Walking Study Protocol

Cynthia J. Brown, MD, MSPH

September 2009
AIMS

1. To develop and assess the efficacy of a hospital walking intervention on key, potentially modifiable institution-related and attitudinal factors hypothesized to be associated with low mobility during hospitalization.
2. To assess the impact of the walking intervention on patient-related factors that may reflect pathophysiological mechanisms for adverse outcomes associated with low mobility.
3. To examine the impact of a hospital walking program on the time spent out of bed during hospitalization, ability with activities of daily living, community mobility, and the occurrence of falls.
4. To monitor the safety of a hospital walking program measured by the frequency of falls and symptom assessments.

PARTICIPANTS

Eligibility Criteria

- Age 65 years or older
- Admitted to the medical wards at the VA Medical Center
- No significant language barriers
- Normal (non-demented) on Mini-Cog
- No sign of delirium on CAM
- Ambulatory 2 weeks PTA, according to ADL self-report
- No previous enrollment in study
- Consent to participate in study

Recruitment

Patients will be recruited on a daily basis, Monday through Friday, by asking the post-call team if any patient 65 years of age or older has been admitted to the medical unit. If so, the research assistant will ask the physician a few brief questions to determine initial eligibility:

- (1) Would the patient’s current cognitive status make him/her incapable of answering some questions?
- (2) Does the patient have an imminently terminal illness? (less than 30 days)
- (3) Does the patient have any medical diagnosis deemed by the primary physician to be a contraindication to ambulation (i.e.: pulmonary embolus, unstable angina, etc.)?
- (4) Is the patient on isolation precautions?
- (5) Is the patient non-English speaking?

If initial eligibility is not met (physician responds with a yes to one or more of the above), withdraw from further questioning. In addition, to avoid having two patients in the same room who are randomized to different groups of the study, thus confounding the results, we will exclude newly admitted patients who are in rooms with an enrolled patient. However, if the patient meets initial eligibility (physician responds with a no to all of the above), proceed to talk with the patient about the research study—begin by briefly informing the patient about the study to gauge interest, then withdraw or provide further details and answer any questions.
PROCEDURE

**Eligibility Screening**
If the patient is interested, administer the Eligibility Screening to assure that the patient is able to give informed consent (not demented or delirious) and meets the final criteria of being ambulatory 2 weeks prior to hospital admission. This screening includes: Mini-Cog, CAM, and a question about ambulatory status. When final eligibility is confirmed, obtain informed consent from the participant and assign a participant identification number.

**Baseline Assessment**
Immediately after consent is obtained, the research assistant will proceed with the baseline assessment, followed by attaching the wireless monitors. However, if a patient cannot finish all these tests at one time, ask them to complete remaining baseline testing at a later time and attach the wireless monitors now. The baseline assessment includes Functional Assessment, Gait Speed, UAB Lifespace Assessment, Self-reported ADL Ability – current and 2 Weeks PTA, Falls Efficacy Scale and Rehabilitation Self-Efficacy, Mobility Knowledge Pre-Test, Abbreviated Geriatric Depression Scale and Baseline Data from Chart.

**Treatment**
After the baseline assessment is complete, patients are randomly assigned to one of the following treatments to determine what type of twice daily visits they will receive through the 7th day of their hospitalization.

**Walking Program (WP) Group**
- **Training Visits** (2-15 minute visits per day): Participants will participate in progressive ambulation and transfer training. The training program will begin with assisted sitting, then standing, progressing to weight shifting and stepping in place, and then to ambulation as tolerated. A rolling walker will be provided for ambulation as needed, to be left in the room if the patient demonstrates they are able to use the device safely and independently. While WP patients will be encouraged to ambulate at each visit by the research assistant, they may refuse any and all sessions. If a patient refuses to participate in a session, they will be asked why they do not wish to participate, and these reasons will be documented verbatim.
- **Behavioral Intervention Strategy** (to increase time spent out of bed): The intervention strategy is based on the key concepts of self efficacy and will include:
  - Knowledge (Vicarious experience)
    - *Self efficacy is affected by social comparison and enhanced through observing the successful attainment of others, especially when those individuals are perceived to be similarly competent as the self.*
    - Provide an information handout about fall prevention and the proven benefits for patients. Verbally emphasize these benefits.
  - Skill (Mastery experience)
    - *Self efficacy is affected by mastery experience or enactive attainment, and more specifically enhanced through successful attainment.*
Provide twice daily training visits to allow practice of standing, transfers, and walking with assistance to encourage confidence in ability and reduce fear-based emotional arousal during these activities.

