HHS Public Access

Author manuscript

Diabetes Educ. Author manuscript; available in PMC 2018 June 01.

Published in final edited form as:

Diabetes Educ. 2017 June ; 43(3): 286–296. doi:10.1177/0145721717706030.

Feasibility and acceptability of a clinic-based Mediterranean-style diet intervention to reduce cardiovascular risk for Hispanic Americans with type 2 diabetes

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Abstract

Purpose—The purpose of the study was to modify a previously tested Spanish language version of a Mediterranean (Med)-style dietary intervention so that the dietary recommendations align with the cultural and social needs of Hispanic Americans (HAs) with type 2 diabetes (T2D) and evaluate the modified intervention's feasibility and acceptability.

Methods—In phase I (formative), semi-structured interviews and focus groups were used to refine the intervention content and format for delivery to HAs with T2D receiving care at a large primary care practice. In phase II (clinical pilot), the 2-month intervention that promoted a Medstyle dietary pattern was given to all participants via 2 face-to-face counseling sessions and 2 telephone counseling sessions. Major outcomes were engagement with study activities and intervention acceptability; dietary behavior change at 2 months using the PREDIMED Med-diet score (range, 0–14, higher indicating better dietary pattern) is also reported.

Results—From clinic records, we identified 86 potentially eligible participants and enrolled 21. Baseline characteristics were: mean age = 52 years, 12 (57%) female, 15 (71%) from Mexico, mean years in the US = 19, low acculturation scores for all, and mean BMI = 33.7 kg/m2. Engagement and acceptability were high, with 19 (90%) completing all intervention visits and follow-up measures, all of whom would recommend the program to others. Mean Med-diet score improved from 5.7 to 7.9 (difference = 2.3; 95% CI, 1.0–3.5; P = .001).

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Conclusions—Intervention engagement and acceptability were high, and there was improvement in self-reported dietary behaviors. This type of intervention should be evaluated in randomized trials enrolling HAs with diabetes.

Hispanic Americans (HAs) now constitute the largest racial or ethnic minority group in the US[1] and are disproportionately affected by diabetes compared to non-Hispanic white Americans.[2–8] Approximately 13% of HAs in the US have been diagnosed with diabetes, a rate almost twice that of non-Hispanic whites (7.6%) and similar to that for African Americans (13.2%).[9] Disparities also exist in diabetes control for HAs,[10] leading to a higher mortality rate[11] and diabetes-related comorbidities. [11] Poor quality dietary intake is a major contributor to obesity, poor glycemic control, and increased cardiovascular disease (CVD) risk among HAs with diabetes, particularly for those who have experienced a nutrition transition to a more Westernized food culture.[8,12–17] Thus, dietary interventions are needed that improve glycemic control[18] and reduce the risk for CVD events among HAs with diabetes.[19]

During the past 20 years, observational studies have demonstrated that the Mediterranean (Med)-dietary pattern has a favorable impact on diabetes risk, diabetes metabolic control, and cardiovascular health.[20–23] With the publication of the PREDIMED randomized controlled trial[19] in 2013, there is now robust evidence that a Med-dietary pattern supplemented with nuts or olive oil lowers CVD risk in those with and without diabetes, as those in the PREDIMED intervention arms experienced a 30% reduction of major CVD events compared to those receiving the control diet. Although studies of Med-diets have been conducted in the US, most of these modified the dietary pattern to reduce fat intake[24] as per older guidelines,[25] and few, if any (and none to our knowledge among HAs), have tested a higher fat diet as evaluated in the PREDIMED trial. Thus, there is strong scientific rationale for translational research to develop and evaluate a dietary intervention to promote a Med-dietary pattern for HAs with diabetes.

