Research Protocol

IRB Project Title

A Smartphone Application to Improve Physical Activity in Underactive Older Adults

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I. Background and Aim

Despite the well-established health benefits of physical activity (PA),[1-7] less than 10% of people aged 60+ years meet national PA guidelines.[8] Barriers to PA that contribute to this bleak statistic include factors such as feeling "too old,"[9] inadequate support,[10-12] and low self-efficacy.[13] Unfortunately, after completing home-based, group, or educational interventions, older adults' PA improvements are minimal and short-lived.[7, 14, 15] In light of these challenges, it is important to investigate alternative interventions for elders that improve PA.

Attention has recently turned toward using smartphone applications (apps) to improve health behaviors.[16] Such technology extends healthcare beyond in-person clinical visits due to its versatility, portability, and potential cost-savings. However, *few health apps are scientifically evaluated[17-19] and even fewer are tailored to the specific needs of older adults.* This research gap has prompted the Centers for Disease Control to call for studies that link mobile health (mHealth) solutions to healthy aging agendas.[20]

In the proposed study, we will develop, test, and optimize a core app and set of attached specialty features that are designed to facilitate older adults' PA. This package, termed the *Moving Up* suite, is distinct from generic fitness apps because it blends evidence-based behavior change techniques (e.g., self-regulation via activity monitoring) in the core app with a set of specialized components that reflect empirically supported constructs from social cognitive[21, 22] and stereotype embodiment theory.[23] Specialty features include: (a) implicit and explicit messaging to promote positive aging views; (b) sedentary activity (SA) monitoring with motivational messaging and peer suggestions; and (c) data-driven, automated remote coaching and support. *To date, no other app has offered a comparable suite that has been systematically optimized to address inactivity in older people, justifying the need to scientifically evaluate this type of tool*. In the clinical trial phase of the study, we will utilize a highly efficient, innovative methodological approach—Multiphase Optimization Strategy (MOST)[24, 25]—to provide an experimental context for evaluating each of the *Moving Up* suite's specialty features. The MOST procedure originated from the field of engineering and is explicitly designed to facilitate selection of intervention components by elucidating their individual and synergistic effects (a key gap in health app research).

The specific aim of the clinical trial phase of this study is to **conduct a pilot test to examine key performance characteristics of the PA-tracking core app and its three specialty features.** This will include the MOST Screening Phase: theory-guided experimentation to identify viable components within a multifaceted preliminary intervention plan.[24] Using a factorial design as specified in MOST procedures, 100 underactive older people (i.e., those accumulating <150 minutes of at least moderate intensity activity/week)[8, 26] will be randomly assigned to one of eight conditions which reflect all possible combinations of presence vs. absence of the three respective specialty features, given usage of the core PA-tracking app. At the end of a four-month intervention period, for the core app as well as for each specialty feature we will examine changes from baseline in *objective PA*, *SA time*, *self-reported PA*, and *functional mobility*. We will also test the association between the app component features and theoretically postulated mediating constructs (*self-efficacy, self-regulation, outcome expectation, social support, aging self-perception,* and *views of aging*). In addition, we will document *usage rate* and *satisfaction* with the app.

II. Approach & Methods

A. Clinical Trial Design

This two-part study initially involves a two-week field test of the PA-tracking app suite followed by a focus group and then a four-month trial of the refined suite. This later segment is the focus of this clinical trial protocol description. A description of the app suite and details of the trial design are provided in the subsequent sections.

A.1. App Intervention

The PA-tracking app suite was designed using SCT[21, 22] and SET[23] as its theoretical framework. SCT posits four determinants of health-promoting behavior: self-regulation, self-efficacy, social support, and outcome expectation.[21, 22] SET describes the process and consequences of internalizing age stereotypes, such that aging self-perceptions and general views of aging are associated with health and survival.[27, 28] Each construct above has been linked empirically to improved PA patterns in elders.[29-32] **Figure 2** depicts the theoretical framework underlying the PA-tracking app suite. For heuristic purposes, arrows represent the *primary* pathways by which we expect the suite components to influence the set of mediators and thereby PA-related outcomes. It is beyond the scope of this proposal, however, to designate all conceivable associations that the app features may have with each theoretical construct.

