DETAILED RESEARCH PROTOCOL

February 5, 2021

A. PURPOSE: State briefly the purpose of the study; usually this will include the hypothesis, which is to be tested.

Many older adults experience increased difficulty moving about their communities and performing one or more of their basic activities of daily living (ADLs) after undergoing a hospitalization. The purposes of this study are (1) to test the effectiveness of a mobility intervention, compared to usual care, on change in mobility after hospitalization; (2) to determine the impact on one-year outcomes (such as nursing home placement); and (3) to identify which patients benefit the most from the intervention. Ultimately, our goal is to improve recovery after hospitalization and reduce disability in hospitalized patients.

B. BACKGROUND: Describe past studies and, if relevant, experimental or clinical findings which led to the plan for this project. This must be succinct and comprehensible without extensive reference to other material. A few pertinent references may be cited. In some cases -- e.g., as in cases where earlier studies have produced conflicting evidence -- it will be necessary to cite these studies and explain how it was decided to rely on one side or the other. For studies designed to compare or evaluate therapies, there should be a statement of the relative advantages or disadvantages of alternative modes of therapy. This section should ordinarily be less than one page long; however, when necessary it may be longer.

Low mobility, defined as mobility limited to bed rest or bed to chair transfers, is common during hospitalization.[1] Our prior work has shown that hospitalized older adults spend greater than 80% of their hospital stay lying in bed and less than 43 minutes per day walking, despite being cognitively intact and able to walk on hospital admission.[2] Low mobility is associated with adverse outcomes including functional decline, nursing home placement, and death, even after controlling for illness severity and comorbidity.[1] Functional disability after hospitalization is common, and up to one-third of those who experience a decline do not recover.[1,3] Mobility is a key component of functional disability. Decreases in functional ability are not restricted to older adults; patients in their 5th decade have been shown to experience declines in strength, pulmonary function and submaximal exercise tolerance after five days of hospitalization.[4] Intervention studies examining the effect of encouraging mobility during hospitalization are sparse and typically measure outcomes in hospital or in the 30 days after discharge.[5-7] While data on the long-term impact of a hospital mobility program is lacking, evidence from observational studies reveals that higher levels of hospital mobility are associated with reduced nursing home use and mortality.[7,8] In our recent VA-funded pilot randomized controlled trial (RCT), we showed that cognitively intact older veterans who received a mobility intervention had higher community mobility, measured with the UAB Life-Space Assessment (LSA), one month after hospital discharge compared with the usual care group.[9] However, this preliminary work was restricted to one month of follow-up of veterans who were cognitively intact and ≥ 65 years of age. A number of important gaps remain in our understanding of the impact of a hospital mobility program: 1) hospital mobility program studies have not used a randomized controlled trial (RCT) design to evaluate the impact; 2) the actual number of steps and time spent walking by participants has not been measured; 3) outcomes beyond 30 days' post-discharge have not been examined; and 4) characteristics of patients most likely to benefit from this type of intervention have not been identified.

For this high-impact study, we propose to use a stepped wedge cluster randomization design on five VA hospital wards and at UAB Hospital on four hospital wards to compare a mobility program (MP) to usual care (UC) among a cohort of veterans and other patients age ≥ 50 years. We will examine pre- to post-hospital mobility and adverse outcomes including functional decline, nursing home admission, emergency department (ED) visits, hospitalization and death in the mobility program (MP) and usual care (UC) groups in the year after hospital discharge. The primary outcome of mobility will be measured by the UAB Life-Space Assessment (LSA).[10-13] Secondary measures of mobility will include self-reported ability to walk ¼ mile and drive a car, as described by Gill, et al.[14] We will identify patient-specific characteristics that modify the effect of the mobility intervention on post-hospital mobility and adverse outcomes to determine which hospitalized patients are most likely to benefit from this intervention.

C. SPECIFIC LOCATION OF STUDY: Where will the research take place? (When other institutions are involved it may be necessary to secure the approval of their Institutional Review Boards.)

Patients admitted to the medical wards of the BVAMC (4A, 4B, 5A, 5B, and 6B) and to medical wards at UAB Hospital (3 Hospitalist Units, and the Tinsley Harrison service) will be eligible to participate in this study. A brief screening interview will be conducted with the ward team to identify patients who meet eligibility criteria; if eligible, consent to interview the patient will be requested from the physician. Interviews to further determine eligibility and to obtain consent will be conducted in patient rooms. While a participant is hospitalized, study assessments, tests, and interventions will be conducted in patient rooms or, for walking sessions and gait speed assessments, in the hallways of the BVAMC or UAB Hospital. Post-discharge assessments will occur over telephone or, in the rare event that a patient has been re-hospitalized at BVAMC or UAB Hospital, in the participant's hospital room. Telephone assessments will be conducted from rooms 8211, 8223, 8224 and 8218 in the BVAMC. Study staff will conduct these assessments from these private offices with the door closed.
Hard copy study records for recruited Birmingham VAMC veterans will be secured in locked file cabinets within locked offices in rooms 8211, 8223, 8224 and 8218 in the BVAMC, with access and key distribution limited to authorized staff. Electronic records will be stored on a VA secure server; only authorized project staff members will have access to the data and the drives/directories on which they are stored. No PHI will be removed from the VA protected environment, nor will any PHI be transmitted electronically. De-identified data sets (data excluding HIPAA identifiers) may be emailed to study statisticians approved by the VA IRB to their UAB email accounts. De-identified data will be stored on secure servers maintained by UAB and accessible solely to study staff on a need-to-know basis. Data sets will be reviewed by the BVAMC Privacy Officer or their representative and will approve all data transfers to UAB. Statisticians will return all analyses to the study PI at BVAMC, and VA data will be deleted from the UAB server when analyses are complete.

Patients admitted to UAB Hospital will also be eligible to participate in this study. Screening and identification of eligible patients will follow the same procedures as at the BVAMC. UAB participants' assessments will occur at UAB; hard copy and electronic records of UAB patients will be stored within UAB facilities as approved by the UAB IRB.

D. PROBABLE DURATION OF PROJECT: This should be the estimate for the entire study. (IRB reapproval is required at least every year as long as the study is continued. In specific cases, more frequent reapproval may be required.)

Active recruitment of participants is expected to last 36 months; all participant assessments are anticipated to be completed in 48 months. Data interpretation and manuscript preparation are anticipated to take two years, for a total estimated study duration of six years.

E. RESEARCH PLAN: This is an orderly description of the intended procedures as they directly affect the subjects. There need not be a detailed account of techniques that do not affect the human subject. Include length of time for various procedures and frequency of repetition, any manipulation that may cause discomfort or inconvenience, and plans for follow-up. If questionnaires or non-standard rating scales are to be used, include copies. (If the rating scale is a standard and familiar one, it is only necessary to name it and no copy need be submitted.)

