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Publication Date

2015-09-01

DOI

10.1016/j.cct.2015.08.004

Peer reviewed

HHS Public Access

Author manuscript

Contemp Clin Trials. Author manuscript; available in PMC 2017 May 18.

Published in final edited form as:

Contemp Clin Trials. 2015 September ; 44: 149–158. doi:10.1016/j.cct.2015.08.004.

Using interactive Internet technology to promote physical activity in Latinas: Rationale, design, and baseline findings of Pasos Hacia La Salud

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Abstract

Internet-based interventions show promise as an effective channel for promoting physical activity. However, a paucity of research has been conducted among underserved groups despite recent increases in Internet access and physical activity-related health disparities in these communities. Thus, the current randomized controlled trial will test the efficacy of an individually tailored, Internet-based physical activity intervention for Latinas. This program was culturally and linguistically adapted for the target population through extensive formative research. Two hundred eighteen sedentary Latinas were randomly assigned to the Tailored Physical Activity Internet Intervention or the Wellness Contact Control Internet Group. The Physical Activity Internet Intervention, based on Social Cognitive Theory and the Transtheoretical Model, utilizes a website with features including self-monitoring, goal setting, discussion forum, links to online resources, individually tailored and motivation-matched physical activity feedback reports, and exercise tip sheets. Participants receive regular emails over the first 6 months with a tapered dose during the second 6 months (maintenance phase) to alert them to new content on the website. The main outcome is differences in minutes/week of moderate to vigorous physical activity at six months as measured by the 7-Day Physical Activity Recall and accelerometer data. High reach, low cost,

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culturally relevant Internet-based interventions that encourage physical activity among Latinas could help reduce health disparities and thus have a substantial positive impact on public health.

Keywords

Physical activity intervention; Latinas; Internet-based intervention

Introduction

Physical activity plays a key role in the prevention and management of multiple chronic health conditions, including cardiovascular disease, type 2 diabetes, high blood pressure, and colon and breast cancer. Despite these benefits, most Americans are insufficiently active[1]. To combat this public health concern, a growing number of studies on Internet-based physical activity interventions have been conducted. Widely used by most Americans[2], Internet-based technology has the potential to reach a large number of people at a relatively low cost, and has demonstrated promising results when utilized for physical activity promotion[3–6].

In a recent review of Internet interventions promoting physical activity in adults[3], most (61.9%) of the 72 identified studies reported significant increases in physical activity, and these findings are consistent with results from previous reviews[4,5] and meta-analyses in this area[6]. However, little research on Internet-based physical activity interventions has been conducted among underserved populations[3]. In fact, the previously referenced review was unable to locate any Internet- and/or web-based physical activity intervention studies focused on racial/ethnic minority groups and identified only one study with a majority (78%) Latino sample[7]. These findings are unfortunate given calls for more research in this area,[3] as Latino women (Latinas) report high rates of inactivity and related chronic diseases[8–10] and are in need of effective interventions.

Latinas often report barriers to physical activity related to childcare and household responsibilities[11–15] and thus might find Internet-based interventions particularly convenient and appealing. Such interventions can be accessed at the time and place most convenient for the participants (e.g., from the comfort of home while children nap), without disrupting family routines or even requiring transportation. Our past research has shown that individually tailored theory-based (Social Cognitive Theory and Transtheoretical Model[19–20]) feedback on their progress that is mail-delivered can produce significant increases in physical activity levels [16–18]. Internet technology allows for tailored intervention messages to be immediately delivered to participants without the delays inherent to other channels (e.g., print, telephone). This can provide increased interactivity and accountability, which were features requested by Latinas in our past physical activity intervention research studies[16–18]. While a slight digital divide remains in terms of Internet use between Whites (84%) and Latinos (74%), recent data indicate that Internet use among racial/ethnic minorities is rapidly nearing levels reported by Whites [2, 21].

The current study capitalizes on this increased access to Internet technology and its likely appeal to address physical activity-related health disparities in this community. We are testing the efficacy of a 6-month culturally and linguistically adapted, individually-tailored

Internet-based physical activity intervention for Latinas. This paper describes the design, rationale, and baseline findings from this randomized controlled trial.

Methods

Overall Design

The Pasos Hacia La Salud study (N=218) is a randomized controlled trial of a 6-month Spanish-language, culturally and linguistically adapted, individually tailored, Internet-based Physical Activity Intervention, compared to a Spanish-language Internet-based Wellness Contact Control condition. The primary dependent variable is minutes per week of moderate to vigorous physical activity (MVPA) as measured by self-report and accelerometer data. The hypothesis is that those in the Tailored Physical Activity Internet Intervention will demonstrate significantly greater increases in physical activity participation from baseline to post-intervention (six months) than the Wellness Contact Control Internet Group. Secondary aims include examining maintenance of behavior change at 12 months post-randomization, exploring potential mediators (e.g., self-efficacy, cognitive and behavioral processes of change, theoretical constructs specifically targeted by the physical activity intervention) and moderators (baseline stage of change and environmental access to physical activity equipment) of treatment effects, and evaluating the cost effectiveness of delivering the intervention. See Figure 1 for Study Schema.

Design Considerations

Several considerations were made when designing the current study. We evaluated the feedback received from participants in previous studies and conducted focus groups with individuals from the target population to help us select the most ideal features and characteristics for the study arms[16–18]. We considered offering the study in both English and Spanish, however Latina participants in prior studies[16–18] showed little interest in receiving materials in English.