- **Reinforcement (Social persuasion)**
  
  *Self efficacy is affected by social persuasion, and more specifically enhanced through positive feedback and encouragement.*
  
  Provide encouragement and praise for efforts made during training visits. Outside of training visits, patients will be encouraged to sit up for meals and perform activity every two hours, at their level of independence. Similar positive feedback will be provided, both written (on goal chart) and verbal.

- **Self Regulation (Cognitive appraisal)**
  
  *Information from the above areas influences self efficacy through cognitive appraisal, how the individual interprets the information. Positive but realistic self efficacy is important for safe and successful participation in activities.*
  
  Provide patients with a journal containing a goal sheet and daily self evaluation pages. The daily pages will have checkboxes for patients to document what mobility they accomplished each day—this information will be used to determine the activity goals for the following day. The patient and research assistant will review and discuss this information and set daily goals regarding amount of time the patient will try to spend out of bed and what level of activity they will work on independently. These goals will be recorded on a chart that is attached to the inside of the journal cover.

**Control—Usual Care (UC) Group**

- **“Friendly visits”** (2-15 minute visits per day): UC patients will receive “friendly visits” from members of the research team, in order to control for the daily attention that WP patients receive.

- **Controlling for diary**: UC patients will be provided with diaries similar to those of WP patients—however, this is simply to control for the presence and use of a diary—UC patients will not receive a behavioral intervention component. Therefore, instead of recording mobility, they will be asked to use the daily self assessment sheets to document the frequency of visitors, both family and healthcare providers. Finally, in lieu of a goal sheet, UC patients will have a comments sheet on which the research assistant will write friendly notes each day to thank the patient for their participation in the visits.

**Daily Assessment**

Patients in both groups are administered a Daily Assessment through the seventh day of their hospitalization, to include: Wireless Monitor Assessments, Functional Assessment, Gait Speed, Orthostatic Blood Pressure, Fall Report (24 Hour), Condensed Memorial Symptom Assessment Scale, Falls Efficacy Scale and Rehabilitation Self Efficacy, Chart Continuous Mobility Barriers, Acute Care Mobility Assessment.

**Discharge Review**

Before a patient is discharged, the Mobility Knowledge Post-Test and Katz ADL Scale will be administered and MD Activity Orders noted. At discharge, the patient’s chart will be reviewed
and the following will be documented: Receipt of Physical Therapy (PT) Services, Receipt of OT, ST, MH, and SW Services and Discharge Destination.

**Post-Hospital Assessment**
Four weeks after patient’s discharge, patients are called on the phone and administered the Post-Hospital Assessment, which includes the following: Self Report of ADL Ability UAB Life-Space Assessment, Falls and Activity Self-Efficacy, Falls in Previous Month, and Condensed Memorial Symptom Assessment.

**MATERIALS**

*Wireless Thigh and Ankle Monitors*
Prior to attaching monitors, place each monitor into the center of a 2x2 gauze pad. The gauze will be placed against the patient’s skin to prevent irritation. A large bandaid will hold all components in place.

**To attach to ankle**
Start at the ankle bone, on the outside of the leg. Measure from the center of the bone, up 4 inches and place the lower edge of the first monitor here. The monitor will be placed so the clear plastic edge will be pointed toward the foot. Be sure to document which leg the monitor is placed on each time.

**To attach to knee**
At the knee, measure 4 inches up the thigh, on the outside of the leg, from the knee joint line and place the lower edge of the monitor here. Again, the clear plastic side will point toward the foot. The monitors should be positioned mid-way between the top and bottom of the thigh—see pictures.

**To assess**
Remove current monitors daily and download data from the previous day—the skin will be examined for erythema (redness) or other skins of skin breakage where the monitor was located. In very rare cases skin irritation may occur. If it becomes bothersome to the patient, remove the monitor and attach it to the opposite leg, following the proper procedure. If it becomes too bothersome for the patient and both legs have been tried without success, then stop collecting data from the patient and alert Dr. Brown immediately.

