Official Study Title: Leveraging Social Networks: a Novel Physical Activity Intervention for Senior Housing

NCT Number: NCT06007664

Document: Study Protocol and Statistical Analysis Plan

Document date: 9/19/2024

Study PI: Noah J. Webster

I. Research Design
    a. Objective
        i. In this pilot study, we will test the feasibility of pairing a social network-based approach with a 6-week Occupational Therapist (OT)-led intervention administered remotely to increase physical function and activity among residents of a HUD subsidized independent-living senior housing community. The social network-based approach will involve systematic identification and involvement of influential human agents of change in the community (i.e., the most respected residents) to help sustain others' participation in the OT intervention. The OT intervention will be comprised of a combination of adapted components from multiple evidence-based interventions including individual meetings with an OT and OT-led group sessions. The goal of the intervention is to increase physical function and activity among older adults through development of habits and skills that address barriers such as pain.
    b. Specific Aims
        i. List of Specific Aims
            1. Identify agents of change (AoC) and implement intervention.
            2. Evaluate feasibility of intervention implementation.
            3. Examine changes in secondary outcomes and differences in process and secondary outcomes by whether knew an AoC at baseline.
        ii. The following process hypotheses will be tested: At least 75% (3 of 4) of identified AoCs will accept the invitation to serve on Advisory Committee; AoC will attend at least 2 of 3 committee meetings; Participants will on average participate in at least 70% (7 of 10) of intervention activities; Residents knowing 1+ committee members at baseline will participate in more intervention activities compared to those who do not; The network influence on participation will be greater among residents reporting more pain at baseline compared to those reporting less pain.
    c. Background
        i. Physical activity (PA) is associated with many personal and societal benefits, e.g., alleviation of pain and improvement in physical function (1). Despite benefits, only 16% of people age 65+ engage in recommended levels of PA. Pain has been cited as a reason for PA intervention dropout (2,3). Research is needed to identify mechanisms that can sustain participation in behavioral interventions when barriers such as pain are present. One promising mechanism is interpersonal and social resources. Social ties affect health behaviors and have powerful effects among lower income older adults and those with health problems.
            1. Centers for Disease Control and Prevention Physical Activity – About Physical Activity – Why it Matters. Last accessed January 14, 2019 from https://www.cdc.gov/physicalactivity/about-physical-activity/why-it-matters.html.

2. Centers for Disease Control and Prevention Adult participation in aerobic and muscle-strengthening physical activities - United States, 2011. Morb Mortal Wkly Rep. 2011;62:326-330. MMWR. [PMC free article] [PubMed] [Google Scholar]
3. Centers for Disease Control and Prevention Physical Activity: How Much Physical Activity Do Older Adults Need? Last accessed January 14, 2019 from http://www.cdc.gov/physicalactivity/basics/older_adults/.

II. Methodology

a. Two sequential cohorts of 12 residents (24 residents total) living in a HUD subsidized independent-living senior housing community in [City Name] will be recruited for participation in this study. Both cohorts will receive the same intervention. The study includes the following components:
b. All research activities will take place in-person, over the phone, or virtually on Zoom.
c. Flyers will be distributed around the community to advertise the in-person recruitment presentation that will be hosted in the community room. The flyer will invite interested residents to attend the presentation to learn more about the program.
d. At the in-person presentation, Noah Webster, the PI, will give a short presentation introducing the program and interested attendees will be invited to complete the screening interview in-person following the presentation to determine if they are eligible to participate.
e. After the presentation, a second recruitment flyer will be distributed around the community with details about the program and an email and phone number for interested residents to contact the study team.
f. Recruitment will be done in two phases, one for each cohort, and recruitment will remain open until 12 residents have been enrolled for each cohort. All residents in the community will be provided information about the study in the same manner and at the same time and we will screen and enroll people in the study on a first come basis. No person will be excluded from the study based on their sex/gender, race, or ethnicity.
g. If the first group of residents taking part in the study does not include a large enough proportion of minority residents, we will initiate more targeted recruitment strategies to engage minority residents. This will involve: 1) Asking the community service coordinators to hand deliver the recruitment flyer to minority residents living in the community. After recruitment and screening of the first cohort is complete it will be determined if the above targeted recruited approach is needed for the second cohort. If it is needed, we will submit an IRB amendment at that time for this approach with the related recruitment materials (recruitment letter and phone recruitment script).
h. We will also recruit from each cohort's group of 12 study participants, two influential agents of change (AoC), who will be identified as being the most respected by other study participants. These study participants will be identified using data collected

during the pre-intervention interview. Specifically, during the interview, study participants will be asked to identify people they know in the community. Then for each person they indicate knowing, they will be asked how much they respect that person on a 5-point Likert scale. The two most respected persons in each cohort will be invited via telephone to be a member of their cohort's Advisory Committee. If either of the two persons declines the invitation, the 3rd most respected person will invite and so on until at least two agree to participate in this role. During the Advisory Committee recruitment call, the role of being a committee member will be described (i.e., attend three committee meetings and remind other participants to attend intervention activities and events).