We also considered including both men and women in the study but chose to focus on women as cultural issues may contribute to the higher rates of inactivity found among Latinas[12,24–29]. Specifically, participants in our previous studies and focus groups frequently described having to fulfill multiple gender-specific roles and responsibilities, such as caregiving and home management, that interfere with their ability to be physically active[15]. Thus, we chose to limit our study to women and include content and support to specifically address these issues in our Internet-based intervention.

Given the rapid increase in the use of mobile technology, such as smartphones, and the benefits of these media channels (interactivity, immediate feedback), we also considered designing the intervention to be delivered via smartphone. However, while smartphone use has increased among Latinos in recent years, only 29% of Spanish-dominant Latinos, and 40% of low-income Latinos own a smart phone device[22–23]. Furthermore, our formative research done with Spanish dominant Latinas in San Diego prior to this study revealed that this population preferred receiving Intervention content via the website and email rather than a mobile device. Therefore, for this particular population, the web-based media channel

appeared to be most appropriate and allowed for inclusion of a high-risk population that may not have been eligible for an intervention requiring smartphones.

Participant Recruitment

Several recruitment methods were used. The primary mode of recruiting participants was through paid ads on Craigslist.org, from which we were contacted by 473 people. Other methods included participant referrals (n=102); advertising in local Spanish language newspapers (n=125); mailed and emailed study information through primary care doctor offices (n=30); advertisements posted around San Diego including churches, primary care offices, grocery stores, hair salons, and laundromats (n = 26); and attending local events including health fairs (n = 90). The total cost of recruitment for this study was $8,585. The cost per randomized participant based on the top three recruitment yields was as follows: paid ads via Craigslist.org ($8.50/person); local Spanish language newspapers ($34/person) and local events ($4.44/person). Although many names were obtained through sign-up interest lists at community events, very few of these people responded when contacted later by staff regarding their potential interest in participating. Therefore, using an Internet-based method, such as Craigslist.org, was the most effective way to recruit for this Internet-based intervention study.

Eligibility Requirements

Inclusion criteria included the following: self-identified as Hispanic or Latino according to the Census Bureau's list of racial/ethnic backgrounds; self-reported insufficient physical activity (defined as participating in MVPA less than 60 minutes per week); 18–65 years of age; verified BMI <45 kg/m^2; regular access to an Internet-connected computer through home, work, or the community (e.g., public library, community center, neighbor's house); and willingness to be randomly assigned to either of the two study conditions. The cutoff of 60 minutes of MVPA per week was used in order to target the most inactive individuals in greatest need of increasing their activity.

Exclusion criteria included the following: unable to read or speak Spanish fluently, history of coronary heart disease (history of myocardial infarction or symptoms of angina), diabetes, stroke, orthopedic conditions which limit mobility, or any other serious medical condition that would make physical activity unsafe; current or planned pregnancy; planning to move from the area within the next year; hospitalization due to a psychiatric disorder in the past 3 years; and/or taking medication that may impair physical activity tolerance or performance (e.g., beta blockers).

Efforts to Reduce Barriers to Participation and Increase Retention

In our team's experience, cost, childcare, and transportation have been barriers to research participation, especially among Latinas. Although the intervention is delivered at no cost to the participant via the Internet, several research activities (e.g., measurement visits) are conducted in person. Therefore, we provide reimbursement for travel and childcare for those in need of these services. We also offer flexible scheduling (i.e., in the morning, afternoon, evening, weekend). We utilize bilingual/bicultural staff to aid in recruitment and retention as we have found that Latinas are more interested in participating in research when approached

by staff they can identify with and are offered an intervention tailored to their particular needs and ethnic identity. Having bicultural/bilingual staff that can build rapport with participants as well as offering a program that is culturally congruent is central to our retention efforts. We employ multiple other strategies to ensure high retention and engagement, including pre-randomization study orientation, multiple unobtrusive reminder contacts, monetary incentives, snacks and refreshments at visits, and non-monetary incentives (e.g., mouse pads, magnets, bags, sunscreen, water bottles, stress balls, and pens). Participants are also compensated for their time and receive $25 for attending six month and twelve month assessments plus a $50 bonus for attending both visits, as well as $10 each month for filling out the online questionnaires.

Protocol

Orientation Session

After potential participants are screened over the phone for eligibility, they are invited to attend an in-person orientation session to obtain more information about the study. Bilingual/bicultural research staff give a presentation describing the study and rights of participation and answer questions from the potential participants. Individuals who remain interested in participation sign the informed consent document, complete questionnaires assessing demographic characteristics and health literacy, and have their height and weight measured. They are given a packet of questionnaires on physical activity-related psychosocial variables (stages and processes of change, self-efficacy, enjoyment, social support, stress, environmental access) to complete prior to the next in-person visit, for measurement. In order to help ensure that participants are capable of using the Internet, they are also required to complete a basic web-accessibility check prior to scheduling their measurement visit.

Measurement Session

Participants return for the measurement visit where the following baseline measures are completed: waist and hip circumference, blood pressure, and percent body fat. The Quantum II bioelectrical body composition analyzer (RJL Systems, Inc., Detroit, MI), a four-electrode system that determines resistance and reactance, is used to conduct body impedance measurement, along with the Segal equation[30] for determining percent body fat. Waist and hip circumference are obtained using the largest circumference of the posterior extension of the buttocks and smallest circumference of the torso (natural waist)[31]. A sitting blood pressure is obtained using a mercury sphygmomanometer. Participants with initial readings greater than > 140 systolic and/or >90 diastolic are asked to rest and repeat the measurement 10 minutes later. If the blood pressure remains elevated, the person is not eligible to participate. At this visit, participants also receive an ActiGraph GT3X+ accelerometer, with instructions to wear the accelerometer during waking hours for seven consecutive days.

