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A randomized feasibility trial of brief telephone counseling to increase fruit and vegetable intakes

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Abstract

Objective—This study examined the feasibility of eliciting dietary changes in subjects recruited from a diverse primary care setting in Michigan using a written, one-page plan, either alone or with telephone counseling.

Methods—A total of 96 subjects were enrolled from 9/28/06 to 5/7/07 (49% minorities). Subjects were randomized into three groups. Group 1 received written materials. Group 2 received written materials plus a one-page form that asked them to make a specific daily plan for substituting one less nutritious food with two servings of fruits and vegetables. Group 3 received the written materials, the one-page form and telephone counseling from a dietitian.

Results—Subject retention was 76% for the 12-week study. Subjects in Groups 1, 2 and 3 changed their mean intakes of fruit and vegetables by 0.4, −0.7 and 1.4 servings/day, respectively. Participants in Group 3 lost an average of 0.73 kg, increased their perception of the importance of eating fruits and vegetables, and 63% increased their serum levels of carotenoids by 20% or more.

Conclusion—Recruitment through a primary care clinic was effective. Formulation of a written plan combined with telephone counseling appears to be promising for improving fruit and vegetable intakes and warrants more definitive study.

Keywords

Diet; Prevention and control; Carotenoids; Behavior therapy

Introduction

Consuming a healthy diet is associated with lower risks for chronic disease. Four of the ten leading causes of death – coronary heart disease, some types of cancer, stroke, and type 2 diabetes – are associated with unhealthy diets (U.S. Preventive Services Task Force, 2003). Despite well-established benefits of consuming a healthy diet, more than 80% of Americans eat fewer than the recommended number of daily servings of fruit, vegetables, and grain products and more than the recommended daily calories from saturated fat and total fat (U.S. Department of Health and Human Services, 2000). Persons with specific health risks, such as those with hyperlipidemia, may have more immediate benefits from dietary counseling, but persons with average health risks should also benefit from healthy diets for maintaining health. As recommended by the U.S. Preventive Services Task Force, more studies are needed to better understand the immediate and long-term outcomes of dietary counseling in primary care

settings, and objective measures of changes in diet need to be utilized as outcome measures (U.S. Preventive Services Task Force, 2003).

Primary care for rendering preventive services, however, is currently under-utilized. One study of 38 non-metropolitan primary care offices, found that only 20–25% of primary care visits included counseling for diet and exercise (Anis et al., 2004). Counseling for adherence to preventive health behaviors often has the challenge of time availability. One very simple model of behavioral intervention that has been investigated for improving health behaviors is that of formulation of implementation intentions (Sheeran et al., 2005a,b). The basis of implementation intentions is that if a specific action plan is formulated by an individual (where, when and how) that then leads to automatic behavior (Brandstatter et al., 2001; Sheeran et al., 2005a,b). This type of simple intervention with formation of a specific, written plan therefore should be applicable to primary care settings to elicit good health behaviors with minimal staff time.

A few previously published studies have examined the utility of implementation intentions for improving diet, with mixed success (Adriaanse et al., 2009; Armitage, 2004; de Nooijer et al., 2006; Jackson et al., 2005; Luszczynska et al., 2007; Prestwich et al., 2008). For example, Armitage et al. reported that implementation intentions for reducing fat intake (formulated by subjects on 4 blank lines that followed 3 sentences of information) resulted in significantly reduced fat intake after 1 month versus control (Armitage, 2004). In a large randomized Dutch study, fruit intake increased over 1½ weeks, but not significantly so, if subjects formulated implementation intentions to eat more fruit (de Nooijer et al., 2006). This method is attractive because of its simplicity, and a modified version was used in the present study for asking subjects to make a written plan on how to replace one less healthy food with fruits and vegetables.

In this study we hypothesized that telephone counseling from a dietitian to increase self-monitoring could help individuals substitute foods to consume more fruits and vegetables (FV). In particular, the study sought to develop an intervention applicable to adults age 40 and older since health risks generally increase with age. It was also important to document the extent of minority participation in the study since many health disparities have been identified in minority populations that are potentially preventable or alleviated by diet such as cardiovascular diseases and diabetes (Adler and Rehkopf, 2008; Crook et al., 2009; Dreeben, 2001). This feasibility trial therefore recruited subjects, age 40 and older, in a family health clinic that serves a diverse community. The study goal was to determine whether or not FV intakes could be increased by formulating a written plan, either with or without telephone counseling from a dietitian, to substitute a less healthful food with FV.

