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Rationale and Study Protocol for a *Unidas por la Vida* (United for Life): A dyadic weight-loss intervention for high-risk Latina mothers and their adult daughters

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Abstract

Background—Half of Mexican-American women are under-active, and nearly 78% are overweight/obese. The high lifetime risk of developing type 2 diabetes necessitates a culturally appropriate lifestyle intervention.

Purpose—Unidas por la Vida is a novel dyadic intervention that capitalizes on the centrality of family in Latino culture to mobilize an existing family dyad as a resource for health behavior change. The intervention aims to improve health behaviors and promote weight loss in two at-risk members of the same family: mothers with type 2 diabetes and their overweight/obese adult daughters who are at risk for developing diabetes.

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Methods—Participants (N=460 mother-adult daughter dyads) will be randomized into one of three conditions: 1) dyadic participation (mothers-daughters) in a lifestyle intervention; 2) individual participation (mothers alone; unrelated daughters alone) in a lifestyle intervention; and 3) mothers-daughters dyad in a usual care only condition.

Results—The primary outcome is weight loss. Secondary outcomes include physical activity, dietary intake, physiological measures (e.g. HbA1c), and body composition. Both the dyadic and individual interventions are expected to produce greater weight loss at 6, 12, and 18 months than those in usual care, with women assigned to the dyadic intervention expected to lose more weight and to maintain the weight loss longer than women assigned to the individual intervention.

Conclusion—Because health risks are often shared by multiple members of at-risk families, culturally appropriate, dyadic interventions have the potential to increase the success of behavior change efforts and to extend their reach to multiple family members.

Trial registration—ClinicalTrials.gov identifier NCT02741037

Keywords

Type 2 diabetes; obesity; behavioral weight loss; Latino/Hispanic; family intervention; dyadic intervention; diabetes prevention program

1.0 Background

Lifestyle and culture combine to place Mexican-American women at increased risk for having diabetes and for developing complications. Approximately half of Mexican-American women report no leisure time physical activity,¹ and they are more likely than non-Hispanic White women to be overweight or obese.² Compared to women in all other U.S. ethnic groups, Mexican-American women have one of the highest lifetime risks of developing type 2 diabetes.³ This high risk may not only be related to low rates of physical activity but also to Americanization of the traditional Mexican diet.⁴ Furthermore, in the family-oriented Latino culture, daughters may also acquire beliefs and practices relevant to the development of obesity.^{5, 6} Mexican-American mothers and daughters are likely to be mutually influential and, therefore, provide an ideal focus for behavior change. Interventions that leverage these existing mother-daughter dyads have the potential to yield substantial and lasting lifestyle changes that may lead to the reduction of obesity and diabetes.

Landmark trials, such as the Look AHEAD (Action for Health in Diabetes) and the Diabetes Prevention Program (DPP), have demonstrated that an intensive lifestyle intervention resulting in modest **weight loss** and increased physical activity can improve control of cardiometabolic risk factors and is likely to be a cost-effective use of resources for persons with dysglycemia (i.e., either diabetes or pre-diabetes).⁷⁻¹³ Although these medical conditions together affect over 80 million Americans, the Look AHEAD and DPP lifestyle interventions were not designed for delivery on a population scale. Moreover, most behavior change programs, including these trials, have focused on changing individuals' behaviors.^{14, 15} The few family-based interventions conducted to date have emphasized parental involvement, with obese children or adolescents as the target population.¹⁶⁻²⁰ Although previous interventions have encouraged family involvement in support groups for diabetes

prevention and treatment, we know of no studies that target adult daughters and mothers in the same family who share a high risk for diabetes and its complications.

Thus, we developed a behavioral lifestyle intervention uniquely designed to leverage the mother-daughter relationship, *Unidas por la Vida* (United for Life), and propose to test the effectiveness of this intervention among a high-risk sample of Mexican-American family dyads: overweight mothers with type 2 diabetes and their overweight/ obese adult daughters who are at risk for developing diabetes. In this article, we report on the study design, procedures, and development of the *Unidas* intervention protocol.

2.0 Methods

2.1 Design

The proposed study is a randomized controlled trial consisting of three intervention arms: 1) mother-daughter pairs in a dyadic *Unidas* intervention (Arm 1); 2) individual mothers or individual daughters (not from the same family) in an individual *Unidas* intervention (Arm 2); and 3) mother-daughter pairs in usual care only (Arm 3). To ensure comparability of family configuration across the study arms and appropriate randomization, all women with type 2 diabetes who are recruited to the study must have an overweight/obese daughter at risk for type 2 diabetes. In Arm 2, however, only one member of these family dyads (either the mother or the adult daughter) will participate in the intervention, but both dyad members will participate in all study assessments. Stratified block sampling will be used, with randomization stratified by site and blocking on co-residence status. Participants will be assessed at baseline, 6, 12, and 18 months. Ethical approval was obtained from the Institutional Review Board at the University of California, Irvine.

2.2 Study Population and Recruitment Procedure and Enrollment

Patients identified through the electronic health record (using administrative/laboratory data) as having diabetes and/or having risk factors for diabetes (i.e. obesity, family history of diabetes, or pre-diabetes diagnoses) will be recruited for the study. Participants will be screened and consented initially as mother-adult daughter dyads, and subsequently assigned to study arms. **Inclusion criteria:** Mothers: 1) Mexican-American ethnicity; 2) BMI ≥ 25 kg/m² and ≥ 43 ; 3) diagnosed with type 2 diabetes defined by two fasting glucose ≥ 126 mg/dl or two random blood glucose ≥ 200 mg/dl, or currently being treated with insulin or oral hypoglycemic agents, or have a diagnosis of type 2 diabetes noted in their medical record (ICD-9 Code 250 or ICD-10 Code E11). Adult daughters: 1) Mexican-American; 2) age 18 or older; 3) BMI ≥ 25 kg/m² and ≥ 43 ; and 4) lives with or within a 25-mile radius of her mother. **Exclusion criteria:** Similar to the Diabetes Prevention Program's exclusion criteria,²¹ participants (mothers or daughters) with vision or hearing impairment, documented major psychiatric illness, or life-threatening illness will be excluded. In addition, participants who have contraindications to starting an exercise regimen or are predisposed to injury will also be excluded (e.g. uncontrolled hypertension, severe autonomic or peripheral neuropathy, advanced retinopathy). Individuals who meet the ADA recommendation of moderate-intensity exercise ≥ 150 minutes/week will also be excluded. In addition, adult daughters who are discovered by screening to have fasting serum glucose ≥ 126 mg/dl will be excluded

from the study and referred to their primary care physician for follow-up of newly diagnosed diabetes. Women who are pregnant or who become pregnant during the course of the study will also be excluded.