Physical Activity Assessment/Randomization Session

One week following the measurement visit, participants return with the accelerometer to an in-person visit. Any participant with insufficient wear time (< 3000 minutes over 4 days or < 5 days of 600 min each) is asked to re-wear the accelerometer and the visit is rescheduled.

Participants then undergo a 10-minute treadmill walk to demonstrate moderate intensity (3–4 miles per hour) physical activity. The goal of this walk is to help improve accuracy of self-report by providing a live, experiential demonstration of a 10-minute bout of moderate intensity physical activity. Protocol for this demonstration was previously developed by our team and has been utilized in prior studies[16–18].

Participants are then assigned to one of two Spanish-language Internet-based conditions: Tailored Physical Activity Intervention or Wellness Contact Control. Group assignment is determined using a permuted block randomization procedure, with small random sized blocks. Randomization stratified by Transtheoritical Model (TTM)[20] stage of change to ensure an equal distribution of treatment assigned across levels of motivational readiness for physical activity. Family members or friends who enter the study at the same time are yoked to ensure randomization into the same group and minimize group contamination. Twelve groups have been yoked (11 pairs and 1 group of four).

Tailored Physical Activity Internet Intervention (Intervention Group)

Participants randomized to the Tailored Physical Activity Internet Intervention condition are walked through the features of the intervention website by study staff. The computer-expert system, individually tailored intervention is based on the Social Cognitive Theory (SCT) and the Transtheoretical Model (TTM)[19–20], which emphasize behavioral strategies for increasing activity levels (i.e., goal-setting, self-monitoring, problem-solving barriers, increasing social support, rewarding oneself for meeting physical activity goals),

Findings from our past studies have shown that this intervention can produce significant increases in physical activity levels among non-Hispanic, predominantly White samples[32–36]. In addition, this intervention was culturally and linguistically adapted for Latinas and delivered via self-help print materials with promising results[16–18.] For the current study, formative research was first conducted with Latinas to gain an understanding of their Internet use behaviors and PA needs to develop this culturally and linguistically adapted, Spanish language Internet PA intervention targeted for Latinas.

Participants complete an online questionnaire assessing key components of SCT and TTM through the website, which generates their first tailored physical activity report. These reports draw from a bank of more than 300 messages from the computer expert system regarding: 1) current stage of motivational readiness for physical activity (e.g., “Your answers to exercise survey show that you are ready to begin exercising regularly. You are no longer just thinking about it, but you have already taken steps to become more active. Congratulations!); 2) self-efficacy (e.g., “Although you are not very active, you seem confident about your ability to exercise… Try making time for a ten-minute walk one or two days this week. It will help you continue to build your confidence about your ability to fit exercise into your lifestyle.”; 3) cognitive and behavioral strategies associated with physical activity (e.g., “You’ve been using reminders to help you think about exercising. This is great! Doing these kind of things, like leaving yourself notes to exercise, or bringing walking shoes to work can be very helpful.”).

In addition, the expert system provides feedback on how the participant compares to individuals who are physically active based on the ACSM guidelines of engaging in the equivalent of 150 min/week of MVPA (normative feedback), and how the participant compares to her prior responses (progress feedback).”

After reading the expert report, the participant receives an online motivation-matched physical activity manual that emphasizes behavioral strategies for increasing activity levels, such as goal-setting, self-monitoring, problem-solving barriers, increasing social support, and rewarding yourself for meeting physical activity goals.

Staff also review physical activity informational pages on the website with the participant. This includes several ways to determine if they are exercising at moderate intensity: target heart rate; rating of perceived exertion; 15–20 minute mile pace; and reference to the 10-minute treadmill walk participants complete. They also receive information on exercising safely and how to report an injury to the study. Lastly, the website provides links to several online and community resources. In addition to these links, an exercise video lending library is also provided, in which participants are able to borrow a DVD or VHS video of Latin-based dance and aerobics. Videos are mailed to participants with a reminder to return within 30 days of rental.

Another main feature of the website is the ability to self-monitor physical activity, set weekly physical activity goals, and view graphs depicting goals, actual activity level, and activity level compared to their goals. Trained study staff assist the participant in setting a personalized exercise goal and making a detailed physical activity plan. Participants are also given an Accusplit AE120XL pedometer to track steps. Potential barriers to completing the plan are discussed, and study staff help the participant to brainstorm ways to overcome the identified barriers.

Lastly, the website encourages social support from other participants and staff through the discussion forum on the website. During the visit, participants are asked to write a message on the board to practice posting and so other participants can welcome them to the study. Participants are encouraged to use the message board weekly to interact with other participants and to ask questions and communicate with study staff. The message board is monitored by staff in order to answer questions and review content of posts. The website also has an “ask the expert” feature where participants can send in physical activity-related questions to be answered by study staff and posted to the website.

The key points stressed at this visit are:

1. Aim to do physical activity at a moderate intensity, for at least 10 minutes at a time
2. Track how much exercise you do every day
3. Wear your pedometer and log your steps every day
4. Review and revise your exercise goal to work up to 150 minutes weekly.

5. Complete your monthly questionnaires in order to receive personally tailored exercise reports
6. Most importantly-have fun!

Intervention participants receive a phone call after one month to review their progress, and answer any questions they have about using the website. In addition, participants in the Intervention group receive an additional phone call one week following randomization to ensure proper use of the pedometer and self-monitoring on the website.

