Residential MapTrek

This title should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied.

Protocol Number: 201904816

National Clinical Trial (NCT) Identified Number: NCT04041869

Principal Investigator: Lucas Carr, PhD

Sponsor:

"Sponsor" indicates an institution, foundation, or individual who takes responsibility for and initiates a clinical investigation; often times this is the university with which the Principal Investigator is affiliated.

Grant Title: Institute for Clinical and Translational Science Pilot Program

Grant Number: UL1TR002537

Funded by: NCATS

Version Number: v.1.007

28 August 2019

All versions should have a version number and a date. Use an international date format (e.g.,YYYY-MM-DD [2017-12-21] or write out the month (e.g., 21 December 2017).
For the initial submission of a protocol to the IRB, indicate "Not applicable; this is the first version of the protocol." in the table below. For any subsequent amendment being submitted to the IRB, add details of the specific changes that are being implemented in the amendment. Please note that Section 10.4 is a high-level summary of all formal protocol versions/amendments.

Summary of Changes from Previous Version:

Affected Section(s)	Summary of Revisions Made	Rationale

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STATEMENT OF COMPLIANCE

Provide a statement that the trial will be conducted in compliance with the protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP) and applicable state, local and federal regulatory requirements. Each engaged institution must have a current Federal-Wide Assurance (FWA) issued by the Office for Human Research Protections (OHRP) and must provide this protocol and the associated informed consent documents and recruitment materials for review and approval by an appropriate Institutional Review Board (IRB) or Ethics Committee (EC) registered with OHRP. Any amendments to the protocol or consent materials must also be approved before implementation. Select one of the two statements below. If the study is an ***intramural*** *NIH study, use the second statement below:*

1. The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

    - United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

    National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.
    OR
2. The trial will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the [specify NIH Institute or Center (IC) [Terms and Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB), and the Investigational New Drug (IND) or Investigational Device Exemption (IDE) sponsor, if applicable, except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.
    For either option above, the following paragraph would be included:
    The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

INVESTIGATOR'S SIGNATURE

Principal Investigator or Clinical Site Investigator:

Signed:	Lucas J. Carr	Date:	8/28/19
Name*:	Lucas J. Carr		
Title*:	Associate Professor		

Investigator Contact Information:

Affiliation*:	University of Iowa
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Telephone:	319-353-5432
Email:	lucas-carr@uiowa.edu

For multi-site studies, the protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site:

Signed:		Date:	
Name:			
Title:			
Affiliation:			

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Residential MapTrek
Grant Number:	UL1TR002537
Study Description:	The overarching goal of our project is to develop an inexpensive and scalable tool to increase volume of physical activity in our target population, older adults living in a residential facility. MapTrek is a web-based application that allows participants to take a virtual walk in interesting locations around the world while tracking their progress against the progress of other older adults living in a retirement community. Steps are counted using a commercially available accelerometer (e.g., Fitbit), and participants see their progress overlaid on Google Maps. The overarching goal of our project is to develop an inexpensive and scalable tool to increase volume of physical activity in our target population, older adults living in a residential facility. All participants will be provided with a Fitbit activity monitor and instructed to wear it 24 hours/day (except for bathing/swimming time) on their wrist for 12 weeks. Participants will participate in four team based walking races, each two weeks long. Participants will view their team progress on TV monitors placed in various locations at the Oaknoll facility. The monitors will present aggregated team data and will not report any individual data that could link back to the individual participant. At the end of the 8 week active intervention, research team members will meet with participants at Oaknoll to administer an exit/process evaluation survey. The exit survey will ask about psychosocial predictors of physical activity as well as participants thoughts and opinions of the MapTrek game. This survey should take approximate 10-15 minutes to complete. We will then ask the participants to wear the Fitbit for four more weeks without playing MapTrek, which will act as a control condition since this is a single-arm study.
Objectives*:	Primary Objective: 1. To determine the efficacy of MapTrek for improving physical activity levels of older adults living in a residential facility. Secondary Objectives: 1. To determine the efficacy of MapTrek for improving psychosocial outcomes(e.g., self-efficacy, social support, outcome

		expectations) among older adults living in a residential facility. 2. To determine the acceptability of MapTrek among older adults living in a residential facility.
Endpoints*:	Primary Endpoint:	8-week active intervention (August 26, 2019)
	Secondary Endpoints:	4-week follow up (September 22, 2019)
Study Population:	Adults (25-64 years) and older adults (65+ years)	
Phase* or Stage:		
Description of Sites/Facilities Enrolling Participants:	One retirement community	

