CHAPTER 16

PHYSICAL MEASUREMENTS

Study Documents Referred to in this Chapter

- 400 m Walk
- SPPB
- Blouse/Shirt
- Grip Strength
- Lateral Mobility Task
- Blood Pressure, Radial Pulse & Weight
- Height
- Physical Exam

CHAPTER 16

PHYSICAL MEASUREMENTS

16.1. 400 Meter walk (400 M Walk)

16.1.1. Overview

This is the primary outcome measure for the study. The 400 Meter Walk test (400 M Walk) is a measure of functional ability. Its potential as a predictor of morbidity and future disability makes it an important outcome measure for cross-sectional, longitudinal, and clinical intervention trials.

16.1.2. Schedule of Administration

The 400 M Walk is performed at screening visit 1 and at all subsequent follow-up clinic visits (or assessments). Please note that this test will not be completed in the home.

16.1.3. Required Equipment

The following equipment is required for the 400 M Walk:

- Redi-Measure distance measuring wheel or equivalent (tape measure). (Redington Counters Inc., Windsor CT)
- Stop Watch
- Small traffic cones
- 2 Standard chairs

16.1.4. Procedures

A Power Point file (PC-compatible) that provides complete instructions for the administration of the 400 M Walk is available for training.

16.1.4.1. Overview of 400 M Walk

During all of the tests, the safety of participants is paramount. Participants who do not feel safe or who are unable to perform a test should not be pressed. All procedures should be clearly demonstrated to the participants prior to performing any test and they should be queried to ensure that they understand the instructions. If it is obvious that the participant has not understood the directions, you may reread the standard instructions, but you should not reword them. To optimize the participant's understanding, go through the instructions slowly while making sure that the participant is paying attention.

You should be completely familiar with the test procedures and practice before attempting to administer the test to a participant. After watching the procedures on the training program several times, you should practice administering the 400 M Walk with a partner who is trained or in training, or practice with a volunteer under the observation of a partner or someone experienced in administering the 400 M Walk. When practicing, the person who is acting as the participant should role-play different levels of physical limitation to give the new examiner experience with people who have difficulty with the test. Also, be sure to practice on some older volunteers, including fully completing the data collection form. After practicing several times, go back and watch the Powerpoint presentation again. To ensure reproducibility, it is imperative that all participants are given the same instructions and that quantitative measurements associated with the tests are made in a uniform manner. You should not develop your own way of giving instructions. Since they are fairly long, you may want to read them from the sheet during the test.

16.1.4.2. The 400 M Walk

In this test, the participant's ability to complete a 400 meter walking course is assessed. You will need a stopwatch and a marked walking course. If this test is being done in a new location, then a course must be laid out on the floor. A diagram for laying out the course is provided in Appendix 16.A. The walking course should be unobstructed and include at least an extra meter on each end. When training to perform this test, it is good practice to have two or more people doing the timing so that timing can be compared for accuracy.

If the participant uses a cane or other assistive device, the walk is to be attempted without the cane or assistive device. **For the follow-up clinic visits (but not the initial screening visit), if the participant does not feel safe doing the walk without a cane or assistive device to complete the walk, one can be used.** This fact should be indicated on the form. At baseline, participants who only feel safe using an assistive device are not eligible. If possible, women wearing high heels should change into another pair of shoes before performing the 400 M Walk. The position of the examiner is critical for the walk. If you are too close, you will set the pace. If you are too far behind, you will not be in a good position if the participant falls. The best position to maintain during the walk is to the side and slightly behind, outside of the participant's visual field.

16.1.4.3. The 400 M Walk Protocol

1. Accompany the participant to the starting line of the 400 meter walk with the script and stop watch. Describe the 400 meter walk:
   Script: "Now I would like to observe how you normally walk. You will be walking 10 complete laps around the course, which corresponds to about ¼ mile. **We would like you to walk at your usual pace and without overexerting yourself.** During this test, I will ask you to rate how hard you feel you are working. When I ask you to rate how hard you are

working during the walk, I want you to think about the total feeling of exertion in your overall body, including your breathing and muscles. At the end of lap 4, while you continue walking, I will ask you how hard you are working. After you have completed all 10 laps, I will tell you to stop, and measure your heart rate. If you develop chest pain, significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few moments."

If subject uses a cane or other assistive device: "I would like you to attempt this test without your cane (or other walking device)."

2. Participant should be prepared to begin the test and asked a final time: **Script:** "Do you feel it would be safe to try and walk up and down this hallway 10 times?"

   At baseline, if the participant says "no", then do not do the test.
3. If the participant is uncertain ask: "Would you be willing to try it and see how you feel?"
4. Demonstrate the walk and ask participant if he/she has any questions.
5. When participant indicates that they feel ready to begin, the test may proceed:

   Script: "When I say 'GO", start walking at a <u>comfortable pace</u> you can maintain. Ready, Go."
6. Start the stop watch when the participant takes their first step. Because there is a risk that a participant may slip and fall, the evaluator should follow the participant at a reasonable distance during the test. The examiner should be close enough to the participant to be able to provide help should the participant falter during the test, but not so close as to dictate the pace of the test. The evaluator should be behind and to the side of the participant, just outside their peripheral vision. For every lap, offer standard encouragement, and call out the number of laps completed

and number remaining. If participants appear short of breath (have difficulty talking while walking) or complain of dizziness, they should be asked if they feel able to continue to walk. If so, they should have stand by guarding by a staff member (staff member stands by the participant at a close distance to prevent falling) for the rest of the walk and should be asked about their symptoms every two minutes for the rest of the walk. Participants may stop the walk at any time, but should not be allowed to lean against any wall or other surface (desk, counter etc.). Staff may stop the walk for evidence of inability to talk while walking, unstable gait, or any other staff concern about the immediate safety of the participant. All participants who exhibit the above symptoms should be escorted to a chair upon stopping the walk and should be guarded when first getting up again.

Script: "You're doing a good job. You have completed __ laps and have __ to go."

7. Record whether or not an assistive was used during the test.
8. When the participant completes 4 laps, their RPE should be recorded.
   Script: “Please tell me how hard you feel you are working right now. Is it “light”, “somewhat hard”, “hard”, or “very hard”?”

9. If the participant reports “hard” or “very hard”, the participant is reminded to walk their “usual pace without overexerting yourself…” (see script below).
   Script: “I would like to remind you to walk at your usual pace without overexerting yourself. If you develop chest pain or significant shortness of breath, or are too uncomfortable to continue, please stop walking and tell me. If you need to, you may stand in place and rest for a few seconds.

10. When the participants completes 400 meters (10 laps, first foot fall across the finish line), stop the stop watch.

a. Record time
b. Record sitting radial pulse for 30 seconds (see Section 16.8)

11. If the participant feels they need to stop and rest, they may stand in one place and rest. Participant should not lean on wall, table or elsewhere. After 30 seconds, ask them if they can continue walking. If they can, continue the walk and record the rest on the form. If they need to rest longer, have them continue to stand. After another 30 seconds, ask them if they can continue walking. If the participant appears to be in obvious distress (excessive sweating, unusually pale, labored breathing, unsteady/wavering gait, appears confused, or unresponsive to questions) or pain, you may recommend that he/she stand in place and rest for a moment. If they can, continue the walk and record the rest stop on the form. If they cannot continue after a 60 second rest or if they need to sit down, stop the test. There is no limit to the number of rest stops as long as they can complete the walk without sitting.

12. During the walk, if the participant requests or needs their cane or assistive device to complete the test, stop the test and be sure to record the point at which they stopped and the time completed. Give them their assistive device and escort them to the nearest chair.

13. The test may be terminated after 15 minutes even if the participant has not walked all 400 meters. Participants who complete the walk in >15 minutes are to be excluded.

