

HHS Public Access

Author manuscript

Ethn Health. Author manuscript; available in PMC 2020 May 01.

Published in final edited form as:

Ethn Health. 2019 May; 24(4): 415-431. doi:10.1080/13557858.2017.1346784.

Feasibility and acceptability of a Mediterranean-style diet intervention to reduce cardiovascular risk for low income Hispanic American women

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Abstract

Objective—Evidence for the cardioprotective effects of a Mediterranean-style (Med-style) diet is strong, however few Medstyle dietary interventions have been developed for and tested among Hispanic Americans (HAs), especially younger HAs of reproductive age whose dietary habits may strongly influence dietary intake for all family members.

Design—We adapted a previously tested and evidence-informed lifestyle intervention to reduce CVD risk and evaluated its feasibility, acceptability, and effects on self-reported lifestyle behaviors in this study enrolling low-income HA women attending a Title X family planning clinic in eastern North Carolina. The 3-month long intervention, given to all participants, promoted a Med-style dietary pattern with a focus on increasing consumption of foods commonly consumed by HA that have high quality dietary fats (polyunsaturated and monounsaturated fats primarily from plant sources and fish) and carbohydrates (fruits, vegetables, and whole grains). The intervention also recommended increasing physical activity and was given during 2 face-to-face counseling sessions and 2 telephone counseling sessions. Major outcomes were engagement with study activities and intervention acceptability; lifestyle behavior change at 3-month follow-up is also reported.

Results—Baseline characteristics (n = 36) were: mean age 33 years, 35 (97%) without health insurance, 32 (89%) born in Mexico, and mean BMI 30 kg/m2. Engagement was high among the 36 participants with 33 (92%) completing the intervention and follow-up measures. At follow-up, most participants thought the intervention was helpful (range: 85–100%) and acceptable (100% agreed 'I would recommend the program to others'). The mean dietary fat quality score improved by 0.5 units (95% CI: 0.0–1.1) and the mean fruit-vegetable servings/day improved by 0.7/day (95% CI: 0.1–1.3).

Conclusion—Intervention engagement and acceptability were high and there was improvement in self-reported dietary behaviors. This type of Med-style dietary pattern intervention should be evaluated in randomized trials enrolling HAs at risk for CVD.

Introduction

Hispanic Americans (HAs), now the fastest growing ethnic minority group in the United States (US), are disproportionately affected by cardiometabolic risk factors (i.e. obesity, high blood pressure, diabetes, and metabolic syndrome) compared to non-Hispanic white Americans (Daviglus et al. 2012; Flegal et al. 2012; Ford, Li, and Zhao 2010; Go et al. 2014; Kurian and Cardarelli 2007; Park et al. 2003; Perez-Escamilla 2011). Poor quality dietary intake is a major contributor to adverse cardiovascular disease (CVD) profiles among HAs, particularly for HAs coming from countries that have experienced a nutrition transition to a more westernized food culture (Batis et al. 2011; Denova-Gutierrez et al. 2010; Flores et al. 2010; Nettleton et al. 2008; Noel et al. 2009; Park et al. 2009; Perez-Escamilla 2011). Furthermore, as HAs become acculturated they have an increased intake of sugar and sugarsweetened beverages, solid fat, and sodium; increased frequency of eating out; and decreased intake of fruits and vegetables (Perez-Escamilla 2011). Additionally, a higher intake of refined carbohydrates and lower intake of fish and omega-3 oils is associated with increased CVD risk among HAs (Denova-Gutierrez et al. 2010; Go et al. 2014; Noel et al. 2009). Therefore, dietary interventions that are effective in reducing cardiometabolic risk and targeted for the HA population are needed to reduce their disparate risk factors for CVD.

In the past 20 years, epidemiological studies have shown beneficial associations between a Mediterranean-style (Med-style) diet pattern and cardiovascular health for diverse populations (Batis et al. 2011; Gardener et al. 2011; Martinez-Gonzalez et al. 2008; Mozaffarian et al. 2013; Nettleton et al. 2008; Salas-Salvado et al. 2011). With the publication of the PREDIMED randomized trial, there is now robust evidence that a Medstyle diet supplemented with nuts or olive oil lowers CVD risk, as those in the PREDIMED intervention arms experienced a 30% reduction of major CVD events compared to those receiving the control diet (Estruch et al. 2013). Although studies of Med-style diets have been conducted in the US, most of these modified the dietary pattern to reduce fat intake as per older guidelines and few, if any, have tested a higher fat diet as evaluated in the PREDIMED trial (Toobert et al. 2011). Moreover, we are aware of no published research that has evaluated a PREDIMED-like diet among low-income Hispanic women of reproductive age. Adoption of culturally relevant food patterns among HAs that include the critical components of the Med-style diet (Hu 2003) (e.g. higher quality oils/fats, variety of nuts, high fruit and vegetable consumption) would be expected to substantially reduce CVD risk in this population.