The Intervention Group also receives email prompts to access the intervention website weekly during month 1, bi-weekly during months 2 and 3, and monthly during months 4–6, with new physical activity information sheets made available on this schedule (see Figure 1). Additional monthly email prompts direct participants to complete the online questionnaire to obtain their tailored report.

Wellness Contact Control Internet Group (Control Group)

The Wellness Contact Control Internet Group receive access to a Spanish language website with information on health topics other than physical activity. Similar to the Intervention Group, study staff show participants in the Control Group their website. The web-based content focuses on diet and other factors associated with CVD risk and included information from a series on heart health developed by the NHLBI for Latinos: Cut Down On Salt and Sodium, Cut Down on Fat and Not on Taste, Learn Your Cholesterol Number, Stress Management, Kick the Smoking Habit, Protect Your Heart-Lower Your Cholesterol, Prevent High Blood Pressure[37]. Participants in the Control Group receive the same number of email contacts on the same schedule as the Intervention Group. Control Group participants log into a separate website from the Intervention Group to complete monthly update surveys on the previously described wellness topics.

Similar to the intervention group, at month 1, participants in the Control Group receive a call from study staff to ensure that they have been receiving the emails and to see if they have any questions about the website or materials.

Measures

Baseline assessments have been completed, and six and twelve month assessments are ongoing. Assessments are conducted to examine the efficacy of the intervention as well as to provide data for the computer expert system to use in generating tailored physical activity counseling messages for the Intervention Group. Demographics were assessed at baseline with a brief questionnaire regarding age, education, income, occupation, race, ethnicity, history of residence in the U.S., and marital status. The Brief Acculturation Scale (BrAS) is a four-item measure that asks about language use across different life contexts (i.e., at home, with friends). The BrAS has good internal consistency (Cronbach alpha=.90) and correlates highly with generational status, time in country, and ethnic identity[38]. The Short Test of Functional Health Literacy in Adults (STOFHLA), a brief (7-minute) measure designed to evaluate adult literacy in the health care setting, was also administered at baseline[39].

The 7-Day Physical Activity Recall (7-Day PAR) was used to produce power estimates for the study and therefore serves as the primary outcome measure[40,41]. The 7-Day PAR is an interviewer-administered instrument that provides details about the types of activities engaged in and an estimate of weekly minutes of MVPA. It uses multiple strategies for increasing accuracy of recall, such as breaking down the week into daily segments (i.e., morning, afternoon, and evening) and asking about many types of activities, including time spent sleeping and in moderate, hard, and very hard activity. The 7-Day PAR has been used across many studies on physical activity and has consistently demonstrated acceptable reliability, internal consistency, and congruent validity with other more objective measures of activity levels[42–44]. Past research indicates that the 7-Day PAR is sensitive to changes in moderate intensity physical activity over time, [45,46] and has good test-retest reliability among Latino participants[47]. The 7-Day PAR data is assessed to overlap with accelerometer wear to corroborate the self-reported data.

Accelerometer measured physical activity (ActiGraph 3X+) serves as an objective measure of the primary outcome. Accelerometers measure both movement and intensity of activity and have been validated with heart rate telemetry[48] and total energy expenditure[49]. Accelerometer data is processed using the ActiLife software, with a cutpoint of 1952 to establish the minimum threshold for moderate intensity activity. Participants are asked to wear the accelerometer for seven days. Valid wear time is classified as five days of at least 600 minutes of wear time each day or at least 3000 minutes of wear time over four days. To be counted in the total minutes/week of activity, activity has to occur in 10 minute bouts.

Psychosocial measures related to depression, social support, stress, and physical activity enjoyment and environment are also completed. The short-version of the Center for Epidemiological Studies Depression Scale (CES-D) is a 10-question measure of depressive symptoms [50] that has been translated and validated across different ethnic groups, with internal consistencies of .87 and above in both English and Spanish[51,52]. Social support for physical activity is examined in terms of support from friends and family members for physical activity. The 13-question measure has three subscales with acceptable internal consistencies (alphas range from 0.61 to 0.91) and good criterion validity[53]. Perceived Stress Scale (PSS)[54] examines the degree to which specific situations are deemed as stressful in the past week. The PSS is well validated and has been used in many studies examining the association between stress and health[55]. The Physical Activity Enjoyment Scale (PACES)[56] assesses the level of personal satisfaction derived from physical activity participation. The measure has 18 items with high internal consistency (alpha = 0.96) and criterion validity[56]. Neighborhood Environment Walkability Scale, Abbreviated (NEWSA) includes 54 items[57, 58] assessing various aspects of the built environment related to walking, neighborhood aesthetics, and traffic. Several studies have supported the test–retest reliability of the NEWS[59] as well as its construct validity by reporting significant differences on some NEWS subscales between neighborhoods selected to differ on walkability[60] and modest correlations between NEWS subscales and accelerometer and self-reported estimates of physical activity[61,62].

Three measures, stage of change, self-efficacy for physical activity, and the processes of change, are administered at baseline and on a monthly basis via the website, and are used to

help generate the tailored expert system feedback reports for the Intervention Group. The 4-item stage of change measure has demonstrated reliability (Kappa = 0.78; intra-class correlation r = 0.84) as well as shown acceptable concurrent validity with measures of self-efficacy and current activity levels[63]. The 40-item processes measure contains 10 sub-scales that address a variety of processes of activity behavior change. Internal consistency of the subscales ranged from .62 to .96[64]. Self-efficacy, or confidence in one's ability to persist with exercising in various situations, such as when feeling fatigued or encountering inclement weather, was measured with a 5-item instrument[63] developed by Marcus and colleagues (alpha = .82).