i. Informed consent will be obtained prior to participation in the screening interview. Screening interviews will be conducted in-person at the housing community and also by telephone. If the screening interview is conducted by phone, we will obtain verbal consent. The date that verbal consent is provided to participate will be noted on a copy of the informed consent document by the interviewer along with the participant's name. Following the screening interview, the dated copy will be stored with the study records and a blank copy will be mailed to the participant to keep for their records. If the screening interview is conducted in-person, prior to beginning the interview the interviewer will go over the informed consent document with the participant. The participant will then be asked to sign the form if they consent to participate in the screening interview. The signed copy will be kept and stored with the study records, and the participant will be given an unsigned copy for their records.
j. Participants will complete a 10-minute screening interview over the phone (or in-person after community presentation) to determine if they are eligible to participate in the study. The screening interview will be administered through Qualtrics. Each person that is screened will be assigned a participant ID. The ID will be generated using the initials of the interviewer and the number of screening interviews conducted in-order by that interviewer. For example, the fifth person that [study team member with initials MK] is interviewing will be assigned "MK05." An excel sheet that links participant identifying information and their ID will be password-protected and saved on an O drive. Data will be kept for all residents that complete the screening interview to meet reporting requirements of the study sponsor (National Institutes of Health).
k. All participants completing the screening interview will receive $10 cash for completing the interview, even if they are found to be ineligible. Those completing the survey in-person following the presentation will receive the money immediately after their interview. Those completing the survey over the phone and are found ineligible will be mailed the $10 in cash within the following the week. Those completing the survey over the phone and are found eligible, will receive the $10 in cash in-person when the study team delivers their study materials.
l. The screening interview is set up to end immediately if the participant does not meet any of the eligibility criteria. At this point, the ineligible participant will be thanked

for their time and asked to confirm their mailing address so that their incentive can be mailed to them.

m. For those who are eligible to participate, the study team will set up: 1) a day/time for a 30-minute pre-program interview administered over the telephone; and 2) before the interview, a day/time for the study team to make a visit to the housing community to drop off study materials and obtain signed consent for the study. For those screened to participate on-site, this informed consent process will occur directly after the screening interview. At the time of the in-person visit, the study team member will go over the consent form with the participant and answer any questions the participant may have. The participant will then be asked to print their name, sign and date the informed consent document. The signed copy will be taken and kept with study records and the participant will be given an unsigned copy for keep for their records. Following this, the time and date for the participant's pre-program interview will be confirmed.
n. The study materials will include a copy of the screening consent form for the participants to keep for their records, the $10 in cash for completing the screening interview, a tablet, a tablet charger cord, an HDMI cable to connect the tablet to a larger screen, a pedometer, an ActivPAL physical activity monitoring device wrapped in a water proof sleeve, Tegaderm adhesive/tape to attach the device to participant's thigh, and a copy of the consent form to participate in the study for the participants to keep for their records. During this visit, the participants will be trained on how to use these devices.
o. Participants will be provided with tablets and pedometers to use during the study. They will be asked to return the tablet upon completion of all study activities, but they can keep the pedometer. These materials will be hand-delivered to all participants after they are determined to be eligible to participate in the program, but before their pre-program interview. Pedometers will be used to track steps and help motivate and inspire participants to reach their activity goals. Following the first remote one-on-one meeting with the OT, the OT will provide each participating resident with a packet of educational materials, information that will be used and covered during group sessions and also include individual pedometer tracking sheets
p. Eligible participants will complete a 30-minute pre-program (baseline) interview over the phone. They will be asked will be asked questions about things they do, physical activities they engage in, their social relationships with other residents in the community, and their health.
q. Pre-program interviews will be administered through Qualtrics, and participants will be asked whether they know each of the other members of their intervention cohort. For each person they indicate knowing, they will be asked how much they respect that person on a 5-point Likert scale. The two most respected persons in each cohort will be invited via telephone to be a member of their respective cohorts' Advisory Committee. If either of the two persons declines the invitation, the 3rd most respected person will be invited. This will continue until two people agree to serve on the committee. During the Advisory Committee member recruitment call,

the role of being a committee member will be described (i.e., attend three committee meetings and remind other participants to attend intervention activities). Advisory Committee members will be asked to remind other cohort members to attend intervention activities only by making note of intervention activities during their regular interactions with the other participants (e.g., when see them in the hallway or in community common areas). They will not be asked to go out of their way to do this.

r. Participants will be asked to wear a physical activity monitoring device (i.e., ActivPAL) on their thigh for 7 consecutive days after their pre- and post-program interviews. This is a small device that would be placed on your thigh with the help of a gentle adhesive. This device will continuously monitor their physical activity including activities like sitting, standing, walking and/or running. It will be recording the energy they had spent while performing the above-mentioned activities. When we retrieve this device from them, we will be looking at a number of values that tell us about their physical activity levels such as time spent sitting, standing, number of steps taken while walking and/or running, as well as energy spent per day.
s. Participants identified to be potential Advisory Committee members must sign a separate consent form to serve in this role. This signed consent will be obtained in-person when the study team returns to participants' homes to pick-up the ActivPAL devices following the initial 7-day of wear. A copy of this consent form will be given to the participant to keep for their records. All the participants serving in this role will receive $100 in cash at the completion of the study. This money will be hand-delivered to them at the end of the program in-person when picking up the ActivPAL device following the post-intervention 7-day of wear and the tablets.
t. Once two cohort members have agreed to serve on the Advisory Committee we will hold an Advisory Committee Kick-Off Meeting. During the meeting the following will be discussed with the Advisory Committee Members: 1) the best day and time for OT weekly group sessions; 2) what the role of Advisory Committee member entails; 2) any questions or concerns regarding the role, which includes: a) attending two additional committee meetings during weeks 3 and 5, and during these meetings provide feedback on how the program is going form their perspective; and b) reminding other cohort members to attend intervention activities. This will include making note of intervention activities only during their regular interactions with the other participants (e.g., when see them in the hallway or in community common areas). During this kick-off meeting the Advisory Committee Members will be instructed how to avoid coercive statements in their reminders. This will be facilitated by providing examples of both non-coercive and coercive statements.
u. Participants will be asked to meet individually with the OT for 60-90 minutes via Zoom to evaluate the relationship between the participant and their apartment for engagement in safe mobility and activity; assess the participant's activity performance, satisfaction, and barriers to activity engagement; establish 3-5 short-term activity goals; and outline the beginning of an individualized home exercise program. This will include the OT providing guidance on use of the program provided pedometer and also demonstration of 1 or 2 exercises that can be performed safely

