (SE)										
Counselor	177	4.7 (0.6)	3.6 (0.3)	−1.1 (−2.1 to −0.1)	.03	170	4.5 (0.6)	5.0 (0.9)	0.5 (−1.1 to 2.1)	.52
Web	173	4.7 (0.9)	3.8 (0.4)	−0.9 (−2.5 to 0.6)	.25	166	4.8 (0.9)	4.2 (0.5)	−0.5 (−2.3 to 1.3)	.57
QOL, SF-12 Mental composite-- mean (SE)										
Counselor	177	52 (0.4)	53 (0.4)	0.5 (−0.5 to 1.5)	.32	170	52 (0.4)	53 (0.4)	0.3 (−0.7 to 1.3)	.60
Web	173	53 (0.5)	52 (0.4)	−0.3 (−1.2 to 0.7)	.61	166	53 (0.5)	53 (0.4)	0.1 (−0.9 to 1.2)	.83
QOL, SF-12 Physical composite -- mean (SE)										
Counselor	177	43 (0.9)	45 (0.9)	2.4 (1.0 to 3.7)	<.001	170	43 (0.9)	45 (0.9)	2.2 (0.7 to 3.6)	.003
Web	173	42 (0.9)	44 (0.9)	1.6 (0.3 to 3.0)	.02	166	42 (0.9)	45 (0.9)	2.2 (0.6 to 3.8)	.01

[a] Framingham risk scores calculated as percent chance of developing angina, myocardial infarction, or coronary heart disease death over a 10 year time frame for those who did not developed cardiovascular disease from baseline to follow-up.

[b] A lower score indicates improved fat quality.

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[c]Carotenoid index, calculated as the sum of α-carotene, β-carotene, β-cryptoxanthin, and zeaxanthin. Data presented are for nonsmokers. A higher index indicates greater fruit and vegetable consumption. Statistical tests performed on log transformed data.

Abbreviations: HCL-C, high density lipoprotein cholesterol; RESIDE, RESIDential Environment Project; LDL-C, low density lipoprotein Cholesterol; HgbA1c, hemoglobin A1c; hsCRP, high sensitivity C-reactive protein; QOL, quality of life.

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Table 3

Comparison of outcomes between study group at 4 and 12 months.[a] Data are for returnees.

Outcome	4 months				12 months			
Continuous variables: Crude and adjusted[b] difference in change of outcome between study groups (change for counselor minus change for web)[c]								
	Crude		Adjusted		Crude		Adjusted	
	Mean (95% CI)	*p*	Mean (95% CI)	*p*	mean (95% CI)	*p*	mean (95% CI)	*p*
Framingham Risk Score[d]	−0.8 (−1.7 to 0.1)	0.09	−1.0 (−1.8 to −0.1)	0.03	−0.2 (−1.4 to 1.0)	0.72	−0.6 (−1.7 to 0.5)	0.30
Components of the Framingham Risk Score								
Systolic blood pressure, mmHg	−1.8 (−5.5 to 1.9)	0.35	−1.5 (−4.5 to 1.5)	0.33	−2.3 (−6.3 to 1.7)	0.26	−2.6 (−6.1 to 0.9)	0.14
Total cholesterol, mg/dL,	−4.3 (−11.5 to 2.9)	0.24	−2.9 (−9.2 to 3.3)	0.36	−4.1 (−12.2 to 4.1)	0.33	−2.4 (−9.8 to 5.1)	0.53
HDL-C, mg/dL	−0.4 (−1.8 to 0.9)	0.54	−0.4 (−1.7 – 1.0)	0.58	−1.7 (−3.3 to −0.2)	0.03	−1.5 (−3.0 to −0.0)	0.05
Dietary Intake								
Fat Quality Screener Score[e]	0.2 (−0.3 to 0.7)	0.46	0.03 (−0.3 to 0.4)	0.87	0.2 (−0.3 to 0.7)	0.51	0.02 (−0.4 to 0.3)	0.93
Fruit and Vegetable servings/d	0.1 (−0.2 to 0.4)	0.46	0.3 (0.0 to 0.5)	0.05	0.02 (−0.3 to 0.3)	0.91	0.1 (−0.1 to 0.4)	0.31
Carotenoid Index[f]	0.4 (−2.9 to 3.7)	0.43	0.2 (−2.6 to 3.1)	0.47	1.9 (−1.6 to 5.4)	0.20	2.3 (−0.9 to 5.6)	0.12
Physical Activity								
RESIDE questionnaire—total walk time (minutes per week)	25.1 (−25.9 to 76.1)	0.33	31.4 (−10.4 to 73.3)	0.14	−41.7 (−99.1 to 15.6)	0.15	−39.6 (−85.6 to 6.5)	0.09
Pedometer, steps per day in prior week	356 (−386 to 1099)	0.34	339 (−376 to 1054)	0.35	455 (−266 to 1176)	0.21	592 (−100 to 1284)	0.09
Other Outcomes								
Diastolic blood pressure, mmHg	−0.6 (−2.7 to 1.5)	0.59	−1.4 (−3. to 0.5)	0.14	−0.8 (−3.0 to 1.3)	0.44	−1.6 (−3.4 to 0.3)	0.10
LDL-C, mg/dL,	−3.3 (−9.5 to 2.9)	0.30	−2.1 (−7.6 to 3.4)	0.46	−2.9 (−9.8 to 4.0)	0.40	−1.0 (−7.4 to 5.3)	0.75
Weight in kg	0.5 (−0.2 to 1.3)	0.13	0.6 (−0.1 to 1.3)	0.10	0.6 (−0.4 to 1.6)	0.27	0.8 (−0.2 to 1.8)	0.13
HgbA1c (all participants)	−0.2 (−0.4 to −0.02)	0.03	−0.1 (−0.3 to 0.04)	0.14	−0.2 (−0.4 to −0.04)	0.02	−0.2 (−0.3 to 0.00)	0.05
HgbA1c (those with diabetes)	−0.2 (−0.5 to 0.1)	0.12	−0.1 (−0.3 to 0.2)	0.48	−0.3 (−0.6 to 0.03)	0.07	−0.2 (−0.4 to 0.1)	0.20
hsCRP	−0.2 (−2.1 to 1.6)	0.82	−0.1 (−1.0 to 0.7)	0.73	1.0 (−1.4 to 3.4)	0.40	0.9 (−0.9 to 2.7)	0.33
QOL, SF−12 Mental composite	0.8 (−0.6 to 2.1)	0.28	0.3 (−0.9 to 1.4)	0.62	0.1 (−1.3 to 1.6)	0.84	−0.5 (−1.5 to 0.6)	0.38
QOL, SF−12 Physical composite	0.7 (−1.1 to 2.6)	0.44	1.1 (−0.6 to 2.8)	0.20	0.0 (−2.2 to 2.1)	0.97	0.8 (−1.2 to 2.7)	0.44
Categorical variables--medication use: Crude difference in percentage at 4 and 12 month follow-up (percentage for counselor minus percentage for web)								
	mean (95% CI)			*P*	mean (95% CI)			*P*