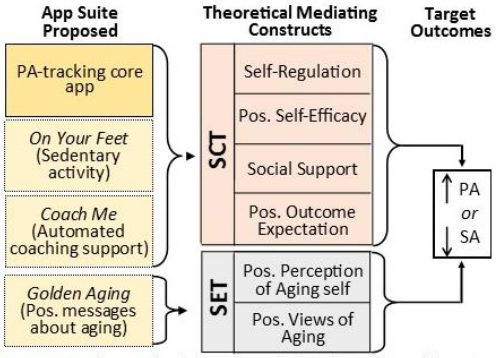

Figure 2. Theoretical Framework for the PA-tracking App Suite. SCT=Social Cognitive Theory; SET=Stereotype Embodiment Theory; PA=Physical activity; SA=Sedentary Activity

The PA-tracking core app mainly targets self-regulation and outcome expectation. Its goal-setting function submits a default, adjustable daily PA benchmark. By displaying real-time PA, it allows visual tracking of goal progress. In addition to the core app, three specialty features are proposed that also address key SCT or SET considerations and are tailored to overcome elder PA barriers: ***(1) Proof Positive***, as motivated by SET, capitalizes on the beneficial effects that exposure to positive aging messages and stereotypes have on health and PA.[29, 33] When activated, users (a) receive texts describing how old age does not equate to physical inability, (b) obtain information about the benefits of growing older, and (c) are presented with a variety of positive aging stereotype tasks modeled after priming activities commonly used in the field (e.g., word scrambles,[34] picture identification,[35], computerized series [33, 36-38]). This last example exposes users to blocks of "positive priming words".[33] Primers are quickly flashed to allow perception without awareness[36] while users focus on an image of activity—a step that builds on Levy's work by simultaneously offering explicit cues that promote PA. ***(2) On Your Feet*** is designed to reduce SA—a health risk factor largely independent of insufficient PA[39]—by using self-regulatory and behavior change techniques including goal-setting, progress feedback, and prompting.[40] Accumulated sedentary time is displayed alongside self-selected goals; audible, vibratory, or text-based reminders to stand are sent at a user-specified frequency; and general tips as well as previously compiled, older adult-identified strategies to reduce SA[6] are texted. Additionally, messages about the benefits of reducing SA and overcoming barriers (e.g., fatigue) are also sent. ***(3) Coach Me*** includes daily messages designed to assist older adults in (a) discovering practical ways to integrate brief bouts of PA into their daily routines and (b) overcoming common PA barriers.[41, 42] Blending PA with productive activity has been identified as a key facilitator of PA engagement in older people.[43, 44] In *Coach Me*, suggestions on how to intensify common daily activities are tailored based on user selections from an activity inventory stored within an individual's *Moving Up* profile. For example, if a user identifies "laundry" on the inventory, *Coach Me* may suggest "heel raises while holding onto the dryer before placing clothing in a basket." This app feature is intended to help older adults become more active in a minimally intrusive way, while allowing for simultaneous engagement in productive and meaningful activities. *Coach Me* asks users to select obstacles to PA encountered in the previous week. Based on those selections, the app sends strategies on how to overcome those barriers in the future, thereby targeting self-efficacy.

A.2. Clinical Trial Design Details

We will utilize the MOST procedure to assess the app suite specialty features' efficacy and other performance aspects. MOST is explicitly designed to disentangle the effects of multiple components that make up an intervention[26,105]—a key project goal given our intent to appraise the merit of novel, previously untested app features. Traditionally, multi-component interventions are subjected to efficacy pilot tests followed by large RCTs, but in the absence of systematic evaluations of singular components. However, in such cases: (a) the intervention may contain inert ingredients that contribute to subpar or cost-inefficient results; or (b) difficulties may arise in determining which intervention aspects contribute to efficacy, due to the presence of multiple components which have not been individually tested. In contrast, following

systematic optimization as facilitated by MOST, subsequent RCTs are expected to produce sharper, more interpretable results.

Based on recommendations from the MOST literature, we will employ a 2x2x2 factorial experiment in which three between-subject factors, corresponding to the presence vs. absence of each specialty feature, will be manipulated in a completely crossed design, given each participant's utilization of the core app. Following random assignment (using a computer algorithm designed for this purpose) to the eight conditions, participants will undergo a four-month intervention interval. Experimental outcomes will consist of pre-to-post change scores on PA-related and mediating variables, and documentation will also be provided for parameters such as usage frequency and user satisfaction that are pertinent to subsequent efforts to achieve optimization.

