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Title: Adherence to different exercise interventions

Project Personnel:

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Objective of study:
Regular exercise, in the form of walking 150 minutes per week, is widely regarded as having many health and fitness benefits (1-5). Despite these well-known benefits, adherence to exercise interventions is extremely low. When sedentary adults start an exercise training program only 50% adhere to the program and meet the national recommendations of 150 minutes per week. A possible explanation of the low adherence is that most adults only walk for exercise, and that providing a variety of exercise may increase adherence. Preliminary observational data does show that a variety of exercise may increase weekly exercise expenditure compared to other interventions (2). The overall objective this study is to investigate the feasibility, adherence, and acceptability of different exercise interventions including 1) walk intervention, 2) variety intervention, and 3) progressive intervention (see below for description).

Participant Characteristics:
Inclusion criteria

- 60 total adults (30 men and 30 women) will be recruited from Cal Poly and the San Luis Obispo area.
- 18-40 years old
- Sedentary (<1 hour per week of exercise)
- BMI 18.5 to 40 kg/m^2
- All participants will be healthy, weight-stable for the previous 6 months, free of any metabolic or chronic disease, non-smoking, and sedentary, assessed by Health and Fitness History and Physical Activity Readiness (PAR-Q) questionnaires.
- All race/ethnicities will be eligible for this study with a target enrollment of 20% Hispanic and 80% non-Hispanic.

Exclusion criteria

- Adults with diagnosed cardiovascular, diabetes, renal, or any other metabolic disease determined by Health and Fitness History questionnaire.
- Any other disability, ailment, or physical characteristics that may hinder the ability to participate in regular exercise.
- Participating in other studies that would interfere with their ability to safely complete the exercise protocols.
- Pregnant or trying to become pregnant, and peri-menopausal or post-menopausal women.
- History of smoking within the last 6 months
- Any vulnerable population (children <18, pregnant women, prisoners, etc.)

Recruitment
Recruitment efforts will be focused on California Polytechnic State University San Luis Obispo and the surrounding area. Participants will be recruited via flyer across campus and in the surrounding area. These flyers will also be distributed electronically via campus listservs and appropriate social media outlets. The flyer will contain both an email address and QR code that will be linked contact information. Once contact information has been obtained, a member of the

research staff will contact the participant. If the participant is deemed eligible for the study (based on script delivered on the phone, on Zoom or by phone), they will be asked to schedule a Zoom or in-person meeting with a member of the research staff to go over the study protocol in more detail and address any questions or concerns the participant may have. Visit 1: If the participant is interested in taking part in the study, they will be provided with an informed consent form (electronic via RedCap or paper copy). After consent has been obtained, participants will be asked to schedule their first visit. The consent visit will take approximately 1 hour. The visit will occur in the William and Linda Frost Center for Research and Innovation.

Methods

Visit 2: Preliminary Tests. After informed consent has been obtained, participants will body weight, height will be measured. In addition, participants will fill out a Health and Fitness History, demographics questionnaire, Physical Activity questionnaire (PAR-Q), Paffenbarger Physical Activity Questionnaire (PPAQ). Participants will also wear a GENE-Active watch on their non-dominant wrist for the entire 4-weeks of the study. The GENE-Active watch is a research grade, lightweight and waterproof watch that provides raw accelerometer data. Participants will be asked to wear the watch throughout the day but may take it off at night and to shower. The watch is designed for public health research and clinical trials, is lightweight and waterproof, and will record for 30 days raw data accelerometer. This visit will take approximately 1 hour and will occur in the William and Linda Frost Center for Research and Innovation in the Center for Health Research Laboratory. We will then collect 3-days of baseline accelerometer data.

Visit 3: After 3 days of baseline, participants will be randomized (by sex, ethnicity, BMI) to one of three exercise interventions: 1) walk intervention, 2) variety intervention, 3) progressive intervention. For the variety intervention, each week participants will be prescribed a different exercise (variety) which will only include cycling, walking/jogging, yoga/Pilates, cross-training (kick boxing, karate, salsa dancing, circuit training), and strength training (e.g., Week 1: cycling, Week 2: walking, Week 3: Cross-training, Week 4: yoga). For the progressive intervention, the same exercises will be included but will be added to the list of options for participants (e.g., Week 1: yoga, Week 2: yoga and walking, Week 3: yoga, walking, and strength training, Week 4: yoga, walking, strength training, cross-training). For the progressive intervention, participants may choose from the list of exercise. They do not have to do them all, and they can do as much or little (none) of whatever they choose. The exercises will be randomized within variety and progressive interventions. If participants are Cal Poly students, the ASI recreation center has classes available for each activity. The exercise prescription of each intervention is to exercise for at least 150 minutes per week. The exercise will not be supervised, and participants will complete the exercise on their own. This visit will take approximately 30 minutes.