In this article, we report the results of the EnForma-Diabetes feasibility study, which had 2 major objectives: first, to modify a previously tested Spanish version of a Med-dietary pattern intervention developed for residents of North Carolina[26] so that the dietary recommendations aligned with the cultural and social needs of HAs with type 2 diabetes (T2D) who reside in North Carolina, and second, to conduct a feasibility study enrolling HAs with T2D to assess engagement with study activities, intervention acceptability, and self-reported lifestyle change at the 2-month follow-up visit. The setting of this study in the southeastern US is appropriate as this region has become a new preferred destination for migration of Hispanics.[27] Of the southeastern states, North Carolina ranks second highest in Hispanic population (8.8%) and ranks 11th in the nation.[27,28] Further, since the 1990s, the southern United States has accounted for the largest percentage growth in Hispanic population.[29]

Methods

Overview and Setting

This study was conducted in 2 phases. The purpose of phase I, the formative phase, was to further refine the content of the intervention for cultural appropriateness and the format of the intervention for delivery in a primary care practice setting. The purpose of phase II, the clinical pilot phase, was to assess the feasibility and acceptability of the adapted Med-diet intervention when given to HAs with T2D. This phase utilized a single-group, pre-post study design. Phase I participants were recruited from the community and from a large academic primary care internal medicine practice located in central North Carolina. Phase II participants were recruited solely from the internal medicine practice. The University of North Carolina at Chapel Hill Institutional Review Board approved and monitored the study, with phase I data collected from February to July 2015 and phase II data collected from September 2015 to February 2016.

Description of Previously Tested

Intervention—The English version of the intervention, described in detail elsewhere,[26] 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), consistent with the evolving literature on the importance of fat and carbohydrate quality in reducing CVD risk.[30–34] Of note, the intervention's dietary recommendations were similar (virtually identical on 9 of the 13 major recommendations of the nut intervention arm)[26] to the intervention diets evaluated in the recently completed PREDIMED randomized trial.[19] The English version of the intervention was recently evaluated in the Heart Healthy Lenoir Project, conducted in eastern North Carolina.[26]

The Heart Healthy Lenoir invervention, which focused on improving diet quality and increasing physical activity, was very well received by participants and yielded substantial improvement in self-reported lifestyle behaviors.[26] This intervention was adapted for the Enforma study,[35] which was designed to assess the acceptability and feasibility of a Spanish version of the intervention. Enforma study participants were younger HA females enrolled at a family planning clinic located in eastern North Carolina.

For the Enforma study, the Heart Healthy Lenoir curriculum was adapted 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.[36] Adaptation included structured interviews with bilingual/bicultural health department staff and 2 focus groups with HA patients receiving care at the health department. This formative work initially explored dietary preferences of the target population; solicited culturally relevant suggestions for revisions to the pictures, illustrations, and food terms used in the English version of the intervention; and assessed appropriateness of the proposed study name, EnForma. Informed by these discussions, a

Spanish version of the intervention was drafted, and focus group participants were invited to comment on the appropriateness of the Spanish translation and cultural relevancy of the content. With this feedback, another phase of further cultural and linguistic adaptation was conducted to develop the final version of the Enforma intervention for testing. The materials developed for this intervenion were well received in the pilot study to assess the intervention's feasiblity and acceptability.[35] These materials were then further refined for the current study, EnForma-Diabetes, for use with our target populaiton of older HA pateints with T2D.

Phase 1—Formative Phase: Adaptation of Original EnForma Intervention— EnForma-Diabetes was adapted from the EnForma intervention through a sequential process. First, the dietary content of the intervention was revised to be appropriate for patients with T2D based on (1) interviews with clinical staff who regularly provided care to HA patients with T2D and (2) the literature on diet and health outcomes for patients with diabetes and current guidelines from the American Diabetes Association.[19,37–39] Then, cultural and linguistic refinements for HAs with T2D were addressed through interviews with HA food preparers and focus groups with HA patients diagnosed with T2D.