Each specialty feature will be provided to half of the participants, leading to respective comparative assessments that involve 45 vs. 45 (feature present vs. absent) participants. Accordingly, it is incorrect to conceptualize this design as a test of outcome differences between eight separate inadequately powered cells; rather, the intent is to collapse information across cells so as to obtain a reasonably large sample size when examining each component's performance.[24] Further, because the specialty features would be inexpensive to download if used in large-scale distributions of the app, and because they have been carefully designed to reflect empirically supported theory, it is important to avoid premature elimination of features on the basis of non-significant experimental effects which in actuality may stem from sample size limitations. Consequently, in evaluating intervention components we will downplay the importance of (though still include) significance testing of PA outcomes, and instead will incorporate the total array of relevant information (e.g., effect sizes, usage rates, satisfaction ratings) in the final component selection and fine-tuning process.

B. Participants, Recruitment, and Consent

For Aim 1, a convenience sample of 15 elders will be recruited from independent-living communities within FPCIW*'s* 2,000-member senior network in Los Angeles (LA) and local senior venues. An estimated 1,300 FPCIW members use smartphones.[45] Iterative phases of product development require only five to seven representative users per prototype iteration,[46] justifying our sample size of 15 (five per app suite specialty feature).

One-hundred community-living older adults who are served by Front Porch Center for Innovation and Wellbeing (FPCIW) will be primarily recruited from FPCIW's 2000-member senior network in Los Angeles. FPCIW will facilitate recruitment, referring its eligible members to the study team. Justification for the targeted sample size is multifold. First, an adequate number of participants will be available to enable meaningful analyses (final N=90) given a four-month attrition rate of 10% (estimate based on averaging interval-adjusted study completion rates in five studies of mHealth or web-based PA interventions for adults aged >40 years[47-52]. Second, the expected overall (N=90) and per-feature (n=45) sample sizes well exceed the number of participants previously described as necessary to determine if a larger trial is warranted.[53] Third, the stipulated sample size is easily achievable and represents roughly the maximum number of participants attainable given available funding resources.

Persons will be deemed eligible based on the following criteria. Inclusion criteria: men or women, 65–84 years old; English speaking; reside in LA or in Pacific Time Zone if participating remotely; score ≥5 on a 6-item cognitive screener[54]; report <150 minutes of moderate-to-vigorous PA/week as per a single-item screener;[55] ambulatory; ability to safely participate in PA as determined by self-report of ability to regularly walk safely; smartphone owner for ≥1 month; observed ability to reliably access and operate a smartphone during orientation; available by telephone for the duration of either study. Exclusion criteria: unwillingness to meet at local community venues and/or via online meetings to comply with study procedures for the length of each study. Although not an eligibility criterion per se, access to a computer and webcam, and sufficient computer skills to participate in virtual orientation is necessary if in-person orientation is not feasible.

Prospective participants who have been referred to the study team by FPCIW or who have responded to advertisements or presentations will be initially screened for eligibility over the phone or in person by authorized research personnel. After initial screening, informed consent materials will be sent or handed to prospective participants for pre-review. Authorized research personnel will then perform the consent process for qualifying participants at local community venues that are convenient to the participants. If an in-person meeting for enrollment (including consenting) is not feasible, we will conduct enrollment activities virtually through phone calls or videoconferencing, and will send consent forms electronically to participants using DocuSign or a REDCap eConsent form to review and complete. Only key personnel who are HIPAA and CITI certified, trained in consenting procedures, and do not have a conflict of interest will conduct the consent process. The consenter will explain the study procedures and describe in detail what will be expected of participants. Participants will have ample time to ask questions about the study and their role in it. If the individual is interested in participating, they will sign the consent form. If participants are not comfortable with the study, they may choose not to participate. Following consent, an assessment battery would be held next.

C. Procedures & Measurement

Participants will complete an orientation, either in-person or online, that includes activation of and training to use select app features on their personal phones. They will be encouraged to carry their phones during activity, a behavior we will reinforce by providing toting accessories (e.g., waist pouch) and monthly telephone check-ins beginning in week one. Participants will be shown how to manually enter PA data that cannot be captured automatically (e.g., due to water-based sports). During check-ins, participants will be offered technology support, and will be questioned about events that may have altered their phone usage or activity patterns (e.g., hospitalization). Additionally, a troubleshooting asynchronous hotline will be made available to participants during the intervention.

Study measures (apart from the four-meter walk test and collection of usage data) will be either (1) mailed or dropped off/picked up through contactless hand delivery to participants, including paper-based instructions or a link to video-based instructions and a pre-addressed/postage pre-paid envelope—telephone assistance will be made available to complete requested study tasks; (2) emailed with instructions for electronic completion—telephone assistance will be made available to complete requested study tasks; and/or (3) administered by a condition-blind tester at a FPCIW or other community venue at baseline and/or post-intervention. A combination of remote plus in-person assessment session contact may be deemed necessary based on participant needs. The most likely scenario for this hybrid contact is if participants need in-person support to don their activity monitor appropriately. This will be decided on a case-by-case basis and is unlikely to be necessary for more than a few participants.