Methods

Recruitment and eligibility

The study was approved by the University of Michigan Medical School Institutional Review Board and registered with ClinicalTrials.gov (NCT00468156). Subjects were recruited in a multi-physician health clinic (family medicine and pediatrics) in Ypsilanti, Michigan which is a community that has a high percentage of minority residents (31% African American in the 2000 U.S. Census). Flyers about the study were posted in the waiting room and the study was listed on the University of Michigan's clinical research website. Study recruiters approached subjects in the waiting room to determine if they would like to participate in the Fruit and Vegetable Study. If so, the recruiter gave them a brief eligibility questionnaire. Eligible persons were asked by the recruiter to review and sign the consent form, and the baseline assessments were administered. The blood sample was drawn by a research nurse. The study procedures

could be done either before or after the subject's health care visit. There was an option to complete the questionnaires by phone within a few days if needed.

The eligibility criteria were: age 40 and older, in general good health, and consuming less than 5.5 servings/day of FV. For rapid determination of eligibility, the National Cancer Institute's Fruit and Vegetable Screener was used (Greene et al., 2008). Eligible FV intakes were less than 5.5 servings/day such that there would be room for improvement. The Dietary Guidelines for Americans 2005 recommend consumption of 2 cups of fruit (4 servings) and 2.5 cups of vegetables (5 servings) for a 2000 kcal/day diet. The exclusion criteria included being on medically prescribed diets that the study would not be consistent with, evidence of eating disorders, or health problems that affect normal eating and activity patterns.

Study design

The goal of this study was to increase FV consumption by at least 2 servings/day. This was to be accomplished without a change in overall energy intakes by decreasing consumption of one less nutritious food, such as those containing added fats and sugars. Substitution of foods is a concept that is often not addressed in fruit and vegetable interventions, but it is critical for prevention of weight gain.

Subjects were randomized to one of three arms for 3 months: 1) education materials only, 2) education materials and a form for formulating a plan for dietary change (with no oral instructions), and 3) education materials, written plan, and telephone counseling using three calls. Subjects were not told of their randomization assignment until after one un-announced 24-hour dietary recall was completed by phone. Subjects were then randomized across the three groups and the appropriate materials were mailed to each subject.

This was a feasibility study which would establish an effect size on fruit and vegetable intakes. Power calculations were done, however, to guide recruitment goals using hypothesized increases in FV intakes of 0.5, 1.5 and 2 servings/day in Groups 1, 2 and 3, respectively. Power to detect these increases was calculated based on published FV intake data for 29,532 U.S. adults in the National Health Interview Survey 2000 (Thompson et al., 2005). The standard deviation (SD) for FV intake data was calculated from the published confidence intervals, pooling across gender. This resulted in 1.8 as the pooled within-group SD. One-way ANOVA was used to base sample size calculations with post-pre differences in mean servings/day of FV as the outcome. The ANOVA model had three study arms. With the given hypothesized increases in FV intakes, the resulting effect size (ratio of between and within-group variance) was 0.12. With a 5% level of significance and 80% power, 28 subjects in each arm would be required. Power would be 64% and 75% for 20 and 25 subjects/arm, respectively. The recruitment goal was therefore 105 subjects to retain 84 for 3 months.

The four-page education hand out given to all subjects contained the following information: USDA dietary recommendations and how to substitute FV for less nutritious foods on page 1 (including examples of substitutions); how fruit and vegetables can maintain health on page 2; lists of FV in color categories, with their approximate caloric values on page 3; and lists of less healthful foods that could be omitted from the diet, in categories based on their caloric content, on page 4. FV were divided into five categories to emphasize the variety of carotenoids and flavonoids that they contain using the Rainbow color scheme developed for the 5-A-Day Program (Produce for Better Health Foundation). The information on energy content of common less nutritious foods was presented to facilitate substitutions since adding 75 kcal/day from 2 servings of fruit and vegetables could result in a weight gain of 7.8 lb/year if not compensated for. These extra calories from fruits and vegetables can be accommodated by replacing or reducing snacks such as potato chips, soda pop or a cookie, or by avoiding or reducing added fats to foods such as mayonnaise, butter, gravy or salad dressing.