Among HAs, women are more affected by obesity, physical inactivity, diabetes and metabolic syndrome than men (Daviglus et al. 2012; Ford, Li, and Zhao 2010; Go et al. 2014; Kurian and Cardarelli 2007; Park et al. 2003). HA women of low socioeconomic status are at highest risk for CVD; yet, are hard to reach in traditional medical settings given their limited access to primary care health services (Daviglus et al. 2012; Schneiderman et al. 2014; Wallace and Bartlett 2013). However, a large number of HA women do receive

family planning services in Title X clinics (Fowler, Gable, and Wang 2014). In this paper, we primarily report on the feasibility and acceptability of a Med-style diet intervention adapted for low-income HA women attending a Title X family planning clinic ineastern North Carolina. Effective dietary interventions for this population may have broader public health impact by improving dietary behaviors for their family members (Grey, Knafl, and McCorkle 2006).

Methods

Study overview

This study was conducted in two phases: 1) a Formative Phase, including interviews with clinic interpreters and focus groups with patients and 2) an Implementation Phase, which utilized a one-group, pre/post study design to assess the feasibility and acceptability of a lifestyle intervention to reduce CVD risk adapted for HA women of reproductive age. Participants for both phases were recruited from the Title X Family Planning Clinic at the Pitt County Health Department in Greenville, NC. This clinic primarily serves uninsured women residing in Pitt County, NC and serves a growing population of HAs, who represent 6% of the county's total population, many living in rural areas of the county (United States Census Bureau 2014).

As outlined in Figure 1, during the Implementation Phase, HA women attending this family planning clinic for routine care were invited to participate in an 8-week intervention program. The intervention was designed for delivery during 2 individual face-to-face counseling sessions (with option for second session to be by phone, per participant preference) and 2 follow-up telephone counseling sessions given at approximately 2–4 week intervals, with outcomes measured at baseline and 3 month follow-up. The University of North Carolina at Chapel Hill Institutional Review Board approved and monitored the study, with data collected from October 4, 2013 to March 31, 2014.

Description of previously tested intervention

The English version of the intervention was designed to be culturally appropriate and individually-tailored for residents of eastern North Carolina, with a major focus on improving consumption of high quality dietary fats (polyunsaturated and monounsaturated fats primarily from plant sources and fish) and carbohydrates (fruits, vegetables, and whole grains) (Keyserling et al. 2016), consistent with the evolving literature on the importance of fat and carbohydrate quality in reducing CVD risk (Jakobsen et al. 2009, 2010; Mozaffarian, Micha, and Wallace 2010, 2011; Siri-Tarino et al. 2010). Of note, the intervention's dietary recommendations were similar (virtually identical on 9 of the 13 major recommendations of the nut intervention arm) to the Med-style intervention diets evaluated in the recently completed PREDIMED randomized trial (Estruch et al. 2013). This updated English version of the intervention was recently evaluated in the Heart Healthy Lenoir Project, conducted in eastern North Carolina (Keyserling et al. 2016). Phase I of the Heart Healthy Lenoir intervention, which focused on improving diet quality and increasing physical activity (and recently described in detail) (Keyserling et al. 2016) was adapted for this study.

Formative phase

The Heart Healthy Lenoir intervention was adapted for our female HA population (adaptation entitled EnForma) using 'surface structure' adaptations – matching intervention materials and messages to observable 'superficial' characteristics of a target population as well as 'deep structure' adaptations – understanding underlying cultural, social, and environmental forces that influence health behavior (Resnicow et al. 1999). Two native Spanish-speaking research assistants, a native Spanish-speaking interventionist, and a bilingual researcher experienced in cultural translation of health promotion interventions (Ko et al. 2014; Reuland et al. 2012) conducted the initial translation of the curriculum. Research staff met with interpreters from the Pitt County Family Planning clinic to discuss the proposed study and gain insight on the HA population served at the clinic. Interpreters shared their perceptions on patients' dietary and food shopping preferences, family structures, and predominant Hispanic nationalities. They also offered insights about recruitment and retention strategies for the study.

Two focus groups were conducted to elicit information on surface and deep structure adaptations needed for tailoring the intervention for low income HA women. At the outset of the focus group sessions, all participants gave written informed consent. Female Hispanic women attending the Family Planning Clinic were eligible to participate if they were 18 years or older, not pregnant, and had received care at the clinic in the last year. Trained research staff recruited eligible participants on site, three days a week or by phone using a daily clinic roster of Spanish speaking patients. An initial focus group with 4 participants was conducted to elicit information on dietary patterns, physical activity practices, obtain feedback on material adapted from the English Heart Healthy Lenoir study manual, and solicit opinions on the ideal design for a nutrition program targeting low income HA women. The discussion explored gastronomic preferences of the target population; solicited culturally relevant suggestions for revisions to the pictures, illustrations, and food terms; and assessed appropriateness of the proposed study name, EnForma. After completing this initial adaptation process a second focus group with 7 participants was conducted to identify areas that needed refinement. During this discussion, the moderator facilitated a section-by-section review of the study materials with participants invited to comment on the appropriateness of the Spanish translation and cultural relevancy of the content. Based on insights gained from the participants, another phase of further cultural and linguistic adaptation was conducted to achieve the final version of the intervention for testing. Further, to address the perception that healthy foods are costly, foods considered accessible to participants, both in terms of cost and availability, were promoted by the program.