*Mini-Cog*
This is a 3-5 minute instrument that assesses mental status by detecting dementia. It is composed of a three item recall and the Clock Drawing Test (CDT). Patients are classified as demented if they recall 0 of the 3 items or recall 1-2 items but draw an abnormal CDT. Patients are classified as non-demented if they recall all 3 items or have partial recall but draw a normal CDT.

*Confusion Assessment Method (CAM)*
This is an assessment method that measures delirium. The research assistant will assess whether the patient is delirious by using direct observation from interactions with the patient. This method entails observing and noting “yes” or “no” for the following 5 characteristics in patient behavior: (1) acute onset of changed mental status (2) fluctuating course of abnormal behavior (3) inattention (4) disorganized thinking (5) altered level of consciousness. A
diagnosis of delirium is suggested when patients present with all of the characteristics or present with 1, 2, and 3 and either inattention or altered consciousness.

**#1 of Self Report of Activities of Daily Living (ADLs): 2 Weeks PTA**
This first question of the Self- Reported ADL instrument indicates whether the patient meets the requirement of ambulatory 2 weeks prior to admission (PTA). It involves asking patients to think about the past 2 weeks prior to coming to the hospital. Ask them to rate their level of independence with walking across a small room. How much help, if any, did they need in order to complete this activity? Patient must have been able to walk across a small room, with or without and assistive device, but independently or with some help, in order to be eligible.

**Self-Report of ADL Ability: Current & 2 Weeks PTA**
This instrument involves asking patients to think back over the 2 weeks before they were admitted to the hospital (Baseline only). Ask them to rate their level of independence with six activities of daily living (walking, bathing, grooming, dressing, feeding, transferring, and toileting). More specifically, they will be asked if they were independent, needed some assistance, or required total assistance with the activity. Then ask the patient to think about the current activities of daily living and rate their current level of independence using the same options.

**Chart Continuous Mobility Barriers (IV, catheter, oxygen, etc.)**
This chart will be used to document the possible barriers to mobility commonly seen in the hospital setting including intravenous lines (IV), urinary catheters, oxygen and restraints. While in the room, visually inspect for the presence or absence of these devices daily.

- **IV:** A continuous IV is one where a large bag of fluid is running at the time of your visit (as opposed to a heplock (IV needle only) or intermittent IV fluids (small bag that is hung several times a day)).
- **Catheter:** The urinary catheter bag may be hooked under the bed, so look on both sides for the bag.
- **Oxygen:** Continuous oxygen is defined as oxygen that is turned on at the wall when you visit. The patient may have the oxygen beside them in bed, but the intent by the healthcare providers is for the oxygen to be worn. This counts as continuous oxygen.
- **Restraints:** Restraints can include wrist or body restraints. The wrist restraints are soft, white and usually are around both wrists, but could be around just one. The body restraint looks like a mesh vest that covers the front of the patient and ties to the back of the bed. Wrist or vest restraints that tie one or both wrists or the body to the bed are all considered restraints.

**Functional Assessment**
This assessment includes a test of the patient’s ability, as measured by actual performance, to turn in bed, to sit up in bed, to stand bearing weight, and to walk a short distance. A patient’s ability to perform these tasks will be graded by the research assistant using a graduated assistance protocol. The level of assistance needed is graded from a request for action (e.g. “please sit up in bed”), to verbal cueing, to gentle guidance to begin movement, to minimal physical assistance, to inability to perform the task without physical assistance. Patients may refuse and this should be documented as a refusal, not an inability to do the activity.
**UAB Life-Space Assessment**
This is a self-report measure designed to assess the mobility of older adults in their community-dwelling environment. It explores the extent of a person’s lifespaces, including the range of places that patients have visited within a specific time frame, reflecting the patient’s community. The research assistant should read the questions to the patient and score the responses appropriately.