14. If the test is terminated prior to the participant completing 400 meters, the point at which they stopped should be marked by placing an object on the course. The direction in which the participant was going should also be noted. The participant should be accompanied to the nearest chair. After the participant is comfortably seated, their accomplished distance should

be measured. Complete laps will be counted as 20 meters each and the remaining incomplete lap should be measured with the Redi-Measure. Record the total distance and time at termination of the test.

<u>Stopping Criteria for 400 Meter Walk:</u> If the participant reports chest pain, tightness or pressure in the chest, shortness of breath, feeling faint, lightheaded or dizzy, or report leg pain, stop the test. Record the reason for stopping. Test duration over 15 minutes.

15. Ask the participant how they feel and note any symptoms related to walking.

If a participant requires medical attention as a result of the below symptoms during the 400 M walk or upon completion of the walk, an Adverse Event report is to be completed and entered into the web-based data entry system.

1. Chest pain, pressure and/or other "anginal symptoms".
2. Severe shortness of breath defined as greater than anticipated for the level of physical exertion during the 400 M walk.
3. Loss of consciousness or an acute or new-onset bout of "dizziness" and/or "lightheadedness" that does not resolve with termination of the test and/or quiet sitting.
4. Persistent severe lower extremity pain that does not resolve with termination of the test.

16.1.4.5. Data Collection

The data for the 400 M Walk test is recorded on the data collection form. Be sure to include the distance covered if a participant does not complete 400 M, the time it takes to complete or when the participant stops.

16.1.4.6. Quality Control

All staff performing the 400 M Walk on LIFE participants must be certified. Certification must be renewed annually.

Course Preparation

The test will be administered on a 20 meter course, with small traffic cones marking each end. Ten laps will be performed for a total of 400 meters. The cones should be placed prior to the test and distance between them measured with the Redi-Measure. Two chairs should be placed, one just beyond the cone marking the start line and one just beyond the turn around. The couse used for the test should be isolated as much as possible.

16.2. Short Physical Performance Battery (SPPB)

16.2.1. Overview

The SPPB, originally developed for the Established Populations for the Epidemiologic Study of the Elderly (EPESE), is a brief performance battery based on timed short distance walk, repeated chair stands, and a set of balance tests. The SPPB can be used to assess how well older persons perform simple movements that represent the building blocks of daily activities that require good lower extremity function. The information concerning functional ability provided by these tests adds valuable insight to the assessment of the older person. The test takes about 10-15 minutes to administer and can be done in the clinic or the home setting. The battery has an excellent safety record. It has been administered to over 10,000 persons in various studies and no serious injuries are known to have occurred.

16.2.2. Schedule of Administration

The SPPB is performed at screening visit 1 and at all in-person follow-up assessments.

16.2.3. Required Equipment

The following equipment is required for the SPPB: stopwatch, masking tape, chain with fine links measuring just over 4 meters (approximately) in length (for home or off-site administration), script, score sheet, and a straight-backed chair with a hard seat. If this type of chair is not available, a chair with a softer seat or a chair with arms may be substituted. Do not use a folding chair, a soft chair, a deep chair, or a chair on wheels.

16.2.4. Procedures

A CD-ROM that provides complete instructions for the administration of the SPPB is available for training.

16.2.4.1. Overview of SPPB

During all of the tests, safety of the participants is paramount. Participants who do not feel safe or who are unable to perform a test should not be pressed. All procedures should be clearly demonstrated to the participants prior to performing any test and they should be queried to ensure that they understand the instructions. If it is obvious that the participant has not understood the directions, you may reread the standard instructions, but you should not reword them. Remember that you will be demonstrating each maneuver and that someone who may not completely understand the verbal instructions may still be able to perform the test following the demonstration. These tests have been successfully used in persons with cognitive impairment. To optimize the participant's understanding, go through the instructions slowly while making sure that the participant is paying attention.

You should be completely familiar with all of the test procedures and practice them before attempting to administer the test battery to a participant. After watching the procedures on the training CD-ROM several times, you should practice administering the battery with a partner who is in training or trained, or

practice with a volunteer under the observation of a partner or someone experienced in administering the battery. When practicing, the person who is acting as the participant should role-play different levels of physical limitation to give the new examiner experience with people who have difficulty with the tests. Also, be sure to practice on some older volunteers, including fully filling out the score sheets. After practicing several times, go back and watch the CD-ROM again. To ensure reproducibility, it is imperative that all participants are given the same instructions and that quantitative measurements associated with the tests are made in a uniform manner. You should not develop your own way of giving instructions. The instructions can be memorized or read but since some of them are fairly long, you may want to read them from the sheet during the test. There are certain parts of the assessment where it is awkward to try to read the instructions and simultaneously demonstrate or administer the test. These portions of the instructions must be memorized.

The SPPB consists of three types of physical maneuvers: the balance tests, the gait speed test, and the chair stand test. The tests are always performed in this order. Each of these three maneuvers is scored separately by the examiner. While the actual performance times can be used to evaluate specific functional abilities, it has also proven useful to classify performance into categories and provide a numerical score. The scores from each of the tests can then be added together to obtain an aggregate or summary score for each participant. Inability to perform any individual component of the battery results in a score of 0, while completion of the maneuver results in a score of 1 to 4. The maximum aggregate score is therefore 12.

If a specific maneuver is not attempted, you should explain why no attempt was made. Select one of the options on the score sheet. It is critical but sometimes very difficult to distinguish between someone who is unable and therefore unwilling to try a test and a person who simply refuses to do the test because they are not interested in participating. This is a judgment that rests with the

examiner. If someone refuses to participate in any of these tests, you would generally mark that they had refused on the answer sheet unless it is quite clear that they are refusing because they just can't do the test or are afraid to attempt it. Refusals are considered missing data and this person will not contribute to the research or clinical evaluation being performed. A participant who is unable to perform the test is scored zero for the particular test. Knowing someone is unable to perform the test is valuable information.

16.2.4.2. Balance Tests

16.2.4.2.1. Overview

The tests of balance provide an assessment of the participant's ability to hold three basic standing positions with the eyes open. No equipment other than a stopwatch, script, and score sheet is needed.

The three positions are side-by-side stand, semi-tandem stand, and full tandem stand (or heel-to-toe) and are performed in this order. Participants taking this test must be able to stand unassisted without using a cane or a walker. Don't assume that a participant who arrives for testing using a cane or walker can't stand unassisted. Ask them if they can stand without the device and are willing to try the test. If they say yes, you can assist them to assume the correct position for testing. Each test is timed and the participant is allowed only one chance to maintain each position.

For each position, the examiner first describes and then demonstrates the appropriate stand. The participant then assumes the correct foot position while supported by the examiner. Once the participant appears to be steady, ask if he or she is ready. When they say yes, the examiner relinquishes support, says "Ready, begin," and starts timing. The timing is continued until the participant moves his or her feet, grasps the examiner for support, or 10 seconds have

elapsed. Record any time less than 10 seconds to the nearest hundredth of a second.

16.2.4.2.2. Side-by-Side Stand

The first position tested is the side-by-side stand. In this balance test, participants are requested to stand for 10 seconds with their feet together in a side-by-side position. Participants who are unable to hold the side-by-side stand for less than 10 seconds do not proceed further with the balance tests and are given a score of 0 for this portion of the battery. Participants who successfully complete the side-by-side test receive 1 point and proceed to the semi-tandem balance test.

You may stabilize the participant by lightly holding their arm until their feet are in the correct position. Many people will need little support to help them into position but others will need strong support until they are in position and steady. Wait until they feel steady before moving on to the next step. If you cannot steady them with support, then do not try the maneuver. Code it as “not attempted” and then circle “Not attempted, you felt unsafe.” This applies to all three balance tests.