Statistical considerations: Studies which cannot be expected to answer the questions posed by the research, because of small numbers, low statistical power or other major flaws in research design, can provide no benefit to the subject and cannot justify even the smallest degree of subject inconvenience, let alone risk. Therefore, except for pilot studies, which are clearly designed to further the development of a more extensive research protocol, this section should include a) the number of subjects expected to enter the study, b) a

statement about the statistical power of the study to test the major hypothesis, and c) a summary of the plans for statistical analysis.

Screening, Recruitment & Consent

258 participants, age ≥ 50 years admitted for any medical illness (e.g. pneumonia, heart failure, COPD exacerbation, or other medical (versus surgical) indication for hospitalization) to either one of the five medical wards of the Birmingham VAMC, or to one of four units at UAB Hospital, will be recruited within 48 hours of hospitalization, and followed throughout their hospitalization and for 12 months after hospital discharge.

Within 48 hours of admission, patients meeting age and ward criteria for the study will be identified daily (as staffing allows) by reviewing the electronic medical record (EMR). Study staff will then contact the medical physician team assigned to the patient and will conduct a brief screening interview with the team to assure the patient meets inclusion and exclusion criteria.

After speaking with the medical team, study staff will meet with eligible patients in their hospital rooms to briefly inform them about the study and ask if they are interested in hearing more details. If a patient expresses interest, the study will be explained and questions answered. Patients will be told they will be visited three times a day and have several assessments done. They will be informed they will be assigned to either MP or UC depending on their ward assignment. All patients will be informed that they will wear a StepWatch®, which counts the steps they take, and that they will be followed with periodic telephone calls for one year after discharge. If the patient is still agreeable, the Mini-Cog[15,16] and CAM[17] will be administered to aid in determining the patient's decision-making capacity.

If the patient is deemed cognitively intact based on the Mini-Cog and CAM scores, the consent process will continue. If the patient consents, a brief physical screen will be administered: Patients will be asked if they were able to walk across a small room in the 2 weeks prior to admission, and a progressive functional assessment will be administered in which the patient will be asked to sit and then to stand. If the patient successfully completes the physical screening, the patient will be randomized. If a patient is deemed to be unsafe based on the functional assessment within the 36-hour recruitment window, then a referral to physical therapy will be sought from the physician and the patient will not be randomized nor take part in further study activities.

If the patient scores < 3 on the Mini-Cog or > 0 on the CAM, the consenting individual will consult with the patient's physician. Study staff will inform the physician of the scores, and ask the physician to determine whether the patient has decision-making capacity. If the physician indicates that the patient does indeed have decision-making capacity, the consent process will continue. If the physician deems that the patient does not have decision-making capacity, study staff will ask the physician to enter a EMR note documenting that the patient does not have decision-making capacity, if such a note or document does not already exist in the EMR. Once such documentation has been created or identified in either the EMR or VISTA, study staff will review the EMR and/or Vista to identify the appropriate Legally Authorized Representative (Power of Attorney, Legal Guardian, or Next of Kin). Once identified, the LAR will be contacted in person at the bedside or via the contact information in the electronic records and informed of the study. If the LAR is contacted on the phone, the study will be briefly described and the LAR will be asked if they are interested in hearing more details. If the LAR expresses interest, the study will be more fully explained and questions answered. Consenting staff will ask if the LAR will be physically present in the BVAMC before the patient has been hospitalized for 48 hours (see inclusion/exclusion criteria). If so, consenting staff will attempt to meet with the LAR at the bedside at a time convenient for the LAR. Consenting staff will meet the LAR and the patient, briefly inform them about the study and ask if they are interested in hearing more details. If a patient expresses interest, the study will be explained and questions answered. Patients will be told they will be visited three times a day and have several assessments done. They will be informed they will be assigned to either MP or UC depending on their ward assignment. All patients will be informed that they will wear a StepWatch®, which counts the steps they take, and that they will be followed with periodic telephone calls for one year after discharge. If the patient and LAR are still agreeable, the consent process can continue. If the patient and LAR consent, a brief physical screen will be administered as described above.

If the LAR is first contacted by visiting the patient's room, then consenting staff will describe the study to the LAR and the patient; if both the LAR and the patient express interest, then the screening process will proceed, as described above.

Identification, contacting, and consenting of potential UAB participants' LARs will follow UAB procedures and guidelines.

Figure 1. Screening Flowchart (BVAMC)