**Abbreviated Geriatric Depression Scale (GDS)**
This is a brief questionnaire designed to measure depression in an older population. Patients will be asked to respond to 15 questions by answering “yes” or “no” in reference to how they have felt over the week prior to the GDS administration. A score of 6 or above indicates a positive screening for depression, while a score of 5 or below indicates a negative result. If a patient scores 6 or above, the research assistant should check the electronic medical record to see if the patient is being followed by a mental health provider. If they are, no notification is needed. If they are not being supervised by a mental health worker, Dr. Brown will notify the resident MD. She will document in a note that she has spoken to resident MD about the positive screening for depression, and then the resident can decide what to do from there.

**Gait speed**
If able to walk a short distance, (based on the functional assessment) patients will be asked to perform a timed 10-foot walk. The 10-foot walk will be performed wearing a gait belt to assure the patient’s safety and, if needed, using a rolling walker. Two walks will be done with the faster of the two times being utilized for analysis.

**Data from Baseline Chart Review**
Data from Day 1 or 2 of the hospitalization will be collected (can be collected at discharge, along with discharge chart review data) from patient’s medical chart and used to determine the Charlson Comorbidity Index Score and illness severity using APACHE II. Both measures will allow assessment of any potential association between illness severity and comorbid illness and the patient’s mobility and compliance with the walking program.

The Charlson Comorbidity Index was developed to provide prognostic information based on number and severity of comorbid illnesses. (Charlson ME, Pompei P, Ales KL, MacKenzie CR (1987). A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chron Dis*, 40(5): 373-383). A variety of diagnoses are included in the scale including: AIDS, Cerebrovascular disease, Chronic pulmonary disease, Congestive heart failure, Connective tissue disease, Dementia, Hemiplegia, Leukemia, Malignant lymphoma, Myocardial infarction, Peripheral vascular disease, Ulcer disease, Diabetes mellitus (none, without end-organ damage or with end-organ damage), Liver disease (none, mild, moderate, severe), Renal disease (none, mild, moderate, severe), Malignant solid tumor (none, non-metastatic, metastatic). After collection of this data, it can be entered into the following website and a number will be generated.

Charlson Comorbidity Index scoring algorithm:  

The Acute Physiology and Chronic Health Evaluation II (APACHE II) is a severity of disease classification system. The point score is calculated from 12 routine physiological
measurements (such as blood pressure, body temperature, heart rate etc.) during the first 24 hours after admission, information about previous health status and some information obtained at admission (such as age). The score ranges from 0-71 with higher scores indicating worse severity of illness on admission to the hospital. The following website can be used to calculate the APACHE II score: http://www.sfar.org/scores2/apache22.html

Orthostatic blood pressure
Once a day, at approximately the same time each day, orthostatic blood pressure measurements will be performed using an automatic cuff. Patients will lay quietly in bed for five minutes prior to the first blood pressure and pulse reading. If unable to lie completely flat, the bed angle will be measured and documented, and the blood pressure will be taken in the flattest position the patient is able to tolerate comfortably. After the first measurement is taken, patients will be assisted into a standing position at the bedside, wearing a gait belt for safety. Blood pressure and pulse readings will be taken one minute and three minutes after standing with patients’ arms held level with their heart. Symptoms of dizziness will also be recorded.

Acute Care Mobility Assessment
The Acute Care Mobility Assessment (ACMA) is a questionnaire designed to provide information about a patient’s level of mobility during the previous 24-hours of hospitalization. The patient is asked to reflect on the previous 24 hours then are asked if they sat on the side of the bed or in a chair, walked in the hospital room, walked in the hall or walked off the unit. For each yes, patients are asked how many times they performed the activity, and if they had help from equipment or another person. They are also asked about what type of equipment they used.

Fall report
Patients will receive an explanation of a fall and near-fall, as defined in the present study. A fall is defined as having occurred whenever a person comes to rest or the ground inadvertently. A near fall is defined as having occurred any time a person loses their balance but is able to catch themselves before they go to the floor. This would include a loss of balance and a catch on furniture, or the wall. To assess patient safety, the research assistant will ask patients to think back a given period of time (past 24 hours during the hospital stay; the past month during the follow-up phone call) and report any falls and any near falls they have had. The chart will also be reviewed for documentation of a fall in the previous 24-hours (in hospital only). The research assistant will record any report or record of a fall and near-fall for this period of time.