Make sure that the participant is stable and that their feet are in the correct position before you release them. Have the stopwatch ready to begin timing as soon as you release their arm. During this and all other balance tests, the examiner should stand next to the participant as they gets into position and then step back a half step as they perform the test. It is important not to crowd the participant so much that they have trouble using their arms to keep their balance. On the other hand, you must be close enough to grab their arm or let them grab your arm if they lose their balance. Based on prior experience, most participants simply step out of position if they lose balance.

It's not important to stop the clock and the test at exactly 10 seconds. The time does not have to be measured exactly if the participant holds the position for more than 10 seconds. Don't watch the stopwatch continuously during the test. Watch the participant and be prepared to stop the watch if the participant steps out of position or grabs your arm. Glance at the watch occasionally to see if the position has been held for 10 seconds.

16.2.4.2.3. Semi-Tandem Stand

In the semi-tandem balance test, each participant starts with the heel of one foot placed to the side of the big toe of the other foot. Either foot can be placed in the forward position. Participants who successfully hold the semi-tandem position for 10 seconds are given 1 additional point and proceed to the final balance test. Those who fail to hold the position for 10 seconds receive no points and do not perform the tandem balance test.

Stabilize the participant by lightly holding their arm until their feet are in the correct position. Make sure that the participant is stable and that their feet are in the correct position before you release them. Have the stopwatch ready to begin timing as soon as you release their arm. Stay close to the participant so they can grab your arm if they lose their balance but not so close that they can't use their arms for balance.

16.2.4.2.4. Tandem Stand

The final position evaluated in the balance tests is the tandem position. To assume the tandem position, the heel of one foot is placed directly in front of the toes of the other foot. Either foot can be placed in the forward position. Participants who hold this position for 10 seconds are awarded 2 additional

points. Those who hold the position for 3 to 9.99 seconds are given 1 additional point. Holding the position for less than 3 seconds results in no points.

Stabilize the participant by lightly holding their arm until their feet are in the correct position. Make sure that the participant is stable and that their feet are in the correct position before you release them. Have the stopwatch ready to begin timing as soon as you release their arm. Stay close to the participant so they can grab your arm if they lose their balance but not so close that they can't use their arms for balance.

16.2.4.3. Gait Speed Test

In this test, the participant's ability to walk 4 meters is assessed. You will need a stopwatch and a marked walking course. If this test is being done in a new location, then a course must be laid out on the floor. Detailed instructions for laying out the course are provided in Appendix 16.B.

The walking course should be unobstructed and include at least an extra one-half meter on each end. Participants are instructed to walk at their usual speed, and timing is stopped when the first foot completely crosses the 4-meter mark. The faster of two timed walks is used for scoring purposes. When training to perform this test, it is good practice to have two or more people doing the timing so that timing can be compared for precision.

A cane or walker may be used during the walk, but if people with such devices can walk short distances without them, they should be encouraged to do so. Many people with assistive devices use them only when they walk outdoors or for long distances indoors. Doing the test without the device provides a much more accurate assessment of the functional limitations of the participant. Ask the participant if she ever walks at home without the device. Then ask the participant

if they think that they can walk a short distance for the test. Participants who normally use assistive devices should be watched particularly closely during the test to prevent falling.

If possible, women wearing high heels should change into another pair of shoes before performing the gait speed test. Press the start/stop button to start the stopwatch when the participant steps over the starting line. Wait until the participant actually begins to move before starting the watch. Do not start the watch when you say “begin.”

The position of the examiner is critical for the walk. If you are too close you will set the pace. If you are too far behind you will not be in a good position if the participant falls. You also need to be in a good position to observe the foot crossing the finish line. The best position to maintain during the walk is to the side and slightly behind, outside of the participant’s visual field. Record the time when the participant’s first foot crosses the 4-meter line. If the foot lands on the line but doesn’t cross it, this is not the end of the test. You need to anticipate when a foot will fully cross the line and be ready to stop the watch as it crosses the line. You should imagine a plane of glass at the finish line that the foot breaks when it crosses. This is the time to stop the watch. Record the time to the nearest hundredth of a second.

If you have trouble with the stopwatch or you think that the timing wasn’t accurate, the gait speed test should be repeated.

Scoring of the gait speed test is based on established categories of completion times that were previously shown to divide the older population into four equal groups. Participants who require more than 8.70 seconds to complete the walk receive 1 point; participants whose completion times fall in the range of 6.21-8.70 seconds receive 2 points; participants who finish in 4.82-6.20 seconds receive 3

points. Participants who finish the walk in less than 4.82 seconds receive the full 4 points. Inability to complete the walk in less than 60 seconds results in a score of 0. If the walk was not attempted or not completed, you should select a reason from the options on the score sheet.

Although 4 meters is the preferred walk distance, an alternate walk distance of 3 meters can be used in those areas (for example, some home settings) where an unobstructed course of 4 meters is not available. Quartiles of completion times and associated scores for the 3-meter course are shown on the score sheet.

16.2.4.4. Chair Stand Test

The final portion of the SPPB is the chair stand test. In this test, participants are first instructed to fold their arms across their chest and to try to stand up one time from an armless chair placed against a wall. To perform this test you will need a stopwatch, the script, a score sheet, and a straight-backed chair with a hard seat. If this type of chair is not available, a chair with a softer seat or a chair with arms may be substituted.

If the participant is successful rising from the chair once, they are then asked to stand up and sit down 5 times as quickly as possible. Timing begins as soon as the command to stand is given and continues until the participant straightens at the end of the fifth stand. When learning to do this, it is useful for two or more people to time the test so that the times can be compared for precision.

For efficiency, it is valuable to have two chairs available so that the examiner can do the demonstration while the participant sits in the other chair and watches. If only one chair is available then the participant will have to get up to watch the demonstrations.

To ensure safety, the examiner should stand in front of the participant and be prepared to catch them if they fall forward. However, do not stand so close that the participant feels hemmed in and slows their pace during the chair stands.

For the first portion of the test, simply record whether the participant was able to rise from the chair without the use of their arms. If the participant is unsuccessful, the examiner should ask the participant to try to stand using their arms. Inability to complete the single chair stand with arms folded or being able to do it only with use of the arms ends the chair stand test and results in a score of zero for this portion of the battery.

For the second portion of the test (multiple chair stands), instruct the participant to stand up straight as quickly as they can five times without stopping in between. After standing up each time, the participant must sit down and then stand up again, keeping their arms folded across their chest. Emphasize the word "quickly" and perform the demonstration quickly to further reinforce this point. The gait speed test is done at normal speed but the chair stand test should be done as quickly as possible. Count the stand number only after the participant has straightened up. Do not pace the test with your counting. If the participant does not stand up completely, stop the test and redemonstrate.

Timing begins when the command to stand is given and continues until the participant straightens their body at the end of the fifth rise. This contrasts with the gait speed test where timing begins only when the participant begins to move. During the test, count out loud as the participant rises up to five times. Do not coach or encourage the participant during the test. Watch the participant closely and stop the test if the participant is tired or short of breath during the repeated chair stands. The test should be stopped if the participant has to use their arms to rise at any time or if the participant has not completed the five chair

rises after one minute. You should also stop the test at your discretion if, for any reason, you are concerned about the participant's safety. If the participant stops before completing the five rises, you should ask them if they can continue. If the participant says yes, continue timing. If the participant says no, stop the test.

Scoring of the chair stand test is based on established categories of completion times of five repetitions that have been shown to divide the older population into four equal groups. Participants who require more than 16.70 but less than 60 seconds receive 1 point. Participants whose completion times fall in the range 13.70-16.69 seconds receive 2 points, while those in the range 11.20-13.69 seconds receive 3 points. Participants who finish the 5 repetitions in less than 11.20 seconds receive the full 4 points.

16.2.4.5. Summary of Scoring

The composite score for the SPPB is simply the sum of the scores of the three individual components. The maximum score that a participant can receive is 12 points. A schematic summary of the scoring for each of the three individual components is provided in Appendix 16.C.