In-person sessions will typically include 2–8 participants, with the assessment battery lasting approximately 1.5 hours. *Objective PA level* (primary targeted outcome) and *objective SA time* will be assessed during a three-day monitoring period pre- and post-intervention the activPAL (Pal Technologies Ltd), a thigh-worn monitor that is considered the gold-standard for tracking sedentary behavior in free-living conditions.[56-58] Proprietary algorithms available from activPAL software analysis program will be used to aggregate PA- and SA-related data. (Although the PA-tracking core app provides useful intervention-facilitating PA feedback,[59] app-based PA records will not be used as outcome data because they have not been validated for this purpose and do not include useful baseline information.) Auto-calculated times identified by activPAL software will be used to identify wear periods and sleep/wake times, with participant reports of these periods as manually entered into the device for the purpose of corroboration.

Self-reported PA will be measured via the Physical Activity Scale for the Elderly (PASE).[60] PASE is a ten-item instrument designed to assess engagement in PAs commonly encountered by older adults, including those related to leisure, household, and occupational tasks. The tool is a valid and reliable measure of PA engagement in older populations.[60, 61] For assessment sessions conducted in-person, *Functional mobility* will be assessed through a four-meter walk test,[62-65] a commonly used, validated measure of physical and functional performance in older adults.

The potential mediators *PA self-efficacy*, *self-regulation*, *outcome expectation*, and *social support* will be measured using the 78-item PA scale of the Health Beliefs Survey.[66, 67] Subscales demonstrate sufficient internal consistencies (Cronbach's α=0.68–0.90) and are predictive of PA.[32] *Aging self-perceptions* will be assessed by the Attitudes Toward Own Aging subscale of the Philadelphia Geriatrics Center Morale Scale.[68, 69] This five-question tool captures the subjective aging experience, shows moderate internal consistency (Cronbach's α=0.61–0.64), and predicts mortality risk.[27] *Views of aging* will be measured using the Attitudes to Ageing Questionnaire,[70] a 24-item tool that assesses subjective views about age-related psychosocial, physical, and psychological changes; is cross-culturally valid; and is psychometrically sound (Cronbach's α=0.68–0.84).[70] *Usage behavior* (e.g., frequency of opening the app) will be captured via the app platform, and *perceived usefulness* of assigned features will be measured via the the Mobile App Rating Scale – Adapted user version [uMARS], as well as the post-study phone interview (included to inform optimization beyond information gleaned from the clinical trial).

Table 1 summarizes the study's measurement plan for Aims 1 and 2. Each of the aforementioned pre-existing assessments has been validated for use with community-dwelling older adults.

Table 1. Overview of Study Variables

Category	Variable(s)	Primary Role in Study	Measurement	Timing
Background: Demographics/ Health/ Smartphone Information	Age, Sex, Race/Ethnicity, Education, Marital Status, Living Status, Income, Employment, Health Conditions, Health Tracking Behavior, Mins PA/Wk, Major Health Problems (e.g., diabetes), Smartphone Ownership Duration, Smartphone Platform, Smartphone Proficiency (self-rate 1-10), Smartphone Carrying Location, Research and Wellness Program Participation	Sample Description Potential Covariates	Demographic/Background Questionnaire [~18 items]	Baseline
Mediators	Views of Aging	Tests of Mediation	Attitudes to Ageing Questionnaire [24 items]	Baseline and post
	Aging Self-Perceptions	Tests of Mediation	Attitudes Toward Own Aging subscale of the Philadelphia Geriatrics Center Morale Scale; [5 items]	Baseline and post
	PA Self-Regulation, PA Self-Efficacy, PA Outcome Expectation, PA Social Support	Tests of Mediation	Health Beliefs Survey [78 items]	Baseline and post
PA-Related Outcomes	Objective PA Level	Primary Dependent Variable	activPAL	Baseline and post
	Self-Reported PA Level	Dependent Variable	Physical Activity Scale [PASE; 10 items]	Baseline and post
	Functional Mobility	Dependent Variable	4-meter Walk Test	Baseline and post
	Objective Sedentary Time	Dependent Variable	activPAL	Baseline and post
Usability	Satisfaction	App Refinement	Mobile App Rating Scale – Adapted User Version [uMARS; 5 items]	Post
			Interview	4-month phone call
	Objective Usage: Proportion of days opening the app	App Refinement	App-Stored Usage Data	full study duration

III. Data Management, Analysis, & Statistical Considerations

Our biostatistician will secure and archive data, and will oversee all data analytic functions. Usage data for each participant will be obtained from storage within the app and downloaded manually at in-person assessment sessions. Data will be transferred to the biostatistician for analysis and storage on the USC secure network. activPAL data will be downloaded and cleaned. Using proprietary algorithms supplied by PAL Technologies, waking-hour wear periods will be identified for use in analysis.