Lastly, during the 12 month follow-up visit, study staff will conduct brief semi-structured qualitative interviews with a sub-sample of intervention participants to explore participants' perceptions and satisfaction with the intervention, as well as their opinions regarding individual components of the website.

Intervention Fidelity

In accordance with the treatment fidelity model outlined by Bellg et al. (2004), evaluation and verification of intervention fidelity for the current study was based on the following: 1) Fidelity to Theory: Participants receive online questionnaires assessing key components of SCT and TTM, and the expert system creates reports based on the SCT and TTM components; 2) Provider Training: Standardized protocols are used in training staff to conduct all study visits, and 10% of randomization sessions are reviewed to ensure adherence to protocol and provide feedback/ supervision; 3) Treatment Implementation: The website captures number of logins and each page visited to provide information of use of the website and access to the information on the website. Participants also complete a questionnaire regarding the degree to which the intervention was accessed and materials read or used; 4) Treatment Receipt: One-week and one-month phone calls are conducted post-randomization to ensure proper use of the pedometer and self-monitoring on the website; participants who are not completing their physical activity logs or their monthly online questionnaires are also contacted; 5) Treatment Enactment: Change in PA are measured by self-report and objective measures at several time points, and monthly questionnaires assess changes in psychosocial variables related to PA. Participants also log their activity and set weekly goals using the study website.

Anticipated Data Analysis and Sample Size Considerations

Data analysis will focus on testing differences in minutes of MVPA between the Intervention Group and Control Group at baseline, 6 and 12 months. The primary variable of interest is the number of minutes of at least moderate intensity activity (as measured by the 7-Day PAR and accelerometer). We will use a single longitudinal mixed effects regression model in order to test both the primary question of interest (differences between groups at 6 months) and the additional aim (testing differences in physical activity during the maintenance phase). To avoid the effects of potential outliers, we will apply a normalizing transformation to the response measure (minutes of reported and objectively measured activity at follow-up) before proceeding with the analysis. The model will include a subject-specific intercept to adjust for correlated outcomes over time within participant and will adjust for potential

confounders, including any variables not balanced by randomization. Additionally, we will explore any potential effects of clustering by yoked pairs. Mixed effects models using a likelihood based approach to estimation and thus make use of all available data without directly imputing missing outcomes. Models for objectively measured MVPA will also control for wear time.

Our sample size calculation is based on the assumption that we will have 80% power for testing the null hypothesis that the intention to treat effect is zero, versus the two-sided alternative that the effect is different for those randomized to the Intervention Group versus those randomized to the Control Group. Our sample size estimates are based on the reported change in MVPA over 6 months amongst a subset of participants from our previous individually-tailored, print-based Latina study (NR009864) who reported having Internet access[16–18]. The mean difference in weekly physical activity minutes from baseline to 6 months in this print-based study was 149.90 (SD=285.21) for those randomized to the Tailored Intervention Group and 50.47(SD=74.58) for those randomized to the Wellness Control Group. Although these effects correspond to only a subset of randomized participants, the content of the intervention materials used were the same as the current study and we felt that this particular group is more similar to our targeted sample than the study sample as a whole.

Reported effects amongst this subset were also similar to those from our recent individually-tailored, Internet-delivered pilot study (Step Into Motion II pilot), in which participants randomized to the Enhanced Internet Intervention group reported greater increases in MVPA over time when compared to a Standard Internet Control group (167.64 vs. 36.43, $p<0.05$) [66,67]. With at least 100 participants randomized to each arm at baseline in the current study, we expect to have sufficient power (80%) to detect differences in minutes of MVPA from baseline to 6 months between the Intervention Group and the Control Group using a two-tailed significance level $\alpha=0.05$. It is important to note that this sample size is deliberately conservative as it does not assume the availability of repeated outcome measures that will be taken throughout the study. By choosing models that make use of the longitudinal data, we will be increasing the power to detect differences between treatment groups[68–69].

Costs and cost-effectiveness analyses will be conducted from a clinic implementation perspective, which will estimate the costs of implementing the intervention in a non-research setting such as a community clinic or wellness center. We will therefore only include costs associated with delivering the intervention or control condition, including materials, hardware and software, costs of maintaining the expert system, and personnel time (including benefits and overhead). Research-related costs, such as baseline assessments and time obtaining consent, will not be included. Cost-effectiveness will be based on change in the primary outcome (physical activity measured by the 7-Day PAR and accelerometer) at six months, and we will report both cost per minute increase in activity in the intervention vs. control as well as incremental costs of the intervention vs. control groups. Additional analyses will be conducted on change in physical activity at 12 months. We will report the costs of developing the website; however, because implementing the intervention in a clinic/

community setting would not require redeveloping the website, we will report cost effectiveness both with and without the cost of the website development.

Results

A total of 838 individuals expressed interest in participation. Of these, 620 were not included in the study because 258 did not meet inclusion criteria, 300 were deemed ineligible prior to randomization, 33 declined to participate, 25 failed to complete the screener, 4 were unable to be scheduled for an orientation. Refer to Figure 2 for the CONSORT diagram.