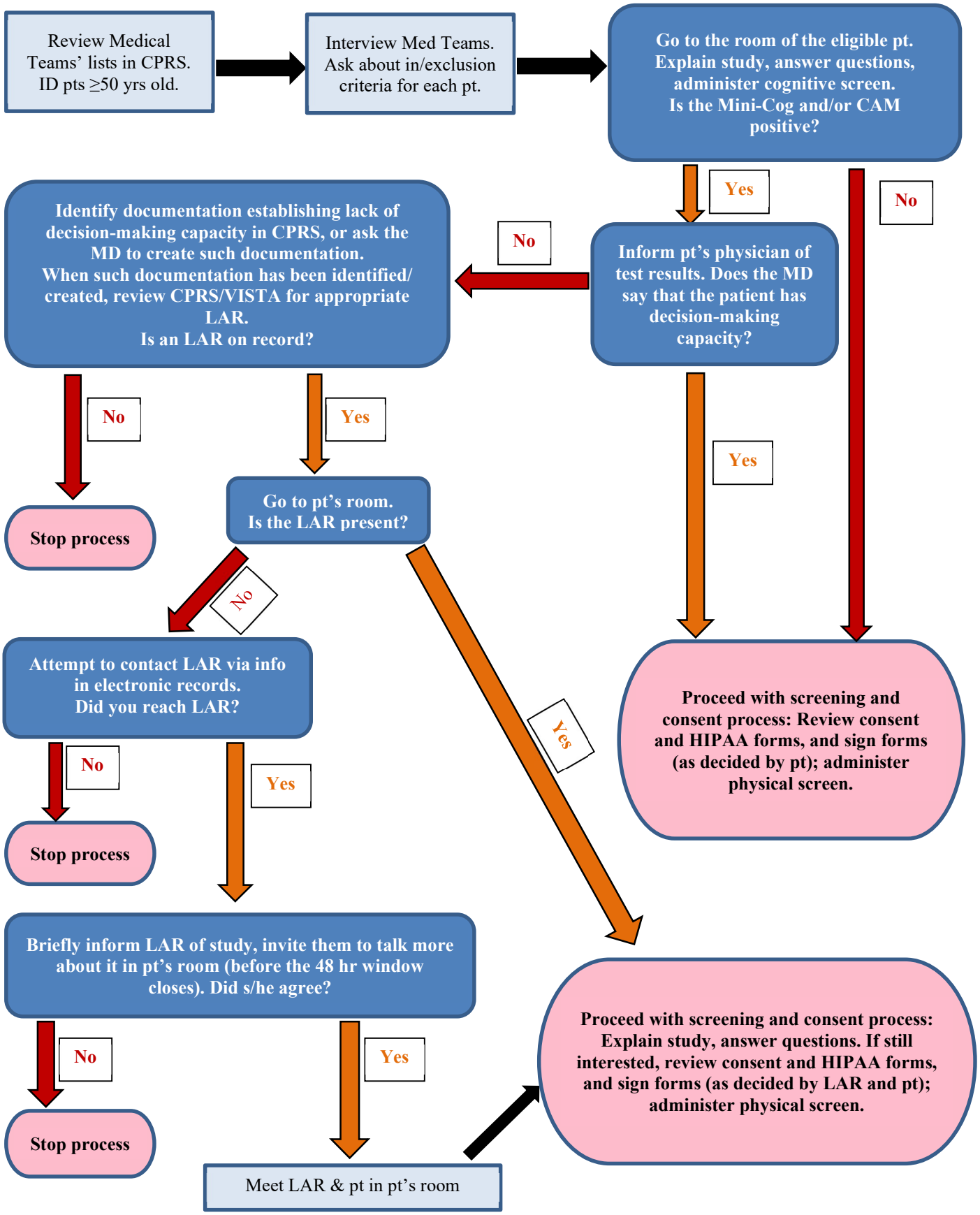

TABLE 1 Screening Procedures		
Procedure	**Length of Time Required of Participants**	**Frequency of Repetition**
EMR review	0 minutes (performed by staff)	Once
Screening interview with medical team	0 minutes (performed by staff)	Once
Mini-cog	5 minutes	Once
Confusion Assessment Method (CAM)	<1 minutes	Once
LAR Identification, as necessary	0 minutes (performed by staff)	Once
Ambulation question	<1 minutes	Once
Progressive functional assessment (sit, stand)	5 minutes	Once
Total	*<12 minutes*	

In-Hospital Procedures

Baseline

Baseline Assessments: After consent, a number of baseline assessments will be administered by study staff using standard testing procedures. These assessments may be administered over two or more sessions: One set of assessments is to be administered on Day 1 of the study and takes a little more than 20 minutes to complete; the second set maybe be completed at any time during hospitalization, and takes about 25 minutes to complete. (See Tables 2 and 3). Study staff will be sensitive to the participant's comfort level, and may postpone or eliminate any assessments if the participant expresses fatigue. Staff will also collect demographic information, as well as contact information for post-discharge assessments.

Depression Assessment: Patients will be administered the Patient Health Questionnaire (PHQ) – 2, which is a 2-question screening tool for depression.[18] Surrogate responses will not be solicited for this assessment. A positive answer to either question is considered a positive screen and will lead the interviewer to complete the PHQ-9.[19] Scores for PHQ-9 range from 0 – 27, with higher scores indicating higher levels of depression. If a patient is noted to have a PHQ-9 ≥11, indicating moderate depression, the patient's BVAMC or UAB physician will be notified by study staff.

TABLE 2 Baseline Assessments, Part 1: to complete on first day in the study		
Procedure	**Length of Time Required of Participants**	**Frequency of Repetition**
Condensed Memorial Symptom Assessment Scale (CMSAS)	5 minutes	Once
Katz ADL	3 minutes	Once
Lawton IADL	3 minutes	Once
UAB Life-Space Assessment	5 minutes	Once
Gait speed	5 minutes	Once
Step count monitoring (via StepWatch)	0 minutes (worn while in hospital)	Continuous during hospitalization
Total	*21 minutes*	

TABLE 3 Baseline Assessments, Part 2: to complete prior to hospital discharge		
Procedure	**Length of Time Required of Participants**	**Frequency of Repetition**
Ability to walk/drive	1 minute	Once
Fall history (previous 4 weeks)	1 minute	Once
ED visit & hospitalization history (previous 6 months)	1-6 minutes	Once
PHQ-2 (& PHQ-9, as appropriate) *(depression screening tool)*	2 – 6 minutes	Once
Lubben Social Network Scale	7 minutes	Once
EQ-5D-3L *(quality of life index)*	5 minutes	Once
Total	*17-26 minutes*	

Mobility Monitoring: The StepWatch® mobility monitor by Modus Health is a small (70 x 50 x 20 mm) waterproof, self-contained accelerometer pedometer that is attached loosely to the ankle via a Velcro strap and captures number of steps taken and when the steps were taken.[20] A StepWatch® pedometer will be applied to the ankle and will be worn for the duration of the in-hospital portion of the study by all participants. All patients in the study will wear a StepWatch to allow comparisons of mobility achieved by both the Mobility Program (MP) and Usual Care (UC) groups. Our team has extensive experience with the StepWatches, having used the device in our previous VA Merit study at the BVAMC. Flyers with the study's pager number will be placed on or near the whiteboard located in all patient rooms, and nursing will be informed of the patient's participation in the study and asked to call study staff if there are any questions about the pedometers. The pedometers will be removed as needed if they interfere with routine care, such as MRIs or other procedures.

Figure 2: StepWatch

The StepWatch pedometer is programmed and downloaded with a standard computer via a docking station that plugs into a USB port. The device itself provides no feedback to the patient and **no PHI will be stored on the device**; the only data recorded is the number of steps per minute per day (see Figure 3, sample output from StepWatch). As no PHI is stored on the device, encryption is not necessary. Data cannot be accessed without the docking station and software provided by Modus Health. We have used this hardware and software with no incidents in our previous study at BVAMC (IRB Study ID #01332). For our new study, an updated version of the software will be necessary; the license will be held by the VA, and will be paid for by VA Merit grant funds. All data will be stored on secure server

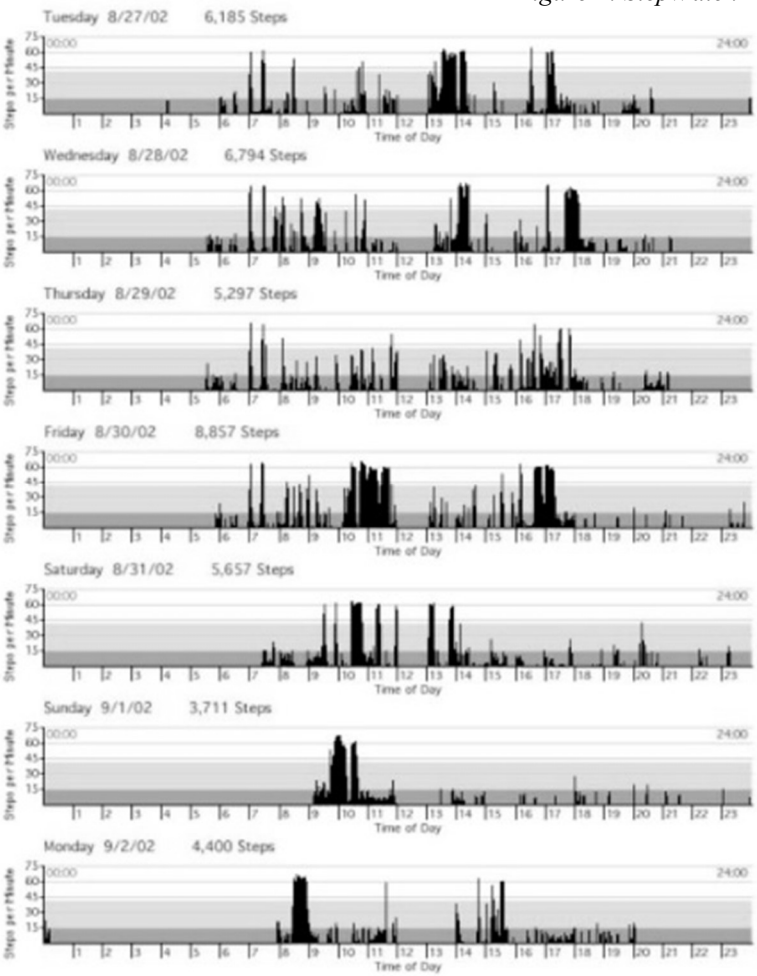

Figure 3: StepWatch data output

(birresearch), accessible only by authorized study staff. No data will be stored in temporary files or on hard drives.