The objective of the interviews with clinic health care providers was to (1) better understand providers' perceptions regarding existing dietary patterns among HAs, including facilitators and barriers to improving dietary patterns among HAs with T2D, and (2) get feedback on the proposed Med-diet intervention. Providers were asked questions, including: What factors have you noticed contribute to better diabetes control among HA patients? What barriers do HA patients report facing when implementing nutrition recommendations? After providing a description of the proposed intervention, along with sample materials, providers were asked for feedback regarding acceptability of the Med-dietary pattern and feasibility of the planned intervention for their HA patients.

Semi-structured interviews were conducted with HA food preparers with the purpose of identifying a range of HA dietary patterns to inform the adaptation of intervention materials and exploring the acceptability of a Med-dietary pattern among HA food preparers. HA food preparers, who cooked for at least 1 member of the household who had T2D, were recruited through fliers, which were posted on community bulletin boards or distributed by Spanish-speaking lay health advisors. Interviewees were asked to describe common meals prepared for family members (including those with T2D), cooking methods, and types of oils used to prepare food. Following a description of the Med-dietary pattern, interviewees were asked to provide general feedback, challenges to incorporating dietary recommendations, and the type of information needed to increase knowledge about the Med-dietary pattern.

Objectives of the focus groups with HAs living with T2D were to obtain existing knowledge on new dietary guidelines with a heightened emphasis on fat quality, learn about cultural and family norms that may impact dietary adherence, and assess interest, acceptability, relevance, and appeal of the proposed intervention to the target population. Hispanic Americans with T2D were recruited for these focus groups through the same approach used to recruit HA food preparers. During focus groups, participants were asked to share the nutrition recommendations they had received on fats and oils, discuss the influence exerted

by family members on meal planning and preparation, and comment on the importance of incorporating family and cultural dietary preferences in a dietary intervention. In addition, the proposed intervention format was described, and a draft version of intervention materials was reviewed. Then, participants were asked to provide feedback on the acceptability of the intervention to HAs with T2D and the feasibility of the counseling session structure and intervention delivery format.

Phase II—Clinical Pilot Pre-post Study—For phase II, a convenience sample from a clinic registry listing participants with diabetes were recruited. Registry queries identified Hispanic patients 21 to 99 years of age with T2D (ICD-9: 250.00). The patients' primary care providers were asked to review and approve recruitment of their patients for this study (none were excluded). Potential participants were mailed an opt-out letter describing the study as a research project to evaluate a Spanish language intervention that promotes healthful foods for patients with diabetes. After the mailing, we contacted potential participants by phone to assess interest. In addition to having a diagnosis of T2D, participants also needed to report a Spanish language preference. Exclusion criteria, assessed by self-report, were severe kidney disease, cancer other than non-melanoma skin cancer, pregnancy or planning to become pregnant in the next 6 months, or a serious medical condition aside from CVD. Recruitment was conducted from September 2015 to December 2015.

As depicted in Figure 1, during the first session, the counselor provided an overview of the program, administered a dietary questionnaire to guide counseling, and reviewed the dietary content for session 1, which included information on oils, dressings, nuts, fish, and meats. At the conclusion of the session, a tailored action plan was co-developed by the counselor and the participant by (1) highlighting potential areas for dietary improvement as identified by the dietary assessment, (2) reviewing pertinent dietary tips for addressing the areas for improvement, and (3) selecting 2 achievable goals to work on before the next counseling session. For each goal, the participant received assistance from the counselor in identifying early steps to achieving the goal. The steps were written on a goal sheet that also included monitoring check boxes for daily success at achieving the goals over the next month. The second counseling session, held a month after the first, followed a similar format but addressed dietary information related to beverages, desserts, fruits and vegetables, grains, and beans.

Telephone sessions were held 2 weeks after each counseling session and lasted approximately 15 minutes. These calls focused on identifying facilitators and barriers to reaching goals and problem solving to identify ways to overcome barriers and reach selected goals. These sessions were tailored to the specific lifestyle goals selected by each participant.

Study Measures

At the beginning of both study phases, all participants gave written informed consent. Phase I measures included structured interview with HA food preparers, focus groups with HA patients who have T2D, and interviews with clinic health professionals serving HA patients.

