REACH (Rehabilitation Enhancing Aging through Connected Health): Detailed Protocol

I. BACKGROUND AND SIGNIFICANCE

a. *Historical background*

For older adults, a decline in mobility skills is a signal event, identifying higher risk for disability and increased healthcare utilization. Whatever the cause, the decline or loss of the ability to walk safely, climb stairs or get up from a chair (collectively termed "mobility skills") are signal events. Without detection and intervention, deterioration of mobility skills can begin an inexorable downward spiral leading to dependency, morbidity, increased health care utilization and mortality.[1,2] On the basis of 20 years of research in this area, we know that mobility limitations are largely preventable and there are opportunities for improving outcomes and access to quality focused care in both healthy and chronically ill older adults. It is estimated that without establishment of new care paradigms specific to treating mobility limitations that these problems alone will add an estimated $42 billion to health care costs by 2040.[2] Currently there is no drug therapy for mobility limitations and the most efficacious treatment is rehabilitative care.

Health care and health care financing in this country are largely predicated on a medical model which prioritizes acute, disease-specific conditions, and on the provision of medical and surgical interventions. However, it has been demonstrated that for older adults, following disease specific guidelines is a major cause of adverse health outcomes and increased costs of care.[3] In contrast, rehabilitative care treats the functional consequences of diseases and conditions, directly addressing individual needs using a comprehensive integrated approach to preserve and improve physical function. Access to high quality rehabilitation services is a major gap in our fragmented healthcare system. There are no established models that focus on treating and preventing mobility decline or that can be scaled to the varied populations of older adults residing in the US.[1,4]

b. *Previous pre-clinical or clinical studies leading up to, and supporting the proposed research*

We have developed a paradigmatically novel program within the Partner's HealthCare System that produces clinically meaningful improvements in physical functioning among mobility limited older adults. A video describing the patient care experience is available online (http://www.spauldingrehab.org/conditions-and-treatments/live-long-walk-strong). This program is unique in a variety of ways. It uses five brief questions, administered in the context of a primary care visit and identifies individuals at increased risk for falls, mobility decline and disability. Also, it targets the most important impairments contributing to mobility decline, employs cognitive behavioral strategies, and motivates life style changes that maintain the functional gains. The benefits are observed over six to eight weeks and with only one to two visits per week. The magnitude of improvement observed (2.3 units on the Short Physical Performance Battery) exceeds thresholds of clinically meaningful improvement.[5,6] Other work from our clinical laboratory at Spaulding Rehabilitation Hospital has guided the content of this clinical program. We have been conducting a longitudinal cohort study of community dwelling older adults served by the primary care practices of Massachusetts General Hospital and Brigham and Women's Hospital. This NIH-funded study, known as the Boston Rehabilitative Impairment Study of the Elderly (Boston RISE), was developed to identify attributes that are most responsible for mobility decline and disability after 2 years of follow up.[7] Boston RISE

specifically focuses on attributes that when impaired can be treated with rehabilitative care. Boston RISE has identified four attributes--limb strength, limb speed, range of motion and trunk muscle endurance--as being the attributes that are predictive of decline in both basic and advanced mobility skills among older adults.[8] All four of these attributes are targeted within our proposed rehabilitative care program, REACH (Rehabilitation Enhancing Aging through Connected Health).

The pilot work of our Boston University collaborators has successfully used multiple approaches to extend the benefits of Physical Therapy (PT) by providing behavioral strategies to increase exercise motivation; remote monitoring by the PT; adaptation and progression of the exercises; and individualized videos and instructions of each exercise.[9] In a three-month RCT of sedentary older adults with Parkinson disease, we compared the efficacy of physical therapy delivered with the mobile health platform to usual delivery of physical therapy. The mobile health platform used was an application called Wellpepper accessed with an iPad. Hereafter, this technology will be referred to as Wellpepper. After a three-month period of exercising a minimum of three days per week, the subjects who received physical therapy delivered using Wellpepper experienced greater improvements in exercise self-efficacy, walking endurance and time spent performing moderate intensity exercise compared to standard PT. Adherence to the exercise program was 81% in the Wellpepper group and 57% in the standard care condition. This gap is expected to widen with observations over longer periods of time. Results from our satisfaction survey reveal that all participants in the Wellpepper condition would like to continue the program and would recommend it to others. This innovative approach to rehabilitation using mobile health technology bridges the transition from outpatient care through home care and finally to independent adoption and maintenance of healthy behaviors.

We have also achieved positive long-term functional outcomes with a novel intervention applied among a particularly vulnerable population of mobility limited elders: those recovering from hip fracture.[10] In these patients, we tested a simple home exercise program after standard post-operative care. With three to four home-based Physical Therapy visits and five subsequent monthly phone calls that provide cognitive-behavioral strategies focused on maintaining physical activity, we observe clinically greater improvements in physical functioning compared to controls at six months. This intervention utilized DVD players and videos to help ensure participation and compliance with the physical activity program. The physical activity program was evidence-based and specifically targeted the physical needs of patients recovering from hip fracture. Notably the clinical improvements observed were even maintained at nine months, three months after the intervention was discontinued, suggesting that patients can adopt these healthy behaviors. Methodological features of this study among hip fracture patients have informed the design of the proposed intervention.