The formulation of a written plan was done on a two-part carbon form and given to subjects randomized to Groups 2 and 3 (Fig. 2). A brief paragraph stated that there is nutritional value in substituting high fat and sugary foods that contain few nutrients with FV. Below that, subjects were asked to answer three questions: how to go about eating less of a less nutritious food, how to eat at least one more serving of vegetables and how to eat at least one more serving of fruit each day. This is distinct from the formal formulation of implementation intentions (Sheeran et al., 2005a) in that the “where” component was not used. This was done to maintain brevity since daily schedules can differ during the week.

Subjects randomized to Group 3 also received three counseling calls from a registered dietitian and a small log book that included check boxes for monitoring consumption of fruit, vegetables and less nutritious foods. Each booklet was sufficient for tracking one month of intake, and each subject received three booklets. Calls were scheduled to be done 1 week, 1 month and 2 months after baseline. The calls consisted of reviewing the written plan, reviewing self-monitoring logs and noting any progress made toward that goal. The importance of fruit and vegetable consumption on health was reaffirmed. The calls were supportive, aimed to build self-efficacy and were based on the standard counseling approach used previously in our more intensive intervention studies (Djuric, et al., 2002; Djuric et al., 2008). Subjects who were not completely successful were encouraged to identify barriers in meeting their plans and to develop strategies to overcome those barriers. Subjects successful in meeting their goals were asked to verbalize a plan on how they will continue with their success, especially through any challenges that they foresee.

Assessments

Assessments included a brief questionnaire on health, physical activity and demographic variables at baseline and a health update questionnaire after 12 weeks. Height, weight and blood pressure also were measured at enrollment and after 12 weeks by research personnel who were blinded to study arm assignment.

Dietary assessments at the two time points were done using two different methods. This included the 19-item National Cancer Institute Fruit and Vegetable Screener which has been shown to give comparable correlations with multiple days of 24-hour recalls as a full-length food frequency questionnaire while displaying significantly less attenuation (Thompson et al., 2004). The second method was one un-announced 24-hour recall at the beginning and end of the study using the USDA five-pass method, using a dietitian who did not provide any of the counseling (Conway et al., 2004; Conway et al., 2003). The recalls were analyzed for nutrient and food group intakes using the Nutrition Data System Research Software (Software and Database version 2006). Increased FV consumption in the place of refined carbohydrates in the diet also should lower the glycemic index, and this was also analyzed from the recalls (Brand-Miller, 2003).

A brief questionnaire was administered at baseline and 12 weeks, and this asked about self-efficacy and self-confidence to eat more fruits and vegetables. Five questions asked “How convinced are you that it is important to: 1) eat two extra servings of fruits and vegetables each day, 2) avoid less nutritious foods like candy, pop and chips, 3) find a way to stick to your goals even when those around you make it difficult for you, 4) control your home environment (shopping, cooking, mealtimes, snacks and time demands) to support your goal of increasing fruits and vegetables in your diet, and 5) control your workplace environment (snacks, lunch and breaks) to support your diet goals”. Five additional questions asked about the confidence to carry out these behaviors by rephrasing the questions by starting with “How confident are you that you can...”. Responses were captured using a 5-point Likert-type scale. Self-efficacy and self-confidence were scored by summing the responses for the 5 questions in each domain.

Blood samples were obtained at study enrollment and study end in the non-fasting state. Serum was prepared after drawing the blood and aliquots were frozen at -80°C . Carotenoids were measured in the serum as markers of fruit and vegetable intakes using our previously published methods (Campbell et al., 1994; Djuric et al., 2006). Briefly, carotenoids were extracted with hexane and analyzed by HPLC using electrochemical detection. Assays for cholesterol, HDL, and triglycerides were done by the Michigan Diabetes Research and Training Center Core Chemistry Laboratory using a Cobas Mira Chemistry analyzer (Roche Diagnostics Corporation, Indianapolis, IN). LDL was calculated from the Friedewald equation (Friedewald et al., 1972). All laboratory staff were blinded to diet arm assignment.