A second major focus of the adaptation of the intervention format was to improve engagement and retention based on our experience in the Heart Healthy Lenoir Project where 14% did not attend any intervention visit and only 67% completed all 4 visits. This was consistent with findings of others who have also reported poor recruitment and retention rates in the target population (Ezeugwu et al. 2011; Robinson and Trochim 2007; Sadler et al. 2010). Thus, face-to-face contact was reduced from 4 visits to 1–2 visits in this study. As content and contact time was reduced, the adapted intervention focused on behaviors that are most likely to improve health outcomes; specifically improving fat and carbohydrate quality.

Table 1 compares the food groupings addressed at each session of Heart Healthy Lenoir Project and EnForma in the following order: 1) nuts, oils, dressings, and spreads, 2) vegetables, fruits, whole grains, and beans, 3) drinks, snacks, desserts, eating out and salt, and 4) fish, meat, poultry, eggs, and dairy. Low fat and full fat milk products were considered acceptable (Huth and Park 2012; Soedamah-Muthu et al. 2011). Though briefer than the tested Heart Healthy Lenoir intervention, the key dietary content (focus on improving fat and carbohydrate quality with foods familiar to the target audience) was preserved in the Enforma intervention.

Implementation phase

Participants—Female HA women were eligible to participate in the intervention if they were 18–44 years old, not pregnant or planning to get pregnant in the next 6 months, and had received care at the Family Planning Clinic in the last year. Trained research staff recruited eligible participants on site, 3 days a week. For the other 2 clinic days, a daily roster of Spanish speaking patients was maintained and used to contact potential participants by phone. Recruitment activities included promotion of the study through distribution of study brochures by clinical staff and study flyers posted in the waiting room. Participants recruited by phone gave verbal consent for assessment of eligibility and for telephone administration of study questionnaires. All participants gave written informed consent for their participation in this study. Recruitment was completed over a 2 month period, from October to December 2013. The study was planned and implemented in collaboration with the Health Department Director and clinical staff at the Family Planning Clinic.

The first face-to-face counseling session was administered in the clinic and lasted 30–45 min; about 2–4 weeks after this session, participants received a follow-up phone counseling session that lasted 10–15 min. About 2–4 weeks after the phone counseling session, a second face-to-face counseling session was planned, to last 30–45 min. For this session, participants were given the option to receive counseling over the phone if they could not meet at the clinic. About 2–4 weeks later, participants received the final follow-up phone counseling session that lasted 10–15 min.

The study interventionist was a bicultural, medical translator familiar with the population served at the family planning clinic. Senior research and nutrition staff at the UNC Center for Health Promotion and Disease Prevention trained the interventionist on motivational interviewing techniques and study content over a 3–4 d period. During weekly meetings, additional feedback was given to the interventionist to address questions about study logistics and to ensure the fidelity of the intervention counseling.

Each participant was given a study binder that included core intervention content and supplementary materials, as described below. During the first face-to-face session, participants completed a lifestyle questionnaire (a modified version of the validated Dietary Risk Assessment) (Jilcott et al. 2007; Sheridan et al. 2013) which was used to tailor lifestyle recommendations to individual behaviors. As outlined in Table 1, after receiving an overview of the intervention, participants received tailored counseling on Oils, Dressings, Nuts, Fish and Meats. At the end of the session participants were encouraged to select 1–2 goals, and identify first steps to achieving those goals during the next 2–4 weeks. Progress at

achieving goals was assessed at the first follow-up telephone counseling session; positive reinforcement was given to those achieving goals and strategies to achieve goals were reviewed for those who did not. During the second face-to-face counseling session, which focused on Drinks, Desserts, Fruits and Vegetables, Grains, and Beans, participants selected new goals and first steps for the next 2 4 weeks. Finally, during the last phone counseling session the interventionist followed up on participants' progress in reaching their goals and addressed strategies to overcome barriers. Participants were encouraged to read the physical activity section at home or discuss it with the interventionist if they had questions about it. This section primarily focused on walking 30 min on most days of the week. Other supplementary information included: suggestions for eating out; information on vegetables oils used for baking, frying, sautéing, and dips; reading food labels; information on salad dressings and mayonnaise; and eating on a budget. Participants received \$20 gift cards for baseline and follow-up measurement sessions and \$10 gift cards for enrollment, Session 1, and Session 3 if it was conducted at the clinic.

Measures

The main goal of the Implementation Phase was to determine the feasibility and acceptability of the EnForma intervention delivered in this context. Feasibility was assessed through recruitment success and participant retention rates. Acceptability of the intervention was assessed using agreement or disagreement Likert type scales and multiple-choice questions administered post-intervention.