Condensed Memorial Symptom Assessment Scale
This scale will be used to assess symptoms reported for the past 24-hour period. The condensed version of the scale asks patients to rate the presence or bothersomeness associated with symptoms relevant to a hospitalized population: lack of appetite, lack of energy, pain, dry mouth, weight loss, feeling drowsy, shortness of breath, constipation, difficulty sleeping, difficulty concentrating, nausea, worrying, feeling sad, and feeling nervous. For the purposes of this study, a fifteenth symptom, dizziness, is added using the same questionnaire technique. If a symptom is present, patients are asked to rate the symptom on a scale of 0 to 4, with zero indicating no distress and four indicating that they are “very much” distressed by the symptom. This scale will help assess the impact of our hospital walking program on symptom burden in our study. If any patient, usual care group or walking group,
reports a bothersome symptom, the research assistant will encourage them to share this information with their healthcare provider.

**Journals**
All participants will be provided with a journal consisting of:

- **Bright file folder**—labeled clearly with the study name
- **Goal or Comments Sheet**—attached to the inside of the file’s cover will be either a goal sheet for patients to write daily goals (Walking group) or a comments sheet for the research assistant to write daily thanks for participation (Control group).
- **Daily Self Assessment Sheets**—attached on the opposite side of the folder will be daily assessment sheets on which the participant will record their mobility (Walking group) or visits with others (Control group)—these will be collected daily by the research assistant.

**Data from Discharge Chart Review**
When a patient is discharged, review their medical chart:

- **MD Activity Orders**
  Record the physician’s medical activity orders. More specifically, using the check list, note which one or ones of the following applied: bedrest, bedrest with bedside commode, bedrest with bathroom (BR) privileges, out of bed (OOB) to chair with assistance, up as tolerated, up with assistance, and other. If orders changed during the hospitalization, document both orders and the dates when they were written.

- **Receipt of Physical Therapy (PT) Services**
  Note whether PT services were received. If PT services were received, also note whether or not he or she walked with PT, how far walked, and what kind of assistive device, if any, was used: none, cane, walker, rolling walker, hand hold by PT.

- **Receipt of OT, ST, MH, and SW Services**
  Note if any of the following services were received: Occupational Therapy (OT), Speech Therapy (ST), Mental Health (MH), and Social Work (SW).

- **Discharge Destination**
  Record the location to which the patient is being discharged. More specifically, using a checklist, mark one of the following: home, home with home health, home with hospice, skilled nursing facility, or other

**Short Falls Efficacy Scale-International (Short FES-I) and modified Rehabilitation Therapy Scale**
Patients will be asked to complete the Short FES-I to rate their level of confidence in their ability to perform ADLs without falling. This measurement asks about a wide range of activities, from getting dressed to walking up stairs, and uses a 4-point Likert response scale. To assess activity self-efficacy, a modified Rehabilitation Therapy self-efficacy scale with a 5-point response scale will be used. The scale asks if participants are confident in their ability to transfer to and from the bed or chair, and walk independently. Perceived ability to perform out of bed activities and perceived mobility expectation of healthcare providers will be assessed using a questionnaire format.

**Mini Nutritional Assessment Measurement**
The MNA is an instrument developed to identify older persons at nutritional risk. To minimize the screening time of at-risk individuals, while retaining the sensitivity and specificity of the original MNA, the MNA-Short Form will be used. The MNA-SF has 6 questions, and takes approximately 3-4 minutes to administer—data is collected via self-report and chart review.

**STUDY FLOW CHART**

1. **Eligibility Assessment**
   - Mini Cog (Normal)
   - Confusion Assessment Method (CAM=0)
   - Ambulatory 2 weeks PTA (yes)

2. **Informed Consent**

3. **Baseline Assessment**
   - Functional Assessment
   - Gait Speed
   - UAB Life-Space Assessment
   - Self-Reported ADL Ability (current & 2 weeks PTA)
   - Falls Efficacy Scale & Rehabilitative Self-Efficacy
   - Mobility Knowledge Pre-Test
   - Abbreviated Geriatric Depression Scale
   - Baseline Data from Chart (for Charlson Comorbidity Score and APACHE II)

4. **Randomization**
   - Patient randomized to group and provided with journal, instruction, and (if walking group), Mobility Knowledge Handout.