Randomization

Participants will be assigned to MP or UC using cluster randomization based on hospital ward at both the Birmingham VAMC and UAB Hospital. At study initiation, all five wards at the Birmingham VAMC will be assigned to the usual care group. Every 5 months a randomly chosen ward will shift from receipt of usual care to the mobility program (See Figure 4). At UAB Hospital, all four wards will be assigned to the usual care group at study initiation, which is expected to be at month 24 of the study. Every 3 months a randomly chosen study ward will shift from receipt of usual care to the mobility program (See Figure 4A). MP patients will receive three daily visits for progressive ambulation; the UC group will receive three daily "friendly visits." Both groups will receive routine medical care as it is currently provided, including the provision of physical therapy if ordered by the physician.

Figure 4: Stepped Wedge Cluster Randomization with 5 VA Hospital Units. The order in which each unit receives the intervention is randomized, with staggered implementation. By conclusion of observation, all units have received the intervention. MP (grey bars) = Mobility Program initiated and continued on ward unit.

	Time (in months)						
Unit	1/18/17-6/18/17	6/19/17 – 11/18/17	11/19/17 – 4/18/18	4/19/18 – 9/18/18	9/19/18 – 2/18/19	2/19/19 – 7/18/19	7/19/19 – 12/31/19
A	Control	MP					
B	Control		MP				
C	Control			MP			
D	Control				MP		
E	Control					MP	

Figure 4A: Stepped Wedge Cluster Randomization with 4 Hospital Units at UAB Hospital. The order in which each unit receives the intervention is randomized, with staggered implementation. By conclusion of observation, all units have received the intervention. MP (grey bars) = Mobility Program initiated and continued on ward unit.

	Time (in months)					
Unit	5/1/18 – 7/31/18	8/1/18 – 10/31/18	11/1/18 – 1/31/19	2/1/29 – 4/30/19	5/1/19 – 7/31/19	8/1/19 – 12/31/19
A	Control	MP				
B	Control		MP			
C	Control			MP		
D	Control				MP	

Daily visits

Mobility Program Group (MP):

MP patients will participate in a program of progressive walking and transfer training up to three times a day, seven days a week (as staffing allows) throughout their hospital stays. MP participants will begin with assisted sitting, then standing, progressing to weight shifting and stepping in place, and then to walking as tolerated. The level of mobility recommended to the MP participant by study staff will be dependent on the individual participant and will incorporate the activities patients were deemed able to do independent of cueing or assistance during each walking session. For example, if a participant could stand at the bedside independently, but required standby assistance for walking, the participant would be encouraged to sit on the side of the bed for meals and stand up beside the bed for 3-5 minutes every two hours as able. To assure participant safety, participants will be instructed not to attempt to transfer or walk without nursing assistance if deemed to be dependent in these activities. The participant and study staff will set daily goals regarding the amount of time the participant will aim to spend out of bed and what level of activity the participant will work on independently. For example, a participant may decide that s/he would like to try to walk to the nurse's station or to the elevators and that activity would be attempted with the help of study staff. We anticipate that each session will take 15 - 20

minutes; the overarching goal is to progress the participant toward walking as tolerated. A rolling walker or rollator will be provided for walking as needed. This ambulatory device may be left in the room if participants wish, and if they demonstrate that they are able to use the device safely and independently.

During each walk, participants will be asked to rate their exertion using the Perceived Exertion Index (PEI), a simple rating scale ranging from 1 (not tired at all) to 10 (maximal fatigue), in order to take into account the effort and fatigue they may experience while walking. They will be encouraged to walk at a pace that is comfortable. If they indicate that their PEI is higher than 6, they will be asked to stop and rest.

While MP participants will be encouraged to walk during each study visit, they may refuse any or all sessions. Study staff will attempt to make several visits for each scheduled walk. If a participant is away at a test or procedure, or busy with another healthcare provider, staff will return at a later time to walk with the participant.

Usual Care Group (UC):

UC participants will receive three times a day "friendly visits," seven days a week as staffing allows, to control for the daily attention that MP patients receive. The "friendly visits" will be approximately 15 - 20 minutes in length. Like the MP group, the UC group will wear a StepWatch throughout their hospital stay. These data will be used to document the amount of mobility attained by the UC group, but will not be shared with UC patients. If a participant is away at a test or procedure, or busy with another healthcare provider, staff will return at a later time to visit with the participant. Like MP participants, UC participants may refuse any or all visits.

Both MP and UC Groups:

Additional data collected for both groups will include daily physician mobility orders, as well as physical barriers to patient mobility such as IVs, oxygen tubes, etc. Also, as noted earlier, all participants will continue to wear the StepWatch, except in the unusual event that it should interfere with care (such as MRIs), or if the participant should request its removal.

A questionnaire, the Acute Care Mobility Assessment (ACMA), has been developed for use at the bedside as an assessment of mobility. In a small pilot study at the Birmingham VAMC, we compared results from wireless mobility monitors to patient's and nurses' ACMA scores and found a correlation of 0.62 for both patients and nurses. We wish to continue our validation of this simple instrument in conjunction with usage of the StepWatches. All patients will complete this 5-minute assessment each day they are in the hospital.

TABLE 4
Daily while in Hospital: Mobility Program (MP) Group

Procedure	Length of Time Required of Participants	Frequency of Repetition
Mobility session (walks w/ goal setting & safe ambulation review)	20 minutes	Up to 3x/day
Acute Care Mobility Assessment (ACMA)	5 minutes	1x/day
Perceived Exertion Index	<1 minute	during walks, up to 3x/day
Daily mobility orders & barriers	0 minutes (performed by staff)	1x/day
Step count monitoring (via StepWatch)	0 minutes (worn while in hospital)	Continuous during hospitalization
Total	*Up to 65 minutes per hospital day*	

TABLE 5 Daily while in Hospital: Usual Care (UC) Group		
Procedure	**Length of Time Required of Participants**	**Frequency of Repetition**
Friendly visit	15-20 minutes	Up to 3x/day
ACMA	5 minutes	1x/day
Daily mobility orders & barriers	0 minutes (performed by staff)	1x/day
Step count monitoring (via StepWatch)	0 minutes (worn while in hospital)	Continuous during hospitalization
Total	*Up to 65 minutes per hospital day*	

Transfer to ICU/CCU or Safe Harbor/Palliative Care Unit

There is a possibility that a participant may be transferred to ICU or CCU after enrollment but before discharge. Should this occur, activities requiring the participant's active involvement will cease (e.g., friendly visits, mobility sessions, questionnaires), but chart reviews will continue. Post-discharge follow-up assessments will be administered per protocol after discharge from ICU/CCU.