Description of Study Intervention/Experimental Manipulation:

All participants will then be provided with a Fitbit activity monitor and instructed to wear it 24 hours/day (except for bathing/swimming time) for the next 4 days. After 4 days of baseline data collection, our team will assign participants to one of three teams through randomization based on their baseline activity data. The three teams will be identified by three colors of wrist bands that hold the Fitbit monitor; black white and teal.

After baseline data collection, the research team will hold a kick-off event for the participants. The research team will give a brief presentation describing the study again. Participants will be informed of their team by a research team member and will be provided a wrist band that corresponds to their team color (black, white or teal). At that point, participants will receive written instructions ("game rules") on how to play the MapTrek intervention (our virtual walking race platform).

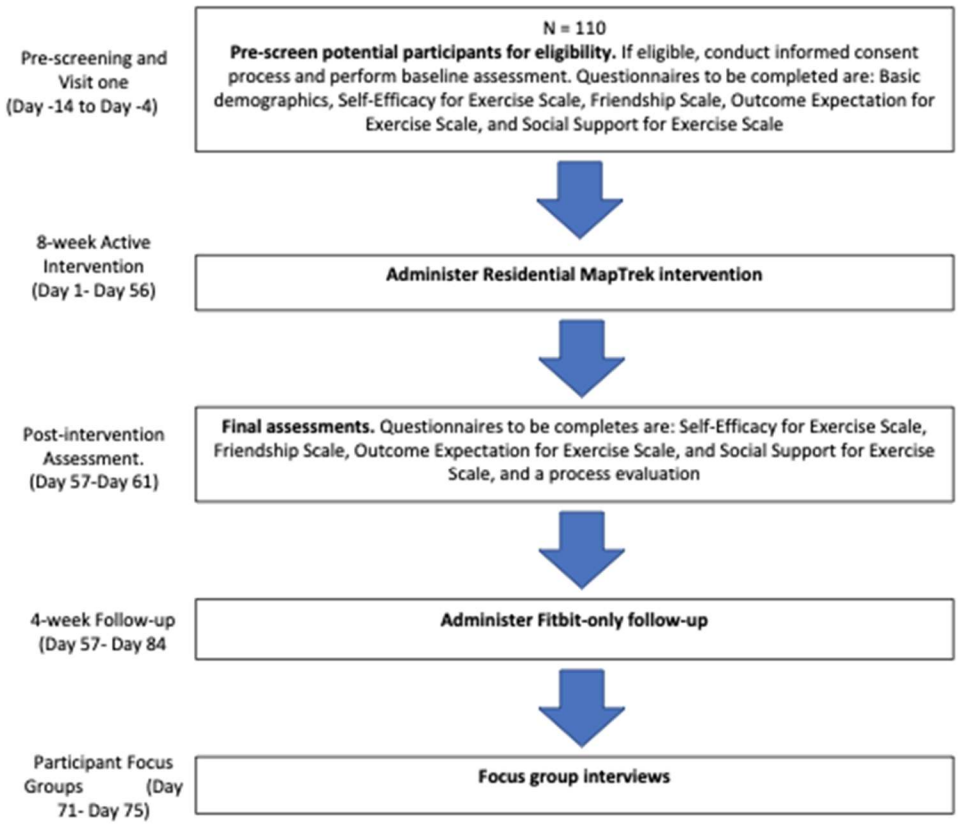
As part of the MapTrek game, participants will be asked to wear their Fitbit activity monitor every day for 12 weeks. For the first eight weeks, participants will participate in four team based walking races, each two weeks long. Participants will view their team progress on TV monitors placed in various locations at the Oaknoll facility. The Oaknoll leadership has given us approval to do this at their facility (see letter of support). The monitors will present aggregated team data and will not report any individual data that could link back to the individual participant. After the 8-week active intervention, we will take MapTrek away and will ask participants to wear the Fitbit for an additional 4 weeks. This will be done to determine the effects of MapTrek had on physical activity compared to a control where participants only wear the Fitbit.

