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## Madres para la Salud: Design of a Theory-based Intervention for Postpartum Latinas

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### Abstract

**Background**—Weight gain in young women suggests that childbearing may be an important contributor to the development of obesity in women. Depressive symptoms can interfere with resumption of normal activity levels following childbirth or with the initiation of or adherence to physical activity programs essential for losing pregnancy weight. Depression symptoms may function directly to promote weight gain through a physiologic mechanism. Obesity and its related insulin resistance may contribute to depressed mood physiologically. Although physical activity has well-established beneficial effects on weight management and depression, women tend to under participate in physical activity during childbearing years. Further, the mechanisms underpinning the interplay of overweight, obesity, physical activity, depression, and inflammatory processes are not clearly explained.

**Objectives**—This report describes the theoretical rationale, design considerations, and cultural relevance for “*Madres para la Salud*” [Mothers for Health].

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**Design and Methods**—*Madres para la Salud* is a 12 month prospective, randomized controlled trial exploring the effectiveness of a culturally specific intervention using “bouts” of physical activity to effect changes in body fat, systemic and fat tissue inflammation, and postpartum depression symptoms in sedentary postpartum Latinas.

**Summary**—The significance and innovation of *Madres para la Salud* includes use of a theory-driven approach to intervention, specification and cultural relevance of a social support intervention, use of a *Promotora* model to incorporate cultural approaches, use of objective measures of physical activity in post partum Latinas women, and the examination of biomarkers indicative of cardiovascular risk related to physical activity behaviors in postpartum Latinas.

### Keywords

Latinas; Hispanics; physical activity; intervention; social support; overweight; obesity; culture; postpartum; exercise

## Introduction

Cross-sectional and retrospective examinations of weight gain in young women suggest that childbearing may be an important contributor to the development of obesity in women [1]. Failure to lose pregnancy weight following childbirth contributes to obesity in this subgroup, with subsequent impact on obesity-related risk and illness [2,3]. For many women, the postpartum period is characterized by a decrease in physical activity and an increase in the likelihood of postpartum depression (PPD) symptoms. Additionally, depressive symptoms can interfere with resumption of normal activity levels following childbirth or with the initiation of or adherence to physical activity programs essential for losing pregnancy weight [4].

Factors that promote physical activity during pregnancy and postpartum among Latinas include safe physical activities conducted in a socially acceptable context [5]. Social support is the most commonly reported correlate to higher levels of physical activity for Latinas. In pregnant and postpartum Mexican-born Latinas, social support is viewed as essential to the maintenance of physical activity, especially when compared with women of other ethnic groups.

In many studies, levels of inflammatory markers are positively related to a decrease in fat estimates, such as BMI. In fact, one postulated mechanism by which physical activity and/or weight loss reduces circulating levels of the inflammatory markers is through a decrease in levels of cytokines produced by fat tissue [6]. Research has shown that depressed adult patients have higher levels of IL-6 and tumor necrosis factor alpha (TNF- $\alpha$ ) when compared to normal controls [7]. In turn, obesity and its related insulin resistance may contribute to depressed mood physiologically as well as psychologically. Notably, mothers with PPD had higher levels of inflammation than nondepressed mothers [8].

Pregnancy-associated weight gain and failure to lose weight after birth contributes to the development of overweight and obesity in Latinas, who have prevalence rates exceeding 70%. This is of concern for Latinas because of their increasing obesity rates [9] and increased opportunity for weight gain associated with childbearing [10]. Although physical activity has well-established beneficial effects on weight management and depression, women tend to under participate or decrease physical activity during childbearing years. Further, the mechanisms underpinning the interplay of overweight, obesity, physical activity, and subsequent risk such as inflammatory processes or PPD are not clear. The purpose of this report is to describe the development and methodology of the intervention

for *Madres para la Salud* [Mothers for Health], a randomized controlled trial (RCT) designed to increase physical activity among overweight or obese postpartum Latinas.

## Methods

This study was funded by the National Institutes of Health, National Institute of Nursing Research NIH/NINR 1 R01NR010356-01A2, *Madres para la Salud* (Mothers for Health). The study protocol was approved by the Arizona State University Institutional Review Board and the Maricopa Integrated Health System Human Subjects Review Board.