There is a very slight possibility that a participant may be transferred to Safe Harbor or the Palliative Care Unit after enrollment but before discharge. Should this occur, the participant will be offered the opportunity to withdraw from the study, or to remain in the study but allow study staff to continue with chart reviews. No study activities will occur in Safe Harbor or in the UAB Hospital Palliative Care unit.

In some unique circumstances, the PI may judge it not in the participants' interest to continue with the study. In such instances the participant will be withdrawn.

Discharge

Prior to discharge, a number of assessments will be conducted and the StepWatch removed; a chart review will be conducted after discharge. Data collected from the EMR will include hospital length of stay, discharge outcome and destination, ICU/CCU stays, admission diagnoses, rehabilitation services, ED visits and hospitalizations in the past 6 months, and information to determine the Cumulative Illness Rating Scale-Geriatrics (CIRS-G). Participants will be asked to confirm their contact information, as well as the times at which they would prefer to be contacted. After discharge, a letter will be sent to the participant thanking them for their contribution to the study, reminding them of the post-hospital follow-ups, and providing them with study contact information.

TABLE 6 Discharge Assessments: to complete on the day of discharge		
Procedure	**Length of Time Required of Participants**	**Frequency of Repetition**
Katz ADL	3 minutes	Once
Condensed Memorial Symptom Assessment Scale (CMSAS)	5 minutes	Once
Gait speed	5 minutes	Once
Chart review	0 minutes (performed by staff)	Once
Total	*13 minutes*	

Post-Discharge Follow-ups

After discharge, participants will be contacted monthly for the first 6 months, at month 9, and at month 12 for follow-up assessments. These assessments will occur over the phone, except in the unlikely event that the participant is hospitalized at BVAMC or UAB Hospital during the assessment window; in that case, the follow-up may occur in the participant's hospital room. Study staff will attempt to contact participants for up to one week after the initiation of the calls. If patients have not been reached within five days of their scheduled call date, the designated contacts provided by the participant will be contacted to help determine if the participant is out of town, hospitalized, admitted to a nursing home, or has died. If the participant cannot be reached within one week

of the initiation of the follow-up call, that follow-up call will be marked as missing and no further calls will be attempted until the next scheduled follow-up. The participant's EMR will also be reviewed by study staff for outcomes of interest including rehabilitation services, ED visits, hospitalizations and discharge diagnoses, nursing home placement, hospice services, and death.

As at baseline, the depression screening tool PHQ – 2 will be administered during each post-discharge follow-up to the participant (surrogate responses will not be solicited). If a participant is noted to have a PHQ-9 ≥11, indicating moderate depression, the participant's VA or UAB primary care physician will be notified by study staff, provided the participant isn't already on an antidepressant or is being followed by mental health.

If a participant successfully completes a follow-up assessment, a letter will be mailed thanking them for their continued participation and reminding them of the next follow-up assessment; when the final follow-up is completed, a letter will be sent thanking them for their contribution and stating that their participation has now ended. If a participant cannot be successfully contacted for a follow-up, a letter will be sent asking them to please contact study staff so that either their contact information can be updated, or so that they may withdraw from the study.

TABLE 7
Post-Discharge Assessments: Months 1, 2, 4, & 5

Procedure	Length of Time Required of Participants	Frequency of Repetition
Living situation; self-reported mobility	1 minute	1x/month
Katz ADL	3 minutes	1x/month
Lawton IADL	3 minutes	1x/month
UAB Life-Space Assessment	5 minutes	1x/month
EQ-5D-3L *(quality of life index)*	5 minutes	1x/month
PHQ-2 (& PHQ-9, as appropriate) *(depression screening tool)*	2 – 6 minutes	1x/month
Falls, ED visits, & hospitalizations	1 - 6 minutes	1x/month
Chart review	0 minutes (performed by staff)	1x/month
Total	*20-29 minutes*	

TABLE 8
Post-Discharge Assessments: Months 3 & 9

Procedure	Length of Time Required of Participants	Frequency of Repetition
Living situation; self-reported mobility	1 minute	1x/month
Katz ADL	3 minutes	1x/month
Lawton IADL	3 minutes	1x/month
UAB Life-Space Assessment	5 minutes	1x/month
EQ-5D-3L *(quality of life index)*	5 minutes	1x/month
PHQ-2 (& PHQ-9, as appropriate) *(depression screening tool)*	2 – 6 minutes	1x/month
Falls, ED visits, & hospitalizations	1 - 6 minutes	1x/month
Social network change question	1 minute	1x/month
If social network change question is positive: Lubben Social Network Scale	0 – 7 minutes	0-1x/month
Chart review	0 minutes (performed by staff)	1x/month
Total	*21-37 minutes*	

TABLE 9 Post-Discharge Assessments: Months 6 & 12		
Procedure	**Length of Time Required of Participants**	**Frequency of Repetition**
Living situation; self-reported mobility	1 minute	1x/month
Katz ADL	3 minutes	1x/month
Lawton IADL	3 minutes	1x/month
UAB Life-Space Assessment	5 minutes	1x/month
EQ-5D-3L *(quality of life index)*	5 minutes	1x/month
PHQ-2 (& PHQ-9, as appropriate) *(depression screening tool)*	2 – 6 minutes	1x/month
Falls, ED visits, & hospitalizations	1 - 6 minutes	1x/month
Lubben Social Network Scale	7 minutes	1x/month
Chart review	0 minutes (performed by staff)	1x/month
Total	*27-36 minutes*	

Withdrawal from the study

We are sensitive to the fact that our study population consists of hospitalized patients. It is possible that participants may receive news while in-hospital that is totally unrelated to our study (e.g., a cancer diagnosis,) that causes them emotional distress, and that the in-hospital assessments may therefore seem more burdensome than it did at the time of consent. Should a participant display such distress during assessments or interventions, study staff will ask if the participant would like to continue the study activity at another time or withdraw. The participant's wishes will be followed. However, if the participant's distress persists, the participant may be withdrawn if the PI determines that further participation in the study is not in that person's best interest. The PI and study coordinator have significant experience assessing in-hospital geriatric patients at the Birmingham VA and UAB Hospital, and are familiar with such situations.