Data analysis will be organized around the goal of providing multiple sources of information useful for future efforts to optimize the Moving Up app suite. We will calculate descriptive statistics at baseline and/or post-intervention for demographic, *app usage behavior* [proportion of days opening the app ≥1 time], *user satisfaction* [perceived app quality, physical activity-related (*objective physical activity* [primary outcome; daily steps], *sedentary activity time* [daily sitting time], *self-reported physical activity*, *functional mobility* [gait speed]), and mediational (i.e., *self-efficacy for physical activity, self-regulation for physical activity, family social support for physical activity, outcome expectation for physical activity, aging self-perceptions, views of aging)* outcome variables, both for the overall sample and by on/off status of each of three specialty features (i.e., Proof Positive, Coach Me, and On Your Feet).

Indicator variables will be created to code whether or not the participant had each of the specialty features installed on their phone as part of the intervention. Results regarding outcomes and hypothesized mediators will be calculated overall and by feature subgroup. The feature subgroups are not mutually exclusive since a participant can be randomized to receive 0, 1, 2, or all 3 of the features.

Specialty feature condition effects on the *objective physical activity* (change in daily steps) primary outcome will be analyzed using a mixed effects linear regression model adjusted for confounders (including presence/absence of other specialty features, between-feature interactions, select demographic variables [age, sex, race/ethnicity, education]), and baseline daily steps. Although significance testing will provide merely one source of information in driving app optimization decisions, the anticipated sample size (N=90) was chosen to enable 80% power (given α=.10 and a one-tailed test, as consistent with recommendations for pilot studies employing MOST) in testing experimentally based pre-post physical activity increases associated with a specialty feature (given an effect size of .45, a feasible value based on prior tests of technology-based physical activity intervention components). Using change-from-baseline scores for *objective physical activity*, we will derive Cohen's *d* effect sizes stratified by presence vs. absence of each specialty feature. For secondary physical activity-related outcomes and proposed mediators, we will conduct multiple one-tailed t-tests (α=.10) to further explore the potential viability of the specialty features. To facilitate later RCT planning, we will also calculate single group pre-post change effect sizes for the full sample. Correlation coefficients will be calculated to assess associations between the primary outcome (change in daily steps) and proposed mediators. To analyze *app usage behavior* and *user satisfaction*, for each intervention feature considered separately, we will perform one-tailed t-tests to examine mean differences in each variable based on whether or not the participant was assigned to receive that feature.

After participants conclude the clinical trial phase, they will take part in an interview about their experience. Interview responses will be audio-recorded, transcribed verbatim, coded, and analyzed using qualitative data analysis software. All qualitative data analyses will be performed by the PI, Co-investigators, and/or authorized Research Assistants. Initial thematic analysis will incorporate codes suggested from the Health-ITUEM.[71] Additional codes will be identified as they arise in the data. Rigor will be achieved through peer review of themes and by maintaining an audit trail of analytic memos.

IV. Protection of Human Subjects

A. Risks to Human Subjects

A.1. Human Subject Involvement, Characteristics, and Design

A total of 100 underactive older adults (accounting for 10% attrition) will participate in the clinical trial phase to accomplish the aims of the study. Subjects will be between the ages of 65 and 84 years old, and will be users of smartphones for ≥1 month. Underactive individuals will be targeted (i.e., those who accumulate <150 minutes of at least moderate intensity physical activity per week) due to their high risk for chronic disease resultant from lack of physical activity engagement and sedentary behavior. Additional inclusion criteria for entrance into the study includes ability to reliably access and operate basic features of a smartphone (ascertained by completion of the two-hour orientation and demo session). Exclusion criteria are unwillingness to meet at local community venues or comply with study procedures for the length of each study.