For phase II, baseline measures included demographic information, level of acculturation assessed by the Marin Short Acculturation Scale,40 and height obtained from the medical record. Pre and post measures included weight assessed by electronic scale at the clinic (Scale-Tronix, Skaneateles Falls, New York), blood pressure assessed after being seated for 5 minutes with 3 automated measurements obtained (Omron HEM-907XL, Omron Healthcare, Lake Forest, Illinois) at 60-second intervals and averaged, and hemoglobin A1C (A1C) assessed by the hospital clinical laboratory. In addition, questionnaires were administered to assess health-related quality of life,[41] physical activity,[41] tobacco use, food financial security, and Med-diet adherence using the 14-item PREDIMED dietary screener.[42] Follow-up questionnaires assessed program acceptability and changes in medication use. Feasibility was assessed through recruitment yield and participant retention rates. Participants received $30 for completion of session 1, $40 at completion of session 2, and $50 at completion of the 2-month follow-up measurement visit.

Sample Size and Statistical Analyses

For the clinical pilot phase, a sample size of 30 was selected to assess the feasibility and acceptability of the intervention and get estimates of variance for outcome measures. Descriptive statistics were used to describe baseline demographic and health characteristics, and 95% confidence intervals are reported for change in pre-post measures. Statistical analyses were performed with Stata software (Release 13, College Station, Texas).

Results

Phase I: Adaptation of Original

EnForma Intervention

Enrollment and Baseline Characteristics of Participants: To obtain feedback on the program structure and dietary content, 3 individual interviews were conducted with health care team members of the clinic, including a Spanish-speaking diabetes care assistant, a Spanish-speaking nurse practitioner, and the clinical dietician who provides dietary counseling for patients. All emphasized counseling on portion size instead of focusing on foods to cut from the diet. The dietician and nurse practitioner recommended that the materials incorporate culturally acceptable foods for various HA groups and dispel myths of the HA diet as being unhealthy. The dietician also recommended that the program include a second face-to-face visit approximately 4 weeks after the initial visit.

To solicit feedback on the cultural and linguistic refinement of the program materials, 6 individual interviews were conducted with HA food preparers, 5 of whom had T2D. All emphasized the need to incorporate traditional foods such as rice, beans, and tortillas into the program. When asked about incorporating heart-healthy oils and nuts into their meals, most interviewees reported a willingness to use these ingredients in their recipes but expressed a need for specific examples or recipes to follow.

After incorporating feedback obtained through individual interviews, we conducted 2 focus groups among 11 individuals with T2D, facilitated by a bilingual and bicultural member of the team. The objective of the focus groups was to assess acceptability of the program

structure, delivery format, and materials. Participants expressed a preference for in-person visits with the counselor over telephone calls and approved of the goal setting aspect of the program. Some participants recommended the use of education on nutrition labels. They also indicated the importance of incorporating culturally acceptable foods into the program since they would be more likely to receive support from family members for the proposed dietary changes when everyone consumes similar foods.

Phase II: Clinical Pilot Pre-Post Study

Enrollment and Baseline Characteristics: As depicted in Figure 1, 86 potentially eligible patients were identified, all of whom were mailed an opt-out letter with none opting out of being called by study staff. Fiftyfive of 86 (64%) patients were successfully contacted by telephone to gauge their interest and eligibility for the study. Nineteen individuals were not interested in participating, and 9 were ineligible. Twenty-seven of those eligible and interested (49%) agreed to take part in the study, but 6 did not show for the enrollment visit.

Twenty-one participants were enrolled, whose characteristics are summarized in Table 1. Participants had a mean age of 52 years, 12 (57%) were female, 15 (71%) reported Other/Hispanic as their race and ethnicity, 15 (71%) were from Mexico, and the mean years in the US was 19 years. Fourteen (67%) had an annual household income of <$20 000, 15 (71%) had less than high school education, 14 (67%) were uninsured, and 17 (81%) lived with a spouse or partner. All 21 (100%) participants had low acculturation. The mean years since diagnosis of T2D was 8, mean weight was 82 kg, mean BMI was 33.7, and mean A1C was 7.9% (63 mmol/mol). Participants lived on average 35 miles (range, 2–91 miles) from the clinic. At baseline, participants had a moderately low average Med-diet adherence score, 5.7.

