

Physical Activity Intervention for Adolescent Girls

Clinical Trials NCT04190225

Study Protocol and Statistical Analysis Plan

September 4, 2024

Trial Design and Setting

Chicas Fuertes is a parallel group randomized trial. Adolescent Latinas (N=200) living in San Diego County are randomized 1:1 to receive either the mobile technology-based MVPA intervention or only a wearable tracker (control group); analyses will test the superiority of the intervention over the control condition in increasing MVPA. Participants assigned to the intervention first receive a face-to-face counseling session to learn behavior change techniques. These sessions are conducted in a number of settings such as local parks, classrooms, and community-based organizations. They then receive a Fitbit and access to a tailored intervention website to reinforce goal setting and self-monitoring. Participants also are connected to a study Instagram account, and receive regular text messages automatically generated by data from wearable trackers that update participants on goal progress and encourage adaptive goal setting. Activity is measured at baseline and follow-up via accelerometers and the 7-Day Physical Activity Recall (PAR) Interview, and throughout the study using Fitbits. Measures are taken again at 12 months to evaluate maintenance of activity gains. The sponsor and funder, the National Institutes of Health, played no part in study design. They have no role in the collection, management, analysis, and interpretation of data. They played no part in writing of the protocol and the decision to submit the protocol for publication. The study protocol uses SPIRIT reporting guidelines ¹.

Participants

Eligibility criteria

Potential participants must self-identify as Latina, be 13-18 years old, read, write, and speak English, and be underactive, defined as regularly participating in MVPA for less than 150 minutes per week. Participants must also have regular (≥ 2 times/week) access to the Internet and to a cell phone that can receive and send text messages. Interested participants who do not have access to a smartphone are provided equipment to sync the Fitbit with a computer and

use the Fitbit website dashboard rather than the smartphone app.

Intervention

Intervention description

The intervention utilizes the same theory-based intervention strategies we have shown to successfully increase MVPA in non-Latino White men and women ², Latina adults ³⁻⁵, Latino men ⁶, and which showed good potential efficacy with Latina adolescents in our pilot trial ⁷. The current intervention focuses on the same core theoretical components and behavior change strategies from multiple psychosocial theories, including Social Cognitive Theory (SCT) and the Transtheoretical Model (TTM), i.e., goal-setting, self-monitoring, problem-solving barriers, increasing social support, social norms, and rewarding oneself for meeting goals, which are reinforced by various technology channels: the Fitbit Inspire HR wrist monitor and Fitbit app, interactive automated text messaging, motivational content on social media (Instagram), and an interactive website. In order to leverage the tools of each channel and avoid fatigue with the technologies, different channels are emphasized at different time points. The schedule and content of the intervention components were refined through an intensive iterative process involving multiple interviews, focus groups, and design workshops with Latina girls (N=50) and beta testing with a Youth Advisory Board; this has been described in detail elsewhere.

Intervention components are summarized in Table 1.

At the baseline one-on-one counseling session with a trained interventionist, the participant learns about MVPA (e.g. guidelines, benefits, intensity, duration) and engages in an individual goal setting. This session is based on principles of motivational interviewing, and teaches individuals to set realistic, specific short-term goals to build up to the long-term goal of meeting national guidelines (300 minutes/week of MVPA for children aged 12-17) ⁸. The interventionist

and the participant review her activity from the baseline week (measured by the Fitbit), and the participant selects her own goal for the following week. The interventionist also helps her identify personal barriers to activity (e.g., time, motivation), and teaches problem-solving strategies. The participant is then oriented to the mHealth technology channels of the intervention. Health coaching sessions are recorded (with participant permission); a random subsample of recordings are evaluated by an external consultant to ensure fidelity of intervention delivery across participants.