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Outcome	4 months		12 months	
smoking	−1% (−6% to 4%)	0.69	−2% (−8% to 4%)	0.59
Taking aspirin	0% (−9% to 10%)	0.95	4% (−7% to 14%)	0..48
Morisky questionnaire for medication adherence—high adherence	−6% (−18% to 7%)	0.36	3% (−11% to 17%)	0.68
Taking blood pressure medication	3% (−2% to 9%)	0.22	6% (−.2% to 12%)	0.06
Taking cholesterol medication	6% (−2% to 14%)	0.16	6% (−3% to 15%)	0.20

[a] See Table 2 for the number of participants with followed data used to calculate the difference scores in this table.

[b] Adjusted for baseline value of variable, age, sex, race (white vs. other), BMI, prescription drug plan, HDL-C, HgA1c, and study site

[c] A negative difference score indicates the value of the outcome is lower in the counselor group.

[d] Framingham risk scores calculated as percent chance of developing angina, myocardial infarction, or coronary heart disease death over a 10 year time frame for those who did not developed cardiovascular disease from baseline to follow-up.

[e] A lower score indicates improved fat quality.

[f] Carotenoid index, calculated as the sum of α-carotene, β-carotene, β-cryptoxanthin, and zeaxanthin. Data presented are for non-smokers. A higher index indicates greater fruit and vegetable consumption. Statistical tests performed on log transformed data.

Abbreviations: HCL-C, high density lipoprotein cholesterol; RESIDE, RESIDential Environment Project; LDL-C, low density lipoprotein Cholesterol; HgbA1c, hemoglobin A1c; hsCRP, high sensitivity C-reactive protein; QOL, quality of life.

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Table 4

Sensitivity Analysis: Change in 10-Year Risk for Coronary Heart Disease as assessed by Adult Treatment Panel (ATP) III and Framingham Risk Equations without Term for Aspirin.

Risk Calculator	Study Group	N	Baseline Mean (SE)	Follow-up Mean (SE)	Change in Mean (95% CI)	*P*-value
4 Month Outcomes						
ATPIII	Counselor	176	10.6 (0.5)	9.7 (0.5)	−0.9 (−1.4 to −0.4)	<.001
	Web	171	10.9 (0.5)	10.1 (0.5)	−0.7 (−1.2 to −0.3)	.002
FRS	Counselor	176	18.0 (0.5)	16.0 (0.5)	−1.9 (−2.6 to −1.3)	<.0001
	Web	171	17.9 (0.5)	16.8 (0.5)	−1.1 (−1.7 to −0.4)	.001
12 Month Outcomes						
ATPIII	Counselor	168	10.5 (0.5)	9.9 (0.5)	−0.6 (−1.2 --to 0.0)	.04
	Web	160	11.0 (0.6)	10.2 (0.6)	−0.8 (−1.4 to −0.1)	.02
FRS	Counselor	168	17.9 (0.5)	16.3 (0.5)	−1.7 (−2.5 to −0.9)	<.001
	Web	160	17.9 (05)	16.6 (0.5)	−1.3 (−2.2 to −0.4)	.006