

Citizen Science to Promote Sustained Physical Activity in Low-Income Communities

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1. PURPOSE OF THE STUDY

a. Brief Summary

The major objective of the study is to increase physical activity among inactive, low income midlife to older adults living in or near public housing sites. Participants are randomized into 2 groups: 1) receive a physical activity program (i.e., Active Living Every Day (ALED) Program) + tradition health education; or 2) receive physical activity program (i.e., Active Living Every Day (ALED) Program) + Our Voice intervention in which study participants use the Discovery Tool app to document (photos and audio narratives) features of their neighborhood that make it easier or harder to be physically active to then discuss and advocate for change in their community with the purpose to promote healthier communities.

b. Objectives

We hope to learn: Whether or not ALED alone OR ALED + Our Voice intervention will achieve sustained physical activity increases at multiple levels over time. If there are changes in a select set of multi-level variables (e.g., personal agency for influencing community decisions; neighborhood cohesion) as potential mediators of intervention effects; and explore the relative costs of the two interventions for PA change. Importance of the new knowledge: If the preliminary evidence supporting the promise of the Our Voice community engagement program is confirmed, it will provide a means for expanding and sustaining the impacts and reach of person-level PA interventions beyond individual participants to the broader neighborhood setting, and can provide a scalable means for sustainable PA promotion that potentially could be enacted across the population

c. Rationale for Research in Humans

There is compelling evidence that regular moderate-intensity and more vigorous physical activity (PA) substantially reduces the risk of diabetes, heart disease and certain cancers in mid-life and older adults. Regular physical activity also helps regulate body weight, a risk factor for a variety of diseases, as well as improving psychological and cognitive functioning in older adults. Despite these documented health benefits, a very small percentage of adults aged 45 years and older meet the national PA guidelines (i.e., that all U.S. adults accumulate at least 30 minutes of daily moderate-intensity PA 5 or more days/week). Low-income older adults are among the most sedentary groups in the U.S. Thus, human subjects, must be used to test the efficacy of the physical activity promotion program.

2. STUDY PROCEDURES

a. Procedures

Recruitment

Subjects will be recruited from affordable housing serving mid-life and older adults from the San Francisco Bay Area.

The primary recruitment methods will consist of targeted mailings to residents of each housing site or low income older adults living near these affordable housing sites. We will supplement these approaches with outreach communications tailored to each housing site (e.g., flyers posted in housing site common areas).

Eligibility Screen

Individuals will go through an initial telephone, face-to-face or online screening process. Those who are initially eligible will proceed to an information session where the study activities and procedures will be explained in greater detail. If interested in continuing at that point, individuals will read and sign an informed consent form approved by Stanford University IRB.

Those adults meeting study criteria in relation to age, physical activity and general health status, and interest will be invited to participate in a baseline assessment. Demographic, health/medical, perceived environment, and psychosocial and behavioral information will be collected from study participants by interview or self-administered questionnaire.

Study Assessments

Study assessments will be collected at baseline, 6, 12, 18, and 24 months for all study participants. Physiologic measures will include ambulatory activity monitors that measure movement throughout the day in the person's natural environment, and physical measurements (height, weight, resting blood pressure, physical function field tests) collected from study participants by trained study staff. These data and material will be obtained specifically for research purposes.

Persons completing this assessment who are eligible will be enrolled in the study.

Study Interventions

Study interventions consists of housing site-based randomization to one of the two study arms: (1) the Active Living Every Day (ALED) program plus a Health

education program, or (2) ALED plus Our Voice neighborhood engagement program. The intervention period for each study arm lasts for at least 12 months and up to 24 months.

b. Procedure Risks

The research procedures are not invasive and pose minimal risk to study participants.

c. Use of Deception in the Study

NA

d. Use of Audio and Video Recordings

As part of the Our Voice neighborhood engagement program, subjects will take photos and record audio narratives about features of their environment that support or hinder physical activity

e. Alternative Procedures or Courses of Treatment

There are no alternative procedures or courses of treatment. The alternative to this research project is not to participate.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