Study Duration*: 12 weeks

Participant Duration: 13 weeks

1.2 SCHEMA

Example #1 Flow diagram *(e.g., single arm, pre-posttest intervention)*



1.3 SCHEDULE OF ACTIVITIES

2 INTRODUCTION

2.1 STUDY RATIONALE

Older adults are a growing population, with projections to reach 83.7 million by 2050. Furthermore, older adults are the most sedentary and least physically active adult population. It is estimated that nearly 90% of older adults 65 years of age or older do not meet the recommended levels of physical activity. Evidence suggests great health benefits can be achieved for older adults who are the most sedentary, and that replacing sitting with even light intensity walking can be beneficial.

2.2 BACKGROUND

Older adults (aged 60 and older) are a growing population, with projections to reach 83.7 million by 2050, almost double the population in 2012 (Ortman, Velkoff, & Hogan, 2014).Increasing age is associated with declines in many physiological systems(Sakuma & Yamaguchi, 20112) and increased risk for several non-communicable chronic health conditions(World Health Organization, 2009). Older adults often experience declines in balance, loss of muscle mass, reductions in muscle strength and endurance, and decreased cognitive function(Piercy et al., 2018; Sakuma & Yamaguchi, 2012; Salthouse, 2003; Warburton, Nicol, & Bredin, 2006) Collectively, these age-related declines can negatively impact older adult's physical function and quality of life(Taylor, 2014).

Physical activity is an important modifiable behavior demonstrated to reduce the risk for several age-related chronic diseases while improving physical function.(Piercy et al., 2018) Maintaining a physically active lifestyle is important for maintaining independence(Taylor, 2014), improving health-related quality of life(Choi, Lee, Lee, & Jung, 2017), and increasing performance in activities of daily (Dionigi, 2007; Piercy et al., 2018). Previous studies have demonstrated favorable financial impacts of physical activity-based wellness programs targeted to older adults.

Older adults are the most sedentary and least physically active adult population. Older adults spend an average of 9.4 hours per day engaged in sedentary behavior(Harvey, Chastin, & Skelton, 2014). The Physical Activity Guidelines for Americans recommend older adults to achieve a minimum of 150 minutes of moderate-to vigorous (MVPA), multicomponent physical activity per week which includes balance training, aerobic and muscle strengthening activities(Piercy et al., 2018). Moreover, older adult who cannot meet the guidelines are encouraged to do any amount of physical activity, to move more and sit less, in order to gain some health benefits(Piercy et al., 2018). However, it is estimated that nearly 90% of older adults 65 years of age or older do not meet the recommended levels of physical activity.(Shepherd, 2011) Evidence suggests great health benefits can be achieved for older adults who are the most

sedentary, and that replacing sitting with even light intensity walking can be beneficial.(Piercy et al., 2018)

Retirement communities and residential living facilities can be important settings to consider when delivering physical activity interventions to older adults. Evidence suggests that older adults living in these facilities may have an increased number of chronic diseases, are frailer, more inactive, and perform worse on physical function tests. (Kang, White, Hayes, & Snow, 2016; Mihalko & Wickley, 2003; Wert, Talkowski, Brach, & VanSwearingen, 2010) Retirement communities and residential living facilities can be an important setting to consider when delivering physical activity interventions to older adults.

Rosenberg et al. (2012) found that facility-dwelling older adults found a walking intervention to be feasible and effective for improving participants' daily steps, cognitive function. neighborhood barriers (i.e., hills, crime, traffic, unsafe crossing, or lack of places to walk) and satisfactions with walking opportunities (i.e., satisfaction with walking and exercise opportunities at their site, local area, and access to safe walking routes). However, a major limitation from this study was that participants used a pedometer to self-report their daily physical activity. With improvements in technology and the increasing use of wearable activity monitors, researchers can increase the quality of reliability of these study designs.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The physical risks include possible fatigue, and/or injury from participating in physical activity. There is a potential of loss of confidentiality of data. The intervention will promote engagement in low to moderate intensity physical activity which poses a low risk for injury.

