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Arriba por la Vida Estudio (AVE): Study protocol for a standing intervention targeting postmenopausal Latinas

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ABSTRACT

Background: Postmenopausal Latinas are a growing population group in the US who are at high risk for cardiovascular disease. Epidemiological studies have shown that excessive sitting is related to cardiovascular disease risk. Older women sit for prolonged periods and most individuals do not meet physical activity guidelines. Reducing sitting through increased standing may improve cardiovascular risk. More research is needed on how to intervene to increase standing in older Latinas.

Objective: To describe the protocol for a randomized controlled trial to increase standing in postmenopausal Latinas: the Arriba por la Vida Estudio (AVE).

Design/methods: Postmenopausal Latinas will be randomized to one of two study arms: an increase standing intervention or a heart healthy attention-comparison condition. A total of 250 overweight postmenopausal Latinas will be recruited and followed for 12 weeks. AVE is based on various models of behavior change including strategies such as self-monitoring, goal setting, and habit formation. Participants will receive three in-personhealth-counseling sessions (including one in-home visit) and five follow-up telephone calls using motivational interviewing techniques. Those in the attention-comparison condition will receive an equal number of contacts as the standing intervention with topics focused on healthy aging. The primary outcome is objectively-measured sitting time over three months measured via thigh-worn inclinometers and secondary outcomes include blood pressure, physical functioning and glucoregulatory and lipid biomarkers.

Conclusions: The findings from this study will provide valuable information about effective approaches to increase standing time in postmenopausal Latinas and its impact on cardiovascular disease risk.

Trial registration: This study is registered at clincialtrials.gov Identifier: NCT02905929

1. Introduction

An estimated 43 million women in the US suffer from cardiovascular disease with 90% of women having one or more risk factors [1]. National data suggest that approximately 75% of Latino adults are considered overweight/obese, which is significantly higher than non-Hispanic whites putting them at higher risk for developing cardiovascular disease [2].

Older adults and Latinos are the fastest growing populations in the US. From 1990 to 2000, the number of Latinos in the US increased from 22.3 million to 35.3 million [3]. By the year 2060, the number of people aged 65 and older in the US is estimated to be 98 million [4]. Rates of obesity and diabetes are higher in Latinos than non-Hispanic whites; likewise, there are higher rates of chronic disease, such as cardiovascular disease in older adults [1]. As these two populations grow, preventing chronic disease costs will be a public health priority. In particular, older women consume more health care than any other segment of the population [5,6].

Increasing physical activity has well-established cardiovascular benefits [7–9]. However, Latinos are less likely than non-Hispanic

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whites to engage in recommended levels of physical activity [10]. When measured objectively via accelerometry, Latinas engage in less physical activity than Latino men [11]. Latinas may have specific barriers to physical activity related to social and environmental influences [12]. In a recent review, Larsen etal. found that Latinas report family obligations and lack of childcare as barriers to physical activity as well as concerns about neighborhood safety [13].

In addition to less physical activity, a study of US Latinos showed that older Latinas had greater sitting time [14]. Increased sitting time has been associated with increased risk of obesity, metabolic syndrome, diabetes, cardiovascular disease, and mortality [15,16]. Observational epidemiologic studies in older adults show relationships between higher sitting time and components of poor cardiovascular health, including greater body fat, weight gain, high waist circumference, and poorer physical function [17–21]. Conversely, accelerometer-measured breaks from inactivity are associated with better health outcomes among older adults [22–25]. Given the challenges of promoting physical activity in older Latinas, standing interventions may be an alternative behavior to explore. Importantly, a recent qualitative study on older adults with obesity, found a standing intervention to be widely accepted among participants [26].

While there have been no sitting reduction studies specifically focused on older Latinas, a number of small studies in older adults have successfully reduced sitting time. Most sitting reduction interventions have focused on workplace settings and reduce sitting by an average of 77 min across an eight-hour workday [27,28]. According to a recent review, to date, nineteen studies evaluated a multicomponent lifestyle intervention targeting a reduction in non-occupational sedentary behavior in older adults [29]. The results from these studies showed intervention feasibility and preliminary effect sizes [30–36], but significant effects exploring longer term outcomes are needed.

