Title: A Personalized Health Behavior System to Promote Well-Being in Older Adults

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1) Protocol Title

A Personalized Health Behavior System to Promote Well-Being in Older Adults

2) Objectives*

Mobile-based, tablet-based, and in-home technologies provide an excellent opportunity for integrating behavior-change interventions and social support into the everyday life of older adults at great economies of scale (Rotheram-Borus, Swendeman, & Chorpita, 2012). Though a large number of mobile and web-based apps aimed at increasing healthy behaviors exist, and there is evidence suggesting they are a feasible and acceptable medium for health interventions, there is a need for more robust research evaluating the efficacy of these approaches, especially with older populations (Payne, Lister, West, & Bernhardt, 2015). The objectives of this study are to examine the usability and efficacy, for diverse older adults, of a new tablet-based dynamic system: the Fittle Senior System (FSS) that will provide: (1) personalized behavior-change programs for increased physical activity, and (2) online social interaction and support from small teams pursuing similar goals. The system builds on two technology-based systems developed by the investigative team: (1) the computer-based PRISM system (Czaja et al., 2015), designed for older populations to support social connectivity and well-being, and (2) the Fittle+ mobile platform (PARC) designed to support positive health behavior change through integrated online social support and personalized coaching based on artificial intelligence (AI).

Specifically, we will compare, using a randomized design, the FSS to a control condition (TC) where participants will receive a tablet and selected internet websites from credible sources (e.g., National Institutes of Health) with exercises appropriate for seniors. The target sample is community-dwelling older adults. Phase 1 of the study is complete; therefore, the proposed study will include (Phase 2) Efficacy Trial, a 12-week active intervention component in which groups will received either the FSS or the TC material, followed by a 12-week maintenance component. Assessment of clinically meaningful outcomes will be obtained at baseline, 3 months (post active treatment), and 6 months (post maintenance/3 months post active treatment).

3) Background*

Significance

People aged 60+ will represent 21% of the U.S. population and increase to about 80 million by 2040, and the *oldest old* (age 85+) will number ~ 14.1 million (Administration on Aging, 2012). Population aging presents both opportunities and challenges for our healthcare, the economy, and existing social support systems. Specifically, the *oldest old*, minorities and those of lower Socio-Economic Status (SES) are particularly vulnerable to chronic health conditions, social isolation, poor diet, and decreased levels of physical activity each of which influence morbidity and mortality (Institute of Medicine Committee on Health and Behavior: Research, 2001).

The 2014 Brain Health Educator Guide of the National Institutes of Health and Centers for Disease Control and Prevention (Administration for Community Living. Brain Health as You Age: Educator Guide; 2014) has highlighted several behavioral risks to healthy aging including poor diet, insufficient sleep, lack of physical activity, and limited social activity. Health promotion interventions – defined as behavioral interventions that use counseling strategies to equip participants with the necessary knowledge and skills to modify and sustain a healthy diet, increased physical activity, and/or healthy weight – can help maintain a healthy body and brain (CDC, 2006; Kennedy et al, 2014). Regular engagement in these health behaviors is protective and the evidence consistently shows that increased physical activity (PA) effectively reduces symptoms of depression and anxiety as well as health risk factors and physical decline

in older adults (Blumenthal et al., 2007; Blake et al., 2008; Petruzzello et al., 1991; Strohle, 2009; Martinsen, 2008; Barbour, 2005; Craft & Landers, 1998). Engagement in PA can also increase older adult life expectancy while limiting the progression of disabling conditions (American College of Sports Medicine, 2009). Thus, health promotion interventions are particularly promising for older adults since they reduce vulnerability factors and enhance protective factors associated with healthy aging.

Despite the multiple physical and mental health benefits of PA, the majority of older adults do not engage in PA on a regular basis. It is critical that effective intervention strategies promoting health behaviors such as physical activity (PA) be developed for older adult populations. Health promotion interventions are particularly needed for vulnerable, disadvantaged populations (Icard, Bourjolly & Siddiqui, 2003). As noted by King and colleagues (King, Rejeski, & Butler, 1998) most PA interventions targeting older adults have been lacking, particularly with respect to accommodating ethnic minorities, those of lower economic status, and older-old adults, the frail elderly, the rural elderly, and socially isolated and depressed older adults.

Software-based applications and mobile technologies (smartphones, tablets) offer the opportunity for uniquely tailoring health promotion programs to accommodate the vast individual differences in health status, medical conditions, social influences and motivation, which exist in older adults. State-of-the-art technologies and health promotion applications also provide opportunities for social and peer support and socialization. The ability of health promotion interventions to build social support may indeed be the key to their ability to affect health outcomes.