2.3.2 KNOWN POTENTIAL BENEFITS

There is no guarantee of a direct benefit from participating in this study. However, participants may improve their health and might feel better.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

We will screen participants carefully and exclude if they do not meet health related eligibility criteria. For the intervention risks, all participants will be informed about the potential risks of increasing their physical activity. However, the physical activity recommended will be of light-moderate intensity which the Physical Activity Guidelines for Americans recommend for all older adults. They will also be instructed to follow simple guidelines when doing physical activity. If something hurts, they should stop and only resume if it feels better. If they feel sick, they should seek medical attention. To minimize the risk of loss of confidentiality of data, we will take several steps including de-identifying and ID coding all electronic data, storing

electronic data on a password protected warehouse accessible only to the PI and the investigative team, and storing paper copies of data and informed consents under lock and key in the PI's office/laboratory

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
1. To determine the efficacy of MapTrek for improving physical activity levels of older adults living in a residential facility.	Assessments made at baseline, 8 weeks and 12 weeks.	We will determine whether the intervention was effective at 8 weeks and whether participants maintained outcomes at 12 weeks.	
Secondary			
1. To determine the efficacy of MapTrek for improving psychosocial outcomes(e.g., self-efficacy, social support, outcome expectations) among older adults living in a residential facility. 2. To determine the acceptability of MapTrek among older adults living in a residential facility.	Assessments made at baseline, 8 weeks and 12 weeks. We will assess acceptability at 8 weeks.	We will determine whether the intervention was effective at 8 weeks and whether participants maintained outcomes at 12 weeks. Participants will have just finished the intervention at 8 weeks.	
Tertiary/Exploratory			

4 STUDY DESIGN

4.1 OVERALL DESIGN

This intervention is a single arm, pre-post test pilot study.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Little physical activity research has been done within retirement communities, even though this is an optimal environment to deliver multilevel interventions (Jancey et al., 2017). Limitations with studies done in retirement communities include using a self-report measure of physical activity (Gallagher, Clarke, & Carr, 2016). Furthermore, studies were either not grounded in behavior change theory (Thompson, Kuhle, Koepp, McCrady-Spitzer, & Levine, 2014), or participants were not able to monitor their physical activity each day, receiving real-time feedback (Kerr et al., 2018). Similarly, there have been few mHealth physical activity interventions conducted with older adults. Of these studies, limitations include not clarifying if behavior change theory was used to drive the intervention design (Jonkman et al., 2018), and self-report measure of physical activity were used (Kim & Glanz, 2013; Muller, Khoo, & Morris, 2016). Finally, to our knowledge little research has been done on gamification of wearable activity monitors (Gremaud et al., 2018), specifically among older adults living in retirement communities.

Our team has developed a mHealth intervention called MapTrek (Gremaud et al., 2018). MapTrek is a mobile-phone based walking game, grounded in behavioral theory that places participants into virtual walking races for the purpose of encouraging more daily physical activity throughout the day. MapTrek was designed to be fun, engaging and interactive. In a recent trial, we found MapTrek to be feasible and efficacious at increasing physical activity among healthy sedentary office workers (Gremaud et al., 2018). Participants were randomized to a MapTrek intervention or a Fitbit control group. Participants in the MapTrek group took an average of 1,455 more steps/day than the control group. At the start of the intervention, MapTrek participants immediately increased their steps by 2,183 steps/day beyond the control group. After the intervention started, both groups started to decrease their average steps/day back to baseline values. The MapTrek group decayed significantly faster at 44.8 steps/day compared to the control group at 24.3 steps/day. Conversely, 70.9% of participants reported MapTrek increased their perceived level of support to be physically active, 77.7% felt motivated to be more active, 70.2% reported MapTrek was a fun, and 93.1% of participants reported MapTrek was easy to play (Gremaud et al., 2018). While these outcomes suggest MapTrek was effective for middle-aged adults in the community, we have not yet tested this approach among older adults. We believe MapTrek could be adapted for use and effective for increasing physical activity levels of older adults living in retirement communities. With the large and growing number of inactive older adults in the U.S., it is crucial that we identify effective and scalable approaches for promoting physical activity among older adults.