Given the high levels of cardiovascular disease risk in Latinas and the potential efficacy of sitting reduction interventions, assessing a standing intervention in a large sample of Latinas is a priority. The purpose of this paper is to describe the study protocol for a RCT to increase standing time and improve cardiovascular risk factors in overweight, postmenopausal Latinas.

2. Study design

A single-blind, randomized controlled trial will be conducted to assess the effectiveness of the Arriba por la Vida Estudio (AVE) intervention to increase standing time in postmenopausal Latina women at risk for heart disease over a 12-week period. Participants will be randomly assigned to one of two study arms: the standing intervention or the heart healthy attention-comparison, using a 1: 1 allocation ratio. Participants will undergo study assessments at baseline and 3 months. The study was funded through a Strategically Funded Research Network through the American Heart Association Go Red for Women Research Network. All study procedures have been approved by the University of California, San Diego Institutional Review Board.

2.1. Study population

Target enrollment for AVE is 250 participants. Participants will self-identify as Latina, be over 55 years of age with no menstruation for at least one year, have a BMI between 25 and 45, and not be taking insulin. Additionally, participants must be able to read and write in English or Spanish, able to give informed consent and complete study protocols, and able to access a telephone to receive counseling. Finally, participants must record an average of > 8 h of sitting/day and < 8000 steps/day across 4 days, as measured by a thigh-worn inclinometer (the ActivPAL micro ™; PALtechnologies).

3. Procedures

3.1. Recruitment

Participants will be reached through multiple strategies including mail, phone, and in-person contacts. They will be recruited through ongoing and prior studies with older Latino participants willing to be re-contacted, through primary care clinics serving low income Latinos, through paid marketing lists targeting Latino neighborhoods, through Latino focused community networks, and community events. Once interest in the study is established, participants will be screened by telephone for study eligibility criteria including age, menstruation status, insulin, and Latina origin.

3.2. Initial screening visit

Interested and eligible participants will be scheduled for an in-person screening visit to sign the consent form, complete a self-reported survey, physical measurements (i.e.,blood pressure, height, weight, and waist circumference), and performance tasks [37]. Following consent and initial measures, participants will be fitted with the ActivPAL and instructions to wear the device for the following seven days.

3.3. Final screening visit

Participants will return the following week for the second screening visit having fasted for at least nine hours. Study staff will download and screen the ActivPAL for eligibility. Participants who sit for > 8 h per day on 4 days and engage in less than an average of 8, 000 steps across the wear period, will have their blood drawn by a certified phlebotomist. HbA1c, lipid panel components, and glucose are measured in whole blood immediately on-site. Aliquots of whole blood, plasma, serum, and white blood cells are subsequently prepared and immediately frozen at -80 °C for future biomarker analyses. Upon successful completion of all screening procedures, participants who meetall the eligibility criteria will be randomized. Table1 shows the timeline of measurement and intervention activities.

3.4. Standing intervention

3.4.1. Theoretical background

The primary goal of the intervention is to increase standing. The intervention was developed based on relevant and previous pilot work in older adults conducted by our group [33,34]. Various models of behavior change guided the intervention content. Specific behavior change strategies from Michie etal. include self-monitoring and feedback, goal setting, habit formation, and relapse prevention as well as environmental cues and social support [38,39]. The intervention will be delivered through in-person and telephone counseling using motivational interviewing techniques, which follow four general principles including expressing empathy through reflective listening, identifying discrepancies between participants' goals and current actions, rolling with resistance by accommodating for participants' resistance instead of opposing it, and supporting and building self-efficacy [40].

In addition to the aforementioned theories, prior studies also informed our approach. Three pilot studies [33,34,41] and additional focus groups [42] in older adults demonstrated the importance of providing standing desks, accurate feedback on standing behaviors, and the need for standing prompts throughout the day. In particular, we learned that sitting varied greatly across and within individuals; therefore, a tailored approach to overcome specific barriers with individual goals is key.