in the home. The participating resident will then be invited to briefly perform the activities demonstrated and feedback will be provided by the OT.

v. Participants will be asked to participate in 4 weekly one hour group OT sessions remotely via Zoom. Each session will include the following format: 1) teaching & education; 2) OT facilitated discussion on successes and challenges with: a) short-term activity goals; b) implementing individualized plans; and c) strategies discussed at prior group sessions; and 3) activity demonstration, engagement and feedback. Each session will focus on a different topic for the teaching and education portion including: mobility, physical activity, pain management, and energy conservation. Each session will conclude with a brief group exercise activity demonstration and engagement led by the OT. The goal of this activity is to establish a foundation and facilitate development of habits. The activity will be repeated at the end of each of the four sessions, and will include rising from a chair, walking in place, and use of breathing techniques during the activity. Following the activity there will be a brief discussion of the experience and feedback provided by the OT if adjustments are needed.
w. Over the course of the 4-weeks of group sessions, participants will be asked to briefly meet individually with the OT remotely via Zoom for 15-20 minutes once a week to answer any questions and or address problems that might arise.
x. Following the completion of the group OT sessions, participants will be asked to again meet individually with the OT for 60 minutes via Zoom to re-evaluate the home for barriers to safe physical function and activity; re-assess activity performance, satisfaction, and barriers; revisit the 3-5 short-term activity goals established during the first one-on-one meeting, and revise as necessary; revisit the partial individualized home exercise program, and revise as necessary. This will include the OT re-demonstrating the participant's partial individualized home exercise program including any revisions, leading the participant in engaging in the activities, and providing feedback.
y. Participants will be asked to complete a 40-minute post-program (follow up) interview over the phone, administered through Qualtrics. They will again be asked questions about things they do, physical activities they engage in, their social relationships with other residents in the community, and their health. They will also be asked questions intended to measure the usefulness and satisfaction with the program. In the post-program interview we will ask participants again whether they know each of the other participants in their cohort, and for each they do know, how much they respect them. The purpose of asking these questions in the post-program interview is to determine if the social connections between participants change over the course of the intervention. This is required in order to determine if and how the Advisory Committee members' position in the network of participants (in terms of being the most respected) changes. It is hypothesized that there will be an increase in the number of participants reported known and also the level of respect will increase. If supported, this will provide evidence of an important secondary outcome of the intervention, which could be useful in sustaining participants' engagement of behaviors introduced during the intervention.

z. Finally, following the post-program interviews, participants will again be asked to wear an ActivPAL physical activity monitoring device on their thigh for 7 consecutive days. The study team will then visit the participants to pick-up the ActivPAL device and all other study materials (e.g., the tablet). At this visit, the participants will receive the remaining incentive in cash and told that this concludes their participation in the study.

aa. Participants will receive $10 for completing the study screening assessment and if they are eligible to participate, they will receive an additional $25 for completing baseline and $30 for completing the follow-up study assessments. Additionally, they will receive $20 to wear an activity monitor for seven consecutive days at baseline and follow-up ($10 for wearing it at baseline and $10 for wearing it at follow-up), for a total of $85 for participating in all parts of the study. Agents of change (AoC) will receive $100 as a token of appreciation for their time to serve in this role, which will be provided following the committee's third (and last) meeting.

bb. Participation will be ended prematurely if a study participant contacts the study team and indicates that they would like to withdraw from the study or if the Occupational Therapist administering the intervention determines at any point that it is not safe for the participant to continue participating. If a participant withdraws from the study, the individual's data will be retained unless the participant requests to have their data destroyed. A participant's data will be destroyed upon their request. However, once findings are used in an analysis it will not be possible to remove a participant's information.

cc. Deidentified data gathered during screening interviews (including from people who are found to be ineligible) will be kept to meet reporting requirements of the study sponsor (the National Institutes of Health). Identifying information including name, address, and phone number of those ineligible will only be kept to mail the screening interview incentive and will then be destroyed/deleted following the mailing. Identifying information of those eligible will be kept for study communication purposes. For participants who did not agree to be contacted for participation in future research, their identifying information will be destroyed/deleted at the time of study conclusion (i.e., after last visit is made to collect study materials and provide the last incentive). For participants who did agree to be contacted again in the future, their identifying information will be retained.