In addition to this previous work developing our intervention, our colleagues at Brandeis University's Heller School have extensive experience in evaluating health care utilization and cost especially as it relates to the care of vulnerable older adults. The team has, for example, evaluated the feasibility and cost effectiveness of CMS's Lifestyle Modification Program Demonstration, a program focused on lifestyle changes around diet, exercise, and stress reduction on cardiovascular disease. The study included 589 participants and 3000 matched controls and found low cost cardiac rehabilitation to be the most cost effect model. The Brandeis team has evaluated many other CMS demonstrations including an expansion of low vision rehabilitation services, expanded coverage for chiropractic services and adult day care.

c. *Rationale behind the proposed research, and potential benefits to patients and/or society*

While the importance of clinical programs targeting mobility has been highlighted in a recent JAMA editorial, no programs exist that can be scaled to serve the needs of older adults across the US. For example, a large multicenter trial recently published in JAMA, known as the LIFE study, demonstrated improvements in mobility outcomes after 2.6 years of follow up.[11] While these findings are very promising, the approach has distinct drawbacks, limiting its ability to be scaled for large numbers of older adults. It required attendance by participants in group-based exercise classes two times per week for a long duration of time (2.6 years). In addition, the program was based on a model of care (use of exercise trainers) that is not currently funded by Medicare. An innovative approach is needed to optimize outcomes, minimize healthcare expenditures and facilitate retention of gains made in the skilled setting.

As part of healthcare reform, Medicare is now mandating that primary care physicians perform an annual wellness visit that prioritizes preventative care strategies. Recognizing that screening of mobility skills is well suited for this sort of wellness visit, our study is designed to evaluate the benefits of rehabilitative care as a treatment within a preventative care paradigm. Primary care physicians do not typically prescribe rehabilitative care in this context, and thus our program is not considered an example of standard practice. In *Table 1*, we describe some of the unique and innovative aspects of our rehabilitative care paradigm in contrast to the existing standard of care commonly prescribed for patients with mobility complaints.

In addition, traditional Medicare models of reimbursement are often focused on limited, episodic care over a shorter period of time and reimbursed in distinct provider settings. The model we are proposing combines provider settings (outpatient and home care) to allow us to observe how the participant performs the recommended exercise program in their home environment and offer modifications to maximize safety and benefit within the unique limitations of their physical space. In addition, we are proposing fewer overall visits spread out over a longer period of time (12 months) and augmented with mobile health technology to keep the participant engaged as well as provide opportunities for progression or modification of the exercise program as needed. The table below highlights some important differences related to the traditional Medicare model of skilled care and the new paradigm we are exploring.

Table 1

Current traditional Medicare Model	**Proposed New REACH Model**
Little to no planned contact with patients between skilled rehab visits	Regular contact via phone and the iPAD via the Wellpepper application
Significant variability in the quality of visual aids/training for home exercise performance	High quality videos of the patients performing the assigned exercises with auditory feedback
Limited course of care over a relatively short period of time (episodic)	Care extended over a longer period of time with decreased frequency as patients assume more of their care independently-augmented by the Wellpepper app
Impairment focused interventional strategy targeting limited deficits	Function focused interventional strategy targeting comprehensive aspects of mobility
Behavioral change strategies are infrequently utilized in care for older adults	Incorporation of behavioral change strategies to encourage long term maintenance and adoption of exercise behaviors

Care typically delivered in one setting per episode of care	Mixture of home/outpatient visits to optimize safe, effective exercise performance and highlight environmental concerns
Limited ability to progress the exercise type and intensity as care episodes are of shorter duration	Extending the course of care over a longer period of time enabling program progression/modification/ as appropriate and able

The proposed pilot study will evaluate the benefit of this care program on physical function and health care utilization. The resulting findings have the potential to change how mobility care is provided and thus to prevent mobility decline in older adults and broadly impact national healthcare reform initiatives.

II. SPECIFIC AIMS

For older adults, a decline in mobility skills is a signal event, identifying higher risk for disability and increased healthcare utilization. Based upon the collective research and clinical experience of our multidisciplinary team, we are proposing an innovative rehabilitative care program for older primary care patients at risk for mobility decline. The program targets newly identified risk factors for mobility decline and utilizes mobile health technology to deliver patient centered care more efficiently. The program is consistent with Medicare funded services, but uses a number of innovations such as mobile health technology to demonstrate the potential for long term benefit. This proof of concept quasi-experimental trial will evaluate the benefit of this unconventional care program on physical function and health care utilization after one year of follow up.

Our project will evaluate three main objectives:

1. In comparison to matched controls derived from the Boston RISE cohort study, we will evaluate the benefit of our mobility care program on **physical function** among 76 older adults at risk for mobility decline after one year of follow up.
   Hypothesis: In comparison to controls, participants in our mobility care program will have significantly greater improvements in physical function after one year of follow up.
2. In comparison to matched controls derived from Medicare claims data, we will evaluate the impact of our mobility care program on **health care utilization** after one year of follow up.
   Hypothesis: In comparison to controls, participants in our mobility care program will have significantly fewer hospitalizations and ED visits after one year of follow up.
3. In comparison to matched controls derived from Medicare claims data, we will evaluate the impact of our mobility care program on **health care costs** after one year of follow up.
   Hypothesis: In comparison to controls and after accounting for the estimated per patient costs of our intervention, participants in our mobility care program will have significantly lower healthcare costs after one year of follow up.