3.4.2. Standing intervention content

The health coach will work with participants to focus on specific strategies to increase standing time. Participants will set a goal to

Table 1
Timeline of intervention and measurement activities.

Week	Description of studies activities	
0	**In-person consent and initial screening (non-fasting)** Written informed consent process, medical screening including anthropemetrics, performance tasks Weartime protocol for ActivPAL for behavioral screening, survey completion	
1	**Screening visit 2 (fasting state)** Venous blood draw, return ActivPAL (controls)	
	Standing intervention	**Heart healthy attention-comparison condition**
1	60-minute in-person counseling: introduction to breaking up sitting time. Review of baseline ActivPAL data, develop action plans (feedback and discussion on where & when to break up sitting and setting of goals). Continue to wear ActivPAL, Jawbone UP distributed. Stand goal: add 30 extra minutes standing in 5 min bouts per day from baseline	60-minute in-person counseling: Caregiver and stress
2	60-minute in-person counseling: check-in with goals, strategies, and tools; review ActivPAL data. Topic: breaking up sitting is more difficult than we thought. Update action plan, problem-solve barriers. Continued wear of ActivPAL Stand goal: add 60 extra minutes standing in 5 min bouts per day	20-minute phone counseling: e.g.,Insomnia & sleep
3	At participant's home, 60-minute in-person health counseling: check-in with goals, strategies, and tools; review ActivPAL data standing table distributed. Topic: Overcoming barriers in the physical and social environment. Stand goal: add 90 extra minutes standing in 5 min bouts per day from baseline	20-minute phone counseling: e.g.,Bladder control
4	20-minute phone counseling: check-in with goals, strategies, and tools. Evaluate additional tools or environmental changes needed. Stand goal: add 120 extra min standing in 5–10 min bouts per day from baseline	20-minute phone counseling: e.g.,Making your home safe
5	Send ActivPAL to intervention participants only for mid-intervention progress check	
6	20-minute phone health counseling: check-in with goals, strategies, and tools. Review ActivPAL feedback. Discuss half-way progress & successes, tools and prompts that are most effective. Re-focus on maintaining changes for next 6 weeks.	20-minute phone counseling: Hydration & drinking water
8	20-minute phone counseling: Review of progress & successes, new & old barriers, continuing to use tools and maintain social & environmental support. Maintaining goals.	20-minute phone counseling: Depression & aging
10	20-minute phone counseling: Review of progress & successes, new & old barriers, continuing to use tools and maintain social & environmental support. Relapse prevention. Maintaining goals.	20-minute phone counseling: Stress management
12	20-minute phone counseling: Review of progress & successes, new & old barriers, continuing to use tools and maintain social & environmental support. Relapse prevention. Maintaining goals for long-term.	20-minute phone counseling: Managing your medicines
12	Send ActivPAL for measurement 2	
13	**Time 2 measurement (fasting state)** Follow up measurement including surveys, blood draws, anthropometrics, return ActivPAL	

gradually increase standing during the first month working towards a two hour per day increase, which equates to a reduction of about 25% of sitting time. Studies have shown that this amount of change may have a positive impact on health outcomes including biomarkers [27].

Participants in the standing intervention will receive three weekly in-person health education sessions followed by biweekly counseling telephone calls over the course the 12-week intervention. During the first visit, the participant and health coach will meet for 1 h to build rapport, discuss the participant's daily routines, describe motivations for joining the study, provide an overview of the intervention and the ultimate goal of increasing standing by 2 h/day, and introduce the variety of intervention tools. Self-monitoring is important for all behavior change interventions but can be particularly challenging for sitting time. Therefore, a variety of timers will be provided including traditional kitchen timers with auditory prompts (Taylor 5827-21 Digital Timer™) or timers with vibration, auditory, and visual prompts (General Tools TI150™). As a wearable option for prompts, all participants will be given a Jawbone UP device (Jawbone™, San Francisco, CA), which provides an inactivity alert vibration which will cue participants to take breaks from sitting every 15 min. Previous sedentary behavior interventions that have included the Jawbone UP have found it to be an effective tool for cueing breaks from sitting [43].