Advantages of providing participants with tablets and using a virtual format for the OT intervention include improving accessibility by providing an opportunity for participants to engage in the program activities from the convenience of their home/apartment unit. This methodology and mode of delivery of the intervention aims to address potential barriers to sustain participation.

Timeline per cohort:

Week 1-2:
Recruitment, eligibility screening, pre-intervention interview, and accelerometry data collection, Social network analysis and Identification of agents of change (AoC)
Week 3:
Formation of Advisory Committee, pre-intervention OT remote 1-on-1 meetings
Week 4-7:
OT-led remote group sessions, brief weekly remote 1-on-1 check-ins
Week 8:
Post-intervention OT remote 1-on-1 meetings
Week 8-9:
Post-intervention interviews and accelerometry data collection

Ame00140806 To assist in the recruitment of the second cohort a letter will be provided to residents of [Community Name] along with the already approved recruitment flyer. Both will appear on a single piece of paper, with the new letter on one side and the already approved flyer on the other (back) side. The single piece of paper will be delivered to each residents' door. Also, the already approved recruitment flyer will be posted in public spaces in the community (e.g., on community bulletin boards). We will invite members of our first cohort to invite other community members they know to consider participating in the second cohort. They will not be asked to go out of their way to do this, and only do so during their regular interactions with other community members (e.g., when see them in the hallway or in community common areas). The following example will be provided to participants as a way they can talk about the program with other community members: "Hi [community member] I've been participating in the University of Michigan's T-VIDA program that you may have seen flyers for around the community. As part of the program I've had the chance to work with an Occupational Therapist to help me increase my physical activity. You might want to consider signing up for the second group. There is contact information on the flyer that we all just received at our doors if you are interested. " Pre-program interviews will be administered over the phone on in-person through Qualtrics.

Ame00141959 Included with this amendment is two new questions added to the follow-up (post-intervention survey) for participants in our first cohort. We recently received IRB approval to invite participants of our first cohort to help invite and recruit others in the community to participate in our second cohort. These new questions inquire about if they talked to other residents in the community about the program and if so, how many.

Ame00151969 Included with this amendment is the change that we were not able to collect data from two sequential cohorts within the same HUD subsidized independent-living senior housing community community ([Community Name]). We will now being recruiting the second cohort at a second HUD subsidized independent-living senior housing community ([Community Name]) in Ann Arbor, MI. The study intervention remains the same.

III. Statistical design

a. Sample size: Two sequential cohorts of 12 residents living in a HUD subsidized independent-living senior housing community in Ypsilanti, MI will be recruited for participation in this study. Both cohorts will receive the same intervention. The size of each cohort is capped at 12 to facilitate participation among all participants during group components of the intervention. A sample size of 24 was estimated to be sufficient in order to reach data saturation from quantitative process measures and theoretical saturation of themes from qualitative (i.e., open-ended) evaluation data (see Aim #2 below).

b. AIM 1) Identify agents of change (AoC) and implement intervention. Within two sequential cohorts of 12 residents living in a HUD subsidized independent-living senior housing community, AoC will identified.

    i. Data analysis plan: Within each group of 12 study participants AoC will be identified using data collected during the pre-intervention interview. Specifically, during the interview, study participants will be asked to identify people they know in the community. Next, social network analysis will be conducted using these data with Ucinet. AoC will be identified as the top two study participants in their cohort on the social network measure of in-degree centrality (i.e., number of other study participants who report knowing them).

    ii. Power analysis: A power analysis was not conducted for the proposed analysis due to the descriptive nature of the social network analyses.

c. AIM 2) Evaluate feasibility of intervention implementation. Process outcomes will be examined following intervention implementation to determine which components were feasible. The process evaluation will be guided by a framework for evaluating complex interventions that assesses implementation, mechanisms of impact, and context. Process measures will include: 1) number of original AoC who accept invitation to serve on the Advisory Committee; 2) number of committee meetings attended by AoC; 3) number of individual (one-on-one) activities attended by study participants; 4) number of group activities attended by study participants; 5) total number of intervention activities attended by study participants; and 6) number of remote activities that study participants attended via zoom. Hypotheses: The following process hypotheses will be tested H2a: At least 75% (3 of 4) of identified AoCs will accept the invitation to serve on Advisory Committee; H2b: AoC will attend at least 2 of 3 committee meetings; H2c: Participants will on average participate in at least 70% (7 of 10) of intervention activities.

    i. Data analysis plan:

        1. Quantitative analysis: Descriptive analysis of process outcomes and intervention usefulness/satisfaction data from post-intervention interviews will be conducted using statistical software (e.g. SPSS). This will include examination of variable frequencies, measures of central tendency, and sample variation.
        2. Qualitative analysis: Analysis of open-ended data from questions about the usefulness and satisfaction with specific intervention

components from the post-intervention interviews will begin with an open-coding process to develop a codebook. This will involve the PI and Graduate Student Research Assistants (GSRAs) working on the program. Each person will read the text responses and independently develop a list of themes in the data. Next the team will meet to discuss the themes with a goal of reaching consensus on the list of themes and develop and agreed upon definition for each theme. This information will then be compiled into a codebook containing the list of themes/codes and their definition. Following this, the GSRAs will conduct axial coding. This will include associating specific passages of text with the themes/codes developed during the open-coding process. This will be done using qualitative data analysis software (NVivo). Inter-rater reliability (kappa) will be calculated for an initial sample of text passages coded by the GSRAs. If discrepancies exist, they will be discussed and the process repeated until kappa >0.80.