Translation of interventions to a population level has been slow and inconsistent. Significant effects on health can be made through widespread adoption and dissemination of interventions (Gonzales, Handley, Ackerman, & O'Sullivan P, 2012)

4.3 JUSTIFICATION FOR INTERVENTION

Older adults are a growing population, with projections to reach 83.7 million by 2050. Furthermore, older adults are the most sedentary and least physically active adult population. It is estimated that nearly 90% of older adults 65 years of age or older do not meet the recommended levels of physical activity. Evidence suggests great health benefits can be achieved for older adults who are the most sedentary, and that replacing sitting with even light intensity walking can be beneficial.

The overarching goal of our project is to develop an inexpensive and scalable tool to increase volume of physical activity in our target population, older adults living in a residential facility. MapTrek is a web-based application that allows participants to take a virtual walk in interesting locations around the world while tracking their progress against the progress of other older adults living in a retirement community. Steps are counted using a commercially available accelerometer (e.g., Fitbit), and participants see their progress overlaid on Google Maps. The overarching goal of our project is to develop an inexpensive and scalable tool to increase volume of physical activity in our target population, older adults living in a residential facility.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the baseline assessment, the 8-week active intervention sessions, and the 4-week follow-up.

The end of the study is defined as completion of the 4-week follow-up assessment.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Participants must have met the following inclusion criteria: 1) between the ages of 25 and 100; 2) do not have any physical or cognitive limitations that prevent them from walking comfortably; 3) have not participated in a study that uses MapTrek; 4) their doctor has not told them that is not safe to be physically active.

5.2 EXCLUSION CRITERIA

Exclusion criteria includes: 1) reporting any physical or cognitive limitations that prevent them from walking comfortably; 2) have participated in a MapTrek study before; 3) their doctor has told them it is not safe to be physically active; 4) there is any other reason why they shouldn't be physically active.

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

Screen failures are defined as individuals who meet one or more of the exclusion criteria. Individuals who meet one or more of the exclusion criteria will not be able to be re-screen for participation in the intervention.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

We anticipate screening 110 individuals including women, minorities, and participants across the lifespan, in order to reach the target enrollment size of 100. We anticipate enrolling 100 participants, 50% female and 50% male. We anticipate accruing 75 older adults and 25 adults over 2-weeks.

At the Oaknoll off-site location, word about the study will be spread by word of mouth and advertisements. Advertisements will be displayed on TV monitors throughout Oaknoll. These materials will be distributed by the Activities Coordinator at Oaknoll. The research team members will spread information about the study through word of mouth. Interested participants will contact the Activities Coordinator to schedule a time and location for testing at Oaknoll. She will send out information about the study through Oaknoll's weekly news. If she receives any questions about the research beyond what is included in the brochures, ads, and posters, she will direct the person to contact a member of the research team. Once a participant shows interest in the study from seeing a poster advertisement or ad in the weekly news, she will schedule a time and location for testing at Oaknoll. The eligibly criteria will be listed in the ad, and all potential participants will be screened before the research team goes over the informed consent. Coercion and undue influence will be minimized by informing the subjects that participation in the study is completely voluntary and that they are free to quit the study at any time without penalty.

All participants will receive a Fitbit activity monitor. For compensation, all participants will be allowed to keep the Fitbit activity monitor at the end of the study. Participants who participate in the focus groups will receive a $50 check for compensation.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

We enrolled two different intervention groups, a group of older adults who live at Oaknoll and a group of Oaknoll employees. Enrolling a group of Oaknoll employees served two functions. First, it exposed the employees to MapTrek so that they can assist the residents with any technical problems or questions they may have during the course of the project period. Second, it fostered intergenerational engagement and generate excitement throughout the entire facility. Third, including employees was another avenue to increase social support for older adults, addressing the interpersonal level of the SEM. Physical activity interventions are likely to have greater effects when different levels are addressed at the same time.

At enrollment, each participant was provided with a Fitbit, shown how to wear it, and consented to the research team accessing their Fitbit data. Participants were asked to complete a baseline survey which asked about demographic information, their self-efficacy for exercise, social support for exercise, outcome expectations for exercise, and social isolation. Total participation in this project lasted for 14 weeks. The first two weeks were used to collected baseline data, where participants wore their Fitbit, but did not receive access to the MapTrek intervention. During the baseline period a kick-off event was held to answer participant's questions, and to give participants their team colored wrist bands. Participants were placed into one of three teams, and stayed on these teams for the duration of the intervention. Three teams were used to help foster competition in the event that one team was walking significantly more or less steps than the others.
After the two-week baseline period, participants received access to MapTrek and competed in four, two week-long races. Four two-week races were used so that teams had the opportunity to walk meaningful distances along each route (e.g., walking on the Grand Canyon Trail). The teams were assigned a new virtual walking route every two weeks. The team with the most steps at the end of two weeks were the winners.