Intervention Participation and Acceptability—Participation rates for study visits was high—participants attended 40 of 42 possible counseling sessions (95%) and completed 40 out of 42 possible phone contacts (95%) (Figure 1). On average, the first intervention visit lasted about 45 minutes and the second about 30 minutes, with phone calls lasting about 15 minutes. Among those (n = 19) completing the 2-month follow-up survey, the individual components of the intervention were well received. Eighteen (95%) strongly agreed and 1 (5%) agreed with the statement, “I would recommend the program to others.” Regarding intervention format, 15 (79%) responded “just the right amount” of information was given, and 18 (95%) reported that “just the right” number of sessions were held as part of the program. Eighteen (95%) reported that the Spanish used in study documents was understandable and adequate, and 17 (90%) responded “Yes, a lot” when asked if the examples in the EnForma-Diabetes manual were relevant to their culture. Participants were also asked what motivated them to take part in this study. Among those responding (n = 18), 17 (94%) strongly agreed and 1 (6%) somewhat agreed with the following statements: “interest in my personal health” and “interest in learning more about nutrition.”

Lifestyle and Physiologic Outcomes

Table 2 outlines the dietary goals, with participants selecting 2 goals per session. At session 1, the most commonly selected goals were “Eat at least 3 portions of nuts every week” 14 (67%), “Eat at least 1 portion of fish every week” 11 (52%), and “Eat at least 3 portions of

full fat dressing and/or mayonnaise every week" 10 (48%). During session 2, the most commonly selected goals were "Try to eat 4 or more portions of vegetables weekly" 16 (84%) and "Choose whole grains options, at least 2 portions a day" 12 (63%).

Table 3 reports the change in the total Med-diet adherence score and change in the 14 individual items. Overall, the mean score increased (indicating better dietary pattern) from 5.7 to 7.9 for a difference of 2.3 (95% CI, 1.0–3.5), P = .001. In addition, there were statistically significant increases (improvement) in the following individual items: carbonated and/or sugar-sweetened beverages consumed per day, servings of fish/seafood consumed per week, and legumes and nut consumption per week. Table 4 shows additional lifestyle outcomes and physiologic outcomes, which were little changed.

No adverse effects of the diet were reported. Also, only 1 patient reported a change in medication for diabetes (increase in dose of metformin).

Discussion

The EnForma-Diabetes adapted dietary intervention proved to be feasible and acceptable to study participants. Overall, the retention and completion rates were high for all study components. Further, among those who returned for the end of study assessment visit, acceptability was high, and there was statistically significant improvement in self-reported adherence to an adapted Mediterranean-style (Med-style) diet, as assessed by the PREDIMED 14-item Med-diet score.42 In this 2-month study with a small sample size, there were no material changes in the measured physiologic outcomes.

This study reports a 2-point increase in the 14-item PREDIMED Med-diet score that was statistically significant and similar in size to that reported for the experimental arms of the PREDIMED study.[42] In addition, there were significant changes for several individual items on the screener, all in the desired direction. Though these results are self-reported, they suggest that participants understood the dietary recommendations and took steps to change their dietary behaviors. Greater adherence to a Med-style dietary pattern was also observed in the intervention group of another study designed for HA patients (post-menopausal women living with diabetes). However, in contrast with Enforma-Diabetes, that dietary intervention sought to increase adoption of a low-fat dietary pattern and required participation in weekly 4 hour meetings over a 6-month period.[43]

The intervention format, which included both face-to-face and phone counseling, was well received by participants, as was a similar format with younger HA patients.[35] Another culturally adapted intervention for Hispanics with diabetes achieved moderate to high adherence to intervention components delivered using a face-to-face intervention approach.[44] Findings provide additional support that HAs with diabetes are likely to benefit from a patient-centered approach that is delivered within clinical settings designed to support behavioral change, such as patient-centered medical homes.[45,46] In addition to the acceptability of format, our findings also support the acceptability of a higher fat dietary pattern to study participants.