## Study Aims

The study aims are to: 1) Examine the effectiveness of the *Madres para la Salud* intervention for reducing the distal outcomes in: (a) body fat (b) systemic and fat tissue inflammation and (c) PPD symptoms among postpartum Latinas compared with an attention control group, at 6 and 12 months, after controlling for dietary intake; 2) Test whether the theoretical mediators, intermediate outcomes, of social support and walking, and environmental factor moderators, affect changes in body fat; systemic and fat tissue inflammation, and PPD symptoms among postpartum Latinas at 6 and 12 months; and 3) Determine the relationship between the immediate outcome of walking (minutes walked per week) and change in the distal outcomes of: (a) body fat (b) systemic and fat tissue inflammation and (c) PPD symptoms.

**Theoretical Rationale**—Seminal work of Bowlby [11] and attachment theory, and Durkheim's [12] work on the intricate relationship between society and health underpins social support as a conceptual framework. Social support is the extent and conditions under which ties are supportive. Barrera et al. [13] refers to the concept of social support as 'elastic' in describing the various definitions and characteristics, including interpersonal ties and relationships, actions involved in resource provision, and affective responses to support received. Social support in this study is defined as aid and assistance exchanged through relationships and interpersonal transactions, and includes four types: (a) emotional, such as expressions of empathy, trust, caring, (b) instrumental, including tangible aid or service, (c) appraisal, including information that is used for self evaluation, and (d) informational, including advice, suggestions, and information [14].

Social support influences physical health outcomes that include the pathways of 1) behavioral processes –health behaviors- and adherence to medical regimens and behaviors that facilitate health behaviors such as exercise and 2) psychological processes that are linked to appraisals, moods or emotions [15]. Few examinations of social support have addressed the cultural specificity or cultural relevance of the framework in diverse ethnic, particularly Latinas. Recent focus group research that included Latinas from Texas shows that members of four underserved populations are likely to respond to strategies that increase social support for physical activity and improve access to venues where women can be physically active [16]. Qualitative methods have further strengthened the rationale for social support as a theoretical and culturally proficient construct. Keller and colleagues [17] analyzed focus group data, photo elicitation, and qualitative interviews with Mexican American women in community health settings to identify specific parameters contributing to: a) walking locals, b) sociocultural resources used in walking, and c) specific culture bound supports used in walking and physical activity [16,18,19]. Using these conceptualizations, we sought to identify culturally relevant activities, behaviors, or materials that would tailor each type of support specifically for the postpartum Latinas in our study. This approach is a unique addition to the literature because few studies have addressed the cultural specificity of social support for diverse groups.

The “*Madres para la Salud*” [Mothers for Health] (figure 1) intervention model illustrates the hypothesized mechanisms through which the culturally relevant social support intervention positively influences regular physical activity and the resulting improvement in body composition, inflammatory markers, and PPD symptoms. One moderator, two mediators, and one confounding variable are considered. Environmental factors (e.g., safety, sidewalks, and traffic) are hypothesized to moderate the effect of the intervention by influencing the number of minutes walked per week, while social support from family and friends and the dose-response of walking in minutes per week mediate the effect of the intervention on the outcomes of body fat, systemic and fat tissue inflammation, and PPD symptoms.

The components of the *Madres para la Salud* intervention were identified through preliminary work and review of the literature. These components include social support as an overarching conceptual perspective, using a community-based, group intervention format led by two trained *Promotoras*. *Promotoras*, literally translated as “developers”, are lay health advisors who work in the community they serve. The Prosumer concept is credited to Alvin Toffler [20]. Toffler predicted that, in the future, there would be a process whereby the consumer and the producer worked together to create the Prosumer [21]. The consumer of the product or service provides significant input to the product producer to make the product useable, tailored and relevant to their needs [22]. Evidence from our formative research supported the notion that older Hispanic women are anxious to take charge of their health [17]. The *Promotoras* provide the intervention that focuses on promoting moderate-intensity walking by fostering the four types of support that underpin the intervention [17].

Formative participatory work refined the *Madres para la Salud* intervention. Initially, we invited Latinas who were interested in physical activity to join us in discussion and strategy development to strengthen the cultural relevance of the intervention. These women named their group *Prosumer Mujeres (Women Prosumers)*. The goals of forming *Prosumer Mujeres* were to explore and inform culturally relevant intervention design by: (a) describing the physical activity experiences of women, to craft effective adherence and motivation strategies, (b) sharing the experiences of Latinas who lived in neighborhoods where our walking intervention would take place for a priori identification of safety concerns and planning and opportunities for walking in daily lives, and (c) guiding participant driven sampling to enhance study participation.