Statistical considerations

Sample Size Calculations

Our primary aim is to evaluate the impact of the mobility program on mobility in the year after hospital discharge using the UAB Life-Space Assessment (LSA). In our previous small VA-funded study of a mobility intervention, patients in the MP group had a mean LSA score that was approximately 10 points highepr than in the UC group at four weeks' post-discharge. It is our expectation that the current study will replicate these results; specifically, that the 10-point difference will be apparent at 1-month post-discharge and persist thereafter. As described below, the primary statistical technique to address the primary aim will be mixed effects models. Assuming an exchangeable covariance structure across the repeated observations, a sample size of 190 participants provides greater than 90% power to detect a persistent 10-point difference in LSA scores at the $\alpha = .05$ level. We must also consider the reduced effective sample size due to clustering. It is a common practice to calculate the intraclass correlation (ICC) among clusters as a measure of how much more similar members of the same cluster are to each other than to the overall population. In this setting, we recognize that subjects at UAB may differ from subjects at the VA, leading to differences in the ICC. However, we still expect much more variability to come from individual patient factors than from the units. Using the data from our recently completed VA longitudinal study, we calculated an ICC for the LSA that rounded to 0; including data from UAB resulted in an ICC approximately 4 times larger. Assuming an ICC of 0.004 and subjects spread across 9 units, a sample size of 206 yields an effective sample size of 190 observations. In our recently completed VA longitudinal study during which patients were followed for 6 months after hospital discharge, 80% of the veterans completed at least 5 of the 6 monthly post-hospital assessments. We had 23 deaths and 3 withdrawals over the 6 months of follow-up among the 200 veterans in the study. Thus, in order to have an adequate (i.e.206) sample size at 12-months, 258 patients will be enrolled allowing for patient losses due to

death or drop outs. Thus, while adding units from UAB to the study does increase the required sample size slightly due to the larger ICC, this is offset by the larger number of potential subjects that can be recruited.

Analytic Approach (for each specific aim)

Descriptive statistics including mean, standard deviations, distribution, maximum and minimum values for the study variables will be calculated. Data will be examined graphically and by summary statistics for outliers and distributional properties (e.g., normality, skewness) that may lead to transformations or nonparametric analyses where indicated.

To analyze differences in LSA while accounting for changes in units over time, we will use a stepped-wedge design (Figure 4, above), a variation of cluster randomization in which each cluster is eventually assigned to intervention.[21] By beginning with a pre-intervention period and implementing the interventions in 'steps' at set times, each unit serves as its own control, with pre-intervention observations used to estimate any underlying long-term or seasonal trends with precision so that effects from the intervention can be distinguished from these 'secular' trends. While the standard stepped-wedge design treats time in discrete blocks (the 'steps'), this trial will be able to provide more robust estimates of secular trends because observations are linked to the date of each patient's admission, providing a much finer temporal resolution. To understand the secular trends, we will start by examining smoothed plots of LSA over time overall and stratified by unit to identify especially large temporal fluctuations that may indicate unanticipated changes in processes or personnel. We will then model LSA during the time prior to the initiation of the intervention using mixed models,[22] to account and test for heterogeneity among hospital units (in both means and trends) and possible nonlinearities. While secular trends must be accounted for in the final models, results from this preliminary analysis will inform whether potential trends can be considered to be linear, and whether all units can be considered to have the same trends over time.

Informed by the modeling of secular trends, the final models will add in indicator terms for whether the observation occurred before or after the intervention, in addition to the appropriate modeling of secular trends. Additional more sophisticated modeling will evaluate the trends in the outcomes over time in the post-intervention periods to see whether temporal trends differ pre-and post- intervention. All statistical tests will be two-sided and will be considered to be significant if the associated p-value is <0.05. All analyses will be intention-to-treat based on the unit's assignment at the time of a patient's admission, and missing data will be imputed using a multiple imputation strategy, based on the characteristics of the data.

AIM 1: To test the effectiveness of a mobility program on recovery to pre-hospital mobility status or better and reduction of adverse outcomes in the year after hospitalization.

To test the effectiveness of the intervention on mobility, LSA scores and changes in LSA scores for patients in the control condition will be compared to LSA scores from patients in the intervention condition. Mixed models will be used to examine and compare mean LSA over time with time considered a random effect. An indicator term will be included to denote whether the observation was from the period prior to or after implementation of the intervention. The indicator term will represent whether there was an overall difference in the LSA during the intervention period versus the pre-intervention period, and its statistical significance in the model for each outcome will be the primary test of whether the intervention had a significant effect on LSA. A priori we believe that an exchangeable covariance structure will be most suitable for the data. For the secondary hypotheses, i.e., self-reported outcomes for driving (yes/no) and ability to walk ¼ of a mile (yes/no), generalized linear mixed models (GLMMs) that account for repeated measures will be used to compare pre- and post-intervention periods. Given the randomized nature of the study design, adjustment for potential confounders will likely be unnecessary as they are expected to be equally distributed between the groups. However, as noted above, we will confirm that any potential confounders, e.g., age, length of hospitalization, and disease burden score (Cumulative Illness Rating Scale-Geriatrics, or CIRS-G[23]) are indeed similar between the pre- and post-intervention periods and, should any not be, we will adjust for them in the statistical models provided they are not deemed to be consequences of the intervention.

To test the effectiveness of the intervention on adverse outcomes, we will use mixed models and GLMMs to model changes in functional decline (ADLs and IADLs), number of ED visits, and number of hospitalizations with an approach similar to the above. To test the effectiveness of the intervention on nursing home admission

and death, we will use Cox proportional hazards models to compare the time from hospital discharge to the time to event between the MP and UC groups, adjusting for potential covariates. Due to the potential interrelationship between risk of nursing home admission and risk of death, competing hazards will be used to model the time to occurrence of the first event. Right censoring of participants will occur with dropout due to any reason (death, loss to follow-up, conclusion of the study period, etc.). Multiple imputation techniques will be used to offset potential bias due to missing predictors in the models.

AIM 2: To identify characteristics which modify the effect of the mobility intervention on recovery to pre-hospital mobility status or better and reduction of adverse outcomes in the year after hospitalization.

Potential effect modifiers include pre-admission ADL and LSA, cognitive function, level of in-hospital mobility, depressive symptoms, and social support. For continuous variables, e.g., activities of daily living score, overall distributions will be reviewed and categorized as low, medium and high based on tertile cut-points. To test for significant effect modification, single second level interaction terms, combining pre-/post-intervention indicators with potential effect modifiers, will be added to mixed models. Resulting F-tests for the interaction terms will be reviewed and p-values <0.05 identified as significant. Examination of potential effect modifiers based upon their tertile groupings not only allows for the identification of significant factors but also has the added benefit of examining factor's dose effect, providing additional internal validity to the analysis.

F. ECONOMIC CONSIDERATIONS: Describe any material inducements that will be offered to subjects in return for their participation: e.g., direct payment, free services, etc. Describe any schedule of payment to subjects based on their complete or partial participation. Will early withdrawal from the study result in a reduced payment? Does it make a difference whether it is the subject or the investigator who decides to terminate the subject's participation? Explain any bonus a subject may receive for completion of the study. These partial or bonus payments must also be explained in the consent form.

Each participant will receive a payment of $20 after completion of the in-hospital portion of the study. Any participant who enrolls will receive $20 compensation, regardless as to whether or not the participant completes all requested study activities, withdraws, or is withdrawn by the investigator. This payment will be made after the participant is discharged from the hospital.