This study has several limitations. Though study engagement and acceptability were high, the intervention only included 2 face-to-face study visits. However, an intervention with more study visits, given over a longer timeframe typical of most lifestyle intervention, may not be able to sustain this level of engagement. With regard to changes in self-reported and physiologic outcomes, our pre-post study design without a control group limits our ability to interpret results as the observed changes may have occurred due to secular trends or other factors. Further, many outcomes are self-reported, which may be exaggerated due to social desirability reporting bias. Also, we present many comparisons, and some P values may be significant by chance. The study sample was small and included participants from only 1 clinical site. Finally, the intervention was given by 1 counselor, all of which limits the generalizability of findings.

Practice and Research Implications

Increasing evidence suggests a Med-style dietary pattern can substantially reduce CVD among patients with diabetes.[19] Thus, there is a compelling need to develop and evaluate evidence-informed Med-style dietary interventions that are culturally appropirate and acceptable to the rapidly growing population of HAs with diabetes. This study found that the adapted EnForma-Diabetes intervention was both feasibile and highly acceptable to study participants and yielded substantial improvement in self-reported dietary behaviors. As the intervention is evidence-infomred, it is appropriate for use in clinical practice at this time. However, larger controlled trials are needed to formally test the effectiveness of this intervention on dietary, cardiometobolic, and clinical outcomes among HAs with diabetes.

Acknowledgments

Funding Support: The research was supported by Grant No. P30DK093002 from the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (NIH), to the University of North Carolina at Chapel Hill (UNC). Other support was provided by Centers for Disease Control and Prevention (CDC) cooperative agreement No. U48/DP001944 to the UNC Center for Health Promotion and Disease Prevention (a CDC Prevention Research Center).

The authours thank Shari Sibenge, RD, Elizabeth Prata, FNP, Bailey A. Minish, BS, and Larry F. Johnston, MA, for their contributions to this research project and study participants, whose willingness to participate made this study possible.

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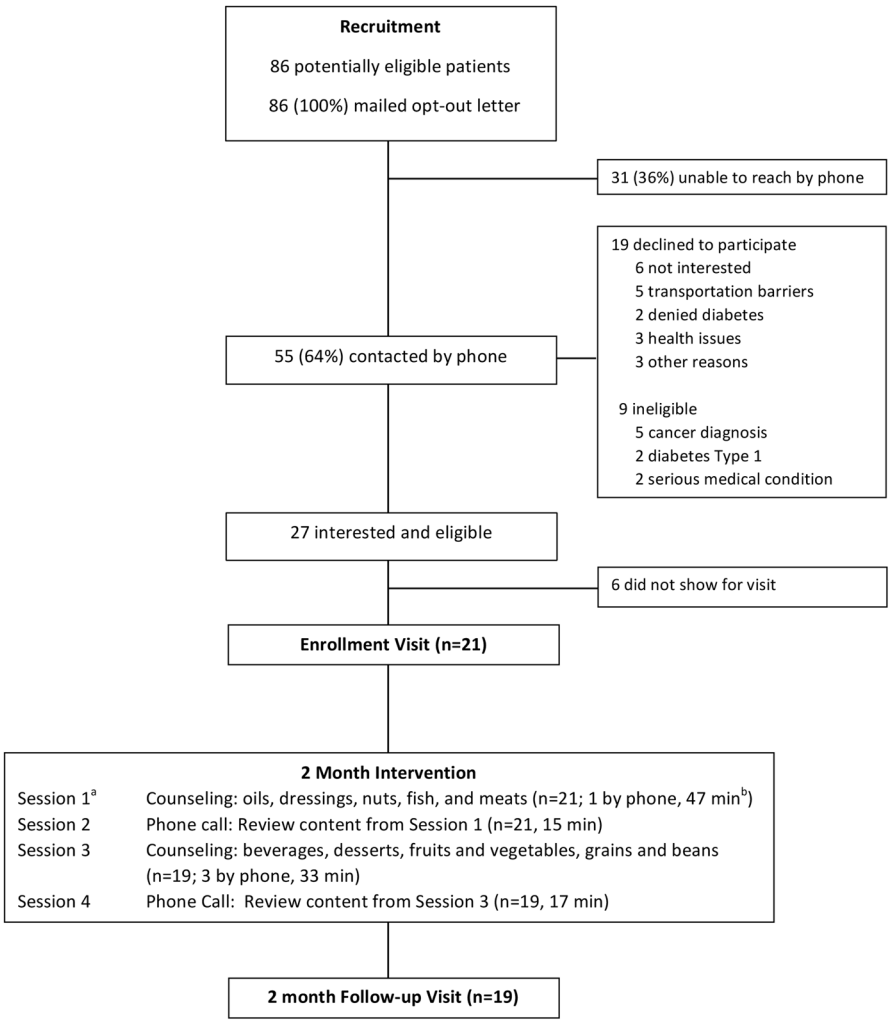