The proposed study will evaluate a new tablet-based dynamic system: the Fittle Senior System (FSS) that will provide: (1) personalized, goal-directed behavior-change programs for increased physical activity and (2) online social interaction and support from small teams pursuing similar goals. The system builds on two technology-based systems developed by the investigative team:
(1) the computer-based PRISM system (Czaja et al., 2015), designed for older populations to support social connectivity and well-being, and (2) the Fittle mobile platform (PARC) designed to support positive health behavior change through integrated online social support and personalized coaching based on artificial intelligence (AI). The Fittle program is based on Self-efficacy and Social Cognitive Theory (Bandura, 1998, 2001), Goal Setting (Locke & Latham, 2002) and the Theory of Planned Behavior (Ajzen, 1991). Social Cognitive Theory posits that health behavior change is the result of the reciprocal relationships between personal factors, attributes of the behavior and the environment and that self-efficacy is a key characteristic in behavior change. According to this theory people will be more successful if they adopt goals they are confident that they can achieve. In addition, according to Goal Setting Theory (Locke & Lathan, 2002) more challenging goals yield higher levels of performance and motivation. The Theory of Planned Behavior posits that behavioral intentions predict actual behaviors and that intentions are shaped by a person's perceived control over the opportunities, resources, and skills needed to perform a behavior, attitudes towards the behavior and belief's regarding support from other people of the behavior.

Fittle + provides support for individuals and teams to progress through lifestyle challenges (e.g., sedentary behavior), helping individuals master one health improving habit after another in a way that builds on previous achievements. Individuals choose from a variety of challenges to accomplish goals via personalized exercises designed for sedentary older adults by an Exercise Scientist, motivational messages, and social support. The objective is to maintain and reinforce perceived self-efficacy with daily goals that are perceived as being achievable, and to improve motivation and ability with goals that are perceived as not too easy. The program provides encouragement and social support through a team component. Thus, Fittle is designed to reinforce and build self-efficacy and positive attitudes about the benefits and values of health behavior change and provide skills and resources as well as social support. A recent trial of Fittle (Du, Youngblood & Pirolli, 2014) with a small sample demonstrated the efficacy of Fittle across three classes of behavior – diet, physical activity and stress reduction. For this study Fittle will be modified for

older adults (FSS) and placed on tablet technology. Currently, Fittle is a smartphone system, however based on our extensive experience with technology and older adults we believe that tablet technology will be more usable for this population.

Preliminary Studies

The proposed research teams led by Dr. Czaja at WCM, Dr. Sharit at UM and Dr. Pirolli at Institute of Human & Machine Cognition (IHMC) (Dr. Pirolli was formally at PARC) have a history of collaboration. Initially this collaboration involved the use of a tool developed at PARC, Weblogger, by the team at UM to track the behavior patterns of older adults searching for Internet information. Dr. Pirolli guided the analytic efforts in these endeavors. The teams then collaborated on a joint project concerned with older adults and health information seeking (Sharit et al., 2008). More recently the investigators at UM and PARC completed a project that evaluated the feasibility and efficacy of Internet information search tools among older adults searching for health information (Hernandez, Sharit, Pirolli and Czaja, in preparation). These efforts led to the proposed project. The teams at UM and WCM include expertise in: gerontology, cognition, human factors engineering, aging and technology, behavioral interventions, and exercise science. The team at IHMC includes expertise in human-computer interaction, cognition and computer science/artificial intelligence.

Center for Research and Education on Aging and Technology Enhancement (CREATE). Funding Agency: NIH/NIA, 1999 -2020. CREATE is a multi-site (University of Miami, Georgia Institute of Technology, Florida State University, Weill Cornell Medicine) multidisciplinary Center, that is dedicated to solving the problems of aging and technology use. The objectives of CREATE are to develop a comprehensive database on aging and technology that consists of information regarding: user preferences and needs, problems with existing systems, and efficiency of design solutions across a range of tasks and technologies. One focus is on applications of technology in the healthcare arena. A hallmark of CREATE is the administration of an extensive cognitive and demographic battery on study participants. The CREATE sample includes > 2000 diverse older adults.