Other outcomes assessed at baseline and at the end of the study (3-month follow-up), include change in self-reported: 1) fruit and vegetable intake (servings/day), 2) fiber intake (grams/day), 3) dietary fat quality, and 4) physical activity (minutes/week). The Fruit-Vegetable-Fiber intake scores (servings/day) were calculated using a 10-item validated Block Fruit-Vegetable-Fiber Screener translated to Spanish (Block et al. 2000), that asks about frequency of consumption in the past year (at baseline) and in the past 2 months (post intervention). Scores were derived using prediction equations for daily nutrient intake (Block et al. 2000). A modified 8-item version of a previously validated fat quality questionnaire (Kraschnewski et al. 2013) was used to assess overall fat quality. Baseline measures were assessed by phone (i.e. demographic information and general health information) and in person during the first face-to-face counseling session (i.e. lifestyle behaviors). For descriptive purposes, baseline physiologic data (e.g. body mass index (BMI), blood pressure) were abstracted from the Family Planning Clinic medical record from the visit before the enrollment date. Follow-up measures were assessed by phone and were collected from all participants, including patients who did not complete all intervention sessions. As most participants did not return for a follow-up clinic visit during the time frame of this study, follow-up physiologic measures are not reported.

Process evaluation

To monitor fidelity of the intervention, the interventionist completed a process evaluation questionnaire after delivery of each session. This questionnaire included items on mode of session delivery (face-to-face/phone), estimated amount of time for the session, lifestyle goals selected for each session, participant's ability to specify first steps and goals, and for

follow-up sessions, participant's success meeting goals. The questionnaire also included items that assessed participant's receptiveness to, active participation with, and comprehension of session activities as well as the interventionist's assessment of overall session quality. Session components and overall session quality were rated using a 5-item Likert scale (e.g. excellent, good, fair, poor, not sure). To provide feedback to the interventionist and to improve intervention fidelity, these questionnaires were reviewed periodically (typically weekly) by study research staff. Additionally, 10% of the counseling sessions were audiotaped and evaluated by two research staff using a standardized evaluation form. Results were used to provide feedback on nutrition counseling and use of motivational interviewing techniques. At the end of the study, an exit interview was conducted with the interventionist to elicit information on each of the intervention components to guide future refinement of the intervention.

Sample size and statistical analyses

For the Implementation phase, a sample size of 40 was selected to assess the feasibility and acceptability of the intervention, and to get estimates of variance for outcome measures, anticipating up to a 20% attrition rate (Browne 1995; Lancaster, Dodd, and Williamson 2004; Sim and Lewis 2012). Descriptive statistics were used to describe baseline demographic and health characteristics, and 95% confidence intervals were estimated for the change, from baseline to follow-up, in dietary and physical activity measures. Statistical analyses were performed with SAS software (Version 9.3, Cary, NC).

Results

Enrollment and baseline characteristics of participants

Figure 1 depicts the rates of participation and retention. A total of 40 patients expressed interest; of these, 38 provided written consent, and 36 completed baseline measures and comprised the sample population. Out of 36 participants, 33 (92%) completed the intervention and follow-up assessment. Participants who dropped out (n = 2) reported limitations of time, child care, and weather conditions. One participant was deemed ineligible during the study after becoming pregnant. Table 2 reports baseline characteristics of study participants (n = 36). The mean age was 33 years, 32 (89%) were born in Mexico, 35 (97%) were uninsured, 34 (94%) were married or living with their partner, and 17 (47%) had less than high school education. Most participants had low acculturation based on Spanish language preference (n = 35, 97%) and an average of 12 years living in the US.

Table 2 also provides information on participants' lifestyle habits and risk factors for CVD. These included eating at a fast food restaurant one or more times a week (n = 30, 83%), being obese (mean BMI = 30 kg/m2), and having diabetes (n = 4, 11%). Only 8 (22%) reported following a diet for weight loss. Additionally (data not shown in Table 2), a low proportion of participants perceived themselves as being more at risk for diabetes (n = 6, 17%) or heart disease (n = 1, 3%) than other women like them, and 18 (50%) reported weighing themselves 'about once a year or less' or 'never.' Most participants cooked at home 7 days/week (n = 28, 78%) and only 8 (22%) reported their current diet to be 'very

similar to country of origin' compared to 22 (61%) reporting 'a little similar' and 6 (17%) reporting 'not at all similar'.

Acceptability

Table 3 presents acceptability results for all of the study participants that completed all intervention visits (n = 33). A high proportion of participants found the first (n = 33, 100%) and second (n = 30, 91%) face-to-face educational information to be 'very helpful.' Similarly, 94% (n = 31) of participants reported the telephone sessions to be 'very helpful.' Slightly lower proportions reported finding the information on walking (n = 28, 85%) and setting goals and first steps to improve diet and PA as 'very helpful' (n = 29, 88%). The majority of participants (n = 31, 94%) found it 'very helpful' to work on identifying problem areas with their diet and PA.

In regards to the overall acceptability of the program, most participants agreed (i.e. 'agree a lot' or 'agree') that the information presented was understandable, and that the program helped them to improve their diet and be more active). Also, most agreed that meeting at the Health Department was easy for them and that they would recommend the program to others). Approximately one third of participants agreed that they or their families disliked the suggested foods or that the cost of the suggested foods was too high. Few women (n = 7, 21%) reported not knowing how to prepare meals and not having time to prepare meals (n = 5, 15%).