Statistical analyses

The baseline characteristics between the three groups were compared using the ANOVA or chi-square for continuous or categorical variables, respectively. Completion rate of the form for a written plan provided to Group 2 and Group 3 was compared using Fisher's exact test. For dietary intakes, self-efficacy scales, and total serum carotenoids, the analysis framework was that of a linear mixed model regression. Group, gender, and baseline BMI were used as between-subject predictors in all models because of the influence of both gender and BMI on dietary intakes. A variable 'time' with two categories (baseline and end of study) was used as a within-subject factor. In addition, a time-group interaction was used to assess if the change over time was similar or different across groups. An unstructured variance-covariance matrix was used to account for the clustering within the same subject. An indicator for current smoking status at baseline was an additional independent variable in the model for total serum carotenoids due to the strong negative impact of smoking on carotenoids (Andersen et al., 2006).

Each regression model was checked for meeting model assumptions through appropriate residual plots. Box-Cox transformation was carried out to identify the transformed outcome that satisfied the model assumptions most closely. A similar mixed model analysis was carried out to assess weight change or changes in lipid profiles over the study period. Chi-square analysis was carried out to investigate group differences in percentages of subjects who increased their total serum carotenoids by at least 20%. A logistic regression analysis of the dichotomous outcome (increased/not increased total carotenoids by at least 20%) was also carried out with group as the primary independent variable and controlling for gender, BMI and smoking status at baseline. The majority of the analyses were performed in the statistical software SPSS version 16 (SPSS Inc., Chicago, IL). Box-Cox transformation was carried out in SAS (SAS 9.2, Cary, NC).

Results

Recruitment and retention

Recruitment occurred from 9/28/06 to 5/7/07. The major source of recruitment was direct solicitation by study staff of adults in the clinic waiting room about 2 days/week on busy clinic days. There were 439 persons approached or called about the study, and 96 were both eligible and enrolled in the study (Fig. 1). Using recruiter-based assessment of race for subjects approached in the clinic, the recruitment success rate was the same among Caucasians and African Americans (21%). This indicates that personal invitation to join the study was an equally effective recruitment strategy in both races. Women were slightly more likely to volunteer for the study when approached than men (25% versus 16%, respectively, $p = 0.08$ by Fisher's exact test).

The only statistically significant demographic difference between the three groups at baseline was observed with respect to body mass index (BMI). The mean BMI of the participants in

Group 3 was significantly higher than in either Group 1 ($p = 0.002$), or Group 2 ($p = 0.018$). The proportion of obese subjects ($\text{BMI} \geq 30$) was likewise significantly higher in Group 3 compared to either Group 1 ($p = 0.01$) or Group 2 ($p = 0.04$).

A total of 73 subjects (76%) were retained for 12 weeks of study and completed the ending study visit. This was lower than the goal of retaining 84, but the recruitment period could not be extended due to funding limitations. Of the subjects who did not finish the study, three subjects withdrew before completing the baseline questionnaires, one subject decided not to complete the final visit and the remaining 19 subjects did not return calls from study staff. Drop-out rates were similar in all three study groups (Table 1). Retention rates over 12 weeks of study were not statistically different between race/ gender sub-groups: 81% for European Americans, 70% for African Americans, 76% for women and 77% for men. There were no study-related adverse events reported.

Compliance with study procedures

Groups 2 and 3 were given a form for formulating a written plan (Fig. 2) and were instructed to mail the form back to the study office using a pre-stamped envelope. The number of subjects returning the form was greater in Group 3 than in Group 2 (Table 1). This difference in form completion rates between Groups 2 and 3 could be due to the first call from the dietitian, which asked about the form, and for some subjects assistance was provided in completing the form.