A four-month intervention period will take place. On a randomized basis, the research participants (N=100) will be assigned to one of eight conditions whereby they will have access to various combinations of the app suite features. Intervention dosage is consistent with small pilot studies of physical activity interventions for older groups of adults. They will complete an orientation session, either in person or online. Check-in phone calls will be made by project staff during months 1, 2, and 3, for purposes of troubleshooting and gleaning initial impressions of app usage. A short interview covering usability and feasibility will be conducted during the final phone check-in just after completion of the 4-month intervention. Pre- and post-intervention, each participant will complete a battery of self-report assessments and clinical measures and complete a three-day physical activity monitoring period using a wearable accelerometer. These assessments will be either (1) mailed to participants or dropped off/picked up

through contactless hand delivery, including paper-based instructions or a link to video-based instructions and a pre-addressed/postage pre-paid envelope—telephone assistance will be made available to complete requested study tasks; (2) emailed with instructions for electronic completion—telephone assistance will be made available to complete requested study tasks; and/or (3) administered by a condition-blind tester at a FPCIW or other community venue. A combination of remote plus in-person assessment session contact may be deemed necessary based on participant needs. The most likely scenario for this hybrid contact is if participants need in-person support to don their activity monitor appropriately. This will be decided on a case-by-case basis and is unlikely to be necessary for more than a few participants. If the full assessment session is held in-person, each session (excluding the three-day physical activity monitoring component) is anticipated to take approximately one hour to complete. Total length of enrollment will be four months and approximately two weeks to account for pre- and post-testing. There are no collaborating sites in this proposed study.

A.2. Sources of Materials

Data will be collected from participants by blinded raters at two assessment sessions (pre- and post-intervention) or via US mail, contactless hand delivery/pick-up, or secure email for digital completion, two three-day activity monitoring periods (pre- and post-intervention), and during a four-month intervention period. Data to be gathered at the pre- and post-intervention assessment sessions include demographic and background information, health beliefs regarding physical activity, self-reported physical activity, and sedentary time. If assessment sessions are held in-person, functional mobility will be assessed during a four-meter walk test administered by trained research personnel. Upon completion of assessment sessions, data coding forms and materials will be delivered to the study center at USC and kept in locked file drawers. During each of the three-day activity monitoring periods, participants will wear a research-grade accelerometer. Activity patterns and wear patterns tracked through this device will be manually downloaded to and stored on a secure database. During the four-month intervention period, participants will be utilizing the PA-tracking core app/mechanical pedometer and specified specialty features on their smartphones. Data automatically captured through the app such as activity patterns (e.g., minutes engaged in moderate intensity activity) and app usage behaviors (e.g., frequency of accessing various app features) will be gathered through the in-app tracking software. These data will be downloaded from the app database and transferred to a secure USC server in coded format as described above. Participants will be educated (verbally and via a written SOP [“Information Collected in App”]) when they install the app, about data that will be collected within the app, what will happen to those data at the end of the study. A short interview to collect usability and feasibility data will be conducted during the final phone check-in just after completion of the 4-month intervention. For this study, participant identities will be known to the project manager and authorized personnel except for research staff who will complete blinded evaluations during the pre- and post-intervention assessment sessions.

A.3. Potential Risks

The overall risk to subjects in this study is low.

Self-report information. It is possible that some participants might feel minor embarrassment when reporting aspects of their personal resources, daily activities and behaviors, and health beliefs regarding physical activity. It is also possible that some participants will feel uncomfortable with selected aspects of the study such as interacting in a small group of peers.

Functional mobility testing. A low risk stems from participation in the functional mobility test (i.e., the four-meter walk test) during the pre- and post-intervention assessment sessions. As with any walking task, there is always the potential risk of falling. It is unlikely that participants will become fatigued during this task given the short distance the test requires to travel.

Physical activity monitoring using accelerometers. The risks associated with wearing the activPAL accelerometer are minor. The devices are small (51 X 34 X 8 mm) and lightweight, about the size of a

men's wristwatch. They are designed for long-term activity monitoring and for use in sleep studies. Individuals may report, though unlikely, discomfort from the cloth straps available.

Physical activity engagement. Engagement in physical activity poses a low risk of physical discomfort to participants. As with any intervention that encourages participants to increase physical activity levels, participants may experience fatigue or minor muscular discomfort that may accompany increased physical activity levels. This discomfort typically resolves in one to two days. There is also a risk for injury related to engaging in PA in a non-supervised setting.

Exposure to explicit and subliminal positive aging stereotype messages. There is a slight risk that exposure to positive messages (both explicit and implicit) about aging may have a neutral or negative influence on participants' views about aging and engagement in PA. For instance, a message that is paired with an image of an older adult playing tennis may discourage someone who is unable to engage in sports due to physical disabilities.