Figure 1.
EnForma-Diabetes study flow diagram.

Table 1

Participant Characteristics at Baseline (n=21)

Characteristics	Mean ± SD, n (%), or range
Demographic	
Age, y	52.3 ±8.2
Sex	
Male	9 (43)
Female	12 (57)
Country of Birth	
Mexico	15 (71)
Central America	4 (19)
South America	2 (10)
Years in US	19 ± 5.8
Annual Household Income	
<$20,000	14 (67)
$20,000 or more	7 (33)
Education	
Less than High School	15 (71)
High School or more	6 (29)
Health Insurance	
Medicare	2 (10)
Medicaid	1 (5)
Private	3 (14)
None	14 (67)
Living with spouse or partner	17 (81)
Low acculturation	21 (100)
Miles between residence and clinic	35.5 (range, 2 – 91)
Years since Type II diagnosis	8.0 ± 4.2
MedDiet adherence score[a]	5.7 ± 2.2
Physiologic	
Weight, kg	82 ± 12.8
BMI, kg/m^2	33.7 ± 5.21
Systolic blood pressure, mm Hg	128 ± 15.3
Diastolic blood pressure, mm Hg	83 ± 10.8
Hemoglobin A1C, %	7.9 ± 2.1
Hemoglobin A1C, mmol/mol	63 ± 23.0

[a]The score for adherence to the Mediterranean diet is based on the 14-item PREDIMED dietary screener (0 indicates minimum adherence, 14 indicates maximum adherence).

Table 2

Choices of Session Goals[a]

Goals	Participants: n (%)
Session 1 (21 participants)	
Eat at least 3 portions of nuts every week	14 (67)
Eat at least 1 portions of fish every week	11 (52)
Eat at least 3 portions of natural dressing and/or mayonnaise every week	10 (48)
Use healthy fats to fry, stew or bake	3 (14)
No more than 2 portions of red meat per day	3 (14)
Reduce consummation of processed meat	1 (5)
Choose margarine without trans fat	0
Session 2 (19 participants)	
Try to eat 4 or more portions of vegetables weekly	16 (84)
Choose whole grains options, at least 2 portions a day	12 (63)
Choose healthy drinks	3 (16)
Careful with chips and cookies. Choose the ones made with vegetable oil	3 (16)
Eat legumes at least 3 times a week	3 (16)
Choose whole grains options for breakfast, at least 3 portions per week.	1 (5)
Choose healthy options for snacks and desserts	0
No more than 2 portions of cold or frozen dessert per week	0
Goal 6: Try to eat 3 different fruits every day	0

[a]Participants were asked to select two achievable goals at each session. All potential goals for each session are listed.