Group 3 was also asked to keep booklets tracking daily intakes of fruit, vegetables and the less healthy foods that they planned to omit. These booklets were to be mailed to the dietitian once a month. At least one booklet was mailed in by 21 of 33 subjects (64%), and 13 of those subjects mailed them in 2–3 times (or 40% of subjects randomized to Group 3). The number of counseling phone calls completed in Group 3 was close to goal with 21 of 23 retained subjects receiving at least two calls each (seven with two calls and 14 with three calls), and only two subjects who completed 12 weeks received only one counseling call. This was mainly due to the inability to contact some subjects at the prescribed times.

Changes in outcome measures

There were no significant differences between groups in blood pressure or blood lipids. At the end of the study, mean weight of Group 3 was significantly higher than the other two groups ($p=0.002$ versus Group 1 and $p=0.02$ versus Group 2). This was similar to the pattern at baseline. There was, however, a trend for slight weight loss in Group 3. Mean weight loss was 0.13 kg (SD 3.21, $n=23$) in Group 1, 0.08 kg (SD 2.45, $n=26$) in Group 2 and 0.73 kg (SD 3.11, $n=24$) in Group 3. Changes in blood pressure and blood lipids were even more variable and did not differ significantly by diet group (data not shown). There were also no significant changes in the score for being convinced about the importance of increasing fruit and vegetable intakes and in confidence to increase fruit and vegetable intakes.

Dietary intakes were assessed by one un-announced 24-hour recall and by the NCI Fruit and Vegetable Screener. It would have been desirable to have more than one recall at each time point, but in this small pilot study this was not feasible. In Fig. 3 we show FV intakes after excluding beans and potatoes from the totals, and FV intake was the primary outcome variable. This data was analyzed using a square-root transformed model for all FV measures and a log-transformed model for energy intake. There was a doubling in FV servings within Group 3 that was statistically significant ($p=0.04$) using the linear mixed model analysis. No other group had a significant change over time. Further, the change over time (end of study–baseline) in Group 3 was significantly higher than that in Group 2 (interaction $\text{beta}=0.57$, $p=0.02$). The results for FV servings per 1000 kcal were similar. The p -value for the change over time within Group 3 was 0.003, while the interaction p -value of 0.005 indicated a higher change in Group

3 compared to Group 2. At the end of study, FV servings per 1000 kcal in Group 2 were significantly lower than either in Group 1 ($p=0.04$) or in Group 3 ($p=0.002$). The FV intakes based on the screener indicated significantly higher intake at the end of study within each of three groups (all $p<0.001$) but again FV intake in Group 3 was significantly higher than that in Group 2 ($p=0.035$). The energy intake in Group 3 at the end of study was significantly lower than that in Group 1 (beta=0.24, $p=0.04$) as well as that in Group 2 (beta=0.26, $p=0.02$). Further, Group 3 is the only group which underwent a significant decrease in energy intake over time (12% mean decrease, $p=0.02$). No significant differences were observed either in glycemic index or in percentage of energy from fat.

A more direct measure of fruit and vegetable intake is serum carotenoids (Campbell et al., 1994). The mean changes based on the linear mixed model with logarithm of total carotenoids as outcome were not significantly different by diet group, either in all subjects or in the non-smokers only. Mean serum carotenoids in non-smokers were 45% higher than that in the smokers ($p<0.001$). Serum carotenoids are also negatively associated with baseline BMI ($p=0.045$). When evaluating how many subjects increased serum carotenoids by at least 20%, there were a greater percentage of subjects with increases in Group 3 (Table 2). In Group 2, 26 subjects completed the study and 14 subjects returned the written plan. Six of the 14 subjects (45%) who returned the form increased their serum carotenoids by at least 20%, but only two of the 12 subjects (17%) who did not return the form showed at least a 20% increase in serum carotenoids ($p=0.216$).