Confidentiality. There is a slight risk that people who are not connected with this study will learn a participant's identity or personal information. During interviews and focus groups, which are audio recorded in a private room, participants will be identified by a false name to protect their identity on the audio transcripts. If audible personally identifying information is recorded during the focus group, this information will be deleted from the written transcriptions. Audio recordings will be listened to in a private setting and stored on a secure server at USC until the transcription process and qualitative data analyses are complete. Pseudonyms and real names will only be connected through one password-protected file on the Division of OS/OT secure server, in a separate location from the original data and transcribed files. An audio recording release form will be required for signature to participate in the focus group.

There is also a slight risk for a potential security breach of the app that stores participants' smartphone usage patterns and information or the USC server where participant data are finally stored for analysis. To mitigate this risk, data auto-collected from the tracking features of the app will be in coded format (i.e., no participant personal identifiers will be included with these data) as will be the case for any data collected during the assessment session. Additionally, the USC servers are password-protected and include network restrictions. Access rights to the servers will be terminated when authorized study personnel leave the study.

Other risks. Participants may choose to use their smartphones in unsafe ways (e.g., accessing an app while crossing the street). Though this behavior is not necessarily isolated to our study, to mitigate the risk we will distribute a safe handling of phones information sheet following the informed consent process.

Overall burden. The level of burden for subjects is a concern in any research study, though we feel participant burden is relatively low for this study. The most identifiable burden is associated with subjects' time devoted to completing the assessment sessions, interviews, or focus groups, and energy and effort involved with utilizing the smartphone app in daily life for four-months. Use of the app is on a voluntary basis for the four-month testing period. Participants may use the app and assigned specialty features as often or as infrequently as they choose. Participants are also free to withdraw at any time should they decide that the burden becomes too great.

B. Adequacy of Protection against Risks

B.1. Recruitment and Informed Consent

We will use a multi-faceted recruitment approach for the proposed research. Participants will be recruited in the following ways: (a) telephone contact of potentially eligible participants as identified by our Front Porch community partner within their network database; and (b) study opportunity presentations delivered at local Front Porch-affiliated community senior centers or outside networks. A Front Porch Project Coordinator will be responsible for contacting prospective participants within their community network. If the individual is agreeable, contact information will be forwarded to the study team for follow-up and further screening.

In all cases, informed consent will be obtained only by authorized, trained study personnel. Each prospective subject is given time to read the consent and discuss his or her options with project staff and family members. To ensure ample time to peruse the consent information, we routinely mail or e-mail copies of a sample document to each interested party. When the prospective participant is ready, a dialogue regarding the study will ensue. The study team member is responsible for guiding the discussion, and will be instructed to follow a standard format to ensure that all required elements are introduced. Explanations will cover all aspects of the intervention, the testing requirements, participants' rights, and other relevant information. Individuals will have an opportunity to ask questions about the study and, if they choose to enroll, will sign a printed or electronic consent form. They will be provided with a printed or electronic copy of the consent form and the Research Subject's Bill of Rights.

B.2. Protections against Risk

A number of safeguards will be in place to minimize risk. All interactions with participants will be performed by qualified study personnel. Prior to performing their duties, all study staff who will interact with participants will undergo specific training for their research tasks, with attention being devoted to issues surrounding risk to human subjects. Toward this end, all staff members will be required to complete HIPAA and IRB certification, and will be informed of potential pitfalls relevant to human subject concerns that surround their job duties. Intervention delivery content sent through the automated remote coach will be overseen by the PI who is a licensed occupational therapist and Co-I Sarkisian who is a medical doctor. At the outset of the study and at subsequent three-month intervals, a project staff meeting will be held in which all study personnel will discuss the safety and proper treatment of research participants. These meetings will be mandatory for all project personnel who have contact with participants or with data that result from the study. Dr. Sarkisian will be present at these meetings, as well as furnish advice regarding the medical safety of the intervention and how to deal with any medically relevant problems that arise.

Self-report information. Subjects may refrain from answering any questions without prejudice. We also have subjects complete their surveys in our presence when possible. This serves two purposes: 1) we can answer questions that arise regarding individual items, and 2) we can provide immediate assistance if necessary. While severe reactions to answering personal questions are rare; we will offer counseling and emergency resources available to those in need. Participants who complete mailed or digital assessments independently will be provided with a phone number to call with any questions or concerns.