The Advisory group *Prosumer Mujeres*, review and feedback from young Latina postpartum women, and expert consultations guided the development of culturally relevant strategies needed to promote social support for walking. Young Latinas had the opportunity to incorporate their own experiences with physical activity, the ways in which group support might facilitate walking, and share what ‘worked’ or did not ‘work’ in their individual lives, social networks, and neighborhood environments. Young Latinas were able to provide insight into assessing core values, beliefs, norms, and significant aspects of the cultural group’s world view and lifestyle [23]. Last, postpartum Latinas participated in providing initial and ongoing feedback and refinement on the applicability and appropriateness of program materials, including language, reading level, and cultural equivalence [24].

**Mediating Processes**—The *Madres para la Salud* mediating processes include social support as a resource from family, friends, and support from the *Madres para la Salud* intervention walking groups within their neighborhoods. Our work with Latinas indicates that sources of support for walking during the life transitions of pregnancy, birth, and postpartum includes family, friends, and neighbors and must accommodate the cultural values ascribed to continuing and new transition roles. Postpartum Latinas value their roles as mothers and as caregivers; women believe that when they are healthy, they are best able

to care for their children and husbands. For these women, support for participating in physical activity helps them to perform their roles as wives and mothers. For others, the caregiver and provider roles may detract from the time available to perform structured physical activity [25]. Women experiencing conflicting time demands shared stories of multiple jobs, the ongoing needs of children, and caring for the home. While physical activity was increased through household chores and caregiving activities, women often felt conflict between the need to care for themselves and the need to care for others [25]. Therefore, it was important to align the foci of our critical inputs of our intervention with these values for healthy motherhood.

**Emotional support:** Emotional and verbal support is provided by *Promotoras*, who share ideas and experiences as ways to initiate and sustain walking, offer encouragement, and develop opportunities to socialize [26]. Emotional support in *Madres* is sharing ideas and experiences as ways to initiate and maintain walking, offering encouragement, and personalizing strategies to maintain walking. Emotional support is initially offered by *Promotoras*. Emotional support is also provided by the immediate family and friends of the participants and is incorporated in to the intervention based on feedback from Latinas from the target population.

Young Latina mothers noted that their spouses' traditional cultural expectations were a significant barrier to physical activity. Traditional attitudes encourage women to focus on caring for their homes and children, rather than taking time for themselves [19]. The *Madres para la Salud* component of emotional support incorporates the embedded culture of *marianismo* and *machismo*. *Marianismo* is a cultural value ascribed to Latinas that emphasizes being "good" wives, mothers, self sacrifice, and caretaking. For Latino men, *machismo* emphasizes domination, role as protector of wife, and family [27,28]. The cultural concepts of *machismo* and *marianismo* were incorporated into the intervention protocol, using open discussions among our Latina advisors and reviewers about these traditional male-female expectations and subsequent role enactments [27]. Women explored ways for us to capitalize on the important characteristics of a *machista*: responsibility for family welfare, protection of the family, and competition. As a result, *Madres para la Salud* participants are encouraged to use strategies that emphasize the husband/partner's role as protector of family health and sustaining health through walking and exercise. For example, a woman may ask the wives or girlfriends of her husband's friends to be her walking support group.

**Instrumental support:** Instrumental support is a set of activities that provides tangible support such as assistance in the form of time and services [29]. Instrumental support is considered tangible aid, such as assistance in the form of time and services. For *Madres para la Salud* intervention this includes the use of pedometers in monitoring regular walking, maps showing safe walking routes, historic facts and local lore of interest around participants' neighborhoods, walking groups, strollers, childcare, and walking shoes. Study participants also wear pedometers daily (Omron, model HJ-112). The pedometers used in *Madres para la Salud* record up to four weeks of data and provide 10 minute bout recordings of walking effort, an essential ingredient in our dose-of-walking physical activity intervention. One session is devoted to the partners and spouses of participants in the study to: (a) explore ways that the Latina participants can be encouraged to keep walking for the study; (b) how walking will help the women's energy levels and caregiving abilities; and (c) how the partners and spouses can help leverage walking opportunities.

For new mothers with small children, instrumental social support is quite specific. Instrumental support is having safe resources for childcare while the mother is walking and strategizing planned 'bouts' of walking that are family-centric. Strollers are made available

so that women can walk with their newborns and babies. Child care is arranged at group walking locations, often using teenage Latinas, while women walk in groups. Fitting walking in to one's everyday life results in specific planned activities, such as walking children to and from school and walking to the market.