III. SUBJECT SELECTION

This proof of concept quasi-experimental pilot study will evaluate the benefit of a novel rehabilitative care program on physical function and health care utilization after one year of follow up. We will recruit 76 community dwelling older adult primary care patients.

Inclusion criteria:

1. Age ≥ 65-95 years
2. Able to understand and communicate in English
3. Difficulty or task modification with walking ½ mile (6 blocks) or climbing one flight of stairs
4. Ability to continuously walk 400 m in less than 15 minutes without stopping for more than a minute at a time, sitting, leaning, or the help of another person
5. Lives in a zip code within 10 mile radius of Spaulding Cambridge Facility
6. Baseline Short Physical Performance Battery (SPPB) scores from 3-12 with <20% of SPPB scores in the 11-12 range

Exclusion Criteria:

1. Presence of a terminal disease (e.g. receiving hospice services, metastatic cancer)
2. Major surgery or Myocardial Infarction in the last 6 months
3. Planned major surgery (e.g. joint replacement)
4. Planned move from the Boston area within 1.5 years
5. Mini-mental state exam (MMSE) score <20
6. Major medical problems interfering with safe and successful testing (examples may include: history hip replacement with recurrent dislocation, uncontrolled hypertension, use of supplemental oxygen)

Recruitment procedures will follow the same methodology utilized within the previously IRB approved Boston RISE cohort study.[7] Prior to contacting any potential participants, Dr. Bean and his staff will convene educational sessions with clinicians from participating primary care practices at Mass General Hospital in order to familiarize their staff with the study. To facilitate continued and regular support with recruitment throughout the course of the study, Dr. Steven Atlas and his research coordinator at MGH primary care are collaborators. They will facilitate recruitment from primary care clinics within the MGH healthcare systems.

The target of the primary care-based recruitment will be adults aged 65 to 95 receiving primary care within clinics of the MGH, representing a diverse population of older adults. Recruitment will *not* specifically target primary care patients who have been referred to physical therapy for treatment of a specific condition that they manifest such as a knee injury. Rather, it is targeting older adults in need of preventative care, which is a novel focus for rehabilitation. Potential participants will be identified through the MGH Primary Care Operations Improvement (PCOI) loyalty cohort (Protocol # 2004P002796) and direct identification by cooperating primary care providers. This patient database (Primary Care Provider Loyalty Cohort, IRB: 2004P002796) is stored on a password-protected server at the MGH Laboratory of Computer Science. At all times, data and results will be protected in conformance with the confidentiality policies of the Massachusetts General Hospital, the security procedures of the Laboratory of Computer Science, and the

applicable policies of Partners Information Systems. Upon receipt of IRB approval, this patient database will be securely imported into the established REDCap tracking database by Dr. Steven Atlas and his team at MGH.

Once in REDCap, this recruitment database will be accessed initially to provide MGH primary care physicians with the names of their patients so that they can corroborate an individual's eligibility and designate those to whom they feel that letters should be sent. Study ID's will be assigned to the remaining potential participants and recruitment letters will be mailed. We may access the recruitment database during the course of the study for the following purposes:

- To contact participants for payment and study-related issues
- To inform design for future studies that may result from this study
- For mandated reporting from the funding agency

The PCOI loyalty cohort is an IRB approved validated algorithm which identifies and links all patients within MGH primary care practices to a specific primary care provider or, if unable to link to a specific provider, to a specific primary care practice. A list of potentially eligible participants will be generated by the PCOI loyalty cohort and organized by provider. The list will also assign a unique study ID number to each potentially eligible participant. Study staff will provide MGH primary care physicians with a patient list via email or in-person. They will eliminate any of their patients who they do not feel are appropriate for this research study.

Initial contact with subjects will be conducted using identical methods to those of other IRB approved primary care-based studies at MGH. Potential subjects will be sent a letter signed by their primary care physician (PCP) and the Principal Investigator (PI) describing the study and offering them the opportunity to state their disinterest in being contacted. Disinterested individuals can indicate their wishes by checking a box and returning a pre paid postcard or contacting project staff directly. If the potentially eligible primary care patient does not return the postcard or contact us within two weeks of receiving the letter, study staff may contact that individual, asking about their interest in participation. Interested individuals will have their initial eligibility determined through completion of a 1-minute telephone questionnaire designed explicitly for the identification of individuals at risk for mobility decline (those who respond that they have difficulty with or task modification in walking a ½ mile and/or climbing one flight of stairs) and through questions addressing exclusion criteria. If it is felt that a personal visit at the primary care office may increase the likelihood that people will agree to participate, we will arrange to conduct group educational sessions at primary care practices.

Once someone appears eligible and expresses interest, they will be promptly scheduled for a baseline screening. Based on our prior experience utilizing this recruitment strategy among older adults with functional limitations, we estimate that we will need to send letters to 209 potential subjects from which 127 people (61%) will allow contact by our staff and meet basic eligibility criteria. Of the 127, we expect 76 people (62% of eligible) to complete the baseline visit. If recruitment is slow, measures can be taken to increase the rate. For example, if we perceive that minorities are more difficult to recruit, we can put more

effort into recruitment at selected clinics with higher minority concentrations. If there are particular areas that have lower cooperation rates, we will make additional efforts to work more closely with primary care staff at those respective clinics in order to enhance recruitment. Additionally, we want to ensure that we recruit individuals with a broad range of physical functioning. Typically, exercise and rehab studies tend to have no difficulty in recruiting higher functioning individuals. Thus, we will ensure that no more than 20% of individuals are higher functioning, scoring an 11 or 12 (out of 12) on the Short Physical Performance Battery. Thus, we will be monitoring baseline SPPB scores and once we have recruited 10% of cohort into either category of high SPPB performance, additional individuals scoring at this level will be excluded from the study.