3. Power analysis: A power analysis was not conducted for the proposed analysis due to the descriptive nature of the proposed analyses, including analysis of open-ended text responses and descriptive analysis of process outcomes across the entire sample of study participants.

d. AIM 3) Examine changes in secondary outcomes and differences in process and secondary outcomes by whether knew an AoC at baseline.
    i. Hypotheses: The following hypotheses based on Social Contagion Theory and the Convoy Model of Social Relations will be tested: H3a-Network influence: Residents knowing 1+ committee members at baseline will participate in more intervention activities compared to those who do not. H3b-Pain as modifier: The network influence on participation will be greater among residents reporting more pain at baseline compared to those reporting less pain.
    ii. Data analysis plan: Analysis for aim 3 will begin with descriptive analysis of secondary outcomes (physical function, PA, and pain) measured via self-report during both the pre- and post-intervention interviews. This will be done using statistical software (e.g., SPSS) and will include examination of variable frequencies, measures of central tendency, and sample variation. Next change scores will be created to document change in these measures from pre- to post-intervention and descriptive analyses conducted on these variables.

e. Analysis of accelerometry data: This study will use an accelerometer (activPAL) to measure physical activity among study participants. The activPAL is worn on the thigh continuously for 7-days. It has been shown to reliably measure sedentary time (including lying and sitting time) and activity intensity (i.e., estimates of energy expenditure) (Lyden et al., 2018). Raw data from the activPAL will be exported using activPAL provided software to a .csv file. The data will then be processed using an R-

package developed by developed specifically for activPAL data (Lyden et al, 2018). The data will be processed at the second level (1-second epochs). The same R-package will then be used to sum the following over the 7-day period I which the device was worn: 1) sedentary (i.e. sitting/lying) time (i.e., number of 1-second epochs of <1.50 metabolic equivalents); 2) light activity (i.e., standing and stepping) time (i.e., number of 1-second epochs between 1.50 and 2.99); and 3) moderate or higher activity time (i.e., number of 1-second epochs 3.00 or higher). The above data preparation and analysis steps will be applied to both the pre- and post-intervention accelerometry data. As a final step we will create changes scores in each of the three objectively measured indicators of activity (sedentary, light, and moderate or higher). Following creation of these variables, descriptive analysis will be conducted on these variable including examination of frequencies, measures of central tendency, and sample variation.

f. Hypothesis testing: To test the proposed hypotheses (i.e., to test the presence of social network influence), mean differences and corresponding 95% confidence intervals in process measures (e.g., number of intervention activities that study participants participated in) and changes in secondary outcomes described above will be compared between study participants who knew one or more AoC at baseline and those who did not. Next, within these two groups we will stratify by pain measures to explore descriptively whether pain moderates network influence on outcomes.
g. Power analysis: A power analysis was not conducted for this pilot study given the proposed small non-representative sample, which is likely to produce inaccurate estimates of effect size and their corresponding standard errors.
h. Reference: Lyden, K., Keadle, S. K., Staudenmayer, J., & Freedson, P. S. (2017). The activPALTM accurately classifies activity intensity categories in healthy adults. Medicine and science in sports and exercise, 49(5), 1022-1028.

‘***Ame00151969*** Included with this amendment is the change that we were not able to collect data from two sequential cohorts within the same HUD subsidized independent-living senior housing community ([Community Name]). We will now being recruiting the second cohort at a second HUD subsidized independent-living senior housing community ([Community Name]) in Ann Arbor, MI. The study intervention remains the same

IV. Foreseeable Risks to Participants

a. 1) Risks Encountered During Data Collection: a) Rare and minimal risk of emotional distress from participating in survey interviews measuring psychosocial constructs. The interviewers conducting the pre- and post-program interviews will be trained to be sensitive to distress among participants. If a participant shows any signs of emotional distress the participant will be provided with a document listing the contact information of agencies they can consult with to receive counseling. b) skin irritation from Tegaderm adhesive used to waterproof and attach physical activity monitoring device (i.e., activPAL accelerometer) to study participants’ thigh. Study team members will train participants on how to properly attach this device to

minimize irritation caused by improper attachment. There is also a minimal risk of an accidental breach or disclosure of identifying information. To prevent accidental breaches or disclosure of data collected, the study team will do the following:

b. 2) In terms of the responses provided during the pre and post-program interviews:
    i. We will use of an online computer program (Qualtrics) to enter the responses during the pre and post-program interviews.
    ii. The program uses encryption and firewalls to ensure the data are not accessed by people outside of the study team.
    iii. Participant's name and other identifying information (phone number and address) will not be entered into the program. We will identify you in the program with a study ID consisting of only numbers.
    iv. Study data will be downloaded from the program and stored on a secure University of Michigan computer network where only study team members will have access.
    v. Only study team members will have access to a password protected file that connect you to your study ID. Additionally this file will be stored on a secure University of Michigan computer network and accessed from password protected computers.
c. 3) In terms of the data collected using the activity monitoring device:
    i. Data collected via the activity monitoring device (activPAL) will only be accessible using a vendor provided docking station and software.
    ii. The data will only be downloaded from the device using a password protected computer at the University of Michigan and stored on a secure computer network.
    iii. The data will be deleted from the device before the device is used again with another study participant.
    iv. There is a serial number located on the device, which will be linked to the unique study ID, which will be stored in the aforementioned password-protected file at the University of Michigan.
    v. If the device is lost or stolen, it will not be possible for the data stored on the device to be linked back to the participant. This research holds a Certificate of Confidentiality from the National Institutes of Health.
d. 4) Risks Encountered During Intervention:
    i. Physical injury or distress during activities related and engaged in throughout the 6-week intervention, which will include establishing and working toward accomplishing goals related to physical function and activity. This could include increasing mobility and engaging in low to moderate intensity physical activities. To minimize risk of physical injury during the OT program activities, medical exclusion criteria common in mobility, function, and physical activity programs will be used. This includes excluding individuals for whom participation is not likely to be safe as well as more broadly those not likely to derive benefit from participation in this program. The OT will also work with all participants individually to create a personalized plan that is safest and most beneficial to each participant.