Website

At the baseline study visit, participants assigned to the intervention group are provided with a unique login and password for the *Chicas Fuertes* website, which serves as a rich resource for MVPA tips and strategies, as well as the platform for MVPA goal setting and monitoring. The website includes a weekly calendar for planning out the upcoming week of activity, including which activities they plan to do, which days and times they plan to do them, where they plan to do them, and for how long. The calendar syncs with the participant's Fitbit so that actual minutes of MVPA are directly imputed to allow participants to visualize planned vs. completed activity. The website also includes a monthly questionnaire, which measures participants' attitudes, beliefs, and strategies for increasing MVPA. Responses to monthly questionnaires are fed into an expert system that automatically generates personalized reports, drawing from a bank of 330 messages addressing different levels of psychosocial and environmental factors affecting physical activity, such as stages of change, decisional balance, and self-efficacy, and tailors messages based on whether scores on these phenomena have increased, decreased, or remained stagnant. Tailored reports address: 1) their current stage of motivational readiness for physical activity; 2) increasing self-efficacy for physical activity; 3) cognitive and behavioral strategies associated with physical activity behavior change (processes of change); 4) how the participant compares to their prior responses (progress feedback); 5) how the participant

compares to other adolescents who are physically active (normative feedback); and, 6) self-monitoring of MVPA (use of online activity logging calendars). Participants complete the questionnaire each month for the first six months of the study, and every other month for the remaining six months, and receive \$10 each time they complete the questionnaire.

Other website features include maps of free or low-cost places to be active locally, strategies to overcome common barriers to MVPA, web links to free online workout videos, and a current activity leaders board that highlights the three most active participants that week (measured by Fitbit activity). The website also has an online message board, moderated by the interventionist, where participants can encourage each other to be active, congratulate and celebrate each other's successes, and seek guidance or support. The website also scrolls the study Instagram feed (see below). To encourage regular use of the *Chicas Fuertes* website, participants receive "engagement points" for logging on, answering the weekly pop quiz question, and setting their weekly MVPA goals. Accrued points can be traded in for a variety of *Chicas Fuertes* branded prizes, such as water bottles, power banks, and Bluetooth speakers.

Fitbit Inspire HR Monitor and app

Participants in both the intervention and control groups are provided with a Fitbit Inspire HR monitor and free Fitbit app for the one-year study; however, only those in the intervention group receive coaching on how to navigate the features of the Fitbit App. At baseline, the interventionist walks the intervention participant through the Fitbit app, focusing on how to monitor PA metrics, such as steps, MVPA minutes, and heartrate, as well as how to set goals for MVPA. Participants are encouraged to monitor their progress regularly on both the Fitbit wrist-worn tracker as well as the Fitbit app, and to update their MVPA goals on the Fitbit app gradually over time as they work toward increasing their weekly MVPA minutes.

Text messaging

In the first month of the intervention, text messaging is primarily used to reinforce other intervention media channels. Participants receive text message reminders to use the website features, which includes a link to take them directly to the website. They receive additional weekly texts reminding them to set goals and wear & sync their Fitbits. In months 2-12, participants also receive algorithm-derived individually tailored text messages updating them on their goal progress mid-week and reviewing MVPA at the end of the week. Data are sourced from the Fitabase software program that monitors Fitbit data in real time and computes total active and very active minutes. Texts encourage adaptive goal setting, asking participants who meet their activity minute goal if they can increase their goal by 10% for the next week until national guidelines are met. Participants who do not meet their goal receive a text calculating how many more minutes they need to add per day to meet their goal and asking if they believe that they can do it for the coming week.

Instagram posts

Instagram posts are used to deliver short, visual, daily intervention content based on specified constructs of psychosocial theories. At baseline, participants assigned to the intervention group are invited to “follow” the study’s private Instagram account. Focus group results prior to the study launch directed the development of Instagram posts that contain brightly colored images and videos featuring relatable girls engaging in MVPA, couched in positive and inspirational messaging. Each day of the week features one post based on constructs from the aforementioned psychosocial theories: benefits/outcomes, social support, modeling, environment, self-efficacy, and a weekly challenge incorporating behavior change techniques for participants to try during the week (see Figure 3 for sample post). Along with daily posts, Instagram stories are posted throughout the week, which include interactive components such as a poll or quiz to engage users. Participants are encouraged to “like” the posts, which indicates to the study team that the post has been seen, and also ensures that *Chicas Fuertes* posts remain at the top of the participant’s Instagram feed.