We made environmental change to Oaknoll. Participants were encouraged to walk by large TV monitors placed in three common areas throughout the facility. A small Raspberry Pi computer will be connected to each monitor. The Raspberry Pi is a credit-card sized computer that plugs into a computer monitor or TV to be used as a normal desktop. Two other Raspberry Pi devices were placed at convenient locations throughout Oaknoll. As participants walked by, their Fitbit data synced to the Raspberry Pi. The Raspberry Pi was used to sync the Fitbit so that (a) participants did not have to manually sync their Fitbit and (b) participants who did not have a computer or smartphone could still participate. Every two weeks during the intervention a new walking route was revealed. The teams will be competing against each other, and their total number of steps will be used to move their character on the map. The map routes were Seattle to San Diego (1,936 miles), through Arizona, Colorado, and Utah (2,194 miles), from New York through Key West to Pensacola, FL (2,422 miles), and from Vancouver to Minnesota down the

Mississippi River to New Orleans (2,540 mils). We made sure each route was long enough in case every team member walked ~5 miles/day.

Three TV monitors were placed in public areas which displayed the virtual walking map, google maps view of the walking route, team leaderboard, and daily news. The daily news displayed messages each day that were developed based on Social Cognitive Theory (Appendix H). These behavior-change techniques addressed specific barriers to physical activity that older adults face such as health concerns, motivation and beliefs, low self-efficacy, access difficulties, and social support.

6.1.2 ADMINISTRATION AND/OR DOSING

The TV monitors displaying MapTrek will stay on during the entire 8-week intervention. The daily news will be updated once per day at 7:00AM CST.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Fidelity of the delivery of the intervention will include checking the TV monitors periodically to make sure they are displaying the MapTrek intervention.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

N/A- this is a non-randomized intervention

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Intervention adherence will be monitored by participants syncing their Fitbit activity monitors.

6.5 CONCOMITANT THERAPY

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

When a subject discontinues from Residential MapTrek, the remaining study procedures will be completed as indicated by the study protocol. The data to be collected at the time of study intervention discontinuation will include the following:

- The reason(s) for discontinuing the participant from the intervention, and methods for determining the need to discontinue

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up; unable to contact subject (see **Section 7.3, Lost to Follow-Up**)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to return for [specify number of visits] scheduled visits and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to return to the clinic for a required study visit:

- The site will attempt to contact the participant, reschedule the missed visit [specify time frame], counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts will be documented in the participant's medical record or study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Demographic characteristics. Participants self-reported their demographics at baseline by taking an online survey through Qualtrics, Inc. The survey was filled out interview-style with research team members on their computers during enrollment. Participants reported their age, gender, race and ethnicity, education level, income, marital status, length of stay at the retirement community, and height (in.) and weight (lb.). Body-mass index (BMI) will be calculated using the formula weight (lb.) / [height (in.)]^2.

Aim 1: Physical activity. At the beginning of the study, participants were given a Fitbit Zip activity monitor to wear on the wrist for 12 weeks. The Fitbit Zip was asked to be worn on the wrist because evidence suggests accelerometers worn on at the hip have lower wear-time compliance. The Fitbit Zip is a small (35.6 x 28.9 x 9.6 mm) commercially-available triaxial accelerometer-based physical activity monitor that estimates steps taken per day. The Fitbit (One or Zip) worn on the hip has been demonstrated as a valid and reliable measure of average steps/day among community dwelling older adults compared to the ActiGraph GT3X+ (ICC=0.94, 95% CI 0.88 to 0.97) (Paul et al., 2015). Through the Fitbit application programming interface, the research team will be able to access each participant's physical activity data minute-by-minute each day the activity monitor is worn. Participants were instructed to wear the monitor during all waking hours (except time spent swimming or bathing) for thirteen consecutive weeks.