Discussion

The recruitment in this diverse community setting was successful in enrolling minority study participants. Although recruitment of minorities has been reported to be difficult in many studies, our study is consistent with other research showing that African Americans may be more likely to enroll when asked by personal invitation (Yancey et al., 2001). Retention of African Americans was, however, somewhat lower than that of European Americans and future studies may need to target methods to improve retention of African Americans. Other important information for future studies that seek to recruit from a clinic setting is that staff time for recruiting would need to be increased for a faster recruitment rate and follow-up counseling by telephone can be problematic. Obtaining a single dietary recalls by telephone in a short time frame was similarly difficult and given that multiple days of recalls are optimal for adequate assessment at the individual level (Thompson et al., 2004), dietary assessment is a major issue that would need to be addressed by exploring using other methods or perhaps increasing incentives to facilitate data collection.

The formulation of a written plan as an intervention is attractive since it is simple and would be feasible to administer in primary care settings. Based on the screener, there was a trend for increased FV intakes among those who completed the written plan in Group 2, but this was not statistically significant and was not reflected in the recalls. This is similar to other studies with formulation of implementation intentions showing mixed success for dietary change (Adriaanse et al., 2009; Armitage, 2004; de Nooijer et al., 2006; Jackson et al., 2005; Luszczynska et al., 2007; Prestwich et al., 2008). FV intakes increased significantly in Group 3 by both measures, and increased blood carotenoid levels (by 20% or more) were found in 63% of subjects in Group 3 (Table 2). There was some evidence that intakes of less nutritious foods may have decreased in Group 3 due to the slight decrease in body weight and decrease in glycemic index (Fig. 3). Increased intakes of FV over 12 weeks by 2 servings/day would be expected to result in a weight gain of 1 kg if not compensated for by decreased intakes of other foods. The slight weight loss observed in Group 3 suggests that subjects were decreasing intakes of other foods to compensate for increases in FV.

Subjects in Group 3, who received telephone counseling, also were more likely to complete and return the written plan for dietary change (Table 1). Often, the dietitian helped subjects complete this form at the first counseling call. The telephone support therefore may have been helpful for both assisting with the formulations of a written plan and with support to follow up on those plans using self-monitoring. More recent literature indicates that formulation of written implementation intentions could be further augmented by providing subjects with more specific motivational messages about the health risks related to diet and especially when worded as health threats (Prestwich et al., 2008). Our written study materials, however, focused mainly on the positive health benefits of nutrients found in FV.

Conclusions

These results indicate that there is reasonably good interest among a diverse population coming to a primary health care clinic in improving their diets. The simplicity of using a form based on implementation intentions makes it conducive to use in multi-site studies with recruitment through primary care clinics. In future studies, dietitian support may be a good way to help individuals form a concrete plan to consume more FV, and the optimal number of contacts needed would be important to establish. In addition, it is not clear whether the follow-up needs to be done by a dietitian or whether other staff available in typical primary care offices, such as nurses or medical assistants, could be trained to provide this service.

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Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) diagram for recruitment and retention of study subjects. Reasons for exclusion based on eligibility were for: persons not over age 40 ($n=29$), eating too many FV ($n=15$), health issues ($n=15$), not fluent enough in the English language ($n=4$), and other ($n=3$). The study was conducted from Sept. of 2006 to August of 2007 in Ypsilanti, MI at a primary health care clinic.

Date: _____ ID: _____

Making Your Own Plan for Diet Change

Of the foods you eat each day, some foods are more nutritious than others. Think about your meals, snacks and beverages. Don't forget to consider the fats and sugars you add to foods or beverages.

We would like for you to cut out at least one less nutritious food, and in its' place have at least 1 serving of fruit and 1 serving of vegetables each day.

Please be specific about which meal or snack the substitution will be made each day.

1) What types of food, food additions or beverage can you do without or eat less of so that you eat more fruit and vegetables?

Food item(s): _____

When you usually eat it: _____

How you will eat less of it: _____

2) When can you fit in at least 1 extra serving of vegetables (see list for examples) each day?

Please be specific about what time (s) of day, snack or meal you can substitute in an extra serving of vegetables.

3) When can you eat at least 1 more piece of fruit (see list for examples) each day?

Please be specific about what time (s) of day, snack or meal you can substitute in an extra serving of fruit.

Fig. 2.

Form for making a written plan to substitute fruits and vegetables for a less nutritious food. The study was conducted from Sept. of 2006 to August of 2007 in Ypsilanti, MI at a primary health care clinic.

Fig. 3.