Potential participants will be recruited from two large medical providers: AltaMed Health Services and the University of California, Irvine (UCI) Family Health Center, Santa Ana. AltaMed is the largest independent Federally Qualified Health Centers (FQHCs) in the U.S. and delivers more than 930,000 annual patient visits through 43 sites in Los Angeles and Orange Counties. The UCI Family Health Center, Santa Ana/Anaheim is also a designated FQHC, and delivers more than 60,000 annual patient visits. Unlike most primary care settings, FQHCs provide enabling services for low-income patients, such as health education, behavioral health services, workforce development, senior care, pharmacy, interpretation, case management, transportation, and outreach. The FQHCs' role is central to the delivery of the Unidas program, both as a site for recruitment, consent, and assessment, and as the site for the delivery of the program. All program staff will be employees of the FQHC.

All the proposed recruitment sites are located in Orange County, CA, which has a large Mexican-American population.²² The county's Latino population is growing rapidly, is younger, and has a larger average family size (5 vs. 3 members) than the general U.S. population. Moreover, approximately 25% of the county's Latino population reports a median family income below the federal poverty line.²³ These figures underscore the need for taking a family approach to treating and preventing diabetes in this low-income, high-risk population.

2.3 Intervention

2.3.1. Conceptual model for the intervention—Theory-based behavioral interventions have been shown to promote successful health behavior change, but the mediating processes remain poorly understood,²⁴ especially among at-risk Latinos.^{25, 26} We draw upon existing research to distill mediating mechanisms most likely to be critical to health behavior change, but we extend this research to consider how the dyadic context of the Unidas intervention uniquely influences these mechanisms. A better understanding of such mediating mechanisms is essential to efforts to streamline, unpack, and disseminate future interventions.

Figure 1 illustrates the key behavior change processes that will be targeted in the intervention. These processes are grouped in three categories that have been identified in the literature as particularly important for health behavior change among women with diabetes and overweight/ obese women, including Latinas: interpersonal processes, cognitive and motivational processes, and behavioral processes.^{25, 27-33} Cells 1-3 of Figure 1 also provide an overview of our reasons for expecting the dyadic (mother-daughter) intervention to be more effective than the individual intervention in activating and sustaining these behavior change processes. Grounded in Social Learning Theory³⁴ and the Health Belief Model of behavior change,³⁵ our conceptual model proposes that people will take action if they: 1) value the perceived consequences of the behavior change^{36, 37} and 2) feel capable of making the behavior change. The Ecological Model of Behavior Change³⁸ calls attention to

the broader social-environmental context of individuals' efforts to modify their health behavior and, specifically, provides a rationale for seeking to strengthen dyadic influences on health behavior. Improving health-enhancing behaviors (cell 4), with the assistance of booster sessions (cell 5), is expected to lead to greater weight loss (cell 6) and greater maintenance of weight loss over time (cell 7). The specific mediators that we will examine, and our reasons for hypothesizing distinct advantages of the dyadic intervention, are elaborated more fully below.

Interpersonal processes: Most theories of health behavior change emphasize the importance of social support.³⁹ Social support, especially family support, has been frequently reported as crucial to the success of Mexican Americans' efforts to improve their health behaviors.^{33, 40-43} Although spouses are most likely to be the natural source of support for behavioral change in non-Hispanic white populations,⁴⁴⁻⁴⁶ the mother-daughter relationship may be a more appropriate source of support for Mexican-American women.^{6, 47} In a family-based intervention conducted in Texas, over half of Mexican-American husbands did not attend group meetings despite being encouraged to do so.⁴³ In addition to lack of time, these men viewed health and nutrition as “women's issues.” In focus group studies, Mexican-American women preferred to exercise with female family members rather than with their spouses.^{47, 48} The cultural tendency for mothers and daughters to engage in daily activities like shopping and preparing meals together can be leveraged to influence healthy behaviors. Using the synergy of this natural intergenerational bond as a point of intervention may be a powerful and culturally important way to effect change.

Moreover, although physical-activity interventions that emphasize social support have been found to increase physical activity and access to social support, it is common for social support to decline after group members or the interventionist, who are not part of participant's natural/existing networks, stop contact with the participant and are, therefore, no longer accessible to provide support.³³ Thus, finding ways to sustain effective social support over time is an important intervention goal. Obesity tends to occur in families, and may be associated with family members' nutritional and exercise habits, food preferences, and caloric intake.⁴⁹ Mexican-American family members are more likely to eat meals together than are whites (also see <https://www.childtrends.org/indicators/family-meals/>).⁵⁰ Family-based interventions that target multiple family members may be more culturally appropriate for Mexican-American women than an individually-focused intervention,^{43, 51, 52} and these interventions have been successful in lowering cholesterol and blood pressure among Mexican-American children.⁵¹ One of the few studies that tested a family-based intervention for weight loss found a trend for greater weight loss among those in the family-based group compared to the individual group.⁴³ The proposed study accordingly seeks to capitalize on a natural and important family dyad (mothers and their adult daughters) as a source of support that is likely to persist over time. Moreover, because both members of the dyad share similar health behavior goals, they are more likely to experience support that is readily available and responsive to their needs. Participants in the partner intervention are also less likely to experience threats to self-esteem or other psychological costs that have been found to be associated with seeking support from others who do not

share, and may not understand, the challenges associated with initiating and sustaining health behavior change.⁵³⁻⁵⁵

Family members and others can also influence another person's health behavior change through social control, or close monitoring and feedback directed toward a person engaged in behavior change attempts.⁵⁶ Such control can be effective in prompting improved health behavior if it is not demeaning or harsh.^{57, 58} Social control that occurs in the context of a close family dyad in which both individuals share common behavior change goals and face similar challenges (as in the partner intervention) is likely to be more constructive and, therefore, more likely to foster behavioral improvement without harming self-efficacy.