The sample includes the remaining 218 eligible women who were randomly assigned to the Intervention (N=104) and Control (N=101) groups, as 13 participants were deemed ineligible post-randomization. On average, participant body mass index (BMI) was in the overweight range. Approximately 87% of Intervention and 77% of Control participants are first generation in the U.S. (majority Mexican), and more than half speak only Spanish or more Spanish than English at home (71% Intervention, 67% Control). More than half of participants reported an annual household income < $30,000 (69% Intervention, 54% Control), and more than half reported at least some college level education (55% Intervention, 66% Control). Participants, on average, had adequate functional health literacy (M score=34.8, SD=2.7; scores between 23–36 categorized as adequate). The average age was 38.84 years old (SD=10.61) for Intervention participants and 39.57 (SD=10.36) for Control. There were no group differences in psychosocial variables at the baseline assessment (see Table 1).

Participants reported low levels of physical activity and related psychosocial process variables at the baseline assessment. The mean minutes per week of MVPA at baseline was 8.01 (SD=14.95) for Intervention participants and 10.44 (SD=23.98) for Controls as measured by the 7-Day PAR. Mean minutes per week recorded by accelerometers were higher, with a mean of 35.77 (SD=69.65) minutes for Intervention participants and 28.67 (SD=48.22) minutes in Controls. Despite these differences, baseline self-reported physical activity levels (7-Day PAR) were significantly correlated with accelerometer data (rho=0.28, p<.01). Participants also reported low levels of self-efficacy, cognitive and behavioral processes of change, and social support from family and friends (see Table 2). The mean CES-D score was 7.83 (SD=5.59), while the average PSS score was 22.58 (SD=8.97) and mean enjoyment was 87.17 (SD=20.22). Neighborhood walkability scales are presented in Table 2.

Discussion

The current study holds both clinical and public health significance as it seeks to test an intervention for a substantial public health problem in the largest racial/ethnic minority group in the United States, Latinos[70]. This target population remains chronically underserved, despite bearing a higher burden of disease for many conditions with which lack of physical activity has been linked[8–10]. The intervention capitalizes upon the recent increases in Internet access and use among Latinos, as well as the target population's

enthusiasm for receiving physical activity information in this manner. Using the Internet as the delivery channel allows for an interactive and tailored intervention that is accessible by this population and can be easily disseminated. Although initial costs are required to develop the Internet site, no costs are associated with additional users. Thus, the potential for cost effectiveness on a large scale is great. In addition, this physical activity intervention has been geared, through a series of formative research, specifically to the needs and preferences of Latinas and is likely to have a strong impact on this important health behavior.

Baseline data suggest we were able to recruit a sample of Latinas in great need of increasing their physical activity. Interestingly, the baseline accelerometer measured physical activity levels were higher than self-reported physical activity. There are several potential reasons for the under-reporting compared to accelerometer. One reason may be that Latinas exhibit higher levels of social desirability[71]. Participants knew they were entering into a study that required insufficient activity and, as a result, may have been minimizing their current activity to ensure enrollment in the study. Another reason may be that participants were not thinking about occupational-related activities (or did not think they should count it as "physical activity") when reporting their physical activity[72]. Alternatively, this finding may just reflect general measurement error. While other research has found that overweight participants are more likely to overestimate their physical activity compared to objective measurement,[73] a review of the literature found that self-report was both higher and lower than directly measured levels of physical activity [35].

In addition to such low starting levels of MVPA, data from several of the process variables suggest that this group may have some challenges when trying to increase their activity levels. Participants reported low levels of self-efficacy for being physically active and low levels of using cognitive and behavior strategies for behavior change. In addition, they reported having low levels of support for physical activity from family and friends. Furthermore, although 60% of our sample reported some college experience, 45% also reported being unemployed. Approximately half (53.7%) of the participants were married at the time of participation in this study, and 87% reported having children under the age of 18 living in the home. Thus, these unemployment rates may be attributable to caring for children at home.

Although participants may report characteristics that may make behavior change difficult, the current intervention is utilizing several features that we hope will overcome these challenges. The Internet delivers tailored materials in real-time, such that after completing the questionnaire the participant's tailored report is immediately given. As previously described, a forum is also provided where participants can ask questions and communicate with staff and other participants to help address their specific needs. Tailored interventions such as this have shown efficacy over non-tailored interventions[74,75].

The evidence for the effectiveness of Internet based interventions continues to grow; however, none have focused specifically on Latinas. With the current study we will not only be able to test if the Internet intervention is effective, but we will also be able to gather more detailed information about participant interaction with the website. The website captures how many times each page is visited, the amount of time spent on each page, and each time

an interactive feature of the website is used. Through this data, we will be able to determine dose of intervention and level of utilization of each of the website features to help future refinement of the intervention.

Limitations

One limitation of this study is that the sample is comprised of mostly healthy Mexican-American volunteers with access to computer/Internet access, criterion that may limit the generalizability of the results to Latinas in general. Because physical activity was unsupervised, for safety purposes participants with chronic health conditions, such as type II diabetes and heart disease, were not included, though this intervention may be especially beneficial for such clinical populations. Also, although baseline measures of physical activity using the 7-Day PAR and accelerometers were significantly correlated, marked differences were observed in the actual minutes reported by each measure. Such correlations may improve over time as participants become more familiar with moderate intensity physical activity, though this discrepancy highlights the importance of completing all analyses for both subjective and objective measures. Finally, although it was most appropriate for the current population, reliance solely on web-based technology without utilizing other mobile technologies such as smartphones may have limited the interactivity of the intervention. As smartphone ownership increases in this population in the future, incorporation of the capabilities of smartphones and other technologies, such as Bluetooth-enabled activity trackers, could further enhance the effectiveness of the intervention.