Changes in dietary intakes over 12 weeks in the three study groups from un-announced 24-hour recalls or the NCI Fruit and Vegetable (FV) Screener in the last set of bars. The study was conducted from Sept. of 2006 to August of 2007 in Ypsilanti, MI at a primary health care clinic. The only statistically significant difference between groups was in servings (serv) of FV per 1000 kcal in Groups 2 and 3 ($p=0.025$). Baseline dietary intakes in Groups 1, 2 and 3, respectively, were: 2273, 2329 and 1958 kcal/day; 34, 36 and 33% of energy from fat; 87, 87 and 87 for the Glycemic Index (GI) versus white bread; 3.18, 2.53 and 2.66 FV/1000 kcal; 6.02, 5.52, and 4.89 FV servings/day from 24-hour recalls; and 2.61, 2.15, and 2.72 FV servings/day from the screener. Potatoes and beans were excluded from all of the FV counts.

Table 1

Characteristics of study participants recruited from 9/28/06 to 5/7/07 in a primary health care clinic in Ypsilanti, Michigan (given as mean and SD or number and percentage).

Characteristic	Group 1, <i>n</i> =30 ^a	Group 2, <i>n</i> =30	Group 3, <i>n</i> =33
Age, years	54.0, 10	53.5, 7	52.4, 9
Gender, female, <i>n</i> , %	24, 80	19, 63	23, 70
Married, <i>n</i> , % ^b	12, 40	15, 50	11, 34
Education, <i>n</i> , %			
Some college or more	13, 45	20, 67	23, 70
Less than high school	5, 17	6, 20	5, 15
Race			
Caucasian, <i>n</i> , %	19, 63	16, 53	14, 42
African American, <i>n</i> , % ^c	8, 27	10, 33	17, 52
Body mass index (BMI)*	29.6, 7.4	31.2, 7.1	35.7, 7.9
Obese (BMI≥30), <i>n</i> , % *	14, 47	16, 53	26, 79
Employed, <i>n</i> , % ^d	14, 47	17, 57	15, 46
Current Smoker, <i>n</i> , %	12, 39	9, 30	12, 36
Completed written form*	-	16, 53	27, 82
Completed ending visit, <i>n</i> , %	23, 77	26, 87	24, 73

Characteristics denoted by an asterisk had significant overall group differences either from ANOVA or the chi-square test. For both “BMI” and “obese”, the Group 3 mean or percentage was significantly higher than the corresponding values for the other two groups with $p = 0.005$ for BMI and $p = 0.022$ for obesity. For number of subjects completing the written planning form for eating more fruits and vegetables, Group 2 was significantly different than Group 3, $p = 0.029$.

^aThree African American subjects withdrew before completing the baseline visit: one from Group 1 and two from Group 2. Data shown are therefore for 30 of 31 subjects assigned to Group 1 and 30 of the 32 subjects assigned to Group 2.

^bPersons either married or in a committed relationship are included in the “married” category.

^cNot shown are two Hispanic, four Native American and two Asian subjects.

^dThe “employed” category refers to being employed outside of the home.

Table 2

Changes in total serum carotenoids given as mean percent change from baseline or as numbers of persons with an increase of 20% or more in each group. Group 1 received written information. Group 2 received the written information and a form for making a plan to eat more fruits and vegetables. Group 3 received the same materials as Group 2 and phone counseling from a dietitian. The study was conducted from Sept. of 2006 to August of 2007 in Ypsilanti, MI at a primary health care clinic.

Group	Percent change, mean, SD, <i>n</i>		Number with 20% or greater increase, <i>n</i> (%)
	Non-smokers only	All subjects	
Group 1 (control)	6, 33, 16	4, 33, 23	7 (30)
Group 2 (written only)	17, 61, 17	11, 53, 26	8 (31)
Group 3 (support)	37, 60, 17	32, 62, 24	15 (63) ^a

^a The proportion of persons who completed the study and achieved a 20% or greater increase in total serum carotenoids was significantly different between groups by the chi-square test ($p=0.034$). Logistic regression controlling for gender, smoking and baseline BMI indicated that Group 3 was significantly different from Group 2.