IV. SUBJECT ENROLLMENT

The informed consent will be mailed or emailed to interested individuals ahead of the baseline screening visit. Any additional questions that arise in between the time of the phone screen and the first visit can be answered by telephone. The Research Coordinator or Physical Therapist will meet with potential participants in a private room at Spaulding Cambridge to review the consent form, review the iPad Information and Responsibility form, answer any questions and confirm understanding. The Principal Investigator will be on site or reachable by phone to answer any additional questions. The Research Coordinator/Physical Therapist will then obtain written consent.

If the participant consents to participate, the study staff will administer three tests to determine the participant's final eligibility for study involvement. These include: Mini Mental Status Exam,[12] the Short Physical Performance Battery (SPPB)[13] and the 400 meter walk test.[14] Those eligible will have the choice of continuing with the baseline assessment during the screening visit or returning for the baseline assessment during a subsequent visit. All baseline and one-year assessments (described below within *study procedures*) will occur at Spaulding Cambridge. Participants will undergo the initiation of the exercise/technology training with a licensed physical therapist at one of two locations: Spaulding Cambridge Outpatient Clinic (SCOC) or the Center for Neurorehabilitation at the College of Health and Rehabilitative Sciences, Sargent College, Boston University. Participants will choose their location based on geographical convenience initially until it is necessary to assign them in order to achieve equal participant numbers at each location.

V. STUDY PROCEDURES

Enrolled participants will complete in-person assessments at baseline and 12 months at SCOC. The main study outcome will be the Late Life Function and Disability Index (LLFDI).[15] Additional assessments include: Hopkins Verbal Learning Test[16], Trail Making (Parts A and B)[17], Digit Symbol Substitution Test[18], Katz Comorbidity Questionnaire[19], depression (PHQ-9)[20], Activities Specific Balance Scale (ABC)[21], Barriers Specific Self-Efficacy Scale[22], Computer Attitude Scale,[23] McGill Pain Map,[24] Brief Pain Inventory[25], Figure 8 walk test,[26] Grip Strength testing with a hand-held dynamometer(Jamar), [27] Single leg press strength and speed testing, [28] ankle/knee ROM, [29] the Trunk extensor endurance test[30], 4-step stair climb and stair climb power test.[31] All questionnaire completion will be done at a slow enough pace so as not to tire individuals. To minimize subject burden during the assessment visits, staff will provide ample time for breaks and resting between assessments. All physical performance tests will be initiated by a demonstration of technique and

an initial repetition/trial of minimal effort in order to ensure familiarity and safety with the procedures. If research staff deems a participant cannot perform a task safely, would be at risk for injury or could exacerbate an existing condition, then the participant will not perform that task. If adverse symptoms or potentially serious side effects develop during any of the testing, procedures will be terminated immediately. Participants may refuse any assessment. During the 12 month visit, assessments may be prioritized and the visit abbreviated based upon the corresponding needs and safety concerns of participants. Study participants who report being unable to do in-person office visits at 12 months may be offered the option of having a home visit conducted by the physical therapist or research assistant. Additionally, those who are unable to do a home visit may be offered the option of doing a phone interview.

At approximately 3 months, 6 months, and 9 months, study staff will contact participants over the phone to administer questions. Participants will be asked to self-report recent falls, hospitalizations, emergency room visits and prescribed physical therapy (*outside of the REACH intervention that is described in more detail below). During the 6 month phone call, study staff will also conduct the Late Life Function and Disability Index (LLFDI)[15] over the phone. Since, the participants will still be participating in PT visits associated with the REACH intervention at the approximate 6 month time point the licensed physical therapist will perform the following performance based assessments during one of their clinic visits: SPPB[13] and ankle/knee ROM[29]. Information regarding the participant's performance will be shared with the participant for the purpose of: (1) providing feedback regarding functional performance changes, (2) enhancing participant motivation to continue to exercise and (3) promoting behavioral change for the adoption of a long term exercise habit.

Table 2: REACH Data Collection Time Table (*in addition to PT intervention)

Assessment	Estimated duration of testing (minutes)	Screen	Baseline	3 Month (Phone)	6 Month (in person & phone)	9 Month (Phone)	12 Month
Informed Consent	30	X					
MMSE	5	X					X
SPPB	10	X			X		X
Long Distance Corridor Walk	15	X					X
Demographic & Health History Questionnaire	5		X				
Technology Experience Survey	2						X
Physical Activity Item	1		X				
Katz Comorbidity	15		X				
Height/Weight & Vitals	5		X				X
Cognitive Testing Hopkins Verbal Learning Test Trail Making Digit Symbol Substitution Test	20-30		X				X
PHQ-9	5		X				X
History of Falls/Hospitalizations/ER/PT	5		X	X	X	X	X
Global measures of function & disability	2		X				X
LLFDI	30		X		X		X
Self-efficacy ABC scale Barriers Specific	15		X				X
Brief Pain Inventory	5		X				X
McGill Pain Map	5		X				X
Computer attitude scale	2		X				X
Grip Strength	5		X				X
Figure 8	5		X				X
Trunk Extensor Endurance	5		X				X
Range of Motion	10		X		X		X
Leg Strength/Power	20		X				X
Stair Climb	5		X				X
4-Step Stair Climb	5		X				X
Visit Total Time		**~ 1 hr**	**~ 2.5- 3 hr**	**5 min**	**~ 1 hr**	**5 min**	**~ 3.5- 4 hr**