**Informational support:** Informational support consisted of facts, advice, and reassurance, and in this study is provided by educational materials that were developed with and for these young Latina mothers to promote moderate-intensity walking, negotiate neighborhood safety, child rearing tips such as infant sleep habits and breastfeeding, and avoiding musculoskeletal injury. Based on recommendations from our Latina advisors, informational support includes specific time-management planning, helping women to carve out planned times for walking, and anticipating planned family care resources to use. *Madres para la Salud* includes 12 social support intervention sessions and booster sessions that include strategies for time management to help set specific appointments for walking and resources for young families and mothers including routines of work, household chores, and childcare. Specific strategies to manage time were developed for Latina mothers, and these coincided with Latinas from the target population who reviewed the intervention manual contributed strategic suggestions to incorporate into the critical inputs of the intervention. Strategies included having an agenda or schedule for a day's activities, making an appointment with one's self for physical activity time, keeping appointments in a cell phone, and planning meals before going grocery shopping.

**Appraisal support:** Appraisal support is feedback consistent with the use of self-monitoring activities. Appraisal support includes feedback on self-identified walking goals set each week. Two major resources are used for feedback: self-evaluation and goal setting. Self-evaluation is facilitated by the use of accelerometers to provide study participants with precise information and feedback that the intensity and accumulation of activity is adequate. Accelerometer data are obtained at five measurement time points throughout the 48-week intervention. *The Actigraph 3TGX* accelerometers are worn for 7 days and are scored to assess time spent in various physical activities by intensity levels. Matthew's cut-points are used to identify time spent in inactivity ( $0-99 \text{ cts}\cdot\text{min}^{-1}$ ), light intensity ( $100-1951 \text{ cts}\cdot\text{min}^{-1}$ ) [30], and Freeson's cut points were used to determine time spent in moderate intensity ( $1952-5724 \text{ cts}\cdot\text{min}^{-1}$ ) and vigorous intensity ( $5725 + \text{ cts}\cdot\text{min}^{-1}$ ) [31]. Every minute spent in each intensity level is averaged across 7 days.

*Promotoras* provide individual weekly feedback to each participant on the degree to which the self-identified goals were met. Participants evaluate their own efforts as well. A strong motivating factor for postpartum walking was self-image and remaining attractive for a partner or spouse. Women were motivated to regain what they described as a "1-baby body," rather than continue with a "5-baby body" (cited from a young Latina who reviewed the intervention manual, describing her weight loss motivation). The four critical inputs of the social support intervention are detailed in Table 1. The table describes the strategies used to implement the critical inputs for social support in young Latina mothers.

## Madres para la Salud Intervention

### Study Design

"*Madres para la Salud*" [Mothers for Health], is a 12 month prospective, randomized controlled trial designed to explore the effectiveness of a culturally specific program using "bouts" of physical activity to effect changes in body fat, systemic and fat tissue inflammation, and postpartum depression symptoms in sedentary Latinas. Figure 2 describes the *Madres* study flowchart.

**Setting**—The settings for recruitment in the study include community centers, a large medical center in an urban southwest city, churches and Hispanic markets. A large percentage of the affiliated medical clinic's clientele are low-income, and many do not have private health insurance. Although this is an urban environment, the area chosen for the intervention includes tree-lined residential neighborhoods with two elementary schools with large playgrounds that create a safe and accessible area for walking. It also includes large air conditioned businesses in the neighborhood, such as the Ranch Market [a large Hispanic grocery store], Wal-Mart, and a mall, for physical activity during hot or inclement weather.

**Sample**—One hundred twelve postpartum Latinas are recruited. Participants are randomly assigned to the intervention or attention-control group, using Random Allocation Software. The total number of participants is entered into the software, and is computed for two groups. Randomization occurs after the baseline data collection (T1).

### Inclusion criteria

Criteria for inclusion define the sample as habitually sedentary Latinas who are between the ages of 18 and 35, at least 6-weeks but less than 6-months post childbirth, and physically able to participate in moderate intensity walking. **Exclusion criteria.** Exclusion criteria includes: (a) participation in regular, strenuous physical activity exceeding 150 minutes of moderate physical activity weekly, (b) severe musculoskeletal or cardiorespiratory problems that would preclude physical activity, (c) currently pregnant or planning on becoming pregnant within the next 12 months, (d) current use of antidepressants, (e) infectious illness, acute or chronic systemic inflammation, (f) BMI less than 25 or greater than 35, or (g) regularly taking high doses of oral steroid medication, and (h) women with osteoporosis at baseline (bone mineral density  $\geq 2.5$  SD below the average). Trained research assistants screened all women for study eligibility using these criteria.