Aim 2: Psychosocial outcomes. This will be measured with the Self-Efficacy for Exercise (SEE) scale, a 13-item questionnaire designed to assess the participant's self-efficacy related to their ability to continue exercising in the face of barriers

Outcome expectations will be measured with the Outcome Expectations for Exercise (OEE) Scale. The OEE is a valid and reliable 9-item scale that assess the participant's outcome expectations and benefits associated with exercise.

Social isolation will be assessed with the Friendship Scale (FS). The FS is a 6-item scale that assesses six dimension contributing to social isolation.

Aim 3: Satisfaction and adherence. To assess the acceptability of the intervention, we will measure participant adherence and satisfaction. Acceptability is important to assess because we want to be able to determine if older adults thought MapTrek was a fun game for increasing physical activity. Specifically, we will be able to determine which intervention features they thought were helpful. Adherence will be measured by examining the enrollment, completion, and compliance rates. Enrollment rate will be assessed by documenting the number of people who enroll in the study from the number of people living in the retirement community, and completion rate will be assessed by the

number of people who finish the study out of those who enrolled. Compliance rates will be assessed by examining the percentage of participants who are wearing and syncing their Fitbit over the course of the intervention. Process evaluations were administered to participants via phone or in-person during the first week after the active intervention. The process evaluation was used to assess the participant's satisfaction with the game features. Participants were asked what they most liked about the game, what barriers prevented them from playing the game, and what improvements they would recommend. This information will be used when developing future intervention in which MapTrek is used to promote physical activity among an older adult population. Focus groups (6-8 participants) will be held the third week of the follow-up timepoint.

8.2 SAFETY ASSESSMENTS

N/A

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

Adverse event means any untoward medical occurrence associated with the use of the physical activity intervention in humans, whether or not considered intervention-related.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

An AE or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

All AEs will be assessed by the team medical director (Dr. Phil Polgreen, MD).

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All AEs will have their relationship to study participation assessed with a level of specificity appropriate to the study design. The medical director will determine whether the AE was related (reasonable possibility event was caused by participation) or unrelated (not reasonable possibility) to the participant's study participation.

8.3.3.3 EXPECTEDNESS

It is possible that participants could report musculoskeletal complications and/or cardiopulmonary complications that have been associated with vigorous bouts of physical activity. However, the intervention will not prescribe vigorous intensity activity, rather walking at a low to moderate intensity will be encouraged.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

Our team will continually be monitoring participant's progress in the study. Participants will be advised to contact our team by phone or email immediately if they experience an adverse event. Our team will be checking our email and voicemail daily.

8.3.5 ADVERSE EVENT REPORTING

Any adverse events reported to our team by participants will be reported to the Human Subjects Office within 10 working days by the principal investigator (Dr. Lucas Carr). We will follow the Human Subjects Office policy for reporting adverse events

8.3.6 SERIOUS ADVERSE EVENT REPORTING

Any adverse events reported to our team by participants will be reported to the Human Subjects Office immediately by the principal investigator (Dr. Lucas Carr). We will follow the Human Subjects Office policy for reporting adverse events

8.3.7 REPORTING EVENTS TO PARTICIPANTS

We will report any significant events that may impact their willingness to participate to participants as we learn of them.

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

Pregnancy is an exclusion criteria for this study. We will not be reporting pregnancy.

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

8.4.2 UNANTICIPATED PROBLEMS REPORTING

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s): We hypothesize that participants will increase their average steps/day from baseline to the initial adoption of the active intervention, there will be a significant difference in average steps/day from baseline to the last week of the active intervention, there will be a significant difference in average steps/day from baseline to the follow-up phase post-active intervention, participants will experience a decrease in average steps/day each day from the start of the 8-week intervention to the end. two to week eight.

- Secondary Efficacy Endpoint(s): We hypothesize participants will increase their feelings of social support, self-efficacy, and outcome expectations, and decrease their feeling of social isolation from baseline to post-active intervention. We hypothesize this will be an acceptable multilevel mHealth intervention among older adults living in a retirement community.