One month call

After one month, participants receive a brief (20-minute) phone call from intervention staff to review progress. The interventionist reviews their goals and progress and helps them set new goals for the coming week and address barriers they have experienced so far. The participant is instructed to fill out their next online questionnaire to generate an individually tailored report on the website. Reminders to fill out questionnaires in subsequent months are automatically sent via text message.

6-month visit

During the 6-month assessment, those in the Intervention arm also engage in a repeat goal setting session and learn strategies to maximize MVPA maintenance over the next six months. The interventionist emphasizes continued self-monitoring using the Fitbit and asks them to identify sources of support to help them stay active.

Control group

The control group receives a Fitbit Inspire HR wrist-worn tracker to wear throughout the 12-month intervention. They are encouraged to wear the Fitbit every day, and sync at least every four days. They have access to all features built into the Fitbit monitor and app (see Table 1), but do not receive explicit instruction on how to use or personalize them. This control group is meant to serve as a “real world” control group, representing the large, growing population of individuals who purchase commercial fitness trackers and receive no additional guidance in using them.

Intervention: adherence

We examine adherence to the intervention through monitoring frequency of Fitbit wear and syncing, tracking logins on the website, and monitoring views and likes on the Instagram

account. Participants receive text messages reminding them to sync their Fitbit if they have not synced for four days. They also receive engagement points for interacting with the website, which can be traded in for prizes.

To increase enrollment and retention in the study, Fitbit devices and incentives in the form of cash payments and gift cards are provided to all participants. At baseline, each participant receives a Fitbit Inspire HR activity tracker to use throughout the study and keep after study participation is completed. Incentive payments of \$25, \$50, and \$50 are provided at the baseline, 6-, and 12-month follow-up measurement visits, respectively. Additionally, participants receive an additional \$25 bonus if they complete all measures at the 6- and 12-month visits. Lastly, while in-person research was suspended at UC San Diego (March 2020 – August 2020) and is limited (August 2020 – present) to mitigate the spread of COVID-19, remote follow-up measurement visits are offered to participants unable to return in-person. This includes completing self-report surveys online.

Outcomes

Primary outcome

The primary outcome is change in weekly minutes of MVPA from baseline to six months measured by the ActiGraph GT3X+ accelerometer. The ActiGraph GT3X+ is a hip-worn triaxial accelerometer which measures movement and intensity of activity and has been validated against heart rate telemetry⁹ and total energy expenditure¹⁰, including in children.¹¹

Participants wear the ActiGraph for ≥ 12 hrs/day ≥ 7 days at baseline and follow-up. Participants receive regular text messages to remind them to wear the ActiGraph. Valid wear time is considered ≥ 3000 minutes on ≥ 4 days. Data is processed using Freedson's age-specific cut points for children to identify activity at various intensities.¹² We will evaluate total minutes of MVPA and total time in 10+ minute bouts.

As an additional measure of MVPA change, at baseline and follow-up participants also engage in the 7-Day PAR interview. The 7-Day PAR is a semi-structured interview that assesses frequency, duration and intensity of MVPA. It has consistently demonstrated acceptable reliability, internal consistency, and congruent validity with objective MVPA measures^{13,14} and sensitivity to changes over time.^{15,16} It has been validated in children as young as 11.¹⁷ Administering the PAR requires annual certification. To ensure fidelity of PAR measures, a random sample of 5% of PAR interviews are recorded and assessed for fidelity by an external consultant.

Secondary outcomes and covariates

Participant demographic information is measured via self-report questionnaire at baseline, and includes age, race, and parents' education, income, and marital status.

We also will assess changes in trajectories of daily MVPA measured by the Fitbit Inspire HR. The Fitbit tracker measures physical activity intensity, energy expenditure, bouts of exercise, steps, distance traveled, and flights of stairs at varying resolutions. We will be evaluating the daily active minutes and steps recorded by the Fitbit.

We will also measure technology engagement with the website, Fitbit, texting interactions, and Instagram. Engagement with the *Chicas Fuertes* website measures number of logins and use of specific features, including goal setting, the weekly quiz, and monthly questionnaire completion. Fitbit use is measured as days worn and sync frequency, while texting is based on the percentage of interactive texts the participants responded to. Instagram engagement is measured by the number of views and likes by participants.