*Madres para la Salud* includes 12 weekly walking sessions and support interventions with *Promotoras*. The attention-control group receives health newsletters and follow-up phone calls. Data are gathered at baseline, 3, 6, 9, and 12 (T1–T5 respectively) months using questionnaires, fat tissue biopsies, blood samples, and a subset sample for DEXA body scans, as well as objective and self-report measures of walking adherence (accelerometers and physical activity recalls).

### Volume and Duration of Physical Activity as They Relate to Dose-Response—

The 2007 American College of Sports Medicine and the American Heart Association (ACSM/AHA) guidelines for physical activity recommend that healthy adults engage moderate-intensity physical activity (equivalent to a brisk walk that accelerates the heart rate) a minimum of 30 minutes a day, five days a week [32]. This dose of activity is equal to 150 min/week that is consistent with the 2008 Physical Activity Guidelines for Adults [33]. The ACSM/AHA recommends an exercise bout as a session of activity that lasts at least 10 minutes and indicates that these short bouts can be accumulated in a day to achieve the 30 minute minimum. The recommendation emphasize that this level of physical activity is (a) the minimum required and (b) in addition to routine activities of daily living or activities lasting less than 10 minutes.

**Rationale for Specific Walking Criteria**—Research shows that sedentary individuals would need to perform  $80 \text{ min}\cdot\text{d}^{-1}$  of moderate-intensity PA or at least  $35 \text{ min}\cdot\text{d}^{-1}$  of vigorous PA to prevent weight regain. [26,29,34]. There is sufficient evidence that moderately vigorous PA of  $150$  to  $250 \text{ min}\cdot\text{d}^{-1}$  with an energy equivalent of 1200 to 2000 kcal $\cdot\text{wk}^{-1}$  (12 to 20 miles $\cdot\text{wk}^{-1}$ ) is sufficient to prevent a weight gain greater than 3% in most adults [26,29,34] The Sedentary Women Physical Activity Adherence Trial study

demonstrated positive fitness changes related to the number of physical activity sessions completed rather than to the intensity of the sessions [35]. When incorporated into one's lifestyle, gradual, moderate-intensity physical activity promotes adherence [29]. There is little research, however, on the additional impact of social support on adherence or the effectiveness of moderate-intensity physical activity on the reduction of body fat.

## Procedures

*Madres para la Salud* uses *Promotoras* to facilitate the provision of family, friends and group support. A *Promotora* (peer counselor or lay health educator) is a member of the community to whom other community members turn for care, advice, information, and support [36]. The use of peers or natural helpers has enhanced the cultural relevance and acceptability of health-promoting interventions [36]. *Promotoras* are an integral part of adjunct care in the community-based and outpatient clinics of our primary study site, and are paid positions. While not *Promotoras* in the strict definition of a lay health advisor who steps forward from the community, our use of the *Promotoras*' role is to implement strategies that influence the participants' social support, a mediating variable in our theoretical model. The *Promotoras* are extensively trained to provide the intervention.

Following the 12 week *Madres para la Salud* intervention, the *Promotoras* schedule a weekly walking session with the cohorts of enrolled women. Each woman is required to walk at least one time each week with the *Promotora*, and during each week of the intervention, *Madres para la Salud* participants set individual "steps per day" and "bouts per day" goals and self-monitor their progress. These intervention group participants use a pedometer and record their accumulated steps taken, numbers of bouts, and minutes walked per day on an Activity Calendar. At weekly meetings, the *Madres para la Salud* participants examine their progress and set new goals with assistance from the *Promotoras*. The walking time, distance, and intensity is measured by training women to walk a 20-minute mile. In addition to mapped distance, *Madres para la Salud* participants use pedometers and receive instruction from the *Promotoras* during walking sessions in pedometer use, and recording physical activity.

To further maximize adherence to walking, alternative routes for walking are mapped by the *Promotoras*. Alternative routes keep interest high and incorporate historical and cultural facts about the walking area. Walking routes include the location and hours of operation of large air conditioned businesses in the neighborhood, such as a large Hispanic grocery store, Wal-Mart and a mall, for physical activity during hot or inclement weather.

The safety of each *Madres para la Salud* participant is of primary concern. Each study participant in *Madres para la Salud* is provided with properly fitted athletic walking shoes prior to beginning the walking. As the geographic location for the study is Phoenix, Arizona, extremely hot temperatures and the potential for dehydration are of concern during the summer months (June – August). In anticipation of rising temperatures, the *Promotoras* provide information during the month of April about walking while avoiding the heat of the day, tips to remain hydrated, and early signs of heat exhaustion. Bottled water is available for participants during the *Promotora*-led walks that occur during summer months.