A Personal Reminder and Information Management System for Seniors (PRISM). S. Czaja PI (*Czaja, Boot, Charness, Fisk, Rogers, Sharit, Lee & Nair, 2015*). Funding Agency: NIH/NIA. The goal of this multi-site randomized clinical trial a part of CREATE was to gather rigorous systematic evidence about the value of technology for older adults, at risk for isolation, and identify factors that affect use and usability, acceptance and adoption. The study evaluated a simple to use Personalized Reminder Information and Social Management System (PRISM) designed to support social connectivity, memory, knowledge about topics, leisure activities (games) and access to resources on indices of social isolation and support and quality of life. In addition, the study evaluated how socio-demographic factors and cognitive abilities impact on adoption of the system and mediated study outcomes. The sample included 300 community-dwelling persons, aged 60-98 yrs., including 43% minorities, the majority of whom were of lower SES status. The results indicated that the system was useful to and usable by the participants and results in enhanced social support and well-being, and decreased loneliness at the 6-month follow-up assessment.

Identifying & Characterizing Online Search Strategies in a Health Decision-Making Scenario. (Sharit, J., Taha, J., Profita, H., & Czaja, S. J. (in press). *J. of Cognitive Engineering and Decision-Making)* This study examined Internet search behavior and performance among a sample of 60 adult Internet users aged 18-85 years. Participants were presented with a scenario and asked to use the Internet to resolve issues regarding disease management and treatment. A methodology was developed for characterizing search strategies and the strategies of the highest performers were contrasted with those of the lowest performers for the participants. Interview data were also collected to compliment the search strategy data. Findings highlight the large variability in information-seeking strategies that exist and provide the basis for a number of recommendations for supporting online health information seeking in support of health problem solving.

Factors Affecting Usage of a Personal Health Record (PHR) to Manage Health*. (Taha, J., Czaja, S.,*

Sharit, J., & D. Morrow. (2013). Psych & Aging) This study evaluated the ability of middle-aged adults and older adults to use a simulated PHR to perform common health management tasks, including medication management, review/interpretation of lab/test results, and health maintenance activities. Results indicated participants had difficulty using the PHR. Particularly, the older adults, those with lower numeracy and technology experience, encountered greater problems using the system. The study also identified important factors to consider in the design of PHRs so that they meet the needs of these two groups of users.

An evaluation of an E-government health website *(Czaja, Sharit, Nair, JAMA, 2008)*. The goals of this study were to examine the ability of older people: 1) to search for health information on the Internet; 2) to integrate that information and make a choice or decision; and 3) to obtain information regarding perceptions of the usability of Internet health information and trust in Internet health information. A focus was on the Medicare website. One hundred and twelve community dwelling adults ranging in age from 50 to 85 years completed the study. The data indicated that the participants had significant difficulty completing the task problems and low performance scores. The participants also indicated that the Medicare website had poor usability but that they valued and would use the Internet as a source of health information.

Efficacy of a Smartphone System to Support Groups in Behavior Change *Programs (Du, Youngblood & Pirolli (2014) Proceedings of the Wireless Health 2014 Conference). The results* of an 8-week field study of Fittle involving 19 adult participants that yielded significant pre- to –post-test improvements in diet, physical activity, and stress management. Adherence to the behavior programs was found to be associated with variance in team membership. Content analysis of within-team interactions suggested that high performance groups were generally more social, more supporting of each other on program goals, and shared more.

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4) Inclusion and Exclusion Criteria*

Phase 2: Efficacy trial

- Age 60+ yrs old
- Speaks English
- Plans to remain in the area for the study duration
- Not blind or deaf
- No health conditions/illness that would affect participation
- Able to perform the study physical activities
- No cognitive impairment
- Limited engagement in physical activities (e.g., no active gym membership)
- Pass TICS (Telephone Screen for Cognitive Status)

5) Procedures Involved*

Phase 2: Efficacy trial

Activities of this phase will take place at the participants' homes, nearby their homes, in the office or at a local community center. This could include telephone and video visits.

We anticipate to screen a maximum of 600 participants. We expect 181 participants to complete the trial. The study will be conducted in English. Participants are capable to provide consent for their study participation. They have to provide a signed waiver or their physician approval for engaging in physical activities as related to the study participation.

The study has a duration of 6 months and involves a brief telephone pre-screening, 3 in-person assessments* (baseline, 12 weeks, and 24 weeks), Up to 2 training sessions (small group format), 11 check-in calls (month 1: weekly; months 2-3: bi-weekly; months 4-6: monthly). In instances where an assessment cannot be conducted in person, assessments will be completed by phone or video call.