16.2.4.6. Quality Control

All staff performing the SPPB on LIFE participants must be certified. Certification must be renewed annually.

16.3. BLOUSE/SHIRT TEST

16.3.1. Overview

The blouse/shirt test is a performance-based measure of upper extremity function and should be performed by the participate while standing. The test has been used previously in the Woman's Health and Aging Study.

16.3.2. Schedule of Administration

The blouse/shirt test is performed at screening visit 2 and at all in-person follow-up assessments.

16.3.3. Required Equipment

Depending on whether the participant is female or male, three women's blouses, sizes medium (12), large (18) and extra-large (22) or three men's shirts, sizes medium, large, and extra-large are required. A stop watch, and chair, if the participant is unable to stand, is also necessary.

16.3.4. Procedures

1. Determine the correct size of the blouse/shirt. If the participant is too large to wear the largest blouse/shirt, do not attempt this task. Score a "9" and explain.

2. Ask the participant to stand up and remove any bulky sweater or jacket. If the participant cannot stand, have her/him put the blouse/shirt on while sitting. Ask participant to move to the edge of the chair if possible.

3. Ask participant to put on the blouse/shirt over their clothes and button it except for the top collar button. The blouse/shirt is considered on if both arms are in the appropriate sleeves and the collar up around the participant's neck (not across the participant's back).

4. Hand the unbuttoned blouse/shirt to the participant and begin timing when participant takes the blouse/shirt.

5. Stop timing when the blouse/shirt is buttoned or after four minutes, whichever comes first.

6. If the blouse/shirt is buttoned unevenly, ask the participant to take the blouse/shirt off and begin again. The participant may be informed if the blouse/shirt was buttoned incorrectly. If the blouse/shirt is still buttoned incorrectly after the second attempt, terminate the task.

7. The participant may not stand in front of a mirror to put the blouse/shirt on.

8. Record whether participant was able to put on the blouse/shirt, whether the participant was able to button the blouse/shirt, the time to complete the task, and whether the participant was standing or sitting for the task.

16.3.5. Quality Control

All staff performing the Blouse/Shirt test on LIFE participants must be certified. Certification must be renewed annually.

16.4. MEASUREMENT OF GRIP STRENGTH

16.4.1. Overview

Hand grip strength is a commonly used measure of upper body skeletal muscle function and has been widely used as a general indicator of frailty with predictive validity for both mortality and functional limitation. Other than possible temporary discomfort during the test itself, there are no known risks for the participant.

16.4.2. Schedule of Administration

Hand grip strength is performed at screening visit 1 and at the 6- and 12-month follow-up clinic visits.

16.4.3. Required Equipment & Personnel

The Jaymar Handheld Dynamometer is used to measure grip strength.

16.4.4. Exclusion Criteria

If the participant reports current flare-up of pain in the wrist or hand, or has undergone fusion, arthroplasty, tendon repair, synovectomy, or other related surgery of the hand or wrist in the past 3 months, the affected side should not be tested.

16.4.5. Procedures

This test should be done with the participant in a seated position. Determine whether the participant is right- or left-handed.

Set the dynamometer handgrip at **position two.** Adjust it for a smaller or larger hand when necessary. Check that arrow is set at ZERO.

The dynamometer is fairly heavy, so caution the participant when handing out the instrument. Allow one practice try to familiarize participant with the feel of the instrument. Ensure that the bars are the proper distance apart for a comfortable grip. The participant's arm should be resting on the table with the elbow bent.

Test both hands. Test the right hand first and then the left hand, with a total of two trials for each hand. Record each value to the nearest 2 kilograms, e.g. 40 (kg). If < 10 kg, right justify and zero fill, e.g. 8 (kg) = 08. After each reading, reset the arrow to ZERO.

For each measurement, instruct the participant to squeeze as hard as they can. Allow 10 seconds between each measurement. Discontinue a measurement with anyone complaining of pain, then code 'unable' noting reason why unable.

16.4.6. Quality Control

All staff performing the grip strength measurements on LIFE participants must be certified. Certification must be renewed annually. The dynamometer should be calibrated monthly. If the device is dropped or mishandled, the calibration should be checked. This is done by slowly lifting 20 kilograms strapped to the handle. The dial reading should be within 2 kilograms of the referenced weight.

16.5. Lateral Mobility Test (LATMOB- done at Wake Forest University only)

16.5.1 Overview

There is ample evidence in the geriatric literature that physical performance measures are a valuable tool for identifying and monitoring functional abilities that are related to physical disability. Currently, however, there are no simple measures available that enable researchers and clinicians to assess the dynamic nature of lateral mobility. The LATMOB task was developed in order to complement those tasks currently being used to assess function in older adults and to fill this assessment gap. The LATMOB task is a simplified version of the CAR task. In the CAR task the participant enters and exits a mock up of the passenger side door and seat of a car. The physical demands of the LATMOB task are similar to those of the CAR task, and include lateral mobility, stooping, weight shift, and transfer.

16.5.2 Schedule of Administration

The LATMOB is performed at Wake Forest University only at screening visit 2 and at 6- and 12-month follow-up assessment visits.

16.5.3 Required Equipment

The following equipment is required for the LATMOB task: two sets of standards one 155 cm (high) tall and the other 60 cm (low) tall, two crossbars, each approximately 133 cm in length, one standard chair (47cm high & 40cm deep), one step bench (20.5 cm high x 40 cm wide x 70.5 cm long), mat template (to facilitate the arrangement of equipment) and one stopwatch.

16.5.4 Procedures

16.5.4.1 Set-up

The low standards should be 138 cm apart and the high standards should be 110 cm apart, center-to-center. One cross bar should be placed between each of the two standards. The two sets of standards should be 61 cm apart from each other, measured from the center of the cross bars. The low cross bar should be 18 cm high, and the high crossbar should be 127 cm high. The chair should be placed adjacent to the high standard, opposite of the low standards, so that the back of the chair is in line with one of the high standards. The step bench should be placed directly in front of the chair. (See diagrams below.)

Diagram 16.1 LATMOB Task

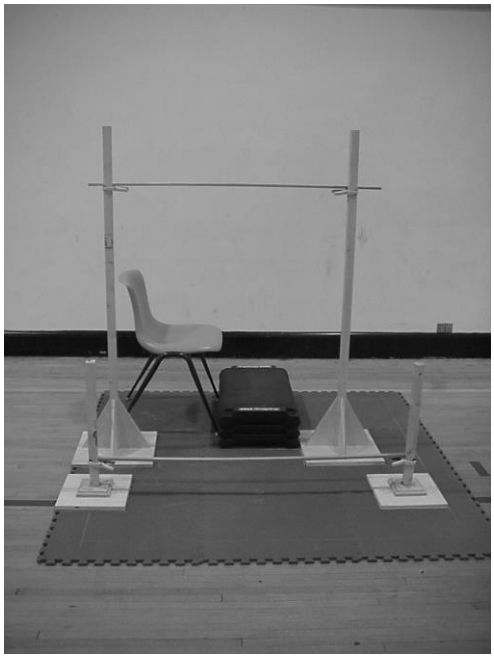
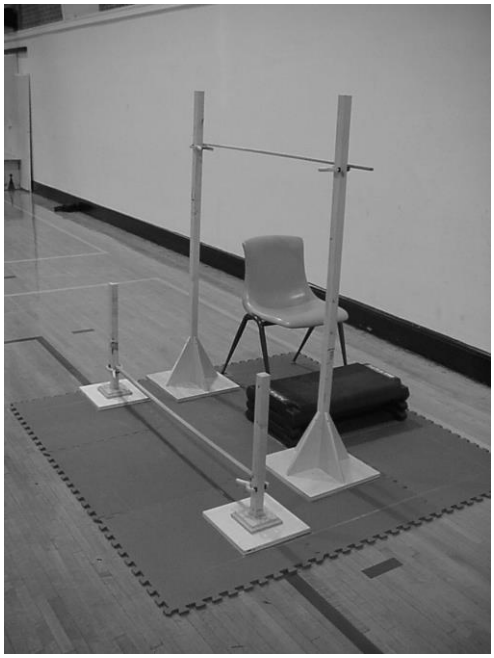