Questionnaires on the website are used to create individual intervention content, and also serve as measures of psychosocial constructs. Stages of Change for Physical Activity (SCPA) is used to stage-match participants, it has been successful in previous trials and has acceptable reliability (Kappa = 0.78; intraclass correlation $r = 0.84$)¹⁸. Processes of Change for Physical Activity (POC) was also administered monthly, POC contains 10 subscales on a variety of cognitive and behavioral processes related to MVPA change. Its subscale internal consistency ranges from .62 to .96.¹⁹ Self-Efficacy for Physical Activity (SE) was used to measure self-efficacy to become physically active across diverse contexts. The SE internal consistency is acceptable ($\alpha = .82$)¹⁸. We also administered the Social Support for Exercise (SSE) scale which has three subscales of family, friends, rewards and punishments and an acceptable internal consistency (alphas .61-.91) and criterion validity²⁰. To assess enjoyment for physical activity, the Physical Activity Enjoyment Scale (PACES) is used to evaluate the level of personal satisfaction from PA. PACES has high internal consistency ($\alpha = 0.96$) and test-retest reliability²¹. Lastly, we used the Outcome Expectations Scale to assess the beliefs regarding the consequences of physical activity participation will be examined by 9 items with internal consistency ($\alpha = .89$) and validity based on confirmatory factor analysis and positive correlations with physical activity and self-efficacy.

Neighborhood environment is measured using the Neighborhood Environment Walkability Scale for Youth (NEWS-Y). The NEWS-Y measures perceptions of neighborhood environment, including recreation facility availability, pedestrian traffic safety, and walking facilities. It has shown acceptable reliability and correlations with objectively measured activity²².

Participants also fill out the CES-D depression inventory at baseline and follow-up visits.

Potential contamination is measured at six and 12 months through a contamination measure asking participants to indicate the number of people they know who were simultaneously in the study, how much contact they had with them, and if they changed any of their behaviors due to their contact with other participants.

At 12 months, participants in the intervention group were asked to complete a consumer satisfaction measure to assess the acceptability of the intervention. This is modified from our previous studies.

Screening and consenting

Potential participants may contact research staff through Instagram direct message, Facebook, email, or text/call via the study phone number. Interested participants are then called to participate in the telephone screener that includes a description of the study purpose, procedures, risks, benefits, and eligibility requirements. If participant is under the age of 18, research staff first talk with her parent/guardian before screening her to ask basic eligibility questions and to receive parental consent to screen the daughter, then speak to the adolescent to complete screening. If eligible, interested participants are invited to engage in an orientation session via Zoom.

Orientation visit

Prior to the orientation session, participants are instructed to download the Fitbit app and set up an account. They are also provided with an orientation packet via mail, including a Fitbit Inspire HR, a hip-worn accelerometer, and an orientation folder that includes a consent form, assent form, instructions on how to use the Fitbit, and instructions for wearing the accelerometer. The girl's parent/guardian is invited to attend the first half of the orientation via Zoom to review a PowerPoint presentation that outlines the procedures, benefits, and expectations of the study. Following the presentations, the participant and their parent/guardian sign the written informed consent and assent forms, which are collected the following week at the baseline visit. The second half of the orientation is used to set up the Fitbit, including syncing it with a smartphone, connecting it to the study's online Fitabase database, and temporarily blinding the Fitbit monitor and app to prevent feedback from influencing baseline activity. We also review the Fitbit and accelerometer expectations, and schedule the Baseline visit for 7 days after the orientation.

Over the next week, participants wear the Fitbit wrist monitor, and a hip worn GT3X+ accelerometer, with instructions to wear it 12 hours per day for seven days. Before the baseline visit, they also fill out online psychosocial measures, including self-efficacy, stage of change for activity, and social support (see Measures).

