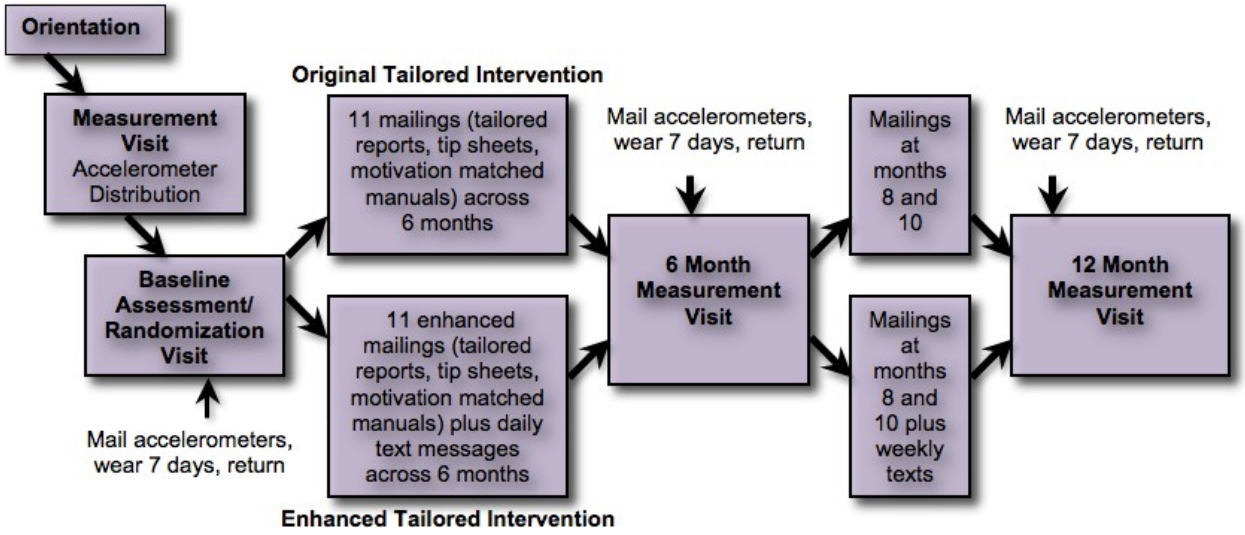
NCT02630953

Culturally and Linguistically Adapted Physical Activity Intervention for Latinas

12-4-2020

Study Protocol

Intervention Schema



Procedure: Prior to randomization, participants will undergo the following procedures: 1) Telephone screening to establish initial eligibility for the study; 2) An in-person orientation session to obtain more information about the study; 3) A measurement visit in which study questionnaires will be administered and accelerometers will be issued; and 4) One week later participants will return to undergo the 7-Day Physical Activity Recall (PAR) interview and return their accelerometers. Once complete baseline data have been collected participants will be randomized. Participants will repeat the measurement visit at 6 and 12 months

Telephone pre-trial screening: Potential participants will be screened over the phone to determine study eligibility. All interested and eligible participants will be invited to attend an in person orientation session.

Orientation: Interested individuals will be invited to a group orientation session in which the bilingual research staff will provide information about the study and will clearly delineate the study requirements, outline the risks and potential benefits and address any individual concerns. At the end of the session, individuals will provide written informed consent if they still want to participate in the study.

Measurement visit: Staff will weigh and measure participants, take blood pressure, collect a fasting blood sample, and have them complete the study questionnaires (See Table 5). At the end of this visit, participants will be instructed how to use an accelerometer (ActiGraph GT3X+) during the coming week.

Baseline assessment/randomization visit: One week later, participants will return for a brief assessment visit. They will return the ActiGraph, which will be checked for proper wearing using well-vetted protocols from previous trials. They will then perform a 10-minute treadmill walk (3-4 miles per hour) to demonstrate moderate-intensity level PA, followed by completion of the 7-Day PAR interview. Then, they will be randomized to one of the two conditions. Participant randomization will be stratified by stage of change to ensure equal distribution of the different levels of motivational readiness for PA between groups. Research staff will then explain the intervention, help participants set realistic PA goals (that can be gradually increased until they meet national guidelines) and identify potential barriers and potential solutions (using materials developed to address the specific barriers/negative attitudes reported during the

formative research).

Six and 12-month assessments: Approximately one week prior to each scheduled follow-up assessment, staff will mail a FedEx packet to the participant including the accelerometer and detailed instructions on how to wear it and complete logs. Participants will be instructed to wear it during the week prior to the assessment visit. We will call participants on the scheduled delivery day to ensure it arrived and will also call them one day before they begin to wear it to remind them of the wear time schedule and to answer any questions. Participants will receive another phone call three days after beginning their wear to ensure compliance and address any problems or questions. Participants will bring their accelerometer to assessment visits, at which time their wear time will be assessed. At these follow-up assessments, participants will also undergo: 1) fasting blood draw; 2) anthropometric and blood pressure measures, 3) 7-Day PAR interviews and 4) battery of questionnaires.