It is also important to recognize that family members and others can have detrimental, rather than beneficial, effects, on another person's health behavior change efforts. Whether or not they intend to do so, family sometimes offer unhealthy foods to individuals who are seeking to improve their diet, interfere with their exercise plans, or criticize or express disregard for their efforts to make needed improvements in their health behavior.^{39, 59, 60} Such social undermining has been found to be associated with worse treatment adherence among individuals with type 2 diabetes.^{39, 59} Interventions that help participants anticipate and prevent or resist actions by others that disrupt their health behavior change efforts should contribute to better health outcomes. By serving as allies, we anticipate that mothers and daughters in the partner intervention, compared to participants in the individual intervention, will be able to help each other ward off or counteract such undermining and, as a result, will experience greater success in sustaining their behavior change efforts with fewer setbacks.

Cognitive and motivational processes: Cognitive and motivational processes provide a foundation for health behavior change and warrant attention in intervention studies directed toward diet and/or physical activity. Processes likely to be affected by the intervention include increases in knowledge, changes in perceptions of benefits and barriers to behavior change, and increases in motivation and self-efficacy.^{31, 61, 62} Limited knowledge of healthy food and exercise guidelines hinders successful health behavior change. Previous studies have shown that Latinas desire more education about how to cook healthier versions of traditional dishes and how to prepare nutritious food on limited budgets.^{48, 63} They also want to learn strategies for integrating more physical activity into their daily routines and family life.^{47, 48} Acquiring such information collaboratively in a dyadic context is likely to be especially effective in reinforcing participants' learning.⁶⁴

Efforts to influence perceptions of the benefits of, and barriers to, making health behavior changes need to be culturally tailored.²⁵ With respect to benefits, Latinas appear to be motivated to adopt healthy lifestyle habits not only to improve their own health but also, importantly, to improve the health of their families. If Latinas believe that improving their health is desirable because it will allow them to live longer to take care of their families, they derive satisfaction from exploring ways to improve their diet and physical activity.⁶⁵ The perceived benefits to the family of improving one's own health behavior are likely to be more salient in an intervention shared with a close family member (i.e., a daughter or mother). Moreover, women in the partner intervention can remind each other, during *and* after the intervention, of the personal and family benefits of improving their health by

modifying their health behaviors. This strong commitment to family needs and obligations can also hinder some Latinas in their efforts to adopt healthier lifestyles, if they believe that doing so has a cost to their family (i.e. interferes with family responsibilities or suggests too much self-focus).⁶⁶ The Unidas intervention accordingly will emphasize that improving one's own health and assisting a daughter (or mother) in improving her health contribute to the current and future well-being of the family. Other barriers to health behavior change among Mexican-American women include "obesity-tolerant" attitudes (e.g., lower importance ascribed to weight control, a lower likelihood of perceiving oneself as overweight) that may limit the motivation for weight loss attempts.⁶⁷⁻⁶⁹ Furthermore, the belief that exercise has negative effects (e.g., fatigue, shortness of breath) may deter Latinas' participation in physical activity.⁶⁵ Addressing such attitudes and beliefs is likely to benefit all intervention participants, but the dyadic intervention will allow mothers and daughters to reinforce new understandings that shift the relative importance of benefits and barriers to health behavior change. This collaborative dyadic process should boost and help to sustain motivation for behavior change efforts, contributing to greater maintenance of health behavior improvements over time.

Self-efficacy, or confidence in one's ability to improve one's health behavior and to maintain improvements in the face of obstacles, is also widely regarded as essential to successful behavior change efforts⁷⁰⁻⁷³ and diabetes self-management.^{27, 74} Moreover, self-efficacy, social support, and problem-solving have been found to make independent contributions to improved diabetes self-management in previous intervention studies.²⁹ We anticipate that gains in self-efficacy are most likely to be achieved and sustained in the dyadic intervention because, by virtue of their shared behavior change goals, the dyad members will be able to share and assist with strategies for overcoming obstacles to improved diet and exercise. They will also be uniquely positioned to express confidence in each other's ability to make needed behavior changes and to bolster each other's self-efficacy following setbacks, and thereby reducing the likelihood of downward spirals in self-efficacy.

Behavioral processes: Behavioral processes that have been found to be important in lifestyle interventions,^{61, 75-78} including interventions with Latinas,²⁵ include goal setting, problem solving, self-monitoring, and self-reward for meeting behavior change goals. Emerging evidence also highlights enjoyment of physical activity as likely to influence efforts to increase physical activity in socioeconomically disadvantaged adults.^{79, 80} We anticipate that participants in the dyadic intervention will experience greater success in developing and implementing plans for improved diet and exercise and more accountability through greater self (and partner) monitoring,⁸¹ and will derive greater enjoyment from physical exercise shared with a partner.

In sum, the conceptual model guiding the proposed research synthesizes elements from several theories, building upon their strengths to address intra-individual and interpersonal determinants of behavior change.

2.3.2. Intervention Details—Unidas is a culturally tailored lifestyle intervention that focuses on achieving weight loss through a reduction of caloric intake (1200-1800 kcal/day) and an increase in moderate-intensity physical activity (150 min/week). Figure 2

summarizes the key features of the dyadic and individual intervention and the assessment protocol (administered at baseline, 6, 12, and 18 months). Unidas draws upon the Diabetes Prevention Program's (DPP) Lifestyle Change Program¹¹ as its model. Although the DPP was designed to prevent diabetes, its focus on healthy eating and increased physical activity can facilitate weight loss among people with diagnosed diabetes. For example, the DPP physical activity goal of 150 minutes/week of moderate-intensity exercise matches the American Diabetes Association's physical activity recommendation for those already diagnosed with diabetes. Building upon and extending the DPP, Unidas will have: 1) clearly defined goals for physical activity and diet; 2) a core curriculum to facilitate standardization of the intervention; 3) frequent contact using a combination of group sessions, home visits, and telephone calls; 4) trained Lifestyle Community Coaches (LCCs); and 5) tailored strategies to address cultural and personal preferences and perspectives. Participants will be referred to their primary care physician to address specific aspects of their medical care (e.g. insulin and oral medication management). The Unidas intervention will be delivered in three 6-month phases: (Phase 1) an intensive intervention phase marked by weekly contact; (Phase 2) a gradually tapered intervention phase; and (Phase 3) a maintenance phase.⁸² In Months 1-6, participants will attend weekly group sessions and have monthly home visits coordinated by the LCCs.