Table 3

Changes in Adherence to the Mediterranean (Med)-diet at 2-month Follow Up (n=19) as assessed by the Med-diet adherence questionnaire

Outcomes	Baseline Mean or n (%)	Final Mean or n (%)	Difference (95% CI)	*P* Value
Med-diet adherence score[a]	5.7	7.9	2.3 (1.0 to 3.5)	.001
Individual Med-Diet Adherence Items				
Do you use olive oil as the principal source of fat for cooking? (Yes)	8 (42)	16 (84)	42 (15% to 70%)	.11
How much olive oil do you consume per day, including that used in frying, salads, meals eaten away from home, etc? (tablespoons)	1.3	2.1	0.8 (−0.1 to 1.8)	.08
How many servings of vegetables do you consume per day? (1 serving = 1/2 cup cooked or 1 cup raw)	2.1	2.1	0.1 (−1.1 to 1.2)	.90
How many pieces of fruit, including fresh-squeezed juice, do you consume per day?	1.5	1.9	0.4 (−0.4 to 1.2)	.30
How many servings of red meat, hamburger, or sausages do you consume per day? (1 serving = 3 oz)	0.8	0.7	−0.1 (−0.4 to 0.6)	.67
How many servings of butter, margarine, or cream do you consume per day? (1 serving=1 teaspoon)	0.4	0.4	0.1 (−0.4 to 0.3)	.75
How many carbonated and/or sugar-sweetened beverages do you consume per day? (1 drink = 12 oz)	0.6	0.2	−0.4 (0.1 to 0.7)	.02
Do you drink wine? How much do you consume per week? (glasses)	0.3	0.3	0.1 (−0.4 to 0.5)	.80
How many servings of legumes do you consume per week? (1 serving = ½ cup)	3.5	5.4	1.9 (0.3 to 3.5)	.02
How many servings of fish/seafood do you consume per week? (1 serving = 2 –3 oz)	1.5	2.5	1.0 (0.3 to 1.7)	.01
How many times do you consume commercial (not homemade) pastry, such as cookies or cake, per week?	1.3	1.0	−0.3 (−0.3 to 0.9)	.27
How many times do you consume nuts per week?	1.4	3.8	2.4 (1.3 to 3.5)	<.001
Do you prefer to eat chicken, or turkey instead of beef, pork, hamburgers, or sausages? (Yes)	17 (90)	18 (95)	5% (−12% to 22%)	.73
How many times per week do you consume boiled vegetables, pasta, rice, or other dishes with a sauce of tomato, garlic, onion, or leeks sautéed in olive oil (*sofrito*)?	2.6	2.8	0.2 (−1.2 to 1.5)	.80

[a]The score for adherence to the Mediterranean diet is based on the 14-item PREDIMED dietary screener (0 indicates minimum adherence, 14 indicates maximum adherence).

Table 4

Changes in Selected Lifestyle Behavior and Physiologic Outcomes at 2-month Follow Up (n=19)

Outcomes	Baseline (Mean)	Final (Mean)	Difference (95% CI)	*P* Value
Lifestyle Behavior				
How many nights did you make dinner at home?	4.4	4.9	0.5 (−1.1 to 2.0)	.53
During a typical day, how many meals do you eat per day?	2.7	2.8	0.1 (−0.2 to 0.4)	.43
During a typical week, how many times do you eat fast food?	1	0.6	−0.4 (−1.1 to 0.3)	.22
Physiologic				
Weight, kg	82	82	0.0 (−0.5 to 0.5)	.99
Systolic blood pressure, mm Hg	129	129	−0.6 (−8.1 to 7.0)	.87
Diastolic blood pressure, mm Hg	83	83	0.1 (−4.5 to 4.8)	.96
Hemoglobin A1C, %	7.5	7.7	0.3 (0.0 to 0.6)	.07
Hemoglobin A1C, mmol/mol	58	61	3.3 (0.0 to 0.6)	