9.2 SAMPLE SIZE DETERMINATION

To achieve 80% power to detect a 1,750 step difference in step counts between the pre- and post-intervention periods, with a standard deviation of 2,000 steps and a significance level of 0.05, we are required to enroll at least 42 participants. If we add an additional 25% for possible drop outs, we will need to enroll at least 50 participants into the older adult group.

9.3 POPULATIONS FOR ANALYSES

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

To analyze descriptive statistics we will use frequencies, mean, and standard deviation.

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

We will used mixed-effect models to Repeated measures ANOVA.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Student's T Test will be used to test the mean scores for social support, self-efficacy, and outcome expectations, and social isolation from baseline to post-intervention. A simple linear regression will be used to examine the linear relationship between changes in psychosocial outcomes and changes in physical activity.

Descriptive statistics (i.e., mean, SD, frequency) and qualitative analysis will be used to analyze acceptability outcomes from the process evaluation.

9.4.4 SAFETY ANALYSES

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Descriptive statistics (i.e., mean, SD, frequency) will be calculated for participant characteristic including age, sex, height, weight, and BMI, education, total annual household income, and length of residence at the retirement community.

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

9.4.9 EXPLORATORY ANALYSES

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention. The following consent materials are submitted with this protocol: informed consent, waiver of informed consent.

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Informed consent documents will be provided to the participants.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

A research team member will review the consent document with participants before they sign it. Participants will indicate their consent by signing the consent document. Participants will be provided a copy of the signed consent form to keep for their records. Coercion and undue influence will be minimized by informing the subjects that participation in the study is completely voluntary and that they are free to quit the study at any time without penalty.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to [study participants, investigator, funding agency, the Investigational New Drug (IND) or Investigational Device Exemption (IDE) sponsor and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the IRB, and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance of study staff to the protocol (i.e., significant protocol violations)
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met

- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, Food and Drug Administration (FDA), or other relevant regulatory or oversight bodies (OHRP, DSMB).

10.1.3 CONFIDENTIALITY AND PRIVACY

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Hard copies of informed consent documents will be stored in a secure cabinet located in a laboratory directed by the PI (Field House room E141). The lab is under lock and key and is only accessible to research staff. All participants will be given a unique study ID# which will be linked to collected data. When collecting data at Oaknoll, all documents will be stored in a temporary container in a research team member's possession and then transported to the storage location at the Field House. Databases that include ID numbers and collected data will be stored on a password protected and secure electronic warehouse accessible only to the principal investigator. All collected data will be destroyed 5 years following completion of data analysis.

- Electronic records (computer files, electronic databases, etc.) - All data will be collected through a UI Qualtrics account for screening and study data collection. Identifying information that we will collect from participants includes their Name, Address, and Phone Number. The storage of the MapTrek data will be on a password-protected, secure servers in Computer Science Dept. It will only be the participant's phone number and Fitbit data. Only members of the research team will have access to this information through a password protected electronic file on a UI protected server. All collected data will be coded and stored in a password protected electronic file on a UI protected server. These servers are password protected with access only to authorized staff. Folders within the server are also made available to only select staff and with password protection as needed for participant data. A separate list of names with ID#s will be stored in a separate password-protected file for repeated measures comparisons. During the informed consent, we will ask participants for permission to store their data for future use. Participants will be given the option (yes or no) to allow us to store their data. For participants who agree to us storing their data (selecting 'Yes'), we will store that data on our protected server for future analyses. If participants do not agree (select 'No'), we will not store their data and will destroy their electronic data within five years of completion of the study.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	**Medical Monitor or Independent Safety Monitor**

10.1.6 SAFETY OVERSIGHT

10.1.7 CLINICAL MONITORING

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

10.1.9.2 STUDY RECORDS RETENTION

10.1.10 PROTOCOL DEVIATIONS

10.1.11 PUBLICATION AND DATA SHARING POLICY

10.1.12 CONFLICT OF INTEREST POLICY

10.2 ADDITIONAL CONSIDERATIONS

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
ANCOVA	Analysis of Covariance
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CMP	Clinical Monitoring Plan

COC	Certificate of Confidentiality
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GWAS	Genome-Wide Association Studies
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMC	Safety Monitoring Committee
SOA	Schedule of Activities
SOC	System Organ Class
SOP	Standard Operating Procedure

UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

Version	Date	Description of Change	Brief Rationale

11 REFERENCES