Training sessions will take place in-person or video-conference in small group format and/or by individual telephone calls. Additional check-in calls may be required for those subjects who exhibit non-use of technology or to maintain engagement of participants. In cases where a participant is unable to complete a follow-up assessment in-person, a subset of the assessments will be done by phone, videoconference or via email via Weill Cornell Medicine's secure file transfer system, in order to obtain outcome measures at the proper timepoint. If an in-person assessment is unable to be conducted within the 24-week visit window, the participant's engagement and participation in the study may continue beyond 24 weeks at the Principal Investigator's discretion and with the verbal agreement of the participant. Record of this verbal agreement to continue will be kept in the research record. If the participant and investigator agree to continuation in the study, an additional in-person follow-up will occur at the earliest opportunity where all measures will be obtained. If by 9 months, an in-person visit is still not feasible, a final visit will be conducted over the phone/video conference to collect the measures and discontinue participation.

Eligible participants will receive a tablet with internet connection for the study duration, a wearable (e.g., Misfit), and a resistance band. They will be randomly assigned to Fittle Senior System (FSS) or tablet control (TC) condition. We will have small groups of training sessions on how to use the Fittle or tablet. If participants have questions, they can always contact the RA.

Participants will receive $30 for completing each assessment. They will receive a total of $90 of financial compensation. For participants requiring a 4th visit beyond 6 months, at the Principal Investigator and participant's discretion, an additional $30 will be provided ($120 total for these participants). Participants will receive roundtrip MetroCards for study visits that take place at the WCM site or another site outside the participant's home. Participants will also be able to keep the tablet and the wearable at the end of the study if they so choose.

As part of the study, we will be collecting participant usage data in the tablet and Fittle and wearable.

Recruitment/Pre-screening:

Upon the approval of the study promotional material, we will display and distribute material in the community and place advertisements in local community newspapers or online newsletters/neighborhood blogs.

Interested participants will contact study-team via telephone or email in order to obtain additional information about the study and check on their eligibility status. The eligibility status is determined via a brief telephone pre-screening of about 20 minutes. During the phone call, the RA will begin by explaining the purpose of the study, followed by the procedure, risks and benefits. The RA will obtain a verbal consent from the potential participant prior to proceeding with a series of questions to assess and determine their eligibility criteria (see the telephone pre-screening script and telephone pre-screening form). We are requesting the waiver of signing of Informed Consent Form (ICF) for the pre-screening. At this point, it is not feasible nor possible to obtain a written consent from the participant because this step takes place over the phone. Having to have a written ICF for this step will mean an in-person pre-screening which will be costly and inefficient because some of these participants might not be eligible. We will obtain a written and signed or electronic ICF during the first visit.

Given the study involves doing physical activities, we will ask the participant to sign a waiver for

participation or have their physician's written approval before training for the study. Waivers or physician approval will be requested of participants found eligible at baseline and will be collected before the participant continues on to training for the study. If a waiver or physician approval is not obtained, the participant will be ineligible for the study.

Baseline assessment visit:

When participant is determined as eligible to participate through pre-screening, the RA will schedule a visit with the participant. This first visit could be as long as 2.5 hours depending on the participant. At the start of the visit, the RA is to begin by introducing the ICF to the participant. The RA will read and review the ICF with the participant and make sure he/she understands it before signing the form. The ICF will include permission for audio/video recording for research or education/training purpose. None of the study-related activities can begin until the participant signs the ICF. The RA will provide a signed and dated ICF to the participant for his/her records. In cases where visits do not take place in-person, an electronic consent will be obtained in a REDCap database. If the participant does not have access to a device with an internet connection, the consent form may be mailed to participants for completion and return. No additional study related activities can begin until the consent is fully signed and complete.

The first study-related activity is to further determine whether the participant is eligible for the study. The RA will administer the vision test, the reading comprehension test (i.e., Woodcock Johnson), and the brief memory test (i.e., MMSE). If the visit is conducted over the phone or video conference, the participant will be asked to read a paragraph of the consent form to ensure adequate vision and reading comprehension required for the study. The MSME will not be given remotely, and instead the TICS collected at pre-screening will be used in lieu of the MMSE for these participants. For in-person assessments, the physical test (i.e., TUG) will be given to help assess physical functioning. The TUG will not be required for screening, and ability to complete study exercises will be assessed at phone screening. There is no particular order to administer these tests. If the participant is not eligible to participate because of any of the above-mentioned tests, the RA will administer a brief demographic questionnaire so we can capture the demographics of those who are not eligible for the study. These non-eligible participants will receive $20 for their time and effort.