Functional mobility testing. In order to minimize risks associated with functional mobility testing (i.e., the 4-meter gait speed test), participants who attend in-person assessment sessions are instructed to walk a self-selected normal pace. A study team member will be nearby throughout the testing to offer assistance as needed. For those individuals who deem any discomfort or instability too extreme, there is the option of discontinuing the testing procedures.

Physical activity monitoring using accelerometers. We will offer the option of wearing a terry cloth thigh-band underneath the accelerometer if participants are experiencing discomfort from straps or adhesive. The additional layer between the skin and accelerometer eliminates any discomfort associated with the device skin contact and does not affect the data collection process. If this option is not acceptable to the participant, the subject may be excluded from further participation in the study.

Physical activity engagement. To mitigate the risk of engaging in increased levels of physical activity, we have included self-reported screening question that asks individuals if they believe they are safe to regularly walk. Co-I Sarkisian—a medical doctor and geriatrician—has deemed this screening question sufficient given the low-risk and non-prescriptive nature of the intervention. If an individual answers "no" to this question, then he/she will be excluded from the study. Activity engagement during the intervention period is voluntary. We will recommend moderate intensity walking, a low risk physical activity for older adults, during the intervention period (i.e., as part of the goal-setting and remote coaching components of the app). The medical doctor and physical therapist on our investigative team will provide ongoing consultation to ensure safe physical activity engagement. We will ask about adverse events whenever our

team has contact with participants to ensure that we capture all events that may affect data outcomes. If research personnel who have contact with participants become aware of any clinically significant problems related to the health of one of the participants, research personnel will recommend that the participant contact his or her primary care facility and will be available to assist him or her with accessing the necessary services. For emergency events that occur during assessment visits, we will follow standard USC health system protocols.

Exposure to explicit and subliminal positive aging messages. The implicit messages that contain priming words used in the intervention were rated positively in two pilot studies in preparation for a larger study. Therefore, the likelihood that the implicit messages will result in negative views about aging is low. The explicit messages have all been reviewed by the team's social psychologist, Dr. Barber, who has expertise in older adult stereotype threat. She has confirmed that the messages do not present negative stereotypes that could adversely affect older adults' views on aging. Because the explicit messages may be paired with images of older adults, our team has carefully selected images that reflect a wide range of daily activity capabilities; images reflecting engagement in extraordinary activities (e.g., skydiving) were avoided. The final assessment session, led by a research assistant, will conclude with a careful and detailed debriefing conversation about aging stereotypes and their effects on health and wellness in older adults.

Confidentiality. All information obtained from the participants will be kept confidential among appropriate members of the study group. During computerized data analysis, anonymity of all study participants will be assured by the appearance of their names next to their study IDs only on a single log, to be maintained and stored in a password-protected and HIPAA-compliant REDCap database. Access to the study ID log will only be granted to users that need this information to follow-up with the participant. With respect to study personnel who will interact with participants, we will maintain strict standards that forbid the leakage of information about study participants to unauthorized individuals either within or outside the study team. These strategies are likely to succeed in eliminating any possible harm to participants due to leaking of personal information. A description of mitigating the risks of being audio recorded during the interviews is included in section IV. A.3: Confidentiality. Each of the above safeguards is expected to substantially reduce the participants' study participation risks.

C. Potential Benefits to Human Subjects and Other

All individuals who complete the four-month intervention will have access to specialty features of a physical activity-based smartphone app not yet commercially available. Because the risks are minimal, and because the study promises to generate knowledge about optimizing a smartphone app to encourage physical activity in older individuals, the benefits of the study outweigh the risks. For all participants, it is likely that the opportunity to participate in a potentially successful mobile health intervention for older adults and the knowledge that one is aiding in the quest to develop improved mobile health interventions will benefit the participants to a degree that outweighs the risks.

D. Importance of Knowledge to be Gained

The knowledge that will result from the study is expected to have important benefits for society. Older adults represent the most physically inactive age group, which places them at high risk for chronic, disabling conditions. The proposed PA app suite is a unique mobile health tool that shows promise in improving older adults' PA and overall health. A feasibility study of this app shows that older adults are willing to utilize a PA-tracking app and find it easy to use and potentially beneficial for health. The proposed study will provide valuable information on how to design and develop an acceptable and usable smartphone app intervention with maximal potential to improve physical activity and overall health in the ever-growing population of older adults. This project will also support future development and testing of the PA-tracking app suite compared to alternative mobile health interventions that target elders and thereby contribute to national healthy aging agendas. The cumulative value of this knowledge far outweighs the risks identified in the previous section.

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