NA

g. Study Endpoint(s)

No treatments are being evaluated in this study. The study will be stopped when all the eligible, consented participants have completed the final survey as planned. The proposed study design represents the minimal amount of time and number of participants necessary to evaluate the objectives.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

While national guidelines for population-wide PA promotion emphasize the importance of appealing, convenient physical activities such as walking, a significant proportion of Americans (33%) remain inactive. This is particularly true for older (45% inactive), low-income (46%), and ethnic minority adults (44%). Such groups have disproportionately high rates of obesity and other chronic conditions (e.g., diabetes),²⁴ a disparity often compounded by reduced access to affordable programs to improve health.

Among the small number of evidence-based PA programs that have been effectively translated and made available to the public is the “lifestyle”- oriented Active Living Every Day program (ALED), for which Dr. King served originally as a scientific consultant. The effectiveness of ALED in teaching relevant individually-adapted behavioral skills and improving PA rates of participating

adults has been validated through several decades of rigorous clinical trials. However, as with the vast majority of person-level behavioral skill building interventions, the ALED program has relatively little focus on understanding and changing local physical and social environmental determinants of PA that have been identified as key contributors to sustainable PA levels across a community. The potential of training residents as local environment data gatherers and contributors to interventions for promoting health has been increasingly explored. Our initial investigations in which local residents from under- resourced communities have been trained as “citizen scientists” have shown that residents of all ages, armed with simple assessment tools, can effectively capture physical and social aspects of their neighborhoods that either foster or hinder walking and other physical activities.

While Some studies have found older adults living in housing sites to be less active than other older adults, they typically have common space in which to run resident programs, and many housing sites have support services managers whose job it is to develop and/or implement programs to enhance the welfare of residents.

b. Findings from Past Animal Experiments

NA

4. PARTICIPANT POPULATION

a. Planned Enrollment

We plan to recruit up to 432 subjects for this study. Our rationale for focusing on the 40 years and older age range is based on data showing that during these decades of life (i.e., the sixth and up) the risks of a number of chronic health conditions (including cancer) increase significantly among women and men. Regular PA begun during this time is associated with the amelioration or control of a number of these conditions.

b. Age, Gender, and Ethnic Background

Age range: 40 years and older

Gender: Men and women

Race/Ethnicity: The racial/ethnic background is diverse and will reflect that of the housing site residents.

c. Vulnerable Populations

Because we are focusing on affordable housing residents for low income older adults, it is possible that these individuals are economically and/or educationally disadvantaged.

Minimizing Potential Risk

Study assessments will be conducted at the designated housing sites by extensively trained and supervised study staff who have experience in collecting the planned study measures in an effort to minimize potential risk. All participants will be fully informed

regarding the purpose and procedures of the study, as well as the risks and benefits. The surveys will be administered by a research assistant who has been trained not to coerce study participants, and participants will be informed that they can refuse to answer any questions that make them feel uncomfortable.

It is possible that a percentage of participants will have relatively low educational levels. Thus, we have also taken the following safeguards to ensure that all participants fully understand their rights:

- Use bullet points to easily identify each component of the consent form and use simple wording, understandable for those who may have no more than a grade school education
- Employ bilingual (Spanish/English) staff to translate and clearly explain all components of the study verbally
- Utilize one-on-one sessions to assist participants with the informed consent process and the completion of questionnaires. Study personnel will be responsible for implementing the consent process and completion of questionnaires.

d. Rationale for Exclusion of Certain Populations

Women and minorities are included in this study. Children are excluded from this trial because children as a group tend to be more active and at reduced risk for chronic diseases relative to older adults.

e. Stanford Populations

No participants will be laboratory personnel, employees, and/or students of Stanford University

f. Healthy Volunteers

All participants will be sedentary, healthy volunteers, free of any medical condition or disorder that would limit participation in moderate intensity physical activity (such as sustained walking), including life-threatening disorders, myocardial ischemia, and major functional disabilities in the orthopedic area. Healthy volunteers are included to reduce the risk of any complications that could arise from participation in a moderate-intensity physical activity program.