The majority of participants also found the amount of information (n = 25, 81%), number of sessions received (n = 28, 85%), and the amount of time for face-to-face (n = 28, 85%) and phone sessions (n = 31, 94%) to be just right/just enough. Twenty-six (79%) of the participants said that the study manual used culturally sensitive examples. Most participants (n = 24, 73%) reported looking at the study manual on their own time 'a little,' while only 6 (18%) reported looking at it 'a lot.' The most important factors that motivated participation included: learning about nutrition (n = 21, 64%), being concerned for their personal health (n = 17, 52%) and family's health (n = 17, 52%), and receiving a gift card (n = 8, 24%). Overall, participants were satisfied with the intervention and suggested to 'continue with programs like this,' 'include weekend sessions,' and 'have group sessions as well.'

Process evaluation

The average duration of the first face-to-face counseling session (n = 36) was 42 min and for the second face-to-face session (n = 33) 35 min. On average, 31 days elapsed between these two face-to-face counseling sessions. The follow-up phone sessions had an average duration of 8–9 min (n = 33), and on average these were conducted 19 days after the first face-to-face session and 29 days after the second face-to-face session. Twenty-eight participants completed the second face-to-face session in person rather than opting for a telephone session. The key themes that emerged from the interview with our study interventionist included: phone recruitment was more efficient than on-site recruitment, participants appeared to experience problems understanding what types of goals to set, some participants asked about group sessions, the majority have very little to no understanding of healthy eating, many were motivated by their interest in improving their family's health, and there

was a need for more examples of what they can eat (or how to modify their current diet) based on culture-specific foods.

Diet and physical activity outcomes

Table 4 presents self-reported diet and physical activity outcomes for study participants (though 3 participants discontinued the intervention after 2 counseling sessions, they completed follow-up measures). Compared to baseline, participants improved their fat quality score by a mean change of 0.5 units (95% CI: 0–1.1). The number of servings of fruits and vegetables increased 0.7 servings/day (95% CI: 0.1–1.3). The total intake of fiber increased 2 grams/day (95% CI: 0.7–3.3). Physical activity increased by a mean change of 42 min/week (95% CI: –5.5–89.5) for moderate physical activity and by a mean change of 13 min/week (95% CI: –32.4–58.3) for vigorous physical activity.

Discussion

The EnForma adapted lifestyle intervention proved to be feasible and acceptable for the low-income HA women attending a Title X family planning clinic in NC. Estimates of effect for fat quality, total dietary fiber and fruit and vegetable intake were suggestive of improvement. Furthermore, there was an increasing trend for self-reported moderate and vigorous physical activity. These results suggest that the intervention could be effective in improving CVD risk factors in HAs.

This study adds to a limited body of evidence regarding med-style dietary interventions in HAs. Estimates of variance and effect for fruit and vegetable intake were similar to those reported in a study that included HAs and used similar dietary measures (Lilly et al. 2014).

Only one other study, which enrolled Latino farm workers (Matias et al. 2013) has evaluated dietary intake of HAs using the Block Fruit/Vegetable/Fiber screener to assess adherence to dietary guidelines. This cross-sectional study (n = 802) reported a mean intake of 5 servings of fruits and vegetables per day; however, when stratified by sex, the daily intake was lower for women compared to men (4.8 vs. 5.2), though still somewhat higher than observed for the HA women in our study. Physical activity measures of effect also mirror those reported by Lilly et al. (Lilly et al. 2014). Recruitment success and retention rates were found to be higher than that reported for larger studies with minorities (Ezeugwu et al. 2011; Robinson and Trochim 2007; Sadler et al. 2010), though the number of face-to-face contact visits in our study was less than in these trials.

Study strengths include the use of a bicultural interventionist who was familiar with the study population and was trained to deliver nutrition education using motivational interviewing skills. Additionally, a team of two fully bilingual and bicultural research staff supported the interventionist with frequent feedback to help ensure intervention fidelity and answer nutrition related questions from participants that the interventionist was not able to address. A major strength of this intervention was that it promoted a Med-style dietary pattern with a focus on foods that are commonly consumed by HAs. This equates to a less restrictive dietary approach that may be more palatable than most tested interventions that focused on a low fat diet (Artinian et al. 2010; Toobert et al. 2011). Finally, this study

achieved very good recruitment and retention rates for this hard-to-reach population (Larkey et al. 2009; Martin et al. 2013; Wallace and Bartlett 2013).

Possible reasons for achieving a high retention rate for this hard-to-reach population include the use of deep and surface structure adaptations of the original intervention content, having fewer face-to-face contacts compared to the English version of the intervention, and allowing participants to complete the second counseling session over the phone. While a majority of participants opted for face-to-face sessions, telephone counseling, known to be an effective behavior change strategy for hard to reach populations (Eakin et al. 2007; Koniak-Griffin et al. 2015; Newman, Flatt, and Pierce 2008; Pierce et al. 2007), allowed the flexibility to accommodate any transportation limitations for this population. It is also possible that this population is different from other populations seen at the Title X clinics and that high rate of participation was motivated by the study's financial incentives.

Our study had limitations. This study tested a shorter duration version of the original English version intervention with less contact time that might be needed for more comprehensive and sustained behavior change. It is possible that higher attrition rates may occur over a longer intervention period. However the use of a bicultural interventionist along with tailored printed materials is likely to sustain participation after a 3-month period, as seen in similar studies using interventionists that are bicultural lay health workers (Balcazar et al. 2011; Corbie-Smith et al. 2010; Elder et al. 2006; Squires and O'Brien 2012; Tran et al. 2014). Another limitation of this study is that our sample was limited to a homogenous group of women, with a majority born in Mexico. This however mirrors the large Hispanic minority population of Mexican origin present in the United States and North Carolina. Finally, the use of brief screeners to assess fat quality, fruits, vegetables and fiber, and physical activity may limit our ability to fully assess behavior change. However, by using brief screeners we were able to obtain reasonable information without undue measurement burden to study participants.