Each participant will receive one payment of $10 for each post-discharge follow-up that is completed: One follow-up will be conducted every month (30 days) after discharge for six months; one follow-up will be conducted 9 months after discharge; and a final follow-up will be conducted 12 months after discharge, for a total of 8 follow-up assessments. These payments will be made individually, as each follow-up is completed. Follow-ups that are not completed due to withdrawal, inability to reach the participant, or any other reason will not receive payments. Thus, each participant will have the opportunity to receive up to $80 for completing post-discharge follow-ups, for a potential total of $100 for full participation in the study.

UAB participants will be paid at the same rate and on the same schedule as BVAMC participants. Compensating UAB participants will involve providing the BVAMC Research Financial Administrative Assistant with UAB participants' names, addresses, and social security numbers. S/he will route the information through established VA channels for participant payment.

G. SUBJECT POPULATION: Describe the requirements for the subject population including the total number of subjects and controls and their ages. If special groups -- e.g., prisoners, children, fetuses, the mentally disabled -- are part of the subject population, please indicate this.

List the specific inclusion and exclusion criteria.

258 patients, age $\geq$ 50 years admitted for any medical illness (e.g. pneumonia, heart failure, COPD exacerbation, or other medical (versus surgical) indication for hospitalization) to one of the five hospital wards of the Birmingham VAMC or one of four hospital units at UAB Hospital will be recruited within 48 hours of hospitalization, and followed throughout their hospitalization and for one year after hospital discharge.

Inclusion criteria include:

- Age ≥ 50 years
- Medical admission to BVAMC wards 4A, 4B, 5A, 5B, or 6B; or to UAB Hospital (3 Hospitalist units and Tinsley Harrison service)
- Direct admission to BVAMC or UAB Hospital, or from ED (not from ICU)
- ≤48 hours since hospital admission
- Access to a telephone after discharge

Exclusion criteria include:

- Inability to walk across a small room 2 weeks prior to admission
- Inability to stand safely with assistance
- Having a diagnosis deemed by the primary physician to be a contraindication to walking (pulmonary embolus, unstable angina, etc.)
- Being on hospice or comfort care
- Non-English speaking, blind, or deaf
- Being enrolled in other VA or UAB mobility research studies
- Isolation precautions for c. difficile, tuberculosis, radioactive treatment, or similar
- Suicidal ideation

Older adults who are either demented or delirious will have the opportunity to participate in this study. Among older adults hospitalized with acute illness, delirium and dementia are common, affecting up to 25% of the population. Exclusion of this group, who may have very different trajectories of recovery after hospitalization, would have a significant impact upon the generalizability of the research results. More importantly, this research may uncover methods by which we can improve hospital care for this vulnerable group who often do poorly when hospitalized.

Screening to determine if a participant has dementia or delirium will occur prior to signed informed consent through use of two standard assessment tools, the Mini Cognitive Assessment (Mini-Cog) and the Confusion Assessment Method (CAM). If a patient scores positively for dementia or delirium based on these tools, the patient's physician will be consulted to determine whether the patient has decision-making capacity. If there is documentation in the EMR or VISTA that the patient does not have decision-making capacity, informed consent will be sought from the appropriate legally authorized representative. Patients with dementia or delirium will be included only if they assent to the study themselves.

H. RISKS: Describe and assess any risks -- physical, psychological, social, economic, legal, or other. If other methods of research present lesser risks, describe those, if any, that were considered and why they will not be used. In general, risks to subjects must be minimized by (a) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Describe the procedures you have taken to minimize these risks.
For all research involving any risk of physical injury, these risks must be specified. If there are none, state: "There are no risks of physical injury." If there are risks of physical injury, there should be for each injury a careful estimate of its probability and severity as well as of its potential duration and the likelihood of its reversibility.

The potential risks for the proposed study include a slight risk of skin irritation due to the StepWatches; falls; increased symptoms such as fatigue or shortness of breath due to ambulation during testing or mobility sessions; a slight risk of distress due to the nature of some study questions; and loss of confidentiality.

Skin irritation: The StepWatches have been used in our previous BVAMC study with only a single instance of a participant experiencing discomfort (in this case, due to the StepWatch making a previously-received bug bite itch). Study staff will evaluate the participant's skin under and around the StepWatch each day to assure there is no erythema, and will remove the StepWatch if concerns arise. We do not expect that participants will experience any skin irritation during this study.

Falls: Falls are common during hospitalization; however, the PI has never had a fall occur during a study walking session in over ten years of research at UAB, and there were no falls during study sessions in our previous, similar study at the Birmingham VA. We do not expect any participants will fall during the study sessions.

Shortness of breath and fatigue: These can occur for some patients when engaging in out-of-bed activities. As the testing and mobility sessions involve simply standing and walking as tolerated by the participant, we expect only a slight increased risk of these symptoms.

Psychological distress: The PHQ-2 and PHQ-9 ask questions designed to determine if a patient is depressed; the risk of experiencing distress from these questions is very slight. We expect that participants will experience no to very mild distress during the PHQ-2 and PHQ-9.

Confidentiality: We do not expect any breaches in confidentiality during the course of this study. Study staff will make every effort to prevent any breaches of confidentiality or privacy, and will follow HIPAA guidelines concerning PHI.

I. CONSENT PROCEDURES: Describe consent procedures to be followed, including how, where, and by whom informed consent will be obtained. The consent form should be appended to the protocol exactly as you plan to submit it to the funding agency and to the subject.

The PI, study coordinator, and TBN study staff will conduct the informed consent discussion in the patient's hospital room. The door will be closed, or the curtain will be pulled to ensure privacy. Efforts will be made to ensure that the discussion occurs while no other health care procedures are in process, especially those that could be considered stressful (e.g., blood draws). Consenting staff will describe the study, invite the patient to participate, and answer any questions. If LAR consent is necessary, staff will follow the same steps with the LAR. If they are interested, consenting staff will read then the consent form and HIPAA authorization along with the patient (and LAR, as appropriate), allowing time for questions. Consenting staff will emphasize statements in the consent form that participation is completely voluntary and that non-participation will in no way impact their medical treatment.

After going through the consent form, the patient/LAR will be asked again if there are any questions, and once all questions are addressed the patient/LAR will be invited to sign the consent form. If they would like more time to consider participation, consenting staff will allow them as much time as they wish. However, since study participants must enroll within 48 hours of admission, it is possible that a patient may delay making a decision until they are no longer eligible for the study. In such a situation, the patient/LAR will be thanked for their interest but will not be enrolled in the study. At no time will patients/LARS be pressured in any way to enroll before they are comfortable due to the 48-hour constraint.

The PI and the study coordinator have multiple years' experience recruiting inpatients as participants for other mobility studies both at the VA and at UAB, and are sensitive to the stressful nature of hospitalization. Great consideration will be given to the patients' situations and recruitment will be conducted with high sensitivity and awareness of this burden.

J. PROTECTION OF SUBJECT: Describe procedures (including confidentiality safeguards) for protecting against or minimizing injuries (physical, psychological and social) and provide an assessment of their likely effectiveness.