Baseline visit

One week after the orientation visit, participants attend an in-person baseline visit. Due to COVID-19 restrictions, in-person visits are conducted outdoors at parks close to the participant's home. Participants return the accelerometer, which is assessed for sufficient wear time (≥ 3000 minutes on ≥ 4 days). After performing a short walk to demonstrate activity of a moderate intensity level, participants complete the 7-Day PAR interview^{13,17}. Once all baseline measures are completed, including all online psychosocial questionnaires, participants are randomized to either the multi-media MVPA intervention, or to a control group receiving only a Fitbit.

Follow-up visits

The primary outcome is change in MVPA from baseline to six months, with maintenance of activity at 12 months serving as a secondary outcome. Follow-up visits are conducted remotely via Zoom software. Prior to the six- and 12-month visits, participants are mailed the accelerometer for one week of wear, similar to baseline. Accelerometers are mailed back and checked for wear time, after which participants complete the PAR interview over Zoom, and fill in online psychosocial questionnaires. Participants also complete a contamination measure at six and 12 months to assess amount and type of contact with participants in other conditions. At 12 months, a consumer satisfaction measure is completed by those in the Intervention arm to assess the acceptability of the Chicas Fuertes MVPA intervention, and a subset of participants engage in a one-on-one interview to give additional feedback about the program. Participants receive \$50 for completing the baseline, 6- and 12-month measures, \$25 for correctly wearing

and returning the accelerometer, and \$25 for completing all other measures. Participants receive an additional \$25 bonus at month 12 if they complete all measures at all visits.

Recruitment

Over three years, we are recruiting a total of 200 adolescent girls (age 13-18) who self-identify as Latina and/or belong to groups considered Latino by the US Census Bureau. Recruitment is done through a variety of approaches including social media advertisements, providing health presentations in classes at local middle and high schools in San Diego County, conducting information sessions at community organization sites, distributing flyers through Latino-serving organizations, and contacting Latina women who have participated in previous studies and given permission to be contacted again to ask if they have family or friends who may be interested in participating.

Randomization, allocation concealment and blinding

Randomization is performed using a random number sequence (generated based on a stratified block randomization procedure) programmed into REDCap clinical trials software.

Randomization is stratified by baseline stage of change according to the TTM (pre-contemplation, contemplation, or preparation) to ensure equal motivational readiness for MVPA adoption across groups. Study group assignment is placed in a sealed envelope based on an order determined by the randomization sequence, with different envelopes designated for each baseline stage of change. Randomization is performed by an interventionist who is not blinded to participant study condition, while staff members completing baseline and follow-up measures remain blinded to condition. Siblings or close friends who enroll together are yoked together into a study arm to minimize contamination between arms; yoked groups are stratified across conditions to ensure equal distribution. After being randomized, participants' Fitbit monitors and app are unblinded to allow for normal use. Participants in the Intervention group then undergo a

goal setting session; those in the control group receive no more direct staff contact until the six-month follow-up visit.

STATISTICAL ANALYSIS

As a preliminary step, the study sample was summarized with respect to baseline socio-demographics and PA rates and compared between groups using t-tests, chi-squared tests and non-parametrics as appropriate. Both participant and parent characteristics at baseline are reported for socio-demographics.

As min/week of MVPA was skewed and attempts to transform towards normality were unsuccessful, a series of quantile regression models with bootstrapped standard errors (10,000 bootstrapped samples) were used to regress median min/week MVPA on baseline values, group, and covariates. Models were run separately for self-reported MVPA (via the PAR) and objectively measured (using accelerometry). Models for the latter further adjusted for accelerometer wear time. As a small proportion of study participants were yoked together during the randomization process (siblings, cousins, or close friends who enrolled together), we adjusted for clustering by yoked group in each of our models (to ensure standard errors were adjusting for non-independence of outcomes within-cluster). All other covariates were balanced at baseline and tested for significance in the model before being dropped.

To understand the group differences in minutes of PA as collected via the Fitbit, we examined data from the weeks corresponding to measurement of PA via the PAR and accelerometer. Using a longitudinal mixed effects model with subject-specific intercepts, we examined group differences adjusting for clustering by yoked pair.

All analyses were carried out in R, with significance level set at .05 a priori.

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