To participate in the group intervention sessions, mother-daughter dyads randomized to Arm 1 will be combined into groups of approximately 10 dyads (20 women; 10 mother and 10 related-adult daughters). Individual mothers or individual daughters randomized to Arm 2 also will be combined to form groups of approximately 20 women (10 mothers and 10 unrelated-adult daughters) each. Group-based interventions have been shown to be particularly effective for promoting health behavior change among socioeconomically disadvantaged women.⁸¹ In the group meetings, a "concept of the week" and a recipe will be presented and discussed. Each participant will receive a study goal for physical activity and weight loss that is tailored to her specific needs and abilities, and will make personal choices about how to achieve her goals. Participants will meet with LCCs in their homes to tailor the information to fit their personal circumstances and to participate in activities that reinforce the information presented. Group meetings will be offered at various times during the day and week (including weekends and evenings), and will last approximately 45-90 min. Beginning in Month 7, the intervention will be tapered to group meetings held every other week, with group phone calls occurring in-between meetings. Participants will be encouraged to increase their moderate-intensity physical activity to an average of at least 45 min per day at least five times each week. The emphasis on increasing physical activity during the maintenance phase is based on research findings indicating that increased physical activity is required to maintain weight loss.⁸³⁻⁸⁵ In Month 12, the intervention moves into the maintenance phase with phone calls occurring every other week.

Both active interventions will be led by a team of bilingual, bicultural intervention staff, fully employed by the FQHC, who have extensive experience working with Mexican-American women. All staff will receive training in the principles of the DPP lifestyle intervention, and staff assigned to the dyadic intervention will receive additional training on the dyadic implementation of the intervention. The LCCs will be trained to work with

participants to develop specific skills, including information seeking, identification of goals, and participation in self- (and dyadic-) monitoring.

2.3.3 Differences between the Dyadic and Individual Intervention—Unlike the individual Unidas intervention, the dyadic Unidas intervention is designed to leverage interpersonal resources (e.g. social support, social control, companionship) to drive and maintain the health behavior changes necessary to promote and sustain weight loss. The unique features of the dyadic intervention are noted in Figure 2 in bold. In month 1, for example, the general goal in both the individual and dyadic Unidas conditions is to introduce the program and identify a personal weight loss goal. In Session 1 of the individual program, the participant is asked to identify what she hopes to achieve by taking part in the program, and how healthy eating and being active will help her and/or others. Women in the dyadic intervention are also asked these questions in Session 1, but they are requested to consider how working with their partner can help them to achieve their weight loss goals.

2.4 Minimal Intervention Control Group

Patients in Arm 3 will be randomized to the minimal intervention control group. Inclusion of this condition will allow us to evaluate the magnitude and duration of the gains associated with the intervention arms relative to gains associated with usual care plus a minimal intervention. This comparison is important given the scarce knowledge that currently exists regarding the effectiveness over time of behavioral lifestyle interventions with low-income, at-risk Latinas.⁸⁶ In this arm of the study, participants will only receive 12 monthly newsletters that provide practical healthy lifestyle tips developed with information derived from national health or governmental organizations (e.g. www.choosemyplate.gov; www.diabetes.org/). The newsletters will also provide healthy, low-fat, diabetic-appropriate, recipes with user-friendly nutrition information. This information will be sent to all study participants, including women in the intervention arms.

2.5 Study Measures

All outcomes will be measured at each of the four assessment time points: baseline (pre-randomization); approximately 6 months post enrollment; approximately 12 months post enrollment; and approximately 18 months post enrollment. The 6-month time point is primary as it is closest to the completion of the most intensive phase of the intervention. The 12- and 18-month time points allow us to examine the short-term and longer-term maintenance effects of the intervention.

2.5.1 Outcomes—Clinical outcomes will be collected as described below. Demographic and psychosocial data will be collected through individual interviews (60-75 min.) conducted separately with each dyad member by trained bilingual staff (blinded to study condition) in patients' homes or other preferred location. Abbreviated interviews will be approximately 30 min. in length. All measures have strong psychometric properties or will be adapted from measures with such properties, and most measures have been used successfully with low-income, limited-literacy Latinas. The assessments will be developed to minimize participant burden. Moreover, our experience with the Unidas feasibility pilot

study suggests that participants welcomed the regular monitoring they received as part of the study and perceived the frequent contact to facilitate attainment of their health goals.⁸⁷

2.5.1.1 Primary clinical outcome: Weight loss at 1 year: Based on the DPP⁸⁸ and other studies,^{89, 90} the ADA has recommended 5-10% weight loss for individuals who are overweight or obese. Although greater weight loss is better, the Finnish DPS⁹⁰ found significant reduction in diabetes incidence with a 5% reduction in body weight. The Go-YDPP Study, an intervention that adapted the DPP lifestyle intervention for delivery in the community (the YMCA), similarly adopted a 5% body weight reduction as the primary goal.⁹¹ Thus, we anticipate 6-7% weight loss for mother-daughter dyads (arm 1), 4-5% for individual mothers and daughters (arm 2), and 1% weight loss in the control condition (arm 3) at 6-months. Participants' height will be measured at baseline using a portable stadiometer. Weight will be measured on a flat, even surface, using a SECA 882 portable scale, which is accurate to 0.2 pounds. Participants will be weighed at the start of the morning, while fasting, after voiding, and with minimal clothing.