Summary

To meet the needs of the growing Latina population, which is at increased risk for health complications related to lack of physical activity, we need effective interventions that keep up with the changing access to technology through using methods such as the Internet. By demonstrating the efficacy and cost-effectiveness of a physical activity intervention for Latinas, the potential for dissemination could have a significant impact on the health of this at risk and understudied group.

Acknowledgments

This work was supported by the National Cancer Institute of the National Institutes of Health (5R01CA159954). We would like to thank Raul Fortunet, Karla Nuñez, Rachelle Edgar, Daniah Tanori, David Bakal, and Veronica Villarreal at the University of California, San Diego, for their valuable research assistance and contributions to this study.

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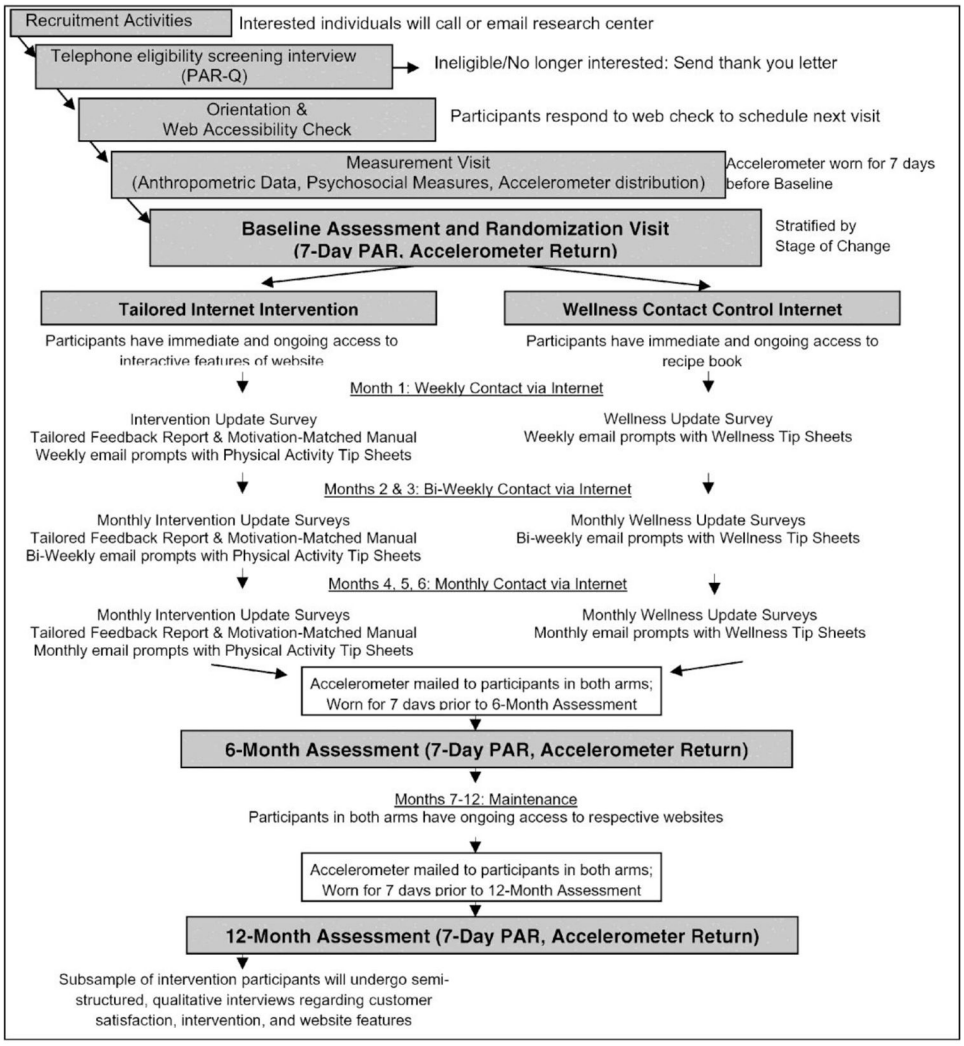