Diagram 16.2 LATMOB Task



16.5.4.2 Administration

a) Tell participant “We are now going to test your ability to get into a car using this setup.”

b) Demonstrate starting position. Participant should be positioned so that they are standing in line with the chair, and the lateral part of their left foot is 53cm from the first cross bar. Tell participant “You will start standing beside the first bar facing away from it as I am now.” When I say ‘Go,’ you will step onto the mat with your left foot, step over the bar left foot first, duck under the second bar, and sit in the chair with both feet flat on the step in front of you.

c) “I will now demonstrate for you. I will be timing you while you perform this task, so do it as quickly as you can.”

d) Demonstrate the task for participant.

e) “I want you to start when I say, ‘Ready? Go.’”
“Do you have any questions?” Answer questions, if any.
”I would like to give you a practice trial.”

f) Allow the participant a practice trial to ensure they understand the directions.

g) With subject in proper starting position, ask, “Are you ready?”
When they reply ‘Yes,’ give the command, “Ready? Go.”

h) Begin timing as soon as the participant places the left foot in front of first bar, and finish timing when the participant places their right foot (or both feet if done simultaneously) on the step. Record the time to the nearest 0.01 second.

i) If participant displaces either bar, stop the trial and have them retry the test. Mark a failed trial on the scoring sheet along with the bar (low/high) that was displaced.

j) **Participant will perform three trials of the task**, unless they knock off one of the crossbars, in which they are to repeat that trial.

k) Participant may not use a cane to perform this task. They are not to hold onto anything while performing this task unless they need assistance stepping over the low bar (in which case the test administrator may assist the participant). This should be noted on the score sheet.

16.5.5 Other Issues

The physical risks associated with the LATMOB task are minimal and there are no known social/psychological/legal risks. We have tested over 150 older adults on the LATMOB task with no reported injuries. If there is any reason either the test administrator or participant feels performing this test would be unsafe, then the task should not be attempted.

This task should be performed in tennis shoes or in shoes with very low or no heels. Ask the respondent if the footwear he/she is wearing is what he/she wears most of the time around the house. Soft soled, heelless slippers should not be worn, since they may cause the participant to slip.

To some participants the detailed verbal instructions may seem tiresome or unnecessary. It may help to say to the individual that you are going to explain the test in detail since this is the best way to ensure that everyone does the test in a similar manner. The protocol for each measure indicates which words are required. Verbally describe the task to the participant as you demonstrate it. It might be necessary to demonstrate the maneuver more than once. If the respondent knows he/she cannot do one or feels it would be unsafe to try, he/she should not attempt to do it. Emphasize this without alarming the respondent.

The practice trial is important to determine if the participant has a good understanding of the requirements of the task. The test administrator may give an additional practice trial if they believe the participant had undue difficulty with the performance of the trial.

If the respondent indicates he/she has a physical problem, discuss with him/her whether he/she should attempt each test, given the physical problem.

If a test is not attempted because the participant refuses or prefers not to, record the reason on the score sheet. If a test is attempted but the administrator or the participant decides that the test cannot be completed, record TRIED BUT UNABLE. If a test is not conducted for safety reasons or lack of appropriate space or furnishings, record the appropriate outcome, for example: NOT ATTEMPTED, INTERVIEWER FELT UNSAFE; NOT ATTEMPTED, PARTICIPANT FELT UNSAFE; PARTICIPANT CANNOT STAND UNASSISTED; OTHER, SPECIFY.

Occasionally a participant will be so unsteady that the administrator will be concerned for his/her safety. The administrator may decide not to perform the

test if the participant appears in imminent danger of falling. In all instances, the administrator should be close to the participant to offer support. Stay close to the side of the participant, rather than in front of him/her, to steady him/her if necessary. After reading the verbal instructions and demonstrating each maneuver for the participant, be sure to ask, “Do you feel it would be safe to try?”

In the unlikely event that a participant should begin to fall, do not attempt to pull him/her up, rather help to lower him/her down gently in order to reduce the impact of the fall. Do not hold the participant by the hand. Rather hold him/her around the torso under the shoulders. If this happens, and the respondent is not injured, help him up by first having him get on his knees or on all fours, place the chair next to him and have him support himself on the chair as you lift under the shoulders. Do not try to lift the participant alone from the floor. It may be helpful to have the stopwatch around your neck or wrist so that you can immediately let go of the stopwatch and have both hands free to help the participant. In the event that the participant requires assistance, simply drop the stopwatch and disregard the timing.

You should be completely familiar with all of procedures for this task and practice them before attempting to administer the test to a participant. It is imperative that all participants are given the same instructions and that quantitative measurements associated with this test are made in a uniform manner.

16.5.6 Summary of Scoring

Each participant completes three trials of the LATMOB task. Of these three trials, the quickest for each participant is used for data analysis purposes.

16.5.7 Quality Control

All staff performing the LATMOB task on LIFE participants must be certified. Certification must be renewed annually.

16.6. MEASUREMENT OF HEIGHT, WEIGHT AND WAIST CIRCUMFERENCE

16.6.1. Overview of Body Size Measurements

Although weight can be measured with accuracy and precision using relatively simple equipment, the preparation of the participant, standardization of procedure, and maintenance of equipment are critical in order to obtain reliable data.

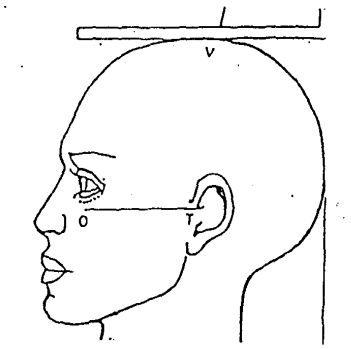
Body weight relative to height, expressed as Quetlet's index, or body mass index (BMI, kg/m^2), is highly correlated with more direct measures of body fat.

All measurements are to be made with the participants wearing light clothing, e.g., a short sleeve shirt or blouse (or surgical gown), shorts, socks and without shoes (for weight and height). A supply of shirts and shorts (or gowns) should be maintained at the clinic for participants who forget to wear or bring the appropriate clothes for body size measurements. Assessors should instruct participants to empty their pockets before the assessments begin.

Body weight will be measured at baseline, the semi-annual clinic visits, and the close-out visit (if applicable). Body height will be measured at baseline only.

16.6.2. Body Height

A wall-mounted stadiometer graduated in centimeters with a horizontal measuring block (or fixed angle) is to be used. If the stadiometer is not wall-mounted, you will need a level to ensure that the horizontal measuring block is level.



ORBITALE:	Lower margin of eye socket
TRAGION:	Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE:	Orbitale tragion line horizontal

The participant stands erect on the platform with his/her back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane is defined by the lower margin of the bony orbit - the bony socket containing the eye - and the most forward point in the supratragal notch -the notch just above the anterior cartilaginous projections of the external ear). The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The participant's height is recorded to the nearest 0.1 cm. The participant should be instructed to stand as straight as possible with feet flat on the floor, with shoes off.

16.6.2.1. Deviations and exceptions to standard positioning:

Obese participants and those with a kyphotic posture may not be able to place the heels, buttocks, and scapulae in a single vertical plane while maintaining a reasonable natural stance. These participants may be positioned so that only the

buttocks, and possibly the scapula, are in contact with the wall-plate. The essential point is that the participant stands erect with the buttocks in contact with the wall plate and the legs as close together as possible. In very obese participants, if it is not possible to obtain contact between the headboard and the top of the skull, then the participant may need to lean back slightly (without tilting the head) until proper contact can be made.