2.5.1.2 Secondary clinical outcomes: The following secondary clinical outcomes will be assessed:

1) Physical activity: The 7-day physical activity recall (PAR) interview will be used to assess physical activity performed during the week preceding each testing session.⁹² The PAR is one of the most commonly used measures of physical activity. Participants report on physical activities performed in moderate to vigorous intensity in bouts of 10 minutes or more. Details of the interview procedures and the methods used to estimate energy expenditure from these physical activity reports have been described elsewhere.⁹³ Energy expenditure estimates from the PAR have been found to be significantly correlated ($r_s = 0.20-0.86$) with other measures of energy expenditure based on diary, questionnaire, heart rate, acceleration count, and double labeled water data.⁹⁴⁻⁹⁶ In a subset of participants (20%), energy expenditure will be assessed using the Actigraph accelerometer, which participants will wear on their waists for a 7-day measurement period. Participants will be instructed to wear it during all waking hours for seven days as they go about their usual activities (only remove water-based activities such as showering). Sedentary time will be defined as the number of minutes/day spent at 0-99 counts per minute.⁹⁷ Non-wear time will be defined as at least 90 consecutive minutes of zero counts.⁹⁸ An adherent day will be defined as at least 10 h of wear time. Participants will need to contribute 3 or more adherent days to be included in the analyses. Accelerometers provide more accurate estimates of energy expenditure (validated against double-labeled water)⁹⁹ and total steps taken (validated against manual step counts)¹⁰⁰ than do mechanical pedometers, particularly for overweight and obese individuals, and for individuals with low levels of physical activity.^{101, 102} We successfully used accelerometers in the pilot study.

2) Dietary intake: Dietary intake will be measured with the Spanish version of the 2005 Block Food Frequency Questionnaire (FFQ). This instrument assesses portion sizes and frequency of consumption of over 100 food items, including foods selected for their cultural appropriateness for Mexican Americans to provide validated estimates of energy intake

(total kilocalories) and macronutrient intake (including fat, carbohydrates and dietary fiber).¹⁰³

3) *Physiological measures:* Serum glucose will be assessed by measuring fasting plasma glucose in the daughters with pre-diabetes and hemoglobin A1c in the mothers with type 2 diabetes. Serum lipids (total cholesterol, LDL, HDL and triglycerides) and blood pressure will be measured in all participants.

4) *Body composition:* Body composition will be assessed by computing BMI (as described above), and by taking anthropometric measurements, including waist circumference (using GULAK 2 tension tapes) and a three-site (triceps, suprailiac, thigh) skin fold thickness using Lange calipers.

5) *Quality of life:* Health-related quality of life (HRQOL) will be measured using the SF-36 (or an abbreviated version).¹⁰⁴ The Spanish version of the SF-36 has been well validated in Spanish-speaking populations.¹⁰⁵

2.5.2 Outcome Assessments—The primary objective of the study is to assess the effectiveness of a dyadic intervention for promoting weight-loss and maintenance of this health outcome over time in a sample of high-risk Latina mothers and their adult-daughters. To that end, the specific study aims are as follows:

Specific Aim 1: To test the hypothesis that Mexican-American overweight mothers with type 2 diabetes and their overweight adult daughters at risk for diabetes who participate in a partner intervention will demonstrate higher percent weight loss at 6 months and weight loss maintenance over time, compared to women who participate in an individual intervention or who receive usual care.

Specific Aim 2: To evaluate whether improvements in diet quality and increases in physical activity are higher among women in the partner intervention, compared to women in an individual intervention or in usual care, and to examine whether changes in these health behaviors mediate the effects of the intervention on weight loss and maintenance.

Specific Aim 3: To evaluate whether changes in theoretically-derived mediating mechanisms (interpersonal, cognitive, behavioral processes) are greatest among women in the partner intervention, compared to women in an individual intervention or in usual care and to examine whether changes in these processes mediate the effects of the intervention on diet and in physical activity.

Specific Aim 4: To examine actor-partner interdependence models to explore group differences in mother-daughter processes of mutual influence across the study arms, with this mutual influence expected to be greater and more strongly related to the primary and secondary outcomes for women in the partner intervention, compared to women in the individual intervention or in usual care.

2.5.2 Assessments of Potential Mediators—The interpersonal, cognitive and motivational, and behavioral processes that are conceptualized as mediators of the intervention will be assessed by asking participants to complete an interviewer-administered survey that takes approximately 60-75 minutes to complete at baseline and 30-45 minutes to complete at all remaining time points. Well-established methods of social network and social exchange assessment¹⁰⁶⁻¹¹² will be used to obtain detailed information about the involvement of participants' social network members in health-related social support, social control, and/or social undermining. Participants will be asked to identify social network members who have helped them make healthy lifestyle changes (social support), have prompted or urged them to do more to make such changes (social control), and/or have interfered (intentionally or unintentionally) with their efforts to make such changes (social undermining). After these key social network members have been identified, the interviewer will assess the nature of their role relationships with the participants (e.g., mother, adult daughter, spouse/partner, other family member, friend), their frequency of involvement in the participant's lifestyle-change efforts, and the perceived helpfulness or unhelpfulness of their involvement. This approach provides an efficient way to assess the sources, frequency, and helpfulness/unhelpfulness of health-related social support, social control, and/or social undermining for specific social network members judged to be important in this regard by the participant. This information will provide a complete mapping of the health-related involvement of participants' family members (and, potentially, non-kin), while also making it possible to determine for each participant the extent and perceived effectiveness of the daughter's (or mother's) health-related involvement.

Cognitive and motivational process will be assessed via the Diabetes Knowledge Questionnaire,¹¹³ the Exercise Benefits and Barriers Scale,¹¹⁴ and the Healthy Eating Benefits and Barriers Scale, modeled after the Exercise Benefits/Barriers Scale.¹¹⁴ Self-efficacy will be measured with the Self-efficacy for Exercise Habits and Eating Habits Scale.¹¹⁵

Behavioral processes will be assessed using a processes-of-change measure developed by Marcus and colleagues¹¹⁶ which has been used successfully in numerous interventions,¹¹⁷ including a physical activity intervention with Latinas.²⁵ Positive feelings elicited by physical activity will be assessed using the Physical Activity Enjoyment Scale¹¹⁸ and the Exercise-Induced Feeling Inventory.¹¹⁹