Next, the participant and health coach will review the ActivPAL-derived feedback charts to identify opportunities to increase standing time. The feedback will provide both numeric and graphic depictions of average daily time spent sitting. All feedback chart data will be reported at a daily level (see Fig. 1). The daily feedback charts will allow the health coach to prepare a detailed action plan with participants based on participants' daily routines and behaviors to increase standing time across the day. Participants will develop stepped goals to increase their standing time in 5 to 10 min bouts. Participants will be encouraged to try different types of reminders (e.g.,timers, Jawbone UP band) and the health coach will use motivational interviewing strategies to help the participant build self-efficacy. The participant will be given an ActivPAL device to wear during the next week.

At the second session, the health coach will review the participant's progress on achieving the goal from the previous week and discuss any specific barriers to accomplishing the goal. They will review the feedback chart from the ActivPAL and discuss a detailed action plan for the following week. The participant will be given a new ActivPAL for the next week and a home visit will be scheduled.

For the third session, the health coach and another research staff

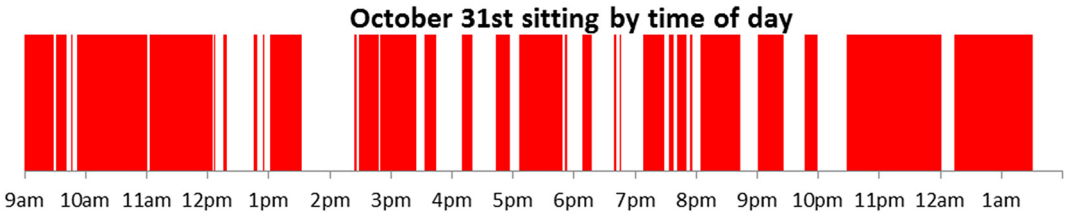

Fig.1. Sample feedback graph used in health counseling sessions. Red indicates extended bouts of sitting. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

member will go to the participant's home to discuss strategies to accomplish the goal of increasing standing time that are specific to the home. Additionally, the health coach will bring a standing table (TECNI MOBILI™ Cadmus Mobile Laptop Stand) and engage the participant in identifying an ideal location for the standing table so that it can serve as a cue and standing support. The health coach will then review the ActivPAL feedback chart and discusses the goal for the following week.

The subsequent health coaching sessions will be by telephone every two weeks for approximately 30 min per session. At the mid-point of the study (i.e.,five weeks), participants will be mailed an ActivPAL to wear for seven-days as a mid-pointcheck-in. The health coach will review the data with the participant at the six-week health coaching session after the data will have been returned by mail. At the end of each session, either in-person or over the telephone, the participant will develop an action plan to increase standing for the following week.

3.4.3. Heart healthy attention-comparison condition

Participants will receive an equal number of contacts as those in the standing intervention. The first session will be in-person while the remaining sessions are conducted via telephone. A new educational topic will be discussed at each session, but none of the topics will cover sedentary behavior or standing. Topics include caregiving and stress, cervical cancer, chronic pain, colorectal cancer, bladder control, communicating with your physician, dementia, depression and aging, healthy bones and osteoporosis, hydration, insomnia and sleep, and preventing falls. Participants choose from the list of topics for each session and set goals for each topic with motivational interviewing techniques applied throughout the sessions. Table1 summarizes and describes the AVE study schedule.

4. Data collection

All measures occur at baseline and 12 weeks. Measurement staff will be blinded to intervention condition.

4.1. Primary outcomes

Time spent sitting during waking hours is measured objectively by the ActivPAL worn for one week at baseline and 12 weeks. The ActivPAL was chosen because it has been used with older adults, is more sensitive to change, and has higher validity than accelerometers when compared to direct observation [30,33]. It is unobtrusive, very light (10 g), 5 mm thick, and worn on the thigh using a waterproof Tegaderm™ dressing so that it does not have to be removed. Participants will be shown how to attach the ActivPAL during the initial screening visit and replacement waterproof dressing will be provided in the event that it needs to be replaced.