Psychological risks of the evaluation. There is a remote risk that persons completing questionnaires focusing on behavioral or psychological content may become distressed from discussing and revealing personal content. There is no evidence that any permanent psychological dysfunction has resulted from such assessments. Participants will have the option to refuse to answer any question.

Medical risks of physical activity programs. The major risks of physical activity programs by initially inactive persons aged 50 and over are orthopedic and cardio-respiratory. Orthopedic problems primarily are of the overuse variety and usually can be treated by rest and change in the mode and amount of physical activity. Frequent minor problems will occur, including temporary soreness or irritation of muscles, tendons and joints. The likelihood of orthopedic and cardio-respiratory risks are greatly minimized through the use of a moderate-intensity exercise program that involves primarily mild to

moderate-intensity walking, as proposed in the current study, and an individualized, progressive approach to physical activity as proposed in the current program.

Measures to Minimize Risk.

- Study assessments will be conducted at the housing sites by extensively trained and supervised study staff
- To ensure participant safety in this study, we will apply the set of screening and oversight procedures that are recommended in the American College of Sports Medicine's (ACSM) guidelines and that we have used successfully in our research studies over the past 20 years. The exercise programs that we have delivered to mid-life and older adults have been shown to be safe, with no participant experiencing a major medical problem or injury related to the physical activity program. As recommended in the current ACSM guidelines, to screen potential participants for appropriateness for the physical activity program, we will have each individual complete the Physical Activity Readiness Questionnaire (PAR-Q), an extensively validated and used screening questionnaire that has been used throughout Canada and the U.S. to screen individuals for community-based physical activity programs. If individuals answer 'yes' to any of the medically related screening items, they will be directed to get physician clearance prior to entry into the study. This protocol has been shown to ensure participant safety without creating unnecessary medical expenses and barriers to participation for persons not deemed at risk for physical activity-related complications---an important issue for the low-income population being targeted. The use of a mild form of physical activity (walking) already being undertaken to at least some extent by community-dwelling individuals to accomplish their daily activities also diminishes risk

The risks of injury resulting from participating in the prescribed physical activity programs will be minimized in several ways:

- Exclusion from the study of any person with overt cardiovascular disease or acute symptomatology.
- Individualized physical activity program aimed at slow, gradual progression of physical activity amount.
- The use of moderate-intensity physical activity programs, involving primarily walking, for all study participants.
- Careful instruction of participants by experienced staff.
- Ongoing supervision of physical activity participation both in person and as part of the intervention program.
- Careful attention to gentle warm-up and cool-down exercises related to walking, as well as to the experience of physical discomfort during physical activity.

g. Recruitment Details

In collaboration with LeadingAge and housing site administrators and staff, we will employ a variety of community outreach strategies that will include making brief presentations at the participating sites' informational meetings and community events, placing posters and flyers at the entrances of the senior center, placing announcements in LeadingAge newsletters as well as other publications produced by the sites, and mailing brochures and personalized letters to older adult residents residing in the sites.

h. Eligibility Criteria

i. Inclusion Criteria

Male and female adults

Aged greater than or equal to 40 years

No plans to move within the next two years

Participants must be willing to increase walking minutes per week if they are not meeting national recommendations of 150 min per week of moderate physical activity or if they are meeting the recommended guidelines they should be willing to maintain their levels of physical activity.

Able to participate in study intervention and assessments

ii. Exclusion Criteria

1. Any medical condition or disorder that would limit participation in moderate intensity PA (such as sustained walking), including life-threatening disorders, myocardial ischemia, and major functional disabilities in the orthopedic area
2. Not stable on their medications, including hormone replacement therapy, for ≥ 3 months (given that changes in medications can create additional stress and burden over and above attempts to change lifestyle behaviors);
3. Inability to participate in the ALED program as a participant
4. Reporting being pregnant, planning to be pregnant or had a baby in the last 12 months.

i. Screening Procedures

Individuals will go through an initial telephone, face-to-face or online screening process.