Findings from this feasibility study helped us identify aspects of the intervention that need further refinement to improve participants' engagement with intervention objectives. As observed and reported by research staff, participants had some trouble with setting goals and first steps to improve diet and physical activity. Future adaptations may consider offering participants more examples on how to set goals and first steps, and further address the perceptions of cost and concern about taste of the recommended dietary pattern. Finally, participants also reported interest in holding group sessions where they may be able to share with others their progress in reaching their goals and learn from the experiences of others.

In summary, increasing evidence suggests a Med-style diet can substantially reduce CVD risk Nettleton et al. 2008; Salas-Salvado et al. 2011). There is need for adaptingevidence-informed Med-style diet interventions such as Heart Healthy Lenoir intervention for Hispanic populations, given their disproportionate cardiometabolic risk. This study found that the adapted EnForma intervention could be feasibly administered and was acceptable to the HA women who took part in this study. It also suggests that this type of intervention is likely to have a positive impact on lifestyle behaviors and provides estimates of variance for

larger controlled trials needed to test the effectiveness of this intervention on dietary, physical activity, and CVD risk factor (biomarker) outcomes among HA women.

Acknowledgments

Funding

This work was supported by Centers for Disease Control and Prevention: [grant number U48DP001944, U48/DP001944]; National Center for Advancing Translational Sciences: [grant number 1UL1TR001111-01].

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Key messages

1. Evidence for the cardioprotective effects of a Med-style diet is strong; however, few Med-style dietary interventions have been developed for and tested among Hispanic Americans.

- **2.** We developed and tested a Med-style diet intervention for low-income Hispanic American women of reproductive age. Intervention engagement and acceptability were high among participants enrolled in this study.
- **3.** Additional research is needed to further evaluate Med-style dietary pattern interventions in Hispanic Americans.

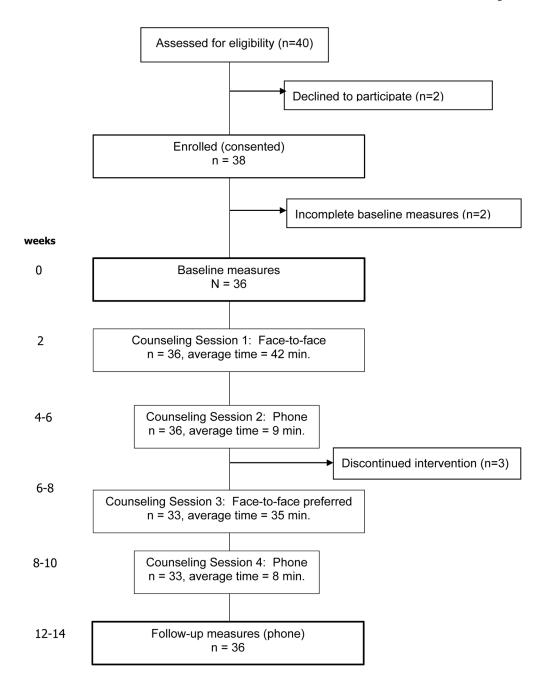


Figure 1.

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Table 1

Dietary intervention content, comparing the original English version of the intervention, Heart Healthy Lenoir, with the Spanish version, EnForma.