For participants with severe spinal curvature, if the spine is the part that protrudes the farthest, then that should be the part that is touching the wall plate, together with heels and buttocks.

For participants with extreme kyphotic posture, it may not be possible to obtain contact between the headboard and scalp when the participant's back is against the wall-plate. In this case, measure height with the participant standing sideways (side of arm and shoulder in contact with the wall-plate) and positioned so that the headboard contacts the scalp. The head should be in the Frankfurt Horizontal Plane. Record that the participant was measured in the sideways position on the scoring form so that follow-up measurements will be made in the same position.

If the participant has 'knock-knees' then have them separate the heels so that the knees are in contact but do not overlap. Obese participants may also not be able to stand comfortably with the heels touching and may stand with the legs together and the heels separated.

16.6.2.2. Quality Control

All staff who measure body height must be certified. Certification must be renewed annually.

16.6.3. Body Weight

16.6.3.1. Overview

Weight is measured in kilograms using a standard certified scale.

16.6.3.2. Required Equipment

Standard certified scale.

Maintenance

If a balance beam scale is used:

- Rest the counterweight (larger weight) in the far right position.
- The top weight should rest in the left or zero position.
- The counterweight should always be lifted carefully before it is moved across the beam. This prevents wear on the notches which could lead to erroneous readings.
- Keep the scale on a level surface and move it as little as possible.

16.6.3.3. Calibration Procedure

Calibration checks should be carried out on equipment in its normal location. A class F certified 20 kg calibration weight will be used for checking scale calibration. The calibration weights should be stored and used according to manufacturer's instructions (which should be saved and filed along with accompanying certificates).

The calibration weights should be stored on the floor against the wall near the scale, NOT on an elevated surface. This will keep carrying the weights to a minimum. Staff should review the recommended procedures for lifting heavy objects (bend at the knees, keep back straight, etc.) Sites might assign a staff member who is more physically capable to do the calibration on a regular basis. Finally, the 20 kg weight could be replaced with two calibrated 10 kg weights. A

good procedure for placing the calibration weight is to put the weight in the center of the scale platform leaving some room at the edges for the feet.

The following procedure checks the repeatability of readings and the linearity of the scale in a portion of the working range.

1. Place the 20 kg weight (gently) on the scale platform. Record the weight indicated on the scale.
2. Remove the weight from the scale platform and allow the display to return to zero.
3. Step (or have an assistant step) on the scale. Record the weight indicated on the scale.
4. Step off the scale. Allow the display to return to zero.
5. Have the assistant step on the scale platform while holding the 20 kg weight. Record the scale reading.
6. Step off the scale. Allow the display to return to zero.

Repeat the six steps above at least once, then compare the values obtained.

If the repeated weighing of the calibration weight, or the assistant's weight, or the weight of the assistant plus the calibration weight do not yield the same values each time, or, if the weight of the assistant plus the calibration weight is more than 0.1 kg different from the sum of the two weighed individually then the scale is probably faulty. .

Results of the above tests should be recorded in the calibration log, signed and dated by the person performing the calibration, and the form will be retained as part of the study documentation. If the tests indicate that the equipment is out of

tolerance or faulty, the nature of the deviation and the action taken should be noted as a comment on the calibration form.

Safety Issues and Exclusions

The measurement of weight using a standard certified scale poses no safety concerns or reasons for exclusion.

Subject and Exam Room Preparation

Study participants are encouraged to empty their bladders and/or bowels prior to the measurement.

Weight is measured without shoes or heavy jewelry and wearing the standard clinic gown; pockets of gown must be emptied of keys and other heavy objects.

If a balance beam scale is used, the scale should be positioned so that the examiner can stand behind the beam facing the subject, and can move the beam weights without reaching around the subject.

Detailed Measurement Procedures

If a balance beam scale is used:

- Before the participant steps onto the scale, lift the counterweight and position it at zero. The participant should stand quietly in the center of the platform, facing the balance beam, with their weight equally distributed on both feet, and not touching or supporting themselves on anything.

- If a participant requires support from a cane while being weighed, weigh yourself with and without the participant's cane, etc., to determine its weight. Subtract the weight of the aid from the participant's weight before recording. In the event that it is necessary for the examiner to support the

participant during weighing, provide the minimum support that is safe.

- Adjust the counterweight, and then the top weight, until the beam is evenly balanced.
- Weight is recorded to the nearest 0.1 kg.

A chart for converting kilograms to pounds should be mounted near the scale, so that participants can be told their weight in pounds. Script: "In order to measure your weight, please remove your shoes and heavyjewelry, and empty your pockets. Please step forward onto the center of the scale."

16.6.3.4. Quality Control

All staff who measure body weight must be certified. Certification must be renewed annually.

16.6.4. WAIST CIRCUMFERENCE

Waist circumference will be measured at SV1 and at the 6 month and 12 month follow up assessment visits. The Gulick II Tape Measure (model 67020) will be used as it accurately and reliably measures waist girth. The design of the tape measure eliminates the guesswork by applying a known amount of tension (four ounces) to the measuring tape. When used properly, tape tension is always four ounces. Therefore, accurate measurements are possible no matter who is doing the measuring.

If an ordinary tape measure (without the special 4 ounce tension indicator device) is used to measure waist circumference, the measurement will depend on how tightly the tape is pulled. If you pull harder and harder, tissue compression will be greater and greater, and the measured circumference will become smaller and smaller. Two consecutive measurements are usually quite different. If two or more people take the same measurement, the results rarely agree. It is clear that only by applying a constant tension (as the Gulick II does), can accurate and repeatable measurements be taken.

The Gulick II Tape Measure uses a no-stretch, retractable tape with both Metric and English gradations (centimeters and inches). The tape is not metallic to avoid the discomfort of a cold object touching the skin and to eliminate any possibility of scratches or cuts. The self-retracting tape is kept at the desired length until the retract button is pushed.

The most important part of the Gulick II Tape Measure is the tensioning device attached to the measuring tape. Its function is to provide a known amount of tension while a measurement is being taken.
Each individual tensioning device is calibrated to indicate precisely a 4-ounce tension. Note that a stainless-steel compression spring is used. This guarantees that the calibration will last a lifetime, since it is impossible to "over-compress" a spring of this type.

To take measurements: Pull an appropriate amount of tape out of the housing. Wrap the tape once around the waist (see instructions below). Align the tape's "zero line" along side of the tape graduations. Use the Metric units (cm). Now simply pull on the end of the tensioning mechanism until the calibration point is just seen. Read the measurement next to the tape's "zero line".

What is meant by "calibration point": When you pull slightly harder and harder on the tensioning device, two colored beads will be seen separated by a silver disk. When you are pulling with exactly 4 ounces of force, you will see a silver disk separating the two beads.
When you see one of the two beads, you are at the "calibration point". Remember, four ounces is not a great deal of force, in fact, it is approximately equal to the force required to lift a stack of 20 U.S. quarters. So don't pull so hard that the beads start to disappear into the end cap of the tensioning device. That is too much force.

Ideally, waist circumference would be measured in the morning after voiding and before breakfast. If this is not possible efforts should be made to measure each subject under conditions as similar as possible on all visits (e.g., same time of day, fasting, limited consumption of fluids.) The participant should remove their clothing on the upper body so that the measurement can be taken on bare skin.

Participants should stand with feet together. The measure should be taken around the abdomen horizontally at midpoint between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line. Mark the midpoint on both sides using a washable marker. (Subject may be asked to assist in passing the tape around the abdomen by holding the end of the tape in position). When the tape is positioned in the horizontal plane at the correct height, the subject should be asked to keep arms at their side and breathe naturally. Ask the subject to breathe in, out, and hold at the end of a normal exhalation. Record circumference to the nearest 0.1 centimeter. Remove the tape and repeat the procedure. If the tape cannot be made horizontal across the waist markings, default to the right hip. If the difference between the first and second measure is more than 5 centimeters, obtain a third measure.