The screening process will consist of answering a series of questions related to inclusion/exclusion criteria. They will also complete an information session.

Consent will be obtained prior to collecting any data. Further, all participants will receive and overview and explanation of the study purpose, time commitment, assessment schedule, and intervention.

j. Participation in Multiple Protocols

During the eligibility screen participants will be asked if they are participating in any other research study.

k. Payments to Participants

Randomized trial participants will receive a gift equivalent to approximately \$10 in value for each assessment completed. Based on previous work, these monetary amounts typically do not place undue pressure on the participant to volunteer for our studies.

l. Costs to Participants

There will be no financial costs associated with participation in this study.

m. Planned Duration of the Study

Participant screening: 60-90 minutes

Duration of participation in the study would be the at least 12 months with follow up for a total of 24 months

Active participation in study: 60- 90 minutes/every other week for up to 6 months, at least once a month for the rest of the study.

5. RISKS

a. Potential Risks

- i. Investigational devices

NA

- ii. Investigational drugs

NA

- iii. Commercially available drugs, biologics, reagents or chemicals

NA

- iv. Procedures

NA

- v. Radioisotopes/radiation-producing machines

NA

- vi. Physical well-being

The major risks of physical activity programs by initially inactive persons aged 40 and over are orthopedic and cardio-respiratory. Orthopedic problems primarily are of the overuse variety and usually can be treated by rest and change in the mode of physical activity. Frequent minor problems will occur, including temporary soreness or irritation of muscles, tendons and joints. The likelihood of orthopedic and cardio-respiratory risks are greatly minimized through the use of a moderate-intensity exercise program that involves primarily mild to moderate-intensity walking, as proposed in the current study, and an individualized, progressive approach to physical activity as proposed in the current program.

For participants in the attention-control condition, there is a small risk that making changes to eating habits (i.e., introducing new foods) may cause transient gastrointestinal upset.

- vii. Psychological well-being

There is a remote risk that persons completing questionnaires focusing on behavioral or psychological content may become distressed. There is no evidence that any permanent psychological dysfunction has resulted from such assessments.

- viii. Economic well-being

NA

- ix. Social well-being

NA

x. Overall evaluation of risk

The risk for participating in this research study is minimal, similar to regular daily activities such as walking.

b. International Research Risk Procedures

NA

c. Procedures to Minimize Risk

Study assessments will be conducted at the designated housing sites by extensively trained and supervised study staff who have experience in collecting the planned study measures.

Physical activity programs. Our research team has had substantial experience in the formulation and execution of physical activity programs for a wide range of patient and non-patient populations, including community-dwelling older adults and other subjects at increased risk for cardiac or orthopedic complications during exercise (those having had coronary artery bypass graft surgery, post-myocardial infarction, hypertension, hyperlipidemia, mobility impairments, and obese patients). For over 30 years we have been prescribing individually-tailored home- and neighborhood-based physical activity programs for midlife and older adults without any major cardiac or other medical complications resulting from the physical activity of which we are aware. To ensure participant safety in this study, we will apply the set of screening and oversight procedures that are recommended in the American College of Sports Medicine's (ACSM) guidelines and that we have used successfully in our research studies over the past 30 years. The physical activity programs that we have delivered to mid-life and older adults (a number that have been more intensive than the moderate-intensity primarily walking program being targeted in the current research) have been shown to be safe, with no participant experiencing a major medical problem or injury related to the physical activity program. As recommended in the current ACSM guidelines, to screen potential participants for appropriateness for the physical activity program, we will have each individual complete the Physical Activity Readiness Questionnaire (PAR-Q), an extensively validated and used screening questionnaire that has been used throughout Canada and the U.S. to screen individuals for community-based physical activity programs. If individuals answer 'yes' to any of the medically related screening items, they will be directed to get physician clearance prior to entry into the study. This protocol has been shown to ensure participant safety without creating unnecessary medical expenses and barriers to participation for persons not deemed at risk for physical activity-related complications---an important issue for the low-income population being targeted. The use of a mild form of physical activity (walking and similar easy-to-do types of physical activity) also diminishes risk. In addition, all subjects will be evaluated for adverse events as part of the study assessments conducted every 6 months using the standard forms approved for use by the Stanford Institutional Review Board.