Eligible participants will continue with rest of the assessment – see Baseline Assessment booklet. We will split this part of the assessment in multiple visits if necessary or if the participant makes the request. The sequence of administering these tests might vary and it can be altered at the discretion of the RA and/or upon the request of the participant. The assessment consists of perceptual questions about participant's social support, social network, physical and emotional well-being, and quality of life. Other questions are related to participant's ability to remember words and understand written sentences, and follow instructions. The assessment is multimodal - paper and pencil, verbal, and interactive using a computer-tablet. Some instructional words will be adapted accordingly when tests are administered on a computer-tablet instead of in paper and pencil. For example, instead of circle/mark the correct answer, it might read select/choose the best answer. The RA will paraphrase the instruction statements accordingly so the participant understands it. For the quality assurance and adherence to protocol, the assessment may be audio recorded. No recording will be done if participant refuses to give consent for the recording. Breaks will be provided as needed.

All eligible participants will receive a tablet with internet connection for the duration of the study.

Training sessions (2 training sessions):

Eligible participants regardless of their randomization condition (Tablet or FSS) will receive 2 training sessions to learn to use the tablet and the FSS system. The first training session will take place in small group format in the office, at a local community center, or over video-conference/telephone and will

last between 60 – 90 minutes. Breaks will be provided accordingly. The second session will be either in-person in small-group or individual format, or will occur over the phone/video-conference. The second session will be approximately 30-60 minutes. These sessions are interactive and involve a lot of practice (training scripts are provided in the MOP). The training scripts are NOT intended to be followed verbatim. These are detailed protocols for the RA to follow. Depending on the skills of the participant, the RA will have to provide more detail or more practice exercises as part of the training. The sequence of the training topics might vary at the discretion of the RA and the participant. More training sessions might be provided upon the participant's request. It depends on the skills and ability of the participant to use the tablet. The training also encompasses information on exercise safety.

Study Intervention

Participants will be randomly assigned to Fittle Senior System (FSS) or a tablet control (TC) condition. The duration of the intervention is 12-week followed by a 12-week maintenance phase. Participants will be assessed at baseline, 3 months post active intervention and 3 months post maintenance phase (6 months following active intervention). Each assessment will last about 2.5 hours. It has paper and pencil questionnaires such as basic socio-demographic information, experience with computer/internet, perceived barriers to exercise, social support and isolation, and general quality of life; and physiological measures such as Timed Up and Go, grip strength, balance, and walking. All participants will be compensated at the rate of $30/assessment. No research-related activity will begin without a written informed consent from the participant.

Fittle is an integrative system that provides personalized exercise goals and exercises, motivational messages and available social support from teammates pursing similar goals. The objective is to maintain and reinforce perceived self- efficacy with daily goals that are perceived as being not too difficult, and improve motivation and ability with goals that are perceived as not too easy. Participants in this condition will receive a Samsung Galaxy and be provided with Internet access for the duration of the intervention (6 months). They will be trained on the use of FSS in the two training sessions. They will also be given an easy to use instructional manual and have access to technical help. During the maintenance phase they can continue to use FSS however, in a more passive way – e.g., they can revisit challenges but they will not have access to the health coaching or the feedback. Participants in this condition will also be given a Misfit activity tracker, which will be integrated with FSS. During training they will also be instructed in the use of the Misfit.

The TC condition is intended to emulate a person receiving a tablet from a family member as a gift and will involve sharing of websites with exercises for older adults, similar to the content of FSS. Participants in this condition will also be given a Misfit activity tracker. We will include 4-8 participants per group and the groups will be conducted in English. During training they will also be instructed in the use of the Misfit.

Check-in calls (11 calls):

The RA will be calling the participant 11 times. These check-in calls are intended to last about 10 minutes. The purpose of the calls are to check-in with the participant to see if there has been any changes in their lives (e.g., moving, grandchildren, illness, vacation, etc.) or if there are any issues with the project technology. These visits will be weekly in month 1 (4 calls), bi-weekly in months 2 and 3 (4 calls), and monthly in months 4-6 (3 calls). Additional check-in calls may be required for those subjects who exhibit non-use of technology or to maintain engagement of participants. Additional calls may be made to check-in with the participant about the technology or certain circumstances, such as in the case of pandemic.