Also, during the 4 weekly brief (15-20) individual meetings, the OT will inquire about the experience of any physical injury or discomfort related to the program activities.

ii. Conflict or tension between resident agents of change (AoC) and other study participants. AoC in their role as members of the intervention Advisory Committee will be asked to remind other study participants in their cohort to participate in intervention activities. These reminders could be perceived as annoying or irritating by other study participants, which could result in relationship conflict or tension. To minimize this risk, AoCs will be provided information on best approaches and practices to remind study participants about intervention activities. This will include making note of intervention activities only during their regular interactions with them. They will not be asked to go out of your way to remind participants. They will also be instructed on how to avoid coercive statements in their reminders to participants. This will be facilitated by providing them with examples of non-coercive statements to use when providing reminders.

e. We believe the potential benefits to study participants outweigh the potential minimal to low risks. While participation in this study poses no serious risks to the study participants, given the focus on older adults and on physical function and activity during the intervention, safeguards to ensure safety of the participants will be put in place. These safeguards include: training for the interviewers conducting the pre- and post-intervention interviews to ensure sensitivity to distress among participants, providing phone numbers to call if emotionally upset or distressed, medical exclusion criteria common in mobility, function, and physical activity interventions will be used to exclude individuals for whom participation is not likely to be safe as well as more broadly those not likely to derive benefit from participation in this intervention, agents of change (AoC) will be provided information on best approaches and practices to encourage and remind study participants about intervention activities to avoid coercive statements in their reminders and decrease potential tensions between the residents. At least one study team member will join the Zoom calls for all group Occupational Therapy (OT) sessions. If a participant experiences any physical injury during the online OT sessions, the study team member will call 911 and send them directly to the participant's apartment. During the one-on-one meetings with the participants, the OT will discuss any physical injuries/

V. Subject Recruitment

a. Study participants will be recruited at the community through use of flyers that will be posted around the housing community and delivered to residents' doors. The flyer will include the name and a brief description of the intervention. The flyer will indicate for interested residents to call the provided number or send an email if they have any questions or to schedule an eligibility screening. When residents call, they will be directed to leave a voicemail with their name and a call back number. The study team will then call them back, using the attached pre-screening phone call

script, then administer the screening interview, over the phone. At the end of the screening interview, the study team will ask all eligible residents for a good time to drop off their study materials and obtain signed consent for the study. For those that send an email, they will receive a reply through email (attached below as the pre-screening email reply) asking for a phone number and a good time for the study team to call them. They will then use the same pre-screening phone script and administer the screening interview, over the phone.

b. The study team will also host an in-person presentation in the community room to allow the resident of [Community Name] to learn more about the program. After the presentation, the study team will administer the screening interview in-person for all interested residents to determine if they are eligible. The presentation will be advertised ahead of time through a separate flyer that will be distributed around the community and all residents will be welcome to attend and be screened, if interested.
c. Recruitment will be done in two phases, one for each cohort, and recruitment will remain open until 12 residents have been enrolled for each cohort. All residents in the community will be provided information about the study in the same manner and at the same time and we will screen and enroll people in the study on a first come basis. No person will be excluded from the study based on their sex/gender, race, or ethnicity.
d. If the first group of residents taking part in the study does not include a large enough proportion of minority residents, we will initiate more targeted recruitment strategies to engage minority residents. This will involve: 1) Asking the community service coordinators to hand deliver the recruitment flyer to minority residents living in the community. After recruitment and screening of the first cohort is complete it will be determined if the above targeted recruited approach is needed for the second cohort. If it is needed, we will submit an IRB amendment at that time for this approach with the related recruitment materials (recruitment letter and phone recruitment script). We will also recruit from each cohort's group of 12 study participants, two influential agents of change (AoC), who will be identified as being the most respected by other study participants. These study participants will be identified using data collected during the pre-intervention interview. Specifically, during the interview, study participants will be asked to identify people they know in the community. Then for each person they indicate knowing, they will be asked how much they respect that person on a 5-point Likert scale. The two most respected persons in each cohort will be invited via telephone to be a member of their cohort's Advisory Committee. If either of the two persons declines the invitation, the 3rd most respected person will invite and so on until at least two agree to participate in this role. During the Advisory Committee recruitment call, the role of being a committee member will be described (i.e., attend three committee meetings and remind other participants to attend intervention activities and events). Advisory Committee members will be provided a $100 cash incentive as a token of appreciation for their time serving in this role. This will be provided after the third Advisory Committee meeting and delivered by a study team member in-person.

e. Deidentified data gathered during screening interviews (including from people who are found to be ineligible) will be kept to meet reporting requirements of the study sponsor (the National Institutes of Health). Identifying information including name, address, and phone number of those ineligible will only be kept to mail the screening interview incentive and will then be destroyed/deleted following the mailing. Identifying information of those eligible will be kept for study communication purposes. For participants who did not agree to be contacted for participation in future research, their identifying information will be destroyed/deleted at the time of study conclusion (i.e., after last visit is made to collect study materials and provide the last incentive). For participants who did agree to be contacted again in the future, their identifying information will be retained.