Seesing 1. Ear 2-6 servings of healthful lats per day. Decisigs, and Ear 2-6 servings of healthful lats per day. Decisigs, and Ear 2-6 servings of healthful legs and the lates often, Aim for 3 a more servings per week. Eich and Means Ear and Means Earl and Earl Earl Earl Earl Earl Earl Earl Earl	Session Heart Healthy Lenoir			Session EnForma	Major Focus of Counseling
Use the healthful vegetable oils for frying, sautéing, and baking. Use full fat salad dressing and mayonmaise. Aim for 6 or more servings per week. Use trans fat free margarine instead of sick margarine. Use trans fat free margarine instead of sick margarine. Thought fats or trans fats can cause heart disease. Avoid fast food, packaged snacks, and bakery foods with trans fats. It is OK to eat foods with saturated fat as long as you also eat the healthful foods suggested by this program. Avoid fast food, packaged snacks, and bakery foods with trans fats. It is OK to eat foods with saturated fat as long as you also eat the healthful foods suggested by this program. Choose more whole grain breads. Aim for 2 or more servings of whole grain products each day. Eat more beams and peas. Aim for 3 or more servings per week. Try other whole grain products for neads from a variety other drinks. Make healthful choices for snacks and desserts. Make healthful choices for snacks and desserts. Make healthful choices when eating out. Take care to choose healthful ment items, especially at fast food restaurants. High salt intake can cause high blood pressure. Limit salt to 2300 mg a day. High salt intake can cause high blood pressure. Limit salt to 2300 mg a day. Boultry is healthful & economical and can be eaten 3 times per week. Though full fat dairy products are high in saturated fat, they do not seem to increase the risk of heart disease. If you enjoy dairy products, 2-3 servings of low or full fat products is a good goal, but limit high sugar dairy products. L3 serving to complet times a week. Eggs are reasonable choice; 1-2 a day is fine.	Session 1 Nuts, Oils, Dressings, and	Eat 2–6 sei	rvings of healthful fats per day. Eat nuts or nut butters often. Aim for 3 or more servings per week.	Session 1 Oils, Dressings, Nuts, Fish and Meats	Key elements of the <i>Heart Healthy Lenoir</i> Session 1 plus key elements of the <i>Heart Healthy</i>
Unhealthy fats or trans fat free margarine instead of stick margarine. Unhealthy fats or trans fat free margarine instead of stick margarine. Unhealthy fats or trans fat free margarine instead of stick margarine. Aroid first food, packaged snacks, and bakery foods with trans fats. It is OK to cat foods with saturated fat as long as you also cat the healthful foods suggested by this program. Order in a sold as food, packaged snacks, and bakery foods with trans fats. It is OK to cat foods with saturated fat as long as you also cat the healthful foods suggested by this program. Order in a sold as you also cat the healthful foods suggested by this program. Eat more beans and peas. Aim for 2 or more servings of whole grain products each day. Eat more beans and peas. Aim for 2 or more servings per week. Try other whole grain products for breakfast and other meals. Sancks. Make healthful choices for snacks and desserts. Make pod choices when eating out. Take care to choose healthful menu items, especially at fast food restaurants. High salt intake can cause high blood pressure. Limit salt to 2300 mg a day. Poultry is healthful & economical and can be eaten 3 times per week. Though full fat dairy products are high in saturated fat, they do not seem to increase the risk of huit in high sugar dairy products are high in saturated fat, they do not seem to increase the risk of huit limit high sugar dairy products are like its cream, ice milk, and frozen yogunt to a couple times a week. Eggs are reasonable choice; 1-2 a day is fine.	Spreads	•	Use healthful vegetable oils for frying, sautéing, and baking.		Lenoir Session 4.
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 Try other whole grain products for breakfast and other meals. Minimize sugar-sweetened drinks. Choose from a variety other drinks. Make healthful choices for snacks and desserts. Make pealthful choices for snacks and desserts. Make good choices when eating out. Take care to choose healthful menu items, especially at fast food restaurants. High salt intake can cause high blood pressure. Limit salt to 2300 mg a day. Eat fish 1 or more times per week. Poultry is healthful & economical and can be eaten 3 times per week. Limit red meat to no more than 1 serving per day and avoid cold cuts and other processed meats. Though full fat dairy products are high in saturated fat, they do not seem to increase the risk of heart disease. If you enjoy dairy products, 2-3 servings of low or full fat products is a good goal, but limit high sugar dairy products like ice cream, ice milk, and frozen yogurt to a couple times a week. Eggs are reasonable choice; 1-2 a day is fine. 	Beans	•	Eat more beans and peas. Aim for 3 or more servings per week.		steps. Provide strategies for overcoming barriers.
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 Make good choices when eating out. Take care to choose healthful menu items, especially at fast food restaurants. High salt intake can cause high blood pressure. Limit salt to 2300 mg a day. Eat fish I or more times per week. Poultry is healthful & economical and can be eaten 3 times per week. Limit red meat to no more than I serving per day and avoid cold cuts and other processed meats. Though full fat dairy products are high in saturated fat, they do not seem to increase the risk of heart disease. If you enjoy dairy products, 2–3 servings of low or full fat products is a good goal, but limit high sugar dairy products like ice cream, ice milk, and frozen yogurt to a couple times a week. Eggs are reasonable choice; 1–2 a day is fine. 	Desserts, Eating	•	Make healthful choices for snacks and desserts.	Drinks, Desserts, Fruits and Vegetables, Grains,	Lenoir Session 5 plus key elements of the Heart Healthy
 High salt intake can cause high blood pressure. Limit salt to 2300 mg a day. Eat fish I or more times per week. Poultry is healthful & economical and can be eaten 3 times per week. Limit red meat to no more than I serving per day and avoid cold cuts and other processed meats. Though full fat dairy products are high in saturated fat, they do not seem to increase the risk of heart disease. If you enjoy dairy products, 2–3 servings of low or full fat products is a good goal, but limit high sugar dairy products like ice cream, ice milk, and frozen yogurt to a couple times a week. Eggs are reasonable choice; 1–2 a day is fine. 	Out, and Salt	•	Make good choices when eating out. Take care to choose healthful menu items, especially at fast food restaurants.	and Beans	Lenoir Session 2.
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	Fish, Meat, Poultry, Dairy, and Eggs	•	Poultry is healthful & economical and can be eaten 3 times per week.		the participants' progress achieving their goals and first
		•	Limit red meat to no more than 1 serving per day and avoid cold cuts and other processed meats.		steps. Provide strategies for overcoming barriers.
• Eggs are reasonable choice; 1–2 a day is fine.		•	Though full fat dairy products are high in saturated fat, they do not seem to increase the risk of heart disease. If you enjoy dairy products, 2–3 servings of low or full fat products is a good goal, but limit high sugar dairy products like ice cream, ice milk, and frozen yogurt to a couple times a week.		o.
		•	Eggs are reasonable choice; 1–2 a day is fine.		