Figure 1.
Study Schema

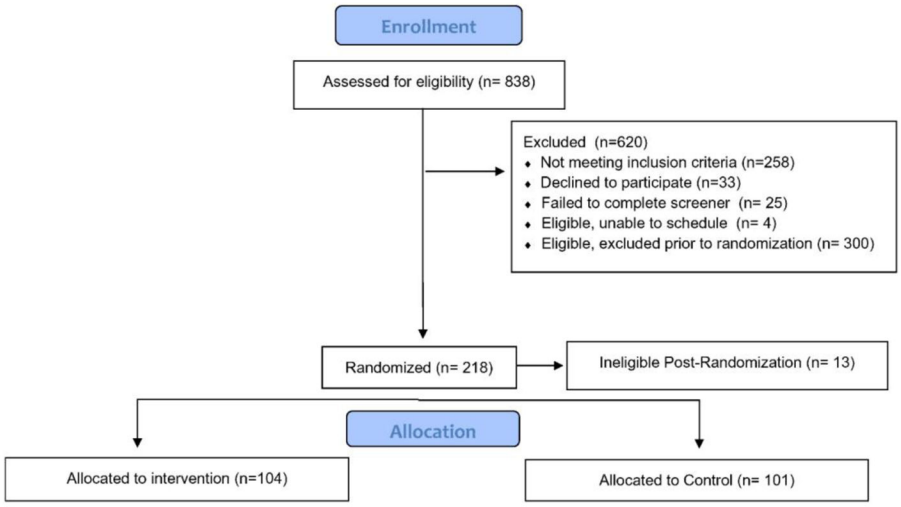

Figure 2.
Baseline Consort Diagram

Table 1

Demographic Characteristics

Characteristics	Intervention (Mean and SD or %) (N=104)	Control (Mean and SD or %) (N=101)	Overall (M and SD or %) (N=205)
Latina	100%	100%	100%
Age	38.84(10.61)	39.57(10.36)	39.20(10.47)
Generation Status in U.S. (% First) N=204	86.5%	77.0%	81.9%
BMI (kg/m2) N=204	29.07 (5.82)	28.58(4.50)	28.83(5.20)
Race			
White	45.2%	58.4%	51.7%
Mixed	17.3%	14.9%	16.1%
Other	30.8%	18.8%	24.9%
Ethnicity			
Mexican	82.7%	86.1%	84.4%
Columbian	1.9%	5.0%	3.4%
Guatemalan	1.9%	0.0%	1.0%
Puerto Rican	1.0%	1.0%	1.0%
Dominican Republic	1.0%	0%	0.5%
Other	14.4%	10.9%	12.7%
Yearly Household Income			
<$30,000	69.3%	63.5%	66.4%
≥$30,00 but < $50,000	17.3%	24.7%	21.0%
≥$50,000	9.6%	6.9%	8.3%
Don't Know	3.8%	5.0%	4.4%
Employment Status			
Unemployed	49.0%	41.0%	45.1%
Part Time	25.0%	30.0%	27.5%
Full Time	25.0%	29.0%	27.0%
Refused/Did Not Answer	1%	0	0.5%
Education Level (N=204)			
<High School Graduate	14.6%	13.9%	14.2%
High School Graduate	15.5%	7.9%	11.8%
Vocational/Tech	14.6%	11.9%	13.2%
≥Some college	55.4%	66.4%	60.8%
Language Spoken in the Home			
Only Spanish	40.4%	34.7%	37.6%
More Spanish than English	30.8%	32.7%	31.7%

Characteristics	Intervention (Mean and SD or %) (N=104)	Control (Mean and SD or %) (N=101)	Overall (M and SD or %) (N=205)
Both Equally	15.4%	23.8%	19.5%
More English than Spanish	11.5%	5.0%	8.3%
Only English	1.9%	4.0%	2.9%
Marital Status			
Married	50.0%	57.4%	53.7%
Living with Partner	4.8%	5.9%	5.4%
Separated	13.5%	3.0%	8.3%
Divorced	10.6%	16.8%	13.7%
Widowed	1.9%	3.0%	2.4%
Never Married or Living with Partner	19.2%	13.9%	16.6%
Health Literacy (*scores of 23–26 "adequate")*	34.8(2.7)	37.3(22.8)	36.02(16.13)

Table 2

Baseline Physical Activity Levels and Related Psychosocial Variables (N=205)

Variables	Intervention (Mean and SD)	Control (Mean and SD)	Overall (Mean and SD)
Self report MVPA (minutes/week, N=205, 7-Day PAR)	8.01(14.95)	10.44(23.98)	9.20(19.91)
Accelerometer measured MVPA in 10 minute bouts (minutes/week, N=200)	35.77(69.65)	28.67 (48.22)	32.25(59.96)
Self-Efficacy (range 1–5), N=200	2.27(0.75)	2.40(0.82)	2.34(0.79)
Processes of Change, N=205			
Cognitive Processes (range 1–4.6)	2.42(0.85)	2.49(0.79)	2.45(0.82)
Behavioral Processes (range 1–4.3)	1.98(0.64)	2.00(0.58)	1.99(0.61)
Social Support N=202			
Friends Participation Score (range 10–49)	15.17(7.30)	14.67(5.59)	14.93(6.52)
Family Participation Score (range 10–50)	17.59(7.43)	17.96(7.81)	17.77(7.60)
Rewards and Punishments (range 3–7)	3.50(1.06)	3.36(0.86)	3.43(0.96)
Stage of Change, N=205			
Pre Contemplation	6.7%	5.0%	5.9%
Contemplation	74.0%	76.2%	75.1%
Preparation	18.3%	17.8%	18.0%
Action	1.0%	1.0%	1.0%
Depression (CES-D), N=205 (range 0–26)	8.08(5.65)	7.58(5.55)	7.83(5.59)
Enjoyment (PACES), N=197 (range 23–124)	86.51(21.68)	87.83(18.75)	87.17(20.22)
Stress (PSS), N=201 (range 4–55)	22.97(8.54)	22.18 (9.43)	22.58(8.97)
Environment (NEWS)			
Residential Density, N=205, range 174–692	250.14(92.43)	228.95(71.97)	239.70(83.46)
Diversity, N=130, range 1–4.96	2.87(0.88)	2.91(0.92)	2.89(0.90)
Access, N=204, range 1–4	3.34(0.72)	3.27(0.74)	3.31(0.73)
Street Connectivity, N=204, range 1–4	3.16(0.70)	3.03(0.80)	3.09(0.75)
SWS,N=204, range 1.33–4	2.86(0.63)	2.98(0.62)	2.91(0.63)
Aesthetic, N=205, range 1–4	2.74(0.81)	2.74(0.86)	2.74(0.83)
Traffic, N=205, range 1–4	2.29(0.76)	2.17(0.756)	2.23(0.76)
Crime, N=204, range 1–4	1.86(0.83)	1.62(0.77)	1.74(0.81)