2.6 Sample size and Power

To test Aims 1-3, power and effect sizes were estimated using our preliminary study data, as well as information from landmark trials.^{9, 88} In our Unidas feasibility study, the within-group standard deviation (SD) of weight loss was 3% overall, and within-group SDs by participant type (mother or daughter) and study arm (intervention, control) ranged from 2.4-3.8%. Studies such as the DPP found a significant reduction in diabetes incidence with a 5% reduction in body weight at year 1; therefore, we target 6.5% weight loss for mother-daughter dyads (Arm 1), 4.0-5.0% for unrelated mothers and daughters assigned to individual intervention (Arm 2), and 1.0% for mothers and daughters in the usual care control condition (Arm 3). To account for the clustering within mother-daughter dyads,

clinic sites, and groups, we will perform sensitivity analyses using assumptions based on the magnitude of the intraclass correlation (ICC) currently noted in the literature.¹²⁰ Thus, the study has been powered to detect a difference between arms 1 and 2 at alpha level 0.05, with n=90 dyads per group at the study conclusion. Given the large and more easily detected difference between each of study arms 1 and 2 versus usual care, we powered the study to detect a smaller difference between arms 1 and 2. The proposed analysis will have >80% power under these assumptions. In our Unidas pilot, the attrition rate was 7.8%. Because the intervention in the proposed study is longer and more intensive, we anticipate a 20% attrition rate (comparable to those reported in other similar studies).^{13, 121-123} Thus, we will seek to recruit $N=(90*1.2)*4=460$ mother-daughter pairs at the start of the study. Note that unlike Arms 1 and 3, Arm 2 requires two sets of mother-daughter pairs by design (See Figure 2).

2.7 Data analyses

Initial analyses will examine the distribution of the primary and secondary outcomes, in order to transform variables toward normality and reduce the effect of outliers, as warranted. The success of randomization will be assessed by comparing study arms on characteristics measured before randomization. The analysis of Aims 1-3 will be based on women assigned to the two active interventions or to usual care; the analysis of Aim 4 will include all women (incorporating the assessment-only women in Arm 2). For analyses that involve multiple comparisons, a Bonferroni correction, or similarly appropriate method, will be applied.

Aims 1 and 2: Analysis of primary and secondary outcomes—The primary outcome will be weight loss at 1 year. Secondary outcomes include glucose control (i.e. fasting plasma glucose for daughters; A1c for mothers), physical activity, dietary intake, body composition, and quality of life. Intention-to-treat analyses (i.e., participants analyzed as randomized, without regard to intervention dose) will be conducted to compare the three arms using a linear mixed model (LMM) to account for the dependency within dyads, clinic site, and group membership within each intervention arm, and adjusting for baseline weight and co-residence status. Specifically, estimation will be based on restricted maximum likelihood with unstructured covariance to account for the dependencies. Other covariance structures will be considered if the model fails to converge. Weight loss maintenance at 18 months and longitudinal weight loss trajectories also will be examined using this approach with an additional term for time (0 to 18 months) will be included in the model.

Aim 3: Analysis of mediators—To evaluate the causal mechanisms of the intervention, we will examine two main classes of mediators: 1) changes in diet and physical activity (PA) and 2) theoretically derived health behavior change processes, including interpersonal, cognitive, and behavioral processes. For example, we will examine whether a greater increase in healthy eating and PA in Arm 1 helps to explain their anticipated greater improvement in weight loss, relative to that of women in Arms 2 and 3. For this purpose, we will utilize the general approach of causal mediation analysis,¹²⁴ using the R statistical software,¹²⁵ or an alternative approach based on linear structural equation modeling.¹²⁶

Aim 4: Analysis of group differences in mother-daughter mutual influence processes—Actor-Partner Interdependence Model (APIM) analyses are a powerful way to

investigate group differences in within-dyad influence processes that may be associated with key outcomes.¹²⁷⁻¹²⁹ APIM is a special case of a LMM (i.e. multilevel model) and can be estimated using software such as SAS PROC MIXED. We will use APIM analyses to estimate effects on outcomes that are attributable to actor and partner effects. For example, do increases in the mother's self-efficacy predict improvements in her own (actor effect) and her daughter's (partner effect) dietary adherence, and are these effects greater in Arm 1 than in Arms 2 and 3? ¹³⁰ APIM analyses will also allow us to examine the potential spillover of benefits in Arm 2 (by including the assessment-only participants in the analyses). Such spillover might occur if participants in the individual intervention spontaneously share their experiences and engage in health-related interactions (e.g., support) with their (assessment-only) family member in a manner akin to that encouraged in the dyadic intervention. Such spillover effects may exist in many lifestyle interventions, but they are rarely evaluated empirically. If the partner effects (e.g., influence of the mother's health-related support on her daughter's weight loss) are equally strong for daughters in the assessment-only subgroup in Arm 2 and daughters in the dyadic intervention in Arm 1, then it would imply that a dyadic intervention is not needed for multiple family members to benefit from one member's participation in a lifestyle intervention. Such a finding would be an important contribution to the literature as it would suggest a potentially cost-effective strategy for spreading the benefits of an individual lifestyle intervention by structuring it to encourage participants to share their experiences and collaborate on health behavior change with other at-risk family members. In contrast, if the partner effects are significantly weaker in the assessment-only subgroup in Arm 2 than in the dyadic intervention in Arm 1, then it would imply that a dyadic intervention is needed for multiple family members to derive benefits. This finding, too, would make an important contribution to the literature as it would underscore the value of a dyadic intervention approach that provides structured opportunities for at-risk family members to forge a sustained collaboration as they work together to improve their health behaviors. Our rich data set also will allow us to examine factors (e.g., acculturation differences, relationship closeness) that are associated with strong, health-enhancing partner effects (as well as actor effects). This knowledge will be helpful in informing health educators about the approaches that are likely to be most effective with particular kinds of participants.