A Three-day Physical Activity Recall modeled after the Ainsworth Physical Activity Recall is used as an assessment of total physical activity (including walking, categorized as a moderate intensity activity) that might be occurring as the participants become more active [37]. Women also complete a personal Activity Calendar by recording the number of bouts and their duration and the number of steps walked per day. Only sessions lasting 10-minutes or more are counted. Three sources of physical activity data will be employed to assess



increases in both intentional and unintentional physical activity. Weekly pedometer data and accelerometer data obtained for one week at each of three data collection points, and weekly recordings on the modified Ainsworth Physical Activity Recall will be analyzed and compared.

## Outcome Variables

### Body Composition

Body composition is assessed through bioelectric impedance (Tanita Corporation of America, Inc, Arlington Heights, I) and DXA examinations, and fat distribution through waist-hip ratios. Research shows significant reductions in total and central body fat and unfavorable blood lipids as a result of moderate levels (150 minutes/week) of walking among women [38,39].

### Depressive Symptoms

Postpartum depression is measured using the Edinburgh Postnatal Depression Scale (EPDS). The EPDS is a 10-item self-report questionnaire with 4-point Likert-type response options (0 to 3). Total scores range from 0 to 30, with higher scores indicating more severe depression symptomatology. Total scores of  $\geq 12$  indicate the likelihood of depression; scores  $\geq 14$  indicate the likelihood of major depression. The EPDS has been validated in numerous clinical studies with postpartum women; sensitivity of 86% and specificity of 78% [40,41] and Cronbach's alphas of  $>.77$  [42–44] have been reported. Spanish versions of the EPDS are available [45,46]. Subject preference determines whether the English or Spanish version is used. The EPDS will be administered at T1, T3, and T5 when subjects in both groups are available for their scheduled DXA tests.

### Systemic and Fat Inflammation

Blood and fat tissue samples are used to assess inflammatory markers in the Latina participants. Fat tissue may contribute to systematic inflammation by producing endocrine and paracrine inflammatory factors (adipokines) [47]. Circulating levels of TNF- $\alpha$  are higher in nonobese, nondiabetic Mexican Americans compared to non-Hispanic white adults [48]. The result is that these individuals could be more prone to obesity-related inflammatory processes. Proinflammatory factors are measured in blood and fat tissue biopsy, respectively, obtained at T1 and T5 (occurring at least 2 days after the last physical activity session). Circulating levels of various proinflammatory factors (CRP, IL-6, IL-8, PAI-1) is determined in the blood samples taken at these time points. High sensitivity CRP concentrations with lower functional sensitivity of 0.1 mg/l are measured using an immunometric assay (DPC Immulite). The CV at  $1.07 \pm 0.04$  mg/l is 4%, whereas at  $0.18 \pm 0.02$  mg/l (near lower limit of detection) the CV is 12.5%. Intra-assay variation for low, medium, and high controls ranges from 1.1–1.7% while inter-assay variation ranges from 4.0–5.4%. IL-6 is measured in duplicate using an enzyme-linked immunosorbent assay (ELISA) kit (R&D Systems). Coefficient variation (CV) for this kit ranges from 4–6% for intra-assay precision and from 5–10% for inter-assay precision. IL-8 is measured in duplicate using an ELISA kit (Assay Designs). Coefficient variation (CV) for this kit ranges from 3–9% for intra-assay precision and from 4–7% for inter-assay precision. PAI-1 is measured in duplicate on platelet depleted plasma by a kit assay (Diagnostica Stago) based on the inhibition of urokinase by PAI-1. This assay ranges from 2.5–6% for intra-assay precision and from 6–8% for inter-assay precision.

### Covariate

Dietary Intake: Dietary intake is obtained by a 24-hour (24R) diet history at T1–T5. With the 24R, the respondent is asked to remember and report all the foods and beverages

consumed in the preceding 24 hours. The 24-hour recall is useful across a wide range of populations [49]. The validity of the 24-hour dietary recall has been studied by comparing respondents' reports of intake with intakes unobtrusively recorded or weighed by trained observers. In general, group mean estimates from 24-hour recalls were similar to observed intakes [49]. This means of obtaining dietary information is appropriate for this population because it does not require literacy or computation skills as does a food frequency questionnaire. In addition, it allows for clarification of portion sizes, composition of combination foods such as casseroles, and what was actually eaten versus what was provided. In a comparison of food record and a 24-hour recall, Montgomery, Ward, Nichamen and Briley [50] note that more food was documented with the 24-hour recall.