Visits 4-6: After each week, the participant will be instructed to meet with a study researcher that will download the watch accelerometer data, measure weight, complete a physical activity diary for the week, and will be provided the next week exercise. Research staff will schedule the

weekly meeting via email or text with the participant, and the participant will meet the research staff in the William and Linda Frost Center for Research and Innovation in the Center for Health Research laboratory. These visits will take approximately 15 minutes each.

Visit 7. Final assessments of watch accelerometer, physical activity diary and questionnaire, and weight will be collected after the 4-weeks. Participants will complete some questions related to acceptability of the intervention. The questions This visit will take approximately 1 hour.

Statistical Analyses: A repeated measures ANOVA (group x time interaction) adjusting for BMI, ethnicity/race, income, sex, and age.

Primary Outcome Measure: Adherence to intervention determined by 150 minutes per week of moderate to vigorous physical activity via the GENE-Active watch.

Secondary Outcomes Measures: Physical activity diary, Paffenbarger Physical Activity Questionnaire (PPAQ), body weight, acceptability of intervention via questionnaire.

Moderators of intervention (Covariates): BMI category, ethnicity/race, income, sex, age.

Potential Risks

Despite the well-documented benefits, there are also a slight risk associated with regular engagement in exercise [1] including musculoskeletal injury. Though this risk increases amongst sedentary individuals, the rate of incidence is exponentially higher for those performing high-impact sports (e.g., soccer, football, etc.). The participants in this study will not be asked to perform any contact sports that may increase the chance of a musculoskeletal injury.

Participants may experience fatigue and muscle soreness due to an increase in physical activity from previous sedentary states. These health risks are small in people with no prior history of cardiovascular, respiratory, or musculoskeletal disease or injury. Any ordinary fatigue or muscle soreness is temporary and usually lasts 24-96 hours. Participants will not be performing any supervised exercise; however, the risks are included in the informed consent.

Finally, there are slight psychological and social risks of completing the questionnaires, and participants may omit any question they do not feel comfortable answering.

Confidentiality and Data Safety

All data will be collected by trained student researchers under the authorization of the lead investigators (Drs. Hagobian and Seal). Data will be examined in a confidential fashion to preserve the privacy of each participant. All members of the research staff will have completed the required CITI training modules on responsible conduct of research. The data collected in this study will be accessible only to the researchers involved. All paper data will be stored in a locked file cabinet, and electronic data will stored on the Center for Health Research's encrypted, password-protected cloud storage hosted by the Baily College of Science and Math using AWS.

Additionally, the informed consent, questionnaires and other data will be administered and stored using RedCap. REDCap is a web application for building and managing online surveys and databases, and thus proper security practices are instituted on the network and server(s) hosting REDCap and within the REDCap software itself. All data will be de-identified using both a unique study and participant ID. The file linking the participant's identifiable information to their ID number and confidential data will be kept in a separate password-protected location. Upon completion of the study, the accelerometer data and profile will be wiped from the device. Data specific to the aim of this study will be shared with scientific journals for publication purposes only, and will not include any names or participant ID.

Data Sharing: All records will be retained in our database for 7 years after the date of the last participant completing the study, or the data may be destroyed if no longer in use before the 7 years. We will follow NIH guidelines, and research data from participants may be shared with the broader scientific community or journals for publication upon request. We will make data and documentation available under a data-sharing agreement that provides for (1) a commitment to use the data for research purposes only; (2) a commitment to securing the data using appropriate computer technology (password protected and encrypted); (3) a commitment to destroying or returning the data after analyses are completed and (4) a commitment not to attempt to identify participants individually. Information shared with outside collaborators will link data to two unique study identifiers (De-Identified) to maintain participant anonymity, and outside researchers and the community will not be allowed to have access to participant names and confidential information.

Compensation and Benefits

There are no costs to participate in this study. There are no incentives for participating in this study. There are no direct benefits associated with the study. These data are collected for research purposes only and are not clinical or diagnostic. These data may further our understanding of methods to increase adherence to exercise interventions.

References

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