Follow-up Assessment (3rd and 6th month):

These assessments should be conducted by an RA who is blinded to the randomization condition of

the participant. It will occur in-person, by telephone or by email via Weill Cornell Medicine's secure file transfer system. The follow-up assessment packet will be reviewed by the Institutional Review Board and include many of the same assessments as baseline. The follow-up will also include system usability and evaluation questionnaires.

In cases where a participant is unable to complete a follow-up assessment in-person, a subset of the assessments will be done by phone or email via Weill Cornell Medicine's secure file transfer system in order to obtain outcome measures at the proper timepoint. If an in-person assessment is unable to be conducted within the 24-week visit window, the participant's engagement and participation in the study may continue beyond 24 weeks at the Principal Investigator's discretion and with the verbal agreement of the participant. If the participant and investigator agree to continuation in the study, an additional in-person follow-up will occur at the earliest opportunity where all measures will be obtained. If an in-person follow-up cannot be obtained by 9 months following training, a final phone/video visit will be scheduled and completed. The participant will be discontinued from the study following this visit.

6) Data and Specimen Banking*

The study does not collect specimens. All the data will be stored and secured using the procedure implemented by the Data Manager at the Center on Aging and Behavioral Research. The access to records and participants data will be allowed only to the study personnel. The data will not contain any identifying information.

Study data request goes through a web-based check-in and check-out procedure implemented by the Center. The Data Manager of the Center or designee monitors the logs. Upon the granting of the approval, the requester will either get the hard copy of the data or link to access the electronic data. The data will not contain any identifying information.

7) Data Management*

Phase 2:

A number of measures are required to address our specific aims. This will allow us to examine the efficacy of the FSS intervention and potential moderators of treatment effects (e.g., gender, age, race/ethnicity) as well as factors that mediate the relationship between treatment and outcome (e.g., social support, self-efficacy). We will examine potential moderating and mediating variables using structural equation modeling techniques guided by current theories of behavior change (e.g., Bandura, 2001; Ajzen, 1991) and technology acceptance and use among older adults (e.g., Venkatesh et al., 2003; Melenhorst et al., 2006; Mitzner et al., 2010). Our study design will also allow us to examine maintenance of treatment effects over time.

Prior to any formal analyses, we will compute descriptive statistics (e.g., frequencies, means, standard deviations) for each variable. Frequency counts will be obtained on interval, ordinal, and categorical data. Variables will be checked for non-normality and, if needed, will be transformed to achieve a normal distribution or hypotheses will be tested using non-parametric tests. Groups-by-periods and differences-against-totals plots will be produced to inspect the data for trends. Multivariate dependencies will be studied using scatter plots and multiple correlation coefficients.

The overall study design is a 2 (treatment condition) x 3 (three measurement points), between-within group design with one between subjects factors and one within subjects factor. There will be three measurement points (baseline, 3 months and 6 months). For the main analyses we will use the General Mixed Model. This model is suitable for analysis of unbalanced data, does not require the assumption of

normality of the dependent variable (in fact it can be used when the response of interest is a binary variable or a count variable), can incorporate account for missing data in statistical models and is implemented in different analytical software packages such as the Proc MIXED in SAS.

In addition to the longitudinal analysis, the model also permits cross-group analyses, which we will perform at baseline, 3 and 6 months post intervention follow-ups. Baseline variables that are statistically significant at baseline will be modeled as covariates. Given our comprehensive outcome measures, where appropriate, we will create composite outcome measures for constructs such as social support/social isolation, and self-efficacy employing multivariate solutions such as principal component analyses and similar multivariate approaches for data reduction.

Data containing missing points due to attrition will be included in analyses and data will be analyzed using the intention-to-treat approach. Multiple imputation techniques will be used to impute missing follow-up outcome values and compared to the data for completers only. We realize that there will be mediators (self-efficacy) as well as moderators (e.g. gender) on particular analyses, which will be managed through structural equation modeling approaches guided by theories of behavior change and technology acceptance. Post-hoc tests of means for any statistically significant main effect will be accomplished using the paired t-tests procedure. Given that there are multiple dependent measures, there is an increased possibility of spurious Type 1 family-wise alpha error. Corrections such as the Bonferroni are very conservative and a substantial loss of power is evidenced when more than five contrasts are subjected to adjustment using this approach. As a result, to minimize the possibility of Type 1 errors but to reduce the likelihood of a Type II error, the test-wise alpha for each F contrast will be set at $p < .01$.