**Components and Operationalization of the Attention-control Condition**—The content given to the *attention-control* group does include the “active ingredients” of the *Madres para la Salud* but includes monthly telephone contact to answer questions about common postpartum or newborn concerns, such as breastfeeding, infant sleep, and sibling rivalry. The attention-control participants participate in data collection on-site at baseline, 6, and 12 months.

**Strategies to Maintain Adherence to Madres para la Salud**—*Madres para la Salud* provides incentives for participation to both the attention-control and the intervention groups. For the intervention group, these incentives include walking shoes, loan of strollers and pedometers from study personnel, and health-related information; for both groups, health-related information is provided. Recruitment and retention materials include t-shirts, visors, water bottles marked with the study logo, and *Madres* hallmark colors- hot pink and aqua. Recruitment materials are clearly marked “free” and “no identification” required. Retention strategies are discussed during instrumental support sessions and participants were encouraged to dialogue about questions such as “What types of incentives are important to you?” and “What conditions are happening in your life that might influence your ability to walk?” Additional incentives include small incentives following the intensive week of Actigraph data completion and return, and gift bags with beauty products from the Dollar Store for meeting weekly walking goals.

**Evaluation of Intervention Fidelity**—To maintain fidelity, a *Madres para la Salud* program manual was developed for training intervention staff and monitoring program delivery. Program sessions, including booster sessions and telephone contacts with intervention participants are randomly audio taped, with the project director evaluating program presentation and content.

**Acceptability**—An intervention acceptability measure is used to evaluate acceptability of *Madres para la Salud* intervention components and target two major aspects of the intervention and its domains: (a) intervention components: utility, effectiveness, credibility, and satisfaction; and (b) mode of delivery: format and strength. The measure is administered one time in the post-intervention period to the intervention group.

Power for the primary analysis (change in body fat) was established at 0.88 with 50 participants (25 in each group) when alpha is set at 0.05 and the difference between the means of two groups is an average body fat loss of 4% (with a pooled standard deviation of 6% at baseline). Our target sample is 70 participants with complete data on 57 participants at T5 and that with imputation data will be available from ~70 participants. The estimate of effect size was taken from the work of Keller and Cantu [18], Keller and Trevino [51], Pronk and Wing [52], and Wing and Phelan [53]. Literature from physical activity intervention programs in diverse patient populations suggests that overweight/obese individuals who maintain a 7% weight loss will show significant health risk reductions and

that 7% weight loss is a reasonable goal in a 12-month physical activity-walking- program [54,55]. It is possible that the amount of physical activity performed will vary from less than the minimal amount expected (30 min, 5 days/wk) to higher levels, but that weight loss will average 4% for the intervention group.

**Data Analysis**—Structural equation modeling (SEM) will be used to evaluate the specific aims, test all relationships simultaneously and give an overall test of model fit. The model will be the portion of Figure 1 consisting of the path from the intervention to the theoretical mediators of social support, adherence, and environmental factors and their paths to the outcomes. Change over time in the outcomes will be modeled with a latent growth model and the intervention and medications will be added to the model as predictors of the intercept and slope of the growth model. Dietary intake will be included in the model as a control variable. Using standard strategies for testing mediation [56,57] we will first assess a direct effect model to make sure that there is a significant relationship between predictors and dependent measures. Then we will compare the overall model with a model that also includes the direct effects of the predictors on the dependent variable. A woman who becomes pregnant early in the study (first 9 months) will be treated as attrition. Women who become pregnant late in the study (> 9 months) will be included in the analysis and remaining data will be imputed.

## Summary

One of the critical elements of this study is the extensive and culturally relevant recruitment, intervention, and retention efforts we are implementing. Deep and enduring partnerships with neighborhood communities, churches and schools, as well as medical partnerships with Latina serving clinics have been essential and instrumental to our efforts.

Program design strategies for *Madres para la Salud* were drawn from the literature in community-based health promotion, which emphasizes both “top down” and “bottom up” development methods [58]. The top down approach incorporates scientific experts in the development of the theory-based social support *Madres para la Salud* intervention, whereas the bottom-up approach involves mobilizing community members to address cultural and contextually relevant strategies to promote social support and walking among young Latinas and their families. A primary concern is to minimize the cost of participating in the intervention, while enhancing the benefits to Latinas in the community, as well as involvement of family members in walking activities as sources of support. Our strategy of involving a Latina Advisory group, and post partum Latinas in the development and refinement include an emphasis on developmental learning, and enduring factors from generational transmission of values and behavior that influence physical activity. For example, kinship and pseudo kinship ties have been shown to influence health and health behavior decisions far beyond perceived risks and benefits of health behavior [59].