3. Discussion

Many of the leading causes of death in the U.S., and reported racial/ethnic disparities in health outcomes, can be linked to group differences in health behaviors. This is certainly the case for diabetes. Health behaviors that put individuals at greater risk for developing diabetes and for poor diabetes control – such as obesity, poor diet, and lack of exercise – are relatively well understood. Less well-understood, however, is the extent to which the social context can either promote or interfere with adopting healthy lifestyle behavior. Diabetes self-management is crucial to maintaining quality of life and preventing long-term complications, and it occurs daily in the context of close interpersonal relationships. The social context of diabetes management includes multiple resources, including family (parents, spouses), peers, romantic partners, and health care providers.^{131, 132}

This study is among the first family-based intervention that targets two adults (mother-adult daughter dyads) in the same family who share a high risk for diabetes and its complications due to unhealthy lifestyles. Previous studies that have included two family members in a lifestyle intervention have seldom focused on family members with a shared disease risk. Rising rates of obesity have led many family members, within and across generations, to share unhealthy behaviors and elevated risks for chronic illness. In view of this trend, family support interventions in which two or more family members collaborate in efforts to change such shared behaviors warrant greater attention. In the context of such interventions, lifestyle changes made by one family member have the potential to catalyze similar changes in another family member, perhaps radiating to other family members, as well.¹³³

3.1. Limitations

A key concern that is sometimes raised about intensive lifestyle interventions like the Unidas program is their cost, but in low-income, high-risk populations, brief low-cost interventions are unlikely to bring about sufficient health behavior change to avoid poor health, compromised quality of life, and spiraling health care costs. Furthermore, such interventions typically fail to address the extent to which diabetes risk persists across generations. Interventions like Unidas that build in reinforcement by a family-partner who shares the same at-risk status and health behavior goals are likely to optimize support for long-term success. Another major strength of Unidas is that it encourages participants to access community resources that exist but may be underutilized (e.g. a school track that is open to the public). Finally, because Unidas is being integrated into an FQHC, it can potentially be funded and reimbursed as part of health promotion/nutritional counseling for individuals with diabetes, pre-diabetes, or overweight/ obesity. Through this integration, programs such as Unidas have great potential to address racial/ethnic health disparities.

4. Conclusions

Effective behavioral interventions to address the prevention and management of chronic are greatly needed, particularly in under-resourced populations that are typically excluded from such programs. The Center for Medicare and Medicaid Services is proposing to implement the Medicare Diabetes Prevention Program (MDPP) starting in 2018. Through this program, Medicare beneficiaries will be able to access evidence-based diabetes prevention services similar to the DPP, leading to possible decreased progression to type II diabetes and improved health. Furthermore, the U.S. Preventive Services Task Force's recommendations on prevention of diabetes and obesity through intensive behavioral therapy¹³⁴ are mandated to be completely covered without patient-copayment by all private health insurance plans. If interventions such as Unidas are found to be effective, they may be ways to implement these interventions in a culturally and linguistically-appropriate way for diverse populations, with appropriate reimbursement from private and public insurance plans. Thus, the potential for sustained maintenance of these programs, beyond the grant funding period, are more likely to be feasible in the current healthcare landscape. Furthermore, because health risks are often shared by multiple family members of at-risk families, culturally-adapted, dyadic intervention have the potential to increase the success of behavior change efforts and to extend their reach to multiple family members.

Trial status

Enrollment into the randomized controlled trial phase of this study began in January 2016 and will conclude in February 2019.

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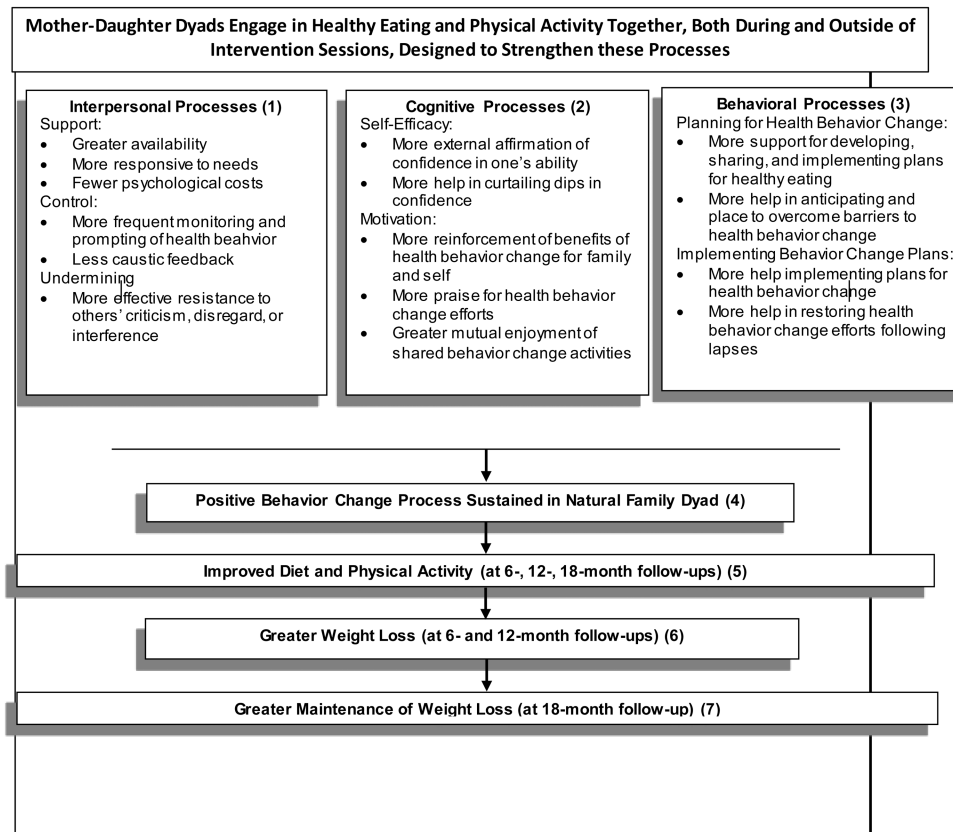
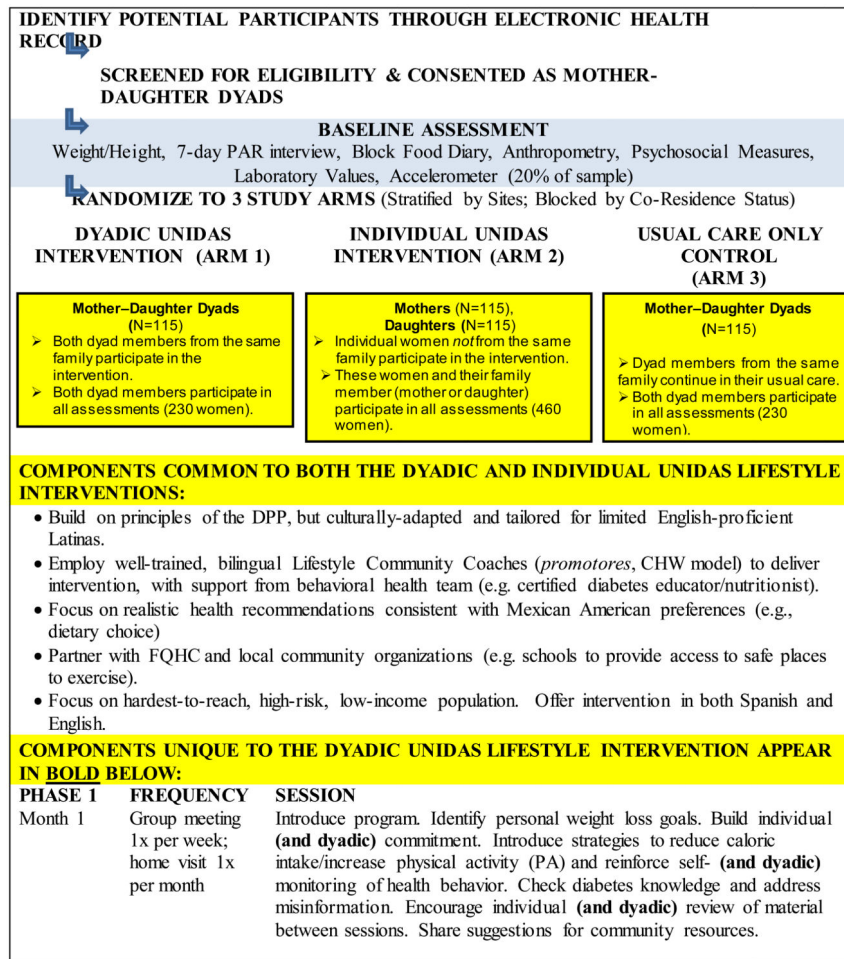