In addition, as noted, use of FSS will be tracked over time. Specifically we will gather information regarding process measures such as frequency of use, features used, social interactions, changes in use and patterns of use over time. This data will be summarized and described using descriptive statistics such as frequencies and means. We will also compute a composite dosage measure. This will also allow us to conduct a dose response relationship for those in the FSS group to examine if level of exposure to FSS is significantly associated with pretest-posttest change on the outcome measures. Finally, we will examine the intervention evaluation data for both groups and the usability measure for those assigned to the FSS condition.

All the study personnel who handle the data completed the CITI course. All the identifying information is removed from the rest of the data as soon as it reaches the Center on Aging and Behavioral Research. Only the study coordinator or designee has access to the password protected identifying information of the participant. The signed informed consent forms are stored in a separate double locked room. E-mail encryption is required when emailing any sensitive data. During transmission of large data files, we will use a secure method of transmission such as transfer.weill.cornell.edu.

8) Risks to Subjects*

The objectives of this study are to examine the usability and efficacy, for diverse older adults, of a new tablet-based dynamic system: the Fittle Senior System (FSS) that will provide:
(1) personalized behavior-change programs for increased physical activity, and (2) online social interaction and support from small teams pursuing similar goals. This is a behavioral intervention involving answering questions, encouraging and supporting other participants to engage and increase physical activities. Participants have to have physical physician clearance or to sign a waiver to participate in the program. We will exclude participants with mobility restrictions or other conditions that would make them unable to participate in the program.

We believe this a not greater than minimal risk study.

9) Potential Benefits to Subjects*

There is no immediate benefit to participants. However, the goal of the study is to promote and increase social support for physical activities. Participants can put in practice the skills learned in the study in their daily life. Their participation in the study can help investigators in refining future technology-based tools and platforms to assist and encourage diverse older adults in practicing healthier behaviors.

10) Vulnerable Populations*

The study involves normal, healthy volunteers who are capable of providing consent to participate in the study.

The research team will not use undue influence or manipulation in order to recruit study participants. Our team has extensive experience in recruiting this population and is aware of the ethical conduct necessary to protect human subjects in research. There is weekly meeting to monitor recruitment activities to discuss and review our recruitment practices and efforts. During recruitment activities and presentations in community events, the research team provides and explains the content of the flyer to potential participants, and answers and clarifies any questions/ concerns that potential participant may have. Interested participants are instructed and directed to call the phone number or send email to the address display in the flyer.

11) Setting

The study takes place at the Weill Cornell Medicine Center on Aging and Behavioral Research, the University of Miami Miller School of Medicine Center on Aging, local community centers, and the participants' homes. The intervention is technology-based, thus facilitating the communication and interaction between RA and participants. Study assessments (baseline, 3rd month, and 6th month) take place at the office, a local community center, over the phone/video, or the participant's home.

12) Resources Available

All the study personnel have their CITI certificate. The PI holds regular meetings with the study coordinator and data manager to review the progress of the study. There are also regular meetings of assessors who are working one-on-one with the participants to monitor and review the progress of the participants.

The Center has extensive experience conducting research studies. Most of the members of this study are involved in other on-going studies at the Center. It also has secure room and cabinets to store study-related documentation.

13) Prior Approvals

NA

14) Recruitment Methods

After IRB approval, the research team will contact potential recruitment sites and inform them about the study. These sites will be provided with IRB approved promotional materials (flyer) for recruitment. At the same time, the UM and WCM PR departments will be informed and notified of the ongoing research. The PR departments will be provided with the promotional materials for the study. UM and WCM sites such as those that make regular postings and newsletters will also be contacted and provided with an approved ad or communication regarding the project. The CITI certified staff member within the project plans to also attend health fairs and /or senior centers and events and have flyers available at various community centers so that potential participants can learn of the study. The IRB approved ad/flyer will also be posted in non-institutional newsletters and advertisement sections.

Promotional material use in this study are: flyer and advertisement blurb.

Once potential participants learn of the study, they will phone the recruitment phone line. A brief telephone interview will be conducted. If these participants are eligible for the study, they will then be scheduled for the baseline assessment.

Participants will not have any financial liabilities for participating in the study. The study provides financial compensation for their time/effort in completing the assessment. Participants will also receive roundtrip MetroCards for visits to the office/community center for the WCM site.

15) Local Number of Subjects

We anticipate to screen a maximum of 600 participants in Phase 2. We expect 181 participants to complete the study. The participants will be from Weill Cornell Medicine and University of Miami.