This research will fill the gap of evidenced based recommendations for physical activity in diverse populations who are low income, inner-city, and have gender-specific support needs to enhance walking. In her review of physical activity dissemination of physical activity interventions, Yancey et al [60] conclude that there is very little data of essential quality on ethnic minority or low-income individuals upon which to base sustainable effective interventions. Our research helps fill the gaps of a paucity of evidence showing the development and testing of the effectiveness of culturally sensitive efforts in intervention implementation.

This study is unique in its approach to recruitment and development of intervention settings that acknowledge the relevance of socio-political issues for Latinas. Recent immigration

legislature and heightened dialogue has produced social fear especially among foreign-born individuals and U.S. born individuals with familial ties to Mexico. While these highly emotionally charged debates occur, individuals may respond to self care, health issues for themselves and their family members, or participation in a research study as low priority, emphasizing more basic needs of food, shelter and safety. Our recruitment settings include neighborhood ministries, churches and clinics that emphasize comprehensive care to address the needs of these hard-to-reach Latinas. We emphasize the fact that no identification is required for participation, and have developed an extensive tracking system for these women in neighborhoods. For example, tracking cards are requested kept of participant's spouse or partner contact information, close friend or relative, and neighbor and work contact information. With our participants, we have found that phone numbers are usually available from these sources, and if there is a gap in service, we continue to try the number, as it is reconnected following payment.

The significance and innovation of *Madres para la Salud* includes use of a theory-driven approach to intervention, verification, specification and cultural relevance of a social support intervention, use of a *Promotora* model to incorporate cultural and social approaches, use of objective measures of physical activity in post partum Latinas women, and the examination of biomarkers indicative of cardiovascular risk related to physical activity behaviors in young Latinas. The study fills the gap in the research on moderate intensity walking in young Latinas by testing social support constructs that are salient and build on cultural strengths of Latinas.

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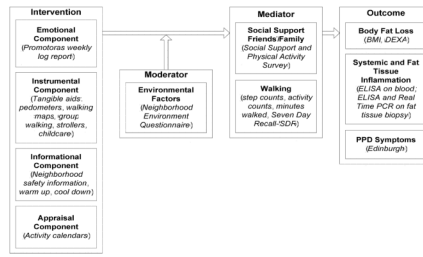
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**Figure 1.**  
*Madres para la Salud* Intervention Model: Concepts and Measurement Indices\*  
 \*Note. Concepts appear in bold. Measurement indices are italicized and in parentheses.





**Figure 2.**  
Study Flow Chart

**Table 1**

**Critical Inputs and Intervention Strategies for *Madres para la Salud***

Critical Inputs	Intervention Strategies
(1) Emotional support provided by <i>Promotoras</i> to initiate and sustain walking, offer encouragement, and develop opportunities to socialize.	<ul style="list-style-type: none"> <li>• Verbal and emotional support to share ideas</li> <li>• Training sessions that incorporate the cultural concepts of <i>marianismo</i> and <i>machismo</i></li> <li>• Support provided during walking groups</li> <li>• Problem-solving challenges and barriers to walking identified</li> <li>• Celebrating walking accomplishments, special holidays and birthdays</li> </ul>
(2) Instrumental support is a set of activities that provide tangible support such as assistance in the form of time and services.	<ul style="list-style-type: none"> <li>• Stroller loaner program</li> <li>• Childcare</li> <li>• Walking shoes</li> <li>• Partners/spouses learn how and why to encourage walking</li> <li>• Mother's bags with baby items, children's soft toys, toys for older children</li> </ul>
(3) <u>Informational support</u> : Information may consist of facts, advice, and reassurance.[61]	<ul style="list-style-type: none"> <li>• Strategies for walking with family members, children, spouses, their mothers</li> <li>• Safe walking routes, walking equipment, body mechanics</li> <li>• Benefits of walking for health and accomplishment of role responsibilities</li> <li>• Time management strategies to help create opportunities for walking</li> </ul>
(4) <u>Appraisal support</u> feedback consistent with the use of self-monitoring activities.	<ul style="list-style-type: none"> <li>• Accelerometer, pedometers, and weekly self-monitoring</li> <li>• Weekly PA Diary includes all activities including household and occupation</li> <li>• <i>Promotora</i> review of physical activity and goal attainment</li> <li>• Goal setting and evaluation</li> </ul>