The risks of injury resulting from participating in the prescribed physical activity programs will be minimized in several ways:

- Exclusion from the study of any person with overt cardiovascular or orthopedic disease.
- Individualized physical activity program aimed at slow, gradual progression of physical activity amount.
- The use of moderate-intensity physical activity programs, involving walking and similar activities, for all study participants.
- Personalized instruction of participants as part of the evidence-based physical activity programs being used.
- Ongoing attention to and advice related to the experience of physical discomfort during physical activity as part of the evidence-based physical activity programs.

The content of the moderate-intensity physical activity program that is being targeted is commensurate with the current national guidelines for physical activity promotion in older adults.

Confidentiality of participant data. Confidentiality of participant data will be maintained by handling individual data by ID number, rather than by name; storing all individual data in locked file cabinets and secured, password protected electronic hard drives and data servers; and not disclosing individual data to anyone other than project staff, except as requested by the participant in writing.

Adverse event monitoring and reporting. Adverse events information will be collected at all assessment points and recorded on standard forms that have been used in our other studies. We will collect information on all potential types of adverse events, including musculo-skeletal soreness and injury, as well as major medical events including injuries or conditions that result in health care provider visits, hospitalization, etc. Consistent with NIH and Stanford IRB policy, adverse events will be promptly reported in writing to the NIH and Stanford IRB.

d. Study Conclusion

Current recommendations are for all healthy adults to engage in physical activity on most, preferably all days of the week. The intervention in this project is designed to encourage people to meet the physical activity goals for 12 months, which is an appropriate length of time to expect people to establish new health habits. There are no guidelines for early termination of an intervention designed to encourage a physically active lifestyle. However, if physical or other conditions develop such that continued participation would constitute undue risk, participation will be discontinued. Guidance on this matter will also be provided by the Project Advisory Committee. Advice given is consistent with current health guidelines, so there is no guideline for early termination. However, if conditions develop such that continued participation would constitute undue risk, participation will be discontinued. Guidance on this matter will also be provided by the Project Advisory Committee

e. Data Safety Monitoring Plan (DSMC)

- i. Data and/or events subject to review

NA

- ii. Person(s) responsible for Data and Safety Monitoring
NA
- iii. Frequency of DSMB meetings
NA
- iv. Specific triggers or stopping rules
NA
- v. DSMB Reporting
NA
- vi. Will the Protocol Director be the only monitoring entity? (Y/N)
Y
- vii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)
N

f. Risks to Special Populations

NA

6. BENEFITS

We believe that all participants will benefit by learning (from the study questionnaires and measurements) about their health and physical activity levels. Those who successfully improve their physical activity levels will have achieved desired goals. Over the study period all participants will benefit from receiving health information.

We believe society will benefit from the results of this project in that it will inform further research aimed at developing effective and appropriate physical activity programs for low-income populations in this age group.

It will shed light on how best to deliver physical activity advice to enhance adoption and maintenance of regular physical activity through programs that include individual-level behavioral skill-building and identification of neighborhood assets for and barriers to regular physical activity. The delivery of these programs in community settings such as congregate housing sites by trained lay advisors and facilitators can substantially broaden the reach of the physical activity interventions to underserved populations at potentially lower-cost than traditional face-to-face or health care provider-delivered approaches. These are public health issues of immense proportions, particularly with the continued growth of the older segment of the U.S. population and the substantial prevalence of inactivity among that population group in general and lower-income segments in particular. In summary, we believe the risks can be kept very low whereas the benefits to participants and society are quite substantial.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.