16.6.5. Quality Control

All staff who measure waist circumference must be certified. Certification must be renewed annually.

16.7. SEATED BLOOD PRESSURE

16.7.1. Overview

Blood pressure measurements will be taken to document baseline blood pressure at baseline and all follow-up assessments.

16.7.2. Required Equipment

- conventional mercury sphygmomanometer

- blood pressure cuffs (small, regular, large and thigh cuffs)
- stethoscope: standard stethoscope and ear pieces with bell, tubing to be maximum of 14 inches long
- tape measure
- chair with back support

16.7.3. Equipment Maintenance

Daily

1. Check the sphygmomanometer for correct zero. Place the instrument flat on the table and disconnect the inflation system. With eyes level with the zero line, assure the top of the meniscus is on the zero line.
2. Check the shape of the meniscus--it should be a smooth, well-defined curve.

Monthly:

1. Check that the mercury rises easily in the tubing and that the mercury column does not bounce noticeably when the valve is closed.
2. Check for cracks in the glass tube.
3. Check the cap at the top of the calibrated glass tube to make sure it is securely in place.
4. Check for spilled mercury in the manometer case.
5. Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears.
6. Check the pressure control valve for sticks or leaks.
7. Check the stethoscope diaphragm for cracks.
8. Make sure when you close the manometer case that:
    a. the manometer tubing is connected and the thumb valve is close
    b. the manometer case is stored on its right side so that the mercury will flow back into the reservoir.
9. Never attempt to repair the equipment yourself. Send the instrument for repair if any of the above checks reveal a problem.

10. Check the sphygmomanometer for air leaks. Roll the cuff around a plastic bottle or tin can and secure in place. Close the valve on the Air-Flo system and inflate the instrument until the mercury rises to 240 mm Hg. Close the valve. The mercury column should remain stable. If the column continues to fall, there is an air leak and the system should be re-inflated until the column rises to 200 mmHg. Pinch the tubing at various locations to localize the area of the leak, then replace the leaking tubing, cuff, or valve.

General:

With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. Do not attempt to clean the glass column with a pipe cleaner, as hazardous levels of mercury aerosol will be produced. Have your QC supervisor send the instrument to your local supplier for repair.

Since mercury is a hazardous, toxic substance, all maintenance and proper disposal procedures must be performed carefully (consult your local institution for guidelines). Do not perform any maintenance procedures that will expose mercury to air. A manometer specialist with expertise in handling toxic substances should be contacted to add or withdraw mercury from the instrument.

Check the blood pressure cuffs on a monthly basis to assure all sizes of cuffs are available. Document the monthly checks of the sphygmomanometer on your Quality Assurance (QA) Equipment Log Form.

Inspect the tape used to measure arm circumference for damage or wear twice a year and record these checks on the QA Equipment Log Form.

16.7.4. Safety Issues and Exclusions

None.

16.7.5. Participant and Exam Room Preparation

Caffeine (from coffee, tea, or soda), eating, heavy physical activity, smoking and alcohol should be proscribed for 30 minutes prior to recording the blood pressure.

16.7.6. Procedures

Arm Circumference Measurement

Measure the participant's right arm to determine the appropriate cuff size before allowing the participant to rest. If the participant's right arm is injured or missing, use the left arm for the arm circumference and blood pressure measurement. Use the following procedures to measure the participant's arm and determine the appropriate cuff size:

- Proper measurement requires that the participant's arm is bare to the shoulder. The participant will be wearing a gown or loose-fitting top provided by the clinic.
- Request the participant to stand, bend the elbow, and put the forearm straight across the chest. The upper arm should be at a 90 degree angle to the lower arm.
- Measure arm length from the bony prominence of the shoulder girdle (acromion) to the tip of the elbow using a tape measure.
- Mark the midpoint on the dorsal (back) surface of the arm.
- Ask the participant to relax their arm along the side of the body.
- Draw the tape measure horizontally around the arm at the midpoint mark, but do not indent the skin.
- Use the measurement to determine the correct cuff size.

Do not use the markings on the blood pressure cuff for reference. Instead, use the following criteria for determining the appropriate cuff size for the participant:

Arm Circumference (cm/in.)	Cuff's Bladder Size (cm)*
16.0 - 22.5 cm (6.4 - 9.0 in)	small cuff (9.0 cm)
22.6 - 30.0 cm (9.1 - 12.0 in)	regular cuff (12.0 cm)
30.1 - 37.5 cm (12.1 - 15.0 in)	large cuff (15.0 cm)
37.6 - 43.7 cm (15.1 - 17.5 in)	thigh cuff (17.5 cm)

Keep the above chart of arm circumference measurements and corresponding cuff sizes readily available for easy reference.

Detailed measurement procedures

In measuring the participant's blood pressure, the participant should rest for approximately five minutes with their feet flat on the floor and legs uncrossed. Participants should not talk during the rest period or during the measurement. The maximum inflation level should be determined and two blood pressure readings obtained. For simplicity, all blood pressure measurements will be made on the participant's right arm. Where this is not feasible, the left arm should be used and the exception noted on the comments section of the form. After the baseline measure, the same arm will be used (if possible) throughout the study.

Application of the Cuff

- Ensure that the participant is seated comfortably in a chair with back supported and both feet are flat on the floor.
- Make sure that the participant's arm is resting on the table at a 90 degree angle with the palm facing up.
- Palpate the brachial artery.
- Mark the brachial artery with an eyebrow pencil.
- Place the appropriate-sized cuff around the upper right arm, approximately at heart level, with the participant's palm facing upward (the participant may rest their forearm and elbow on a table or arm of the chair). Place the lower edge of the cuff with its tubing connections about one inch above the natural crease across the inner aspect of the elbow.
- Wrap the cuff snugly about the arm, with the inflatable inner bladder centered over the area of the brachial artery. The brachial artery is usually found at the crease of the arm, slightly toward the body. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over

the area that it overlaps the cuff. You should be able to insert two fingers under the cuff.

- If it is not feasible to measure blood pressure using the right arm, the left arm may be used. The change in arm and the reason for the change should be noted on the comments section of the form.

Rest Period

Ask the participant to sit with both feet flat on the floor and to rest without smoking or talking for five minutes before measuring their blood pressure. Instruct the participant on the correct posture with the back supported and both feet flat on the floor. The work station should be free of excessive noise and the participant should not be interviewed nor asked to read anything at this time.

Determining the Maximal Inflation Level (MIL)

Ausculatory Gap

An ausculatory gap is the fading or disappearance of sound after the first sounds are heard. The sound then reappears at a level well above the diastolic pressure. The radial pulse can still be felt during the silent phase and the gap usually occurs between Phase I and II. This phenomenon is seen more frequently in older participants.

This means that in an adult with an ausculatory gap, the real systolic pressure may be missed and read as a much lower BP. For example:

Real systolic is 172 but sounds fade at:
168 and reappear at
152 and disappear at
98.

If the correct procedure (inflating to MIL) for BP measurement is not used, this participant's BP may be read as 152/98 instead of 172/98. The only way to avoid this error is to obtain the MIL before BP measurement.

Determine the pressure to which to inflate the cuff for the measurement of the systolic blood pressure. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and allows you to hear the first Korotkoff sound. The procedures for determining maximal inflation level are as follows:

- Attach the cuff tubing to the conventional mercury sphygmomanometer.
- Palpate the radial pulse (if the radial pulse is difficult to palpate, the brachial pulse may be used).
- Inflate the cuff to 70 mmHg. Then increase by 10 mmHg increments until the radial pulse is no longer felt (palpated systolic).
- Deflate the cuff quickly and completely.
- Inflate the cuff to 30 mmHg above the palpated systolic pressure for all subsequent readings.
- Repeat the MIL if the first attempt was unsatisfactory or you have had to readjust the cuff after measuring the MIL. Wait 30 seconds before making a second attempt if the first is unsatisfactory. If the second attempt is unsatisfactory, terminate the procedure and note the problem on the form.
- If the radial pulse is still felt at a level of 270 mm Hg or higher (which means that the MIL is 30 mm Hg higher) repeat the MIL. If the MIL is still 300 mm Hg, terminate the blood pressure measurements and write in “300/MIL” on the form.