Upon completion of the baseline assessment, participants will be assigned to either the Boston University or Spaulding Cambridge Outpatient Clinic training site to begin the REACH model of rehabilitative care. Participants will participate in an average of 8-10 clinic or home visits that can be increased up to 16 total visits as needed and interspersed over a 9-month period with a physical therapist licensed in MA. During the clinic/home visits, the assigned exercises are video recorded using the Wellpepper clinician version of the exercise application housed on an iPad mini. During and after the in-person visits, the PTs will remotely monitor exercise adherence, provide feedback, progress the exercise program and answer participants' questions using the chat feature of the Wellpepper application. PT support will be tapered over the course of this nine-month period as the participants become more successful at integrating exercise into their lives. Over the final three months of the study (months 10-12), subjects will continue to use the iPAD and the Wellpepper application to perform their exercises independently. The PT will not initiate communication with the participants; however, PT support will be available through the chat feature if participants have questions or concerns.

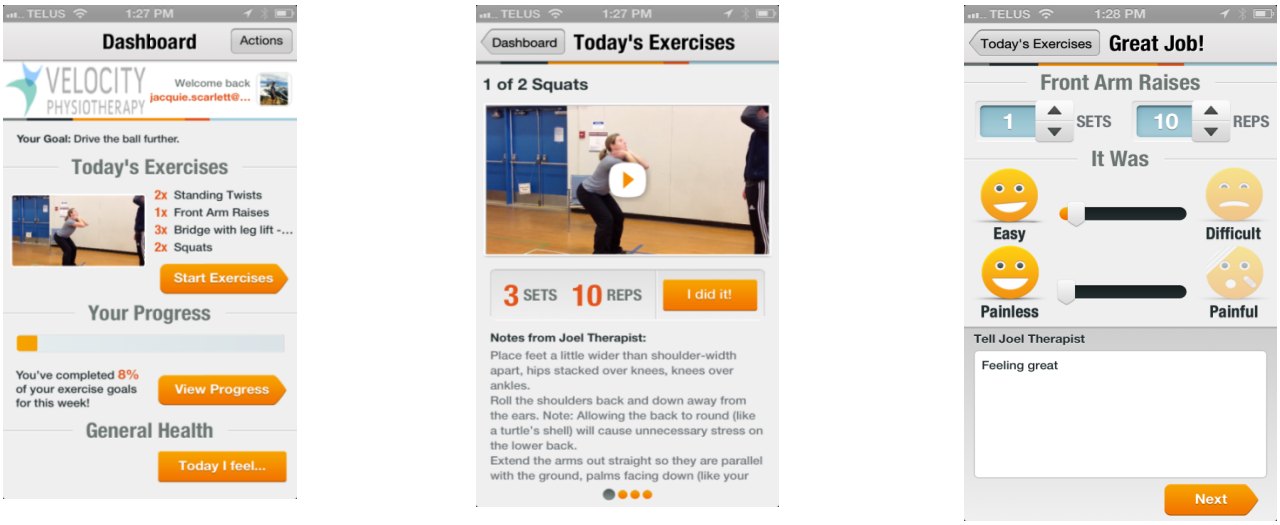
Participants are introduced to the Wellpepper iPad platform early in the intervention phase of the study to ensure they are adequately trained on proper use of the iPad and the exercise application. When the iPad is issued to the participant, their responsibilities will be reviewed again and they will be asked to sign a form indicating that they understand and agree with their responsibilities (see the submitted REACH iPad Information and Responsibility form). The participant will receive a copy of the form and the original form will be kept in a locked cabinet in the research office at the Cambridge study site. Each participant will understand that the iPad is to be returned upon treatment completion or early withdrawal. Participants will be told that there will be no financial consequences if the issued iPad is damaged, lost or stolen, but that they should handle the iPad carefully and keep it secured against theft.

Home visits are interwoven among the clinic visits to foster integration of the exercise program into daily routines with the support and guidance of a physical therapist. Optimizing exercise performance and strategizing overcoming barriers to exercising to facilitate long-term engagement in exercise will be a primary focus of the home visits. The specific number of visits and the location of the visits will be determined by the participant and the physical therapist.

During the initial PT sessions, the exercises are recorded using the clinician version of the Wellpepper exercise application housed on an iPad mini. These exercises are stored on the "cloud". The therapist downloads the participant version of the Wellpepper exercise app on an iPad mini that will be provided to each participant to take home. Each participant is instructed in how to open the exercise application and is able to view him/herself performing a subset of exercises that were uploaded by the PT (see Figure 1). The visual illustrations are accompanied with an audio component consisting of directions and cues from the PT that are tailored to each participant to ensure optimal technique when performing each exercise. The number of exercises prescribed at any one time is limited to 7 exercises as studies have shown that too many exercises contributes to poor adherence. [32] The participant views the video prior to performing each exercise and is able to replay or repeat as needed. Participants are instructed to implement the exercise program 5x/week for 30 minutes each session. Participant progress will be monitored and the ideal is that they exercise five times per week and engage in a walking program. However, we understand that this may

not be feasible for all participants. Therapists will be working with each participant to achieve this goal. The Technology Experience Survey will be administered to each participant by the study PT about a month after being issued the iPad to assess initial response and experience with the technology component of the exercise intervention.