Ame00140806 To assist in the recruitment of the second cohort a letter will be provided to residents of [Community Name] along with the already approved recruitment flyer. Both will appear on a single piece of paper, with the new letter on one side and the already approved flyer on the other (back) side. The single piece of paper will be delivered to each residents' door. Also, the already approved recruitment flyer will be posted in public spaces in the community (e.g., on community bulletin boards).

f. We will invite members of our first cohort to invite other community members they know to consider participating in the second cohort. They will not be asked to go out of their way to do this, and only do so during their regular interactions with other community members (e.g., when see them in the hallway or in community common areas). The following example will be provided to participants as a way they can talk about the program with other community members: "Hi [community member] I've been participating in the University of Michigan's T-VIDA program that you may have seen flyers for around the community. As part of the program I've had the chance to work with an Occupational Therapist to help me increase my physical activity. You might want to consider signing up for the second group. There is contact information on the flyer that we all just received at our doors if you are interested."

******Ame00151969***Included with this amendment is the change that we will be giving a presentation for our second cohort at [Community Name].

g. The staff of the community will assist in the best way for us to reach everyone living in the community. All residents in the community will be provided information about the study in the same manner and at the same time (via a recruitment flyer posted in common areas and delivered to doors) and we will screen and enroll people in the study on a first come basis. No person will be excluded from the study based on their sex/gender, race, or ethnicity. If the first group of residents taking part in the study does not include a large enough proportion of minority residents, we will initiate more targeted recruitment strategies to engage minority residents (e.g., targeted recruitment flyers, selective recruitment of minority residents from volunteers) for the second phase of recruitment.

h. Flyers that will advertise the in-person recruitment presentation will be distributed around [Community Name] inviting all interested residents to attend and learn more about the program. At this on-site presentation, the study team will share information about the program and seek participants. If participants indicate interest at the event, then they will be screened in-person at a location in the community of their choosing and notified of eligibility immediately after. Following this presentation, a second recruitment flyer will be distributed around [Community Name] with an email and phone number for interested residents to contact. All interested residents will then be contacted to do the screening interview over the telephone.

Ame00151969 For our second cohort, the same two flyers used previously for [Community Name], to advertise the in-person recruitment presentation, and distributed after the event will be used at [Community Name].

VI. Informed consent

a. We will obtain informed consent three times during the study for three different types of participation: 1) participation in a screening interview to determine if the participant is eligible to participate; 2) participation in the intervention program and evaluation aspects (i.e., pre and post-program interview and wearing of an activity monitor (activPAL) for 7-days after the pre and post-program interviews; and 3) for two specific participants (i.e., the most respected in the cohort) agreement to serve on the program Advisory Committee.
b. First, informed consent will be obtained prior to participation in the screening interview. Screening interviews will be conducted in-person at the housing community and also by telephone. If the screening interview is conducted by phone, we will obtain verbal consent. The date that verbal consent is provided to participate will be noted on a copy of the informed consent document by the interviewer along with the participant's name. Following the screening interview, the dated copy will be stored with the study records and a blank copy will be mailed to the participant to keep for their records. If the screening interview is conducted in-person, prior to beginning the interview the interviewer will go over the informed consent document with the participant. The participant will then be asked to sign the form if they consent to participate in the screening interview. The signed copy will be kept and stored with the study records, and the participant will be given an unsigned copy for their records.
c. If a participant is screened over the phone and they are determined to be ineligible to participate in the study, following their screening interview, they will be mailed a copy of the screening consent.
d. If a participant is determined to be eligible to participate in the study, following their screening interview two appointments will be set-up: 1) to visit the participant in-person in the housing community to obtained signed consent to participate in the study and drop-off study materials. This consent will be for participation in the pre-program/intervention interview, pre-intervention accelerometry data collection, the

intervention itself, the post-intervention interview, and post-intervention accelerometry data collection. 2) to complete the first study activity, a pre-intervention interview over the telephone.

e. For those screened to participate on-site, this informed consent process will occur directly after the screening interview. At the time of the in-person visit, the study team member will go over the consent form with the participant and answer any questions the participant may have. The participant will then be asked to print their name, sign and date the informed consent document. The signed copy will be taken and kept with study records and the participant will be given an unsigned copy for keep for their records. Following this, the time and date for the participant's pre-program interview will be confirmed.
f. Consent will be collected a third time for only specific participants, the study's identified agents of change (AoC) for their role in the intervention as a member of the intervention's Advisory Committee. Two AoC per cohort will be recruited over the telephone. If they are interested in the role, consent to take on the role will be obtained in-person when visiting the participant to pick up their activity monitor.
g. At the time of the in-person visit, the study team member will go over the consent form with the participant and answer any questions the participant may have about the role. The participant will then be asked to print their name, sign and date the informed consent document. The signed copy will be taken and kept with study records and the participant will be given an unsigned copy for keep for their records. All study informed consent documents will contain a statement informing participants that results from this study will be posted online at ClinicalTrails.gov.