The potential risks for the proposed study include a small risk of skin irritation due to the StepWatches; falls and increased symptoms such as fatigue or shortness of breath due to increased ambulation during tests; a slight risk of psychological distress; and loss of confidentiality.

Skin Irritation: To address the small risk of skin irritation, study staff will check the skin under and near StepWatch at least once a day for signs of erythema. New Velcro straps will be provided whenever the old ones become wet or soiled. If signs of erythema are noted, the pedometers will be moved to the contralateral side or removed entirely, as appropriate. Flyers with the study's pager number will be placed on or near the whiteboard located in all patient rooms, and nursing will be asked to call study staff if there are any questions about the pedometers. Previous studies by the PI using the same pedometers at the Birmingham VA Medical Center had no skin issues develop. To date we have had < five patients remove the StepWatch independently, with the most common reason cited by the patients being anticipation of discharge.

Falls, shortness of breath, and fatigue: To address the issue of falls and of worsening symptoms such as fatigue and shortness of breath while walking, a physical therapist (Dr. Diane Clark, PT, PhD) will train study staff on safe ambulation techniques. If a patient is weak, defined as being unable to walk without moderate assistance, or has a BMI greater than 35, two study staff will walk with the patient. If there are not sufficient study staff for this to be possible, the session or test will be skipped. Patients will wear a gait belt whenever they are working with the study researchers. Participants will be asked to rate their exertion using the Perceived Exertion Index during mobility sessions, and staff will encourage participants to rest if they become tired or short of breath.

The level of mobility recommended to the MP participant will be dependent on the individual patient and will incorporate the activities patients were deemed able to do independent of cueing or assistance during each walking session. For example, if a patient could stand at the bedside independently, but required standby assistance for walking, the patient would be encouraged to sit on the side of the bed for meals and stand up beside the bed for 3-5 minutes every two hours as able. To assure patient safety, patients will be instructed not to attempt to transfer or walk without nursing assistance if deemed to be dependent in these activities. MP participants will be provided with a basic safety procedure handout that will include safe mobility strategies.

Psychological distress: As the PHQ-2 and PHQ-9 ask questions designed to determine if a patient is depressed, there is a slight risk of experiencing distress from these questions. We expect that participants will experience no to only very mild distress while answering these questions. However, if the patient experiences distress, the PHQ will be halted and the PI notified. The PI may notify the participant's attending physician, as she deems appropriate. In addition, if the participant scores ≥11 on the PHQ-9, the patient's BVAMC or UAB physician will be notified.

Confidentiality: To help protect confidentiality, participants will be interviewed in their ward rooms with the door closed or the curtain pulled; telephone assessments will be conducted from private offices with the doors closed. To help protect privacy, participants will be provided with appropriate gown coverage if they walk in the hallways during study walking sessions.

For Birmingham VAMC veterans, data will be collected using paper records; while on the wards, these will be physically present with study staff at all times. Paper records will be stored in locked file cabinets behind locked doors in study staff offices in the BVAMC, rooms 8211, 8223, 8224 and 8218. As with the paper records, active StepWatches will be physically present with study staff at all times (when not worn by the participant). No hard-copy data will be removed from the VA protected environment, nor will any PHI be transmitted electronically.

Data will be entered by study staff into MS Office applications under VA license, and will be stored on the secure research server (birresearch) in a secure folder to which only study staff will have access. StepWatch data will likewise be stored in this secure folder. No study data will be stored in temporary files or on a computer hard drive. Information from this study will only be reported in aggregate for research purposes without the possibility of identifying individuals in the study. Data retention and data destruction will follow current regulations.

The PI will have ultimate responsibility for the security of the data. Study staff will contact the PI and study coordinator immediately in the case of any suspected or confirmed theft, loss, or unauthorized access of data, or of non-compliance with security controls. The PI or study coordinator will report incidents to the PO and ISO by phone and/or email, and to the National Service Desk by submitting a ticket via phone, email, or online ticket submission system [see VHA Handbook 1200.05 ¶10j, VHA Handbook 1058.01 ¶11.a, VA Handbook 6500, Appendix D, and VHA Handbook 6500.2].

Study personnel who leave the research team will have their access to the secure folder terminated and will turn in all keys to offices and file cabinets upon leaving the team.

UAB participants' data will be stored in UAB facilities per UAB guidelines. This data will be de-identified and combined with de-identified data from VA participants for the purposes of conducting analysis.

Data Safety and Monitoring Board (DSMB) The Data Safety and Monitoring Board will be charged with recommending changes in the study protocol or closure of the study if the incidence of falls or another adverse event in the intervention group at BVAMC is significantly greater than that observed in the control group at BVAMC. The board's membership will include a physician, a physical therapist and a nurse. The DSMB will meet quarterly either in-person or by conference call to discuss the study and any issues or concerns. Incidents will be reported to the DSMB by email.

The following incidents which occur at BVAMC will be reported to the DSMB and IRB immediately:

1. Falls by participants that occur during the inpatient portion of the study
2. Open wounds (Stage II or greater pressure ulcers indicating a breach of the skin's integrity) under the area of the StepWatch

The following incidents which occur at BVAMC will be reported to the DSMB quarterly:

1. Falls by participants that occur after the inpatient portion of the study, but while enrolled, together with statistics on the current fall rate at BVAMC
2. Participants' deaths that occur after the inpatient portion of the study, but while enrolled
3. Emergency department visits that occur after the inpatient portion of the study, but while enrolled
4. Rehospitalizations that occur after the inpatient portion of the study, but while enrolled
5. Participant transferred to ICU/CCU or Safe Harbor during the inpatient portion of the study
6. Participant dies during the inpatient portion of the study
7. Skin irritation in the immediate vicinity of the StepWatch

AEs, SAEs, and other incidents which involve UAB participants will be reported to the UAB IRB.

K. POTENTIAL BENEFITS: Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.

For the group of patients who receive the hospital mobility intervention, it is expected they will maintain or improve their mobility to a greater degree than those in the usual care group. As ability to walk is a key component of all basic activities of daily living, the MP group may also experience an improvement in their ADL ability to a greater degree after hospital discharge. As mobility disability is associated with a reduction in quality of life, the MP group may experience an improvement in quality of life.

It is expected that there will be little direct benefit to those participants who are randomized to the control group. However, they will be visited three times a day for social visits, which may increase their feeling of wellbeing.

L. THE RISK-BENEFIT RATIO: This section should consist of the investigator's explanation of how he or she concluded that the risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

The risks to the subjects are very small, whereas the results of this study will add substantively to what is currently known about how to improve outcomes due to low mobility for middle-aged and older adults who have a hospitalization. Functional decline, loss of mobility, and nursing home admission are well-recognized negative outcomes associated with hospitalization, and available evidence suggests low mobility to be a contributor to these adverse outcomes; determining the effectiveness of a hospital mobility program could have significant impact on functional decline and loss of mobility for hospitalized patients. The potential benefits are great if the study allows for the development of a hospital mobility program intervention that could ultimately decrease loss of mobility and functional decline and reduce ED visits, hospitalizations and the need for nursing home care after hospitalization.

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