Figure 1. Hypothesized Advantages of Culturally-Adapted, Dyadic Intervention for Health Behavior Change Processes



Month 2	Group meeting 1x per week; home visit 1x per month	Teach components of healthy eating and meal planning. Emphasize importance of healthy eating and PA for weight loss. Teach skills for a healthy lifestyle (e.g., estimating portion size, tracking PA). Assess personal PA likes and dislikes. Reinforce individual (and dyadic) attendance at meetings. Practice skills (with dyad partner) during and between sessions.
Month 3	Group meeting 1x per week; home visit 1x per month	Identify (with dyad partner) barriers and facilitators to healthier eating and increased PA. Discuss (with dyad partner) strategies for overcoming. Practice problem-solving (with dyad partner) during and between sessions. Continue to reinforce self- (and dyadic) monitoring of key health behaviors. Discuss ways to address undermining <i>or other negative family dynamics</i> that interfere with health goals.
Month 4	Group meeting 1x per week; home visit 1x per month	Discuss (with dyad partner) personal stress triggers, <i>including possible family undermining or conflict</i> . Continue to discuss (with dyad partner) other barriers and facilitators to health behavior change. Understand that setbacks are normal, and learn how to recognize personal triggers for setbacks. Develop (with dyad partner) action plan for managing setbacks and for coping with making changes.
Month 5	Group meeting 1x per week; home visit 1x per month	Introduce ways to manage eating away from home, including family gatherings. Practice (with dyad partner) stress management skills and ways to restore motivation after setbacks. Express (with dyad partner) confidence in success.
Month 6	Group meeting 1x per week; home visit 1x per month	Develop self (and dyadic) strategies for staying motivated during and between sessions. Identify (with dyad partner) ways to avoid environmental and social cues for unhealthy behaviors and to substitute cues for healthy behaviors. Review (with dyad partner) and update weight loss and life-style goals.
PHASE 2 (Tapering)	6 MONTH MEASUREMENT VISIT (ABBREVIATED)	
	Weight, 7-day PAR, Block Food Diary, Anthropometry, Abbreviated Psychosocial Measures, Laboratory Values, Accelerometer (with sub-sample)	
Month 7	Group meeting & group phone; each bi-monthly	Discuss (with dyad partner) ways to maintain motivation. Continue self (and dyadic) monitoring. Increase PA to 45 minutes, 5 times per week. Continue to review community resources that may be helpful in maintaining a healthy lifestyle.
Month 8	Group meeting & group phone; each bi-monthly	Review (with dyad partner) ways to avoid and overcome setbacks. Share (with dyad partner) strategies for success, including self (and dyadic) reward for progress.
Month 9	Group meeting & group phone; each bi-monthly	Review (with dyad partner) ways to overcome barriers (e.g., stress, role-conflicts, undermining by others). Discuss (with dyad partner) how to enlist ongoing support for a healthy lifestyle.
Month 10	Group meeting & group phone; each bi-monthly	Review (with dyad partner) importance of staying active. Discuss (with dyad partner) ways to increase intensity and enjoyment of PA.
Month 11	Group meeting & group phone; each bi-monthly	Discuss (with dyad partner) plans for moving forward with diet and PA goals. Review/practice (with dyad partner) strategies for managing setbacks and countering low motivation.
Month 12	Group meeting & group phone; each bi-monthly	Discuss (with dyad partner) plans for staying engaged and supporting behavior change. Continue to review/practice (with dyad partner) strategies for managing setbacks and countering low motivation.
PHASE 3 (Maintenance)	12 MONTH MEASUREMENT VISIT (ABBREVIATED)	
	Weight, 7-day PAR, Block Food Diary, Anthropometry, Abbreviated Psychosocial Measures, Laboratory Values, Accelerometer (with sub-sample)	
Months 13-18	Group phone bi-monthly	Booster sessions: Check in, review and reward progress, address barriers and ways to maintain momentum. (Encourage dyad partners to continue support each other's healthy lifestyles.)
	18 MONTH MEASUREMENT VISIT (ABBREVIATED)	
	Weight, 7-day PAR, Block Food Diary, Anthropometry, Abbreviated Psychosocial Measures, Laboratory Values, Accelerometer (with sub-sample)	

Figure 2. Overview of Study Design and Summary of Intervention Components