Following completion of each exercise, the participant inputs the number of sets and repetitions completed and the level of pain or difficulty experienced (Figure 1). In addition, the participant can communicate with the PT using a chat feature to ask a question or seek clarification. Participant's exercise adherence is recorded and graphically displayed, allowing participants and the PT to track progress over the entire exercise program. The Wellpepper platform uses notifications (i.e. automated prompts and reminders) to motivate participants to complete their exercise programs at pre-scheduled times. Exercises are grouped according to degree of difficulty (bronze – easiest; silver – moderate; gold – most challenging level). Participants can view progress toward more challenging exercises and receive rewards (automated motivational messages) as they move from one level to the next. Each participant will practice using the application and performing the exercises over the course of the outpatient and home PT sessions.



Daily Exercises A video clip and instructions Communication back to the PT

Figure 1. Screen shots of the mHealth Application, PT Intervention

The PT will initiate and respond to each participant though the Wellpepper application over a 9 month period. The PT will view the dashboard remotely on the clinician version of the application to review each participant's performance and progress. In response to feedback from the participant regarding pain, level of difficulty and success, the PT will remove or add exercises. The PT will also upload motivational video content. These videos contain messages from the PT about the benefits of exercise. The PT also receives automated alerts when a participant leaves a message using the chat feature in addition to when participants have not performed their exercises for more than one week. PT support will be tapered over the course of this nine month period as the patients become more successful at integrating exercise into their lives. During months 10-12, participants will continue to use the iPad and the Wellpepper application

to perform their exercises independently without PT initiated support. Participants will be able to contact the PT through the chat feature if questions or problems arise during the final 3 months of the study.

Regarding home exercise compliance, the expectation is that the participant will comply with the assigned videotaped exercises, 5 days a week for 30 minutes each session throughout the duration of the 12 months that they are active in the study. Participants may exceed the recommendation if they so choose. The physical therapist will be monitoring participant home exercise compliance through the in-person visits and the Wellpepper App. While a 5 times per week exercise schedule is the ultimate goal, we understand that this may not be feasible for all participants or it may take time to work up to this frequency. In addition, we realize that illness or other events may interfere with regular exercise performance. Therapists will be working with each participant to help them achieve the 5 times per week goal. The PT will receive an alert when a participant has not performed their assigned exercises for more than one week. The PT will communicate with the participant by phone or through the Wellpepper App chat feature to determine the reason for non-compliance. Non-compliance with the assigned exercises will not be grounds for study dismal. We recognize that exercising once per week is better than not exercising at all. Our intent is to encourage increased exercise performance through the enhanced communication feature of the iPad and the Wellpepper app, not penalize a participant in any way for non-compliance.

The exercises are based upon standard rehabilitative techniques advocated for older adults. They will address attributes known to impact mobility such as leg strength, leg speed, trunk muscle endurance, limb flexibility, postural stability and cardiovascular endurance. Exercise specifics will target upright functional movements with progressive levels of difficulty and intensity with the goal of providing a safe, robust stimulus that is acceptable and most likely to produce improved function. A variety of exercises are included to guard against adaptation or boredom over the 12 month study. The exercises will utilize limited equipment and lend themselves to safe, independent performance in the home environment. See attachment, "Sample Exercises for REACH Study". Each patient will be assigned up to seven exercises at any given time. Exercises will be progressed or modified in response to participant feedback. In addition, the participants will be instructed in a progressive walking program that will be monitored via participant report relative to the frequency and time spent in the activity. The uniqueness of this interventional protocol lies in the method of physical therapy delivery: 1) limited face to face treatment sessions spaced over a longer period of time 2) remote monitoring for an extended period 3) enhanced exercise performance with provision of videos/communications via the Wellpepper application.

As mentioned in our "*Background and Significance"*, our collaborators at Brandeis have evaluated health care utilization in many studies, including cardiac and vision studies. They will utilize similar methodology and access the Medicare claims data for all of our participants. More details about their data access and management are provided later within the *"Monitoring and Quality Assurance"* section. The claims data requested will include the one year time period during which the participant is active in the study as well as the 6 months following their one-year assessment. The additional 6 months allows for an appropriate "run-out" to account for the discrepancies between when health care utilization (such as an Emergency Room visit) occurs versus when the event appears in the claims data. The Heller School at Brandeis University has developed a comprehensive information security policy and built a secure data network to house sensitive

data, including Medicare claims. Brandeis has a long standing relationship with the Center for Medicaid and Medicare Services and houses a large volume of administrative claims that are used for a variety of evaluation and development activities.

We will not be recruiting a control group, but selecting a matched group of participants from the Boston RISE cohort study as controls for aim 1, which focuses on functional outcome measures. The Boston RISE cohort study is a longitudinal cohort study evaluating mobility decline among older primary care patients. Boston RISE contains all of the primary and secondary outcome measures of the study. For outcomes utilizing Medicare Claims data, data is only available for a geographic region encompassing a minimum of 250,000 individuals. Thus, for aims 2 and 3, our collaborators at Brandeis will also identify a second matched control group based upon scientifically relevant data elements, such as age, gender, race, chronic conditions, etc.