VII. Confidentiality/security/privacy

a. To ensure participants' privacy is protected during the duration of the study, all phone calls, zoom meetings, and interviews (both over the phone and in-person) will be conducted in a private setting.
b. During the home visits to drop off study materials, we will ask to speak to the participants alone in a private setting of their choice. The management and staff at [Community Name] will not be told information about the participants including but not limited to, who screened for the study, who is participating, who has ended their participation early. This information (including answers to questions about social relationships within the community) will also not be shared with any other residents or participants.
c. ***Ame00151969*** The management and staff at [Community Name] will not be told information about the participants including but not limited to, who screened for the study, who is participating, who has ended their participation early. This information (including answers to questions about social relationships within the community) will also not be shared with any other residents or participants.

VIII. Retention of data

a. To ensure protection of study participant confidentiality during collection and storing of study data, each study participant will be assigned a unique ID. This ID will

be used during data collection activities to ensure immediate separation of participant identifying information from their study data. Additionally, all signed informed consent documents (containing study participant name) will be kept in a locked filing cabinet in the PI's office.

b. 1) In terms of the responses provided by participants during the screening and pre and post-program interviews:
    i. We will use of an online computer program (Qualtrics) to enter the responses you provide us during your pre and post-program. The program uses encryption and firewalls to ensure your data are not accessed by people outside of the study team.
    ii. Participants' name and other identifying information (phone number and address) will not be entered into the program. We will identify participants in the program with a study ID consisting of only numbers and interviewer initials.
    iii. Study data will be downloaded from the program and stored on a secure University of Michigan computer network where only study team members will have access.
    iv. Only study team members will have access to a password protected file that connects participants names to their study ID. Additionally, this file will be stored on a secure University of Michigan computer network and accessed from password protected computers.
    v. -The National Institutes of Health, who is providing the funding for this study may inspect and copy records pertaining to this research study. Also, a description of this study will be publicly available on www.ClinicalTrials.gov, as required by U.S. law. This description will not include information that can identify the participants. At most, the description posted on this website will include a summary of the results. You can search this website at any time.
c. 2) In terms of the data collected using the activity monitoring device:
    i. Data collected via the activity monitoring device (activPAL) will only be accessible using a vendor provided docking station and software.
    ii. Participant data will only be downloaded from the device using a password protected computer at the University of Michigan and stored on a secure computer network.
    iii. Participant data will be deleted from the device before the device is used again with another study participant.
    iv. There is a serial number located on the device, which will be linked to a participant's unique study ID, which will be stored in the aforementioned password-protected file at the University of Michigan.
    v. If the device is lost or stolen, it will not be possible for the data stored on the device to be linked back to a specific study particpant. Protection of confidentiality will be ensured during required data and safety monitoring and reporting. Specifically, data will be presented in a blinded manner in the quarterly data and safety reports submitted to the study's locally appointed safety officer, and the study sponsors.

*****Ame00137652***** Protection of confidentiality will be ensured during required data and safety monitoring and reporting. Specifically, data will be presented in a blinded manner in the data and safety reports submitted to the study's sponsor.

IX. Subject payments or incentives

a. Participants will receive $10 for completing the study screening assessment and if they are eligible to participate, they will receive an additional $25 for completing baseline and $30 for completing the follow-up study assessments. Additionally, they will receive $20 to wear an activity monitor for seven consecutive days at baseline and follow-up ($10 for wearing it at baseline and $10 for wearing it at follow-up), for a total of $85 for participating in all parts of the study. Agents of change (AoC) will receive $100 as a token of appreciation for their time to serve in this role, which will be provided following the committee's third (and last) meeting.
b. The incentives are a token of appreciation of the time taken to complete data collection activities. Amounts are consistent with others similar in time. For agents of change (AoC), their incentive is a token of appreciation for the time to participate in multiple meetings as well as involvement in intervention administration (e.g., reminding others to attend meetings).
c. Participants will only be compensated accordingly for completing the specific study activity. If they withdraw from the study, they will be compensated for the activities they completed prior to withdrawal.

X. Healthcare Treatments and Procedures

a. Participants will be involved in virtual group occupational therapy sessions. These sessions will be held on Zoom where an Occupational Therapist (OT) will lead four weekly one hour sessions with participating residents. Each session will include the following format: 1) teaching & education; 2) OT facilitated discussion on successes and challenges with: a) short-term activity goals; b) implementing individualized plans; and c) strategies discussed at prior group sessions; and 3) activity demonstration, engagement and feedback. Each session will focus on a different topic for the teaching and education portion including: mobility, physical activity, pain management, and energy conservation. Each topic is detailed in a document attached in the 'Additional Supporting Documents' section of this application. Each group session will conclude with a brief group exercise activity demonstration and engagement led by the OT. The goal of this activity is to establish a foundation and facilitate development of habits. The activity will be repeated at the end of each of the four sessions, and will include rising from a chair, walking in place, and use of breathing techniques during the activity. Following the activity there will be a brief discussion of the experience and feedback provided by the OT if adjustments are needed.