16) Confidentiality

This study does not collect specimens. The data are questionnaire based and participants will be completing them on paper or online using a secure and unique log. All the data will be stored and secured using the procedure implemented by the Center for Cognitive Neuroscience and Aging. The access to records and participants data will be allowed only to the study personnel. The data will not contain any identifying information.

The hard copy data will be stored in a double locked office at Center. The electronic and audio recorded data/interview will be kept in server computer at the Center as well. The data will be backed-up on a regular basis and the copies will be kept in a double locked office at the Center. Only study-related staff (listed in the IRB protocol) will have access to the data.

The online data will be collected on REDCap (WCM has approved this survey/data collection service and has a subscription to it). Connections to the server are 128-bit SSL encrypted. Minimum levels of password complexity will be enforced. The Tablet will be locked down, requiring a 4-digit PIN.

17) Provisions to Protect the Privacy Interests of Subjects

During the informed consent process, participants are made aware of who will have access to the study data (see section of Confidentiality). The participants are instructed to sign the Informed Consent Form only when he/she is completely satisfied with the information in the ICF, and all his/her questions are answered fully. We will not release participant information to anybody who is not listed in the Confidentiality section of the ICF.

18) Consent Process

The research team will not use undue influence or manipulation in order to recruit study participants. Our team has extensive experience in recruiting this population and is aware of the ethical conduct necessary to protect human subjects in research. They are all CITI certified.
There are regular meetings to monitor recruitment activities to discuss and review our recruitment practices and efforts. Most of the members of the research team who have an active role in the conduct of the study (screening, assessment, and conducting the study) will also be involved in the recruitment and consent process.

During recruitment activities and presentations at community events, the research team provides and explains the content of the flyer to potential participants, and answers and clarifies any questions/concerns that potential participants may have. Interested participants are instructed and directed to call the phone number or send an email to the address displayed in the flyer.

The study involves adults who have the capacity to consent. These potential participants are able

to read and comprehend the information written in the Informed Consent Form.
Questions will be answered and addressed accordingly. Therefore, no additional process will be used to obtain consent from them.

Phase 2:

When a person who is interested in the study contacts us via telephone or email to request information, a trained and certified screener/assessor will call the participant back and explain the basics of the study, and then ask for participant's permission to ask questions that would lead us to make a decision as to whether or not he/she might be an appropriate candidate for the study or basically would qualify for the study. This process is a preliminary screening done over the telephone, which is not feasible to do by having a written consent. If and only when a person,
1) has agreed to be screened over the phone; 2) understands that this study represents research; and 3) understands their participation is voluntary and that they can withdraw their consent at any time, will the screening process proceed. We will not obtain a written consent form for the phone screening process as this research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (45 CFR 46.117 (c) (2)). It is not possible to have written consent from each potential participant for practical as well as cost reasons.

Upon the completion of the telephone screening and if the participant appears eligible for the study, an in-person visit with one of the research team members (CITI certified) will be scheduled. A written informed consent form will be obtained by the CITI-certified and protocol trained RA during the first visit. Before any additional study-specific information is obtained, participants will be asked to read the IRB- approved consent form as well as the consent for audio/visual recording. The potential participant is asked to read the consent form and, if agreeable to participating in the project, sign it in the presence of an assessor.

During the phone screening process and other screening steps and after the potential participant verbally consents to participating in the study, they will be scheduled for an appointment in-person.

19) Process to Document Consent in Writing

Phase 2:

The RA (CITI certified) will obtain an Informed Consent Form from the participant during the first visit. Prior to engaging in any study-related activities, the RA must obtain the signed ICFs.

The Informed Consent Process can be done in English. The participant is asked to read the ICF and ask questions. If the RA detects the participant is having difficulty reading the ICF, the RA will read with the participant alternating paragraphs. In order to assess whether the participant comprehends the ICF, the RA will ask the participant to paraphrase the content of the ICF.

Participant will sign and date the ICF in the presence of the RA once all his/her questions and concerns have been answered. The ICF will be stored in a separate location from the rest of the study data. Written ICF will be obtained for all in-person baseline study visits. In the event that the baseline visit cannot take place in-person, electronic informed consent will be obtained in a secure REDCap database. The electronic informed consent process will be facilitated by a phone or video call between the assessor (RA) and participant where the informed consent process described above can be followed. For remote baseline visits where the participant does not have access to a device with an internet connection to complete an electronic consent form, the paper consent form will be mailed to the potential participant for completion and return. The review of consent can take place over the telephone. Additional research activities will not take place until Informed Consent is obtained.