4.2. Secondary outcome measures

The secondary outcomes include glucoregulatory and lipid biomarkers, blood pressure, depressive symptoms, quality of life, anthropometrics, and physical functioning. To minimize variability due to diet or activity, participants are instructed not to perform physical activity for 24 h prior to the visit. Additionally, the evening meal prior to each measurement study visit will be standardized. Participants will be instructed to have no food or drink other than water after the meal and refrain from consuming alcohol and caffeine in the 48 h preceding each experimental condition.

Venous blood samples will be collected (45 mL total) in Ethylenediaminetetraacetic acid (EDTA), heparin and serum collection tubes. From these collections, whole blood aliquot (1 .5mL) will be saved from EDTA and heparin plasma, serum, and buffy coat PBMC fractions will be prepared by centrifugation and aliquotting. Biomarkers include fasting levels of glucose, insulin, lipid panel components (i.e.,total cholesterol, LDL, HDL, and triglycerides) and hemoglobin A1c (HbA1c).

Blood pressure (BP) will be measured by the Omron HEM 907XL BP monitor to capture diastolic and systolic BP; measures will be taken 3 times and the mean of the 2nd and 3rd readings will be used. BP will be taken after individuals have been resting while seated for five minutes. Depressive symptoms will be measured with Centers for Epidemiologic Studies Depression Scale short form. Scores > 10 indicate probable depressive symptoms [44]. Quality of Life will be measured with the EURO-QOL5-D, a brief 5-item standard scale that has demonstrated validity in populations with diabetes and cardiovascular diseases [45,46]. Weight will be measured using a calibrated portable digital scale (Detecto DR400-750). We will also measure height with a stadiometer (Charder HM200P). Waist circumference will be measured in duplicate at the superior border of the iliac crest and the average of two measurements used [47]. Finally, the Short Physical Performance Battery (SPPB) will objectively evaluate lower extremity function including balance, gait speed, and strength with three brief tasks (i.e.,standing with feet together in side-by-side, semi-tandem, and tandem positions; time to walk three meters; time to rise from a chair and sit back down five times) [37,48]. Physical function will also be included as a covariate in analyses.

4.3. Mediators, moderators & covariates

Age, sex, education, marital status, work status, and other pertinent demographics will be measured using self-reported items on the baseline survey. Some of these demographic variables will also be considered covariates in analyses. We will use measures adapted from our pilot including benefits and barriers, self-efficacy [49–51], social support [52], and home environment supports [53]. Habit formation will be assessed with the Self-Report Habit Index (e.g.,sitting is something I do without thinking) [54].

4.4. Sample size calculation

We will enroll 250 postmenopausal Latinas for the study. The total sample size was chosen to ensure 90% power to detect a significant reduction of at least 45 min in sitting time between the intervention and control at three months at a significance level of $p < .05$, after adjusting for approximately 10% drop out. Given our pilot results and that the intervention targets a 120 min reduction in sitting time, reducing sitting time by 45 min is achievable. We assumed a standard deviation

(SD) in sitting time of 1.8 h/day based on prior studies. Further, this sample size provides sufficient power for secondary outcomes such as blood pressure in which we will have 90% power to detect a difference of 5.81 mmHg change in Systolic BP (14 SD) and 2.91 mmHg change in Diastolic BP (7 SD). Interventions aimed at decreasing sedentary/sitting time in adults & increasing standing observed effect-sizes between 0.39 & 0.49 on fasting insulin. There are many more trials of physical activity and/or lifestyle interventions on biomarkers with reported effect-sizes between 0.2 and 0.55 on insulin/glucose/metabolic index. Thus, we based sample-size estimates on an assumed effect-size of 0.4at 3 months and will have 80% power to observe biomarker outcomes collected.

5. Statistical analyses

The statistician will be blinded to condition. Summary statistics will be calculated; groups will be compared on baseline characteristics, and variables that are not balanced across study arms will be adjusted for in subsequent analyses. We will use a mixed-effects analysis approach, in which all available assessments on an individual can be included in the model. Gaussian link functions will be used for the continuous outcomes (e.g.,sitting time); a binomial or loglinear link will be used for binary/categorical outcomes (e.g.,obesity status). Biomarker outcomes will be transformed as needed using log transformations to better approximate Gaussian distributions for model residuals. Analyses will use the intent-to-treat (ITT) principle [55]. We will also conduct a per-protocol analysis as protocol violations and informative drop-outs could bias results towards equivalence.