VI. BIOSTATISTICAL ANAYLSIS

This quasi-experimental study will use a difference-in-difference (D-in-D) approach to assess the impact of mHealth supported PT compared to treatment as usual. We will use a strong matching algorithm, such as exact matching on age, sex and the propensity to participate in treatment, to ensure comparability on observable characteristics between treatments and control group members. For this study the propensity score serves as a form of data reduction, taking many diagnostic flags and reducing them to a single covariate. The basic model estimates the effect of treatment on the change in outcome between baseline and follow-up: $y_{it} = \beta_0 + \beta_1 treatment_i + \beta_s post_{it} + \beta_3 treament_i * post_{it} + \gamma controls_{it} + \alpha_i + \varepsilon_{it}$ where y_{it} is cost, $\gamma controls_{it}$ are patient socio-demographic characteristics and $treament_i$ is a 0/1 variable indicating treatment status. β_3 is the parameter of interest, capturing the joint effect of being in the treatment group at time 2. For the first study object, this model can be extended to include repeated measures of functional status over time. This is a proof of concept pilot study and thus we may not be powered to observe statistically significant differences among our outcomes between groups. However, the effect sizes will be utilized to inform the design of larger trials. For example, meaningful differences in the LLFDI have been published by our group and will help interpret the magnitude of treatment effects observed.

VII. RISKS AND DISCOMFORTS

Common risks and discomforts

All of the proposed measures have been validated among older adults of varying health status. The staff has extensive experience conducting these measures safely among older adults with mobility problems. Many of the assessments for this study involve minimal risk to the participants such as questionnaires, measures of leg strength and power using a double leg press machine, measurement of core muscle weakness, performance of simple balance testing, standing up from a chair, walking eight feet, and balancing with feet in a tandem position. Thus the risks are expected to be similar to those risks involved in participating in a physical therapy program, standing, stair climbing, walking, and activities of daily living. The balance and walk tests could potentially result in a fall, but the protocol includes careful personal monitoring during the

testing. Lastly, there is the rare possibility that the Long Distance Corridor Walk could precipitate cardiovascular symptoms. A research assistant (RA) will prepare the course, provide instructions and walk with the participant. In addition, the RA will take vitals before and after the test. Testing may be terminated if participants exhibit significant physical symptoms of shortness of breath, angina, feeling faint or leg pain during or after the test. This test has been used successfully in the context we propose in many population-based studies of older adults as well as the aforementioned LIFE study.[11]

Risks and discomforts related to the exercise intervention include muscle soreness associated with resistance training. This is a natural, expected phenomenon that occurs with rehabilitative exercise, particularly when a person has been inactive for a period of time. This type of soreness is expected to be transient. Other risks and discomforts include the possibility of muscle strain associated with improper technique or attempting to work with a resistance that is not appropriate. As with any physical activity, there is a risk of a cardiovascular event, such as abnormal blood pressure, fainting, irregular heartbeat, or cardiac ischemia and heart attack.

Uncommon risks and discomforts

The criteria for discontinuing a subject's participation include the subject's request, as well as any life-threatening or potentially disabling event. Examples of these events include syncope, an injurious non-accidental fall, hemodynamic collapse, stroke, transient ischemic attack, dysrhythmia, angina, myocardial infarction or hospitalization for acute illness. The risk for these adverse events is very low and no different than what would be encountered in standard outpatient geriatric rehabilitative care. The BU and SCOC sites care for older adults on a daily basis and the therapists employing care as part of the study are very experienced clinicians. Consistent with standard operating procedures for safety, if the participant experiences an acute life-threatening event, they will be initially assessed by the study PT and if immediate urgent care is required 911 will be contacted. Any chronic, or non-life threatening event will be discussed with the Principal Investigator, a Physiatrist with expertise in Geriatric Rehabilitative Care who is either on site or reachable by phone. Additionally, we will have a study safety officer. This will be a clinician with Geriatric expertise that will adjudicate the safety for continued participation of any individual experiencing an adverse event. All events will be recorded and included in the database and reported to the IRB. Any participant who develops adverse events during the conduct of study protocols will be given immediate medical care under the direction of the PI. They will be referred to their primary care physician for ongoing care. It is also possible that the Safety Officer and PCP will decide a participant should temporarily stop participation rather than withdraw. In such cases, the PCP will need to grant clearance following recovery from illness/injury and prior to prior to participants resuming their participation in the study.

VIII. POTENTIAL BENEFITS

Participants may experience the benefits of rehabilitative care and regular exercise. These benefits may include: improvements in muscular strength/power, postural stability, flexibility and endurance and therefore activities of daily living that utilize these attributes. In addition, participants may experience positive psychological benefits of exercise and increased physical activity such as mood enhancement, stress

reduction, and increased self-confidence. Lastly, participants might develop a habit of regular exercise that would produce health benefits long after study completion.

The results of this project will have great relevance for the care of older adults. The project has the potential to inform several fields within healthcare, including: primary care, rehabilitative care and health services research. The research may improve the prevention and treatment of mobility decline in older adults, which in turn, may decrease healthcare costs at large.