Table 2

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TD 11 1 4 141	N. 1 N.	
Baseline characteristics of the stud	ly population (n	= 36).

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Baseline characteristics	Number or Mean	Mean ± SD or n(%)
Age (years)		33 ± 5
Language preference (Spanish)		35 (97)
Country of Birth (Mexico)		32 (89)
Employment ^a		
Employed		8 (22)
Unemployed		9 (25)
Homemaker		26 (72)
Student		1 (3)
Married or living with partner		34 (94)
Education		
Less than high school		17 (47)
High school		19 (53)
College graduate/advanced degree		0
Have children		36 (100)
No.children		
1–2		16 (44)
3		13 (36)
>4		7 (19)
No health insurance		35 (97)
Gross income ($\$$), ($n = 34$)		$16,286 \pm 8,029$
No. in family $(n = 34)$		4 ± 1.2
Time living in the US (years)		12 ± 4.2
Can afford a healthy diet		29 (81)
Smoked at least 1 cigarette last month		2 (6)
Moderate physical activity (>10 min/week)		25 (69)
Vigorous physical activity (>10 min/week)		17 (47)
Following a heart healthy diet		3 (8)
Following a weight loss diet		8 (22)
Frequency of fast food (times/week)		
0		6 (17)
1		25 (69)
2		4 (11)
3		1 (3)
${\it High cholesterol}{}^{b}$		1 (3)
Diabetes b		4 (11)
High blood pressure c,d		1 (3)
Height (in), $(n=32)^{C}$		61 ± 3.2
Weight (lbs), $(n=35)^{C}$		156 ± 31.3

Baseline characteristics	Number or Mean	Mean ± SD or n(%)

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Note: SD, standard deviation.

Body Mass Index (BMI), e(n = 32)

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 30 ± 5.2

 $^{^{\}it a}_{\rm Participants}$ could chose more than one response option.

b_{Self-reported.}

^cData extracted from participants' medical charts.

 $[\]frac{d}{\text{High Blood pressure}} = \text{systolic blood pressure} > 140 \text{ mmHG and/or diastolic blood pressure} > 90 \text{ mmHg}.$

 $^{^{}e}$ Calculated as BMI= kg/ m².

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Table 3

Acceptability of the intervention

			n, %		
How helpful was the following? $(n=33)$	Very helpful	Somewhat helpful	Somewhat unhelpful	Very unhelpful	N/A
Information on oils, dressings, nuts, fish, meat	33(100)				
Information on beverages, desserts, fruits, vegetables, grains, beans	30 (91)	3 (9)			
Information on walking	28 (85)	5 (15)			
Identifying problem areas to improve your diet and PA	31 (94)	2 (6)			
Setting goals and first steps to improve diet and PA	29(88)	2 (6)	2 (6)		
Telephone sessions	31 (94)	2 (6)			
			n, %		
Agreement scale (n=33)	Agree a lot	Agree	Disagree	Disagree a lot	
Information was easily understood	20 (61)	13 (40)			
The program helped me improve my diet	19 (56)	14 (42)			
The program helped me be more active	15 (45)	18 (55)			
It was easy to meet at the Health Dept.	18 (55)	15 (45)			
I would recommend this program	17 (52)	16 (48)			
The cost of the suggested foods is too high	2 (6)	11 (33)	20 (61)		
I did not like the taste of the suggested foods	2 (6)	9 (27)	22 (67)		
My family did not like the suggested foods	1 (3)	10 (30)	21 (64)	1 (3)	
I don't know how to prepare meals with the suggested foods	2 (6)	5 (15)	26 (79)		
I don't have time to prepare meals with the suggested foods	1 (3)	4 (12)	27 (82)	1 (3)	
The Spanish in the study manual was understandable and adequate for me	19 (58)	14 (42)			

Note: N/A, not applicable and PA, physical activity.

Table 4

Dietary and physical activity outcomes.

	Baseline Mean ± SD	Follow-up Mean ± SD	Mean difference, 95% CI ^a
Dietary			
Total fat score ($n = 36$)	10.4 ± 1.4	10.9 ± 1.1	0.5 (0.0–1.1)
Fruit/vegetable Servings/day ($n = 36$)	3.3 ± 1.4	4 ± 1.6	0.7 (0.1–1.3)
Fiber grams/day $(n = 36)$	14.7 ± 3.7	16.7 ± 4.2	2.0 (3.3 to 0.7)
Physical activity ^b			
Moderate min/week ($n = 21$)	76 ± 66.7	118 ± 137.6	42 (-5.5-89.5)
Vigorous min/week (n = 10)	114 ± 111.8	127 ± 112.3	13 (-32.4–58.3)

Note: SD, standard deviation.

 $^{{}^}a3$ months follow-up minus baseline, 95% confidence interval.

 $^{^{}b}$ Physical activity (minutes/week) calculated only for those participants who did at least 10 minutes per week of moderate/vigorous physical activity.