To investigate the three-month effect of the intervention on behavioral outcomes of sitting, standing, and stepping as measured by the ActivPAL, a mixed effects regression model [56,57] with daily minutes of sitting, standing and stepping with baseline and three-month values as the dependent variable will be employed; time (0, 12 weeks), group (intervention and control), and the group*time interaction will be the fixed-effect independent variables. We will include a random subject-specific intercept term. We chose a mixed-effects model because it allows inclusion of partially missing records (e.g.,missing 12-week data), which is not possible with a repeated measures design. Under a missing-at-random assumption, the mixed model should provide valid estimates of regression coefficients. As a sensitivity analysis, we will also conduct a completers analysis.

6. Discussion

The American Heart Association's Science Advisory recently reviewed the current evidence for sedentary behavior and cardiovascular morbidity and mortality. The conclusions supported promoting the advisory, “Sit less, move more” based on the current state of the science. The authors noted the absence of sufficient data to recommend specific quantitative guidelines [58]. In addition, the American Diabetes Association recently released a position statement on physical activity, which included a recommendation to interrupt sitting every 30 min [59]. Both bodies call for more intervention research with health outcomes in diverse and at-risk populations to improve future guidelines.

AVE is the first large-scale randomized controlled trial focused on increasing standing time in postmenopausal Latinas and examining the impact of behavior change on cardiometabolic risk markers. Given the growing number of Latinas in the US combined with the increased risk of cardiovascular disease attributable to low levels of physical activity and high rates of sitting time in this population, innovative approaches to improve health in this population are needed. Standing interventions present an alternative approach to traditional physical activity interventions that may not be feasible in a population with physical limitations. Few sedentary behavior interventions to date have targeted older adults and the majority were small pilots or pre-post designs. Additionally, the majority of previous sedentary behavior interventions target workplace sitting and include changes to the worksite environment; however, many older adults may be transitioning from full-time employment into retirement. Therefore, developing comprehensive interventions that translate across the spectrum of environments and span the entire week is imperative.

Strengths of AVE include comprehensive evaluation with state of the science measurement tools including objective assessments of physical activity and sedentary behavior, anthropometrics and biomarkers, as well as psychosocial and physical functioning. However, our study is not without limitations. Specifically, our study is unable to ascertain long-term health effects from the intervention due to the conclusion of data collection at three months. Future studies should explore the maintenance of these behaviors by including a longer follow-up. Furthermore, the results from AVE may not be generalizable to other populations as the intervention specifically targets post-menopausal Latinas. The intervention is theory-based and designed to improve cardiovascular health in a high-risk population. Additionally, AVE includes a number of effective tools to change standing time such as the Jawbone UP as a reminder and the standing table to modify the home environment. AVE combines various strategies from previous interventions including prompts from wearable technology, modifications to the environment, and motivational interviewing to improve the likelihood of increasing standing time.

In conclusion, the findings from our study will provide valuable information about effective approaches to increase standing in post-menopausal Latinas. Furthermore, by including the blood outcomes, we can explore how increases in standing time affects biomarkers in a three-month intervention. Although sedentary behavior research has grown, more data from randomized trials is needed to move the field forward. AVE will provide valuable insights into the effectiveness of a sedentary behavior intervention to improve cardiovascular health in a population of high-risk Latinas.

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Conflicts of interest

None.

Author contributions

Designed and delivered the original study: MT, NV, GT, MA, DR, DD, DS, NO, JK. Wrote the manuscript: MT, MS, JK. All authors read and approved the final manuscript.

Disclosures

All authors have contributed and reviewed the proposed manuscript. The manuscript has not been published or submitted elsewhere and it does not contain data that are currently submitted or published elsewhere. Additionally, the authors have full control over all the primary data and agree to allow the journal to review the data if requested. Ethics approval was granted by the Human Research Protections Program of the University of California, San Diego (Protocol #160682). Participants provided written informed consent.

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