IX. MONITORING AND QUALITY ASSURANCE

Research staff and physical therapists will be required to demonstrate competence in performing data collection. Training will be based on standardized materials developed for the study. Training will be provided by the PI and his lab manager who have experience in conducting all proposed study measures. Under the supervision of the Principal Investigator and the Research Coordinator, study staff will assess all data collection forms for completeness and accuracy as well as protocol compliance on a weekly basis. Data will be entered directly into and stored within a password protected, HIPAA compliant web-based application hosted by Partners HealthCare Research Computing, Enterprise: REDCap. Each participant will be assigned a study ID number. All data will be coded by study ID only. No personal identifiers will be retained in the outcomes database.

The master list linking ID numbers to subject identifiers will reside in a separate REDCap database. This tracking database will contain patient contact information and will be used to (a) document all contacts with participants from initial scheduling calls, to study visits, through the final follow-up including telephone follow-up; (b) prompt staff to contact participants to schedule follow-up visits (c) generate periodic reports on response rates and success of follow-up contact efforts. Additional study logs tracking communications with participants, study progress and adverse events will also be stored on Syncplicity. Syncplicity is Partners-approved data storage and file sharing system. Only study staff will have access to these files on Syncplicity. We will use Syncplicity to share data with our collaborators at the Center for Neurorehabilitation at Boston University College of Health and Rehabilitation Sciences: Sargent College and the Heller School at Brandeis University.

Exercise videos and communications with research staff via the Wellpepper application will be identified with the same subject ID. Wellpepper runs in a virtual private cloud on Amazon Web Services using MySQL and MongoDB databases. PHI is encrypted on the disk using AES256 encryption. Data is also encrypted over the wire using HTTPS (port 443). Wellpepper, Inc has filed the Vendor Information Security Plan (VISP) with Partners HealthCare. Approval is pending for use of the Wellpepper app for compliance with safety in handling of personal information and compliance with HIPPA regulations. Similarly, Partners Information Systems will prepare all of the iPad minis so that they meet Partner's IS security standards and can be disabled if a device is lost or stolen. Participants will be instructed to utilize cellular data over the course of their study participation and use of Wellpepper. They will be cautioned against less secure networks such as wireless networks that are not password-protected.

This consent form will be stored in a locked filing cabinet to which only study staff have the key. Identifying information about a subject will not be used during the discussion, presentation, or publication of any research data.

The Heller School at Brandeis University has developed a comprehensive information security policy and built a secure data network to house sensitive data, including Medicare claims. All data is logged and tracked from the point of arrival to the point of data destruction. We house all original media (which in this case will come from CMS on an encrypted hard drive) with the original files in a locked cabinet. New hard drives are logged in physical media tracking book. A copy of the data files will be placed inside the Heller School secure domain in a folder with limited access (only people who sign the DUA can be given permission to the folder). All analytic files and SAS programs will be stored within the Heller School secure domain. Aggregated results will be exported using a sFTP. All statistical programming and project staff sign a code of personal conduct and agree to follow the rules of the Heller School and the governing DUA (regardless of institution). In the case of CMS paid claims, we cannot take any results out of the secure domain with cell sizes below 12. Both the programmers and site PI, Jennifer Perloff, make sure no results that violate this rule are taken outside of the secure domain. When the project is over the original files and aggregate data sets are destroyed using a triple swipe method that has been approved by CMS. The certification of destruction (COD) is sent to CMS and logged in the Heller School DUA tracking system.

The only identifier in the Medicare claims data will be a person level 'link key'. This is a fake ID created for the CMS Chronic Condition Data Warehouse and is different from the beneficiary's Medicare number or Social Security Number. This number is on all claims for the individual. When we destroy the claims data, we destroy the person identifier. There are no other cross-walk files. The only other sensitive information is dates of services.

For CMS projects, data use is governed by the CMS Data Use Agreement (DUA). CMS has a standard DUA that limits the team to the specific project described in the Privacy Board packet. The data cannot be used for any other purpose. The PI of the project is responsible for enforcing this and all other data security requirements.

The Principal Investigator, Dr. Bean, will be responsible for monitoring the data to ensure participant safety. Participants will be asked to contact study staff with any adverse symptoms. The PI will speak with subjects to make a determination as to the seriousness and nature of the event and what appropriate treatment should include. Study staff will discuss participant safety and any issues that arise at weekly meetings with the PI and our collaborators at BU, or more frequently as needed. Dr. Bean will review the safety and progress of the study with collaborators on a monthly basis.

Safety monitoring procedures will also be reviewed by a Safety Officer (SO). The SO will review the study protocol and safety-monitoring plan with all study staff prior to the start of the study. The SO will subsequently meet with study staff as needed to review standardized reports addressing subject symptoms and deviations from the study protocol. Biannual meetings will be organized with the SO to review the

progress of recruitment and retention of subjects, compliance with the protocol, and operating procedures with study staff.

The Safety officer will be Sanja Percac-Lima, MD, PhD, a clinician researcher with expertise in geriatrics and primary care and credentialed within the Partners Healthcare System. She will be readily accessible for urgent consultation, since she is from the local area.

The study staff, upon discovery, will review adverse events in keeping with Partners Human Research Policies. All adverse events/serious adverse events will be reported to the IRB by telephone and in writing according to PHS guidelines. Standardized adverse event monitoring forms will be completed. Non-serious adverse events will be continually tracked and included in the annual report to the IRB.

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