5. **Hospital Walking Program**
   - Twice daily walks with assistance
   - Behavioral Intervention to encourage walking
   - Journal

6. **Usual Care Group**
   - Twice daily “friendly visits”
   - Journal

7. **Daily Assessment**
   - Wireless Monitor Assessments
   - Functional Assessment
   - Gait speed
   - Orthostatic Blood Pressure
   - Falls in Previous 24 Hours
   - Condensed Memorial Symptom Assessment Scale
   - Falls Efficacy Scale and Rehabilitation Self-Efficacy
   - Chart Continuous Mobility Barriers
   - Acute Care Mobility Assessment

8. **Discharge Assessment**
   - Mobility Knowledge Post-Test
   - Katz ADL Scale at discharge
   - Chart Review: Receipt of services, Discharge Destination, & MD Activity Orders

4 Weeks Post-Hospital Assessment
Data Analysis Plan (from grant)

**Power Calculations:** Our major goal is to evaluate the impact of the program on time spent out of bed. In our previous VA-funded study, patients who had at least 24 hours of available data spent an average of 17.1% or 4.1 hours out of bed per 24-hour period of time, with a standard deviation of 2.9 hours. Our goal is to increase this by 2 hours to an average of 6.1 hours. This results in an effect size of 0.69 standard deviation units. A sample size of 45 per group provides 90% power to detect this 2-hour difference in the amount of time patients spend out of bed at the \( \alpha = .05 \) level. A sample size of 50 per group allows for patient losses due to changes in medical status.

**Analytic Approach** (for each specific aim):
Descriptive statistics including mean, standard deviations, distribution, maximum and minimum values for the monitor data and other study variables will be calculated. Data will be examined for outliers and distributional properties (e.g., normality, skewness) that may lead to transformations or nonparametric analyses where indicated. Other study variables will be used to describe the sample.

**AIM 1:** To assess the impact on time patients spend out of bed and safety of a walking intervention as measured by previously validated wireless mobility monitors. Safety measures include occurrence of falls and reports of relevant symptoms as measured by the Condensed Memorial Symptom Assessment Scale. To assess the impact of the intervention on time out of bed, wireless monitor data will be used to determine the time spent sitting, standing or walking throughout the hospitalization using a previous defined algorithm. Using analyses of variances (ANOVAs), differences in mobility, as measured by the wireless monitors, between the WP group and UC group will be examined. Analyses will be conducted that both include and exclude wireless monitor data collected during the intervention itself. To address the safety of the intervention, patients will be asked daily about falls that occurred during the previous 24-hours. Chi-square analyses will be run to compare the groups on rates of falling, and Fisher's exact test will be used if the rate of falling is low, as expected. The daily results of the Condensed Memorial Symptom Assessment Scale will be compared between the WP and UC group using ANOVA. Patients in the WP group should not have an increase in adverse events, specifically an increase in reported falls or symptoms when compared to the UC group. Any other untoward effects will be documented and categorized.

**AIM 2:** To assess secondary functional measures of impact including changes in gait speed, balance, strength and endurance as measured by a brief functional assessment. Secondary measures will include comparisons of changes from admission to discharge in functional ability as measured by the functional assessment, gait speed, balance, and timed chair stands. Analyses of covariance (ANCOVAs) will typically be used to compare the groups on these changes, with admission scores serving as a covariate. We will also examine other potential covariates such as length of stay or illness severity, which might also impact on these secondary measures of interest.

**AIM 3:** To determine the impact of a hospital walking program on daily orthostatic blood pressures. At approximately the same time each day, participant’s blood pressure will be measured in supine and standing according to a standard protocol. The presence or absence of orthostatic hypotension, defined as having a drop of 20 mm Hg is systolic or 10 mm Hg in diastolic blood pressure will be noted. Presence or absence of orthostatic hypotension among the two groups will be compared using a \( \chi^2 \) test.

**AIM 4:** To examine the impact of a hospital walking program on post-hospital community mobility one month after discharge as measured by the UAB Life-Space Assessment.
To examine the impact of the hospital walking program on function after discharge, data will be collected by phone one month after the intervention using the UAB LSA.28-30 ANCOVA will be used to compare the two groups on life-space after taking into account covariates such as the length of stay, previous life-space and the patient’s admission illness severity.