Performing the Measurement

- Place the ear pieces of the stethoscope, with the tips turned forward, into your ears.
- Apply the bell of the stethoscope over the brachial artery with light pressure, ensuring skin contact at all points. Effective use of the bell requires careful palpation of the brachial artery to know exactly where to place the bell. Place the bell just below, but not touching, the cuff or tubing.

- Close the thumb valve and squeeze the bulb, inflating the cuff at a rapid but smooth and continuous rate to the maximal inflation level. Note: Your eyes should be level with the mid-range of the manometer scale and focused on the level to which you will raise the pressure.
- Open the thumb valve very slightly and maintain a constant rate of deflation at no more than 2-3 mm per second, allowing the cuff to deflate. Listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard) until 10 mmHg below the level of the diastolic reading (i.e., 10 mmHg below the level where you hear the last regular sound).

The systolic value (Phase I) is the pressure at which you hear the first of two or more knocking sounds in appropriate rhythm. The diastolic sound (Phase V) is the pressure at which you hear the last muffled sound.

- Deflate the cuff fully by separating the tubing and remove the stethoscope ear pieces.
- Record the systolic and diastolic values from the first reading in the spaces provided on the form.
- Hold the participant's arm vertically above their head for a full five seconds to relieve blood pooling.
- Have the participant sit quietly for 30 seconds, then repeat the blood pressure measurement and record the systolic and diastolic values from the second blood pressure measurement on the form.

Criteria for Systolic and Diastolic Blood Pressure

To identify correctly systolic (Phase I) and diastolic (Phase V) Korotkoff values, listen carefully via the stethoscope while reading and interpreting the mercury column.

- The systolic value is the pressure level at which you hear the first of two or more knocking sounds in the appropriate rhythm. Note: A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) does not alter the interpretation of blood pressure).
- The diastolic value can be identified as the pressure level at which you hear the last of these rhythmic sounds (usually muffled).
- Make the mercury column drop at 2 to 3 mmHg per second, from the maximum inflation pressure until 10 mmHg below that of the last regular sound heard. The control of the deflation rate at 2 to 3 mmHg per second is essential for accurate readings and depends on the handling of the bulb and its control valve.

Guidelines for Blood Pressure Readings

- Record all readings to the nearest even digit, rounding up (i.e., read any value that appears to fall exactly between the markings on the mercury column to the next higher even marking).
- Make readings at the top of the meniscus, or rounded surface of the mercury columns.
- When the pressure is released too quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer or doing a repeat measurement.
- Repeat the MIL whenever a systolic blood pressure reading is less than 10 mm mercury from the MIL, or if sounds are heard immediately.
- If a measurement was interrupted, use the following guidelines:
    1. Repeat the MIL only if the cuff was removed or more than five minutes has lapsed between the MIL and the first blood pressure reading or between any two blood pressure readings.
    2. Note on the form in the comments section that the measurement was repeated, and indicate why.

- If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the bell headpiece directly over the pulse point. Take care to wait at least 30 seconds between measurements. Use the procedure to enhance the sounds (see below) and take the second reading, placing the stethoscope in the same position. Note the use of the enhancement procedures in the comments section of the form.

Procedures to Enhance the Brachial Pulse Sounds

If you are having difficulty hearing the blood pressure sounds, there are three methods that can be used to increase the intensity and loudness of the sounds.

1. Reduce room noise.
2. Instruct the participant to open and close their fist 8 to 10 times. Inflate the cuff and take the BP immediately.
3. Have the participant raise their arm and forearm over their head and make a fist several times for at least 60 seconds. Inflate the cuff while the arm is still overhead, but the hand relaxed, to a level 50 mm Hg above the expected systolic level. Then lower the arm rapidly and measure the blood pressure in the usual manner.

16.7.7. Quality Control

All staff who measure blood pressure must be certified. Certification must be renewed annually.

16.8. Radial Pulse

Be sure to wait until the participant has been resting for 5 minutes. Have the participant turn their palm upward. Palpate the radial pulse with your index and middle fingers. Use the stopwatch to count the pulse for 30 seconds and record the number of beats in 30 seconds as Measurement 1 on the Blood Pressure,

Radial Pulse and Weight form; Count the pulse for 30 seconds again, and record the number of beats as Measurement 2.

16.8.1. Quality Control

All staff who measure radial pulse must be certified. Certification must be renewed annually.

16.9 Screening Physical Examination

16.9.1 Purpose and Overview

The purpose of the screening physical examination is to detect medical concerns that would create unacceptable risks from the proposed LIFE walking exercise program. All participants who reach the physical examination visit in the LIFE study will have undergone a telephone screen for medical symptoms or recent medical events that preclude exercise (Telephone Screening Interview)(see flow diagram chapter 21 Safety). Participants who respond in the affirmative to telephone screening items about high risk medical symptoms or events have been excluded. All participants will also have completed a 400 meter walk test prior to the physical examination. The screening physical examination is designed to be used in combination with the Telephone Screening Interview, Medication Inventory, Medical and Hospital Admission History forms, 400 meter walk, vital signs and the screening electrocardiogram to make a determination of medical safety for participation. Since medical problems and physical findings among older adults are common, extremely heterogeneous and of greatly varying clinical significance, the physical examination form can only provide general guidelines and requires professional judgement and clinical experience. The professional who carries out these examinations should have prior training and experience in physical examination of all major body systems and should be familiar with abnormal findings in the older adult. The health professional can be an advanced nurse practitioner, physician assistant or physician and must be

licensed to practice in the state in which the study site is located. A major purpose of the physical examination is to detect high risk problems that are asymptomatic or unreported by the participant. In case of borderline or questionable findings, the participant's clinical status should be reviewed with the site physician and additional medical information may be required.

16.9.2 Schedule of Administration

The Physical Examination is performed at the time of the initial clinic visit.

16.9.3 Equipment

The Physical Examination requires the use of a stethoscope.

16.9.4 General Appearance

Observe for evidence of poor perfusion or oxygenation such as dyspnea at rest or cyanosis.

16.9.5 Skin

Examine the feet for open lesions, especially on the plantar surfaces and bony prominences.

16.9.6 Neck

Examine for severe pain with rotation.

16.9.7 Lungs

Auscultate anterior and posterior fields bilaterally. Note presence of crackles or wheezes. If present, query patient about dyspnea with exertion and examine extremities for edema.

16.9.8 Cardiovascular

Auscultate anterior chest for heart sounds. Note murmurs that are grade 3 or higher. All such murmurs should be reviewed by a study physician. Note rate and rhythm.

16.9.9 Abdomen

Palpate for masses, especially midline pulsatile mass suspicious for aneurysm

16.9.10 Extremities

Examine for pitting edema. Range of motion of major lower extremity joints should be at least 90 degrees flexion at the hip and 120 degrees at the knee. Knee extension should be full or restricted no more than 5 degrees. Ankle dorsiflexion should be to at least neutral (plus 0 degrees) and plantarflexion to at least 30 degrees.

16.9.11 Vascular

Listen for bruits bilaterally over the carotids and femoral arteries. Audible bruits require physician review.

16.9.12 Neurological

Note gross abnormalities.

16.9.13 Comments

Any additional significant abnormalities that have the potential to affect the safety of exercise should be noted here.

16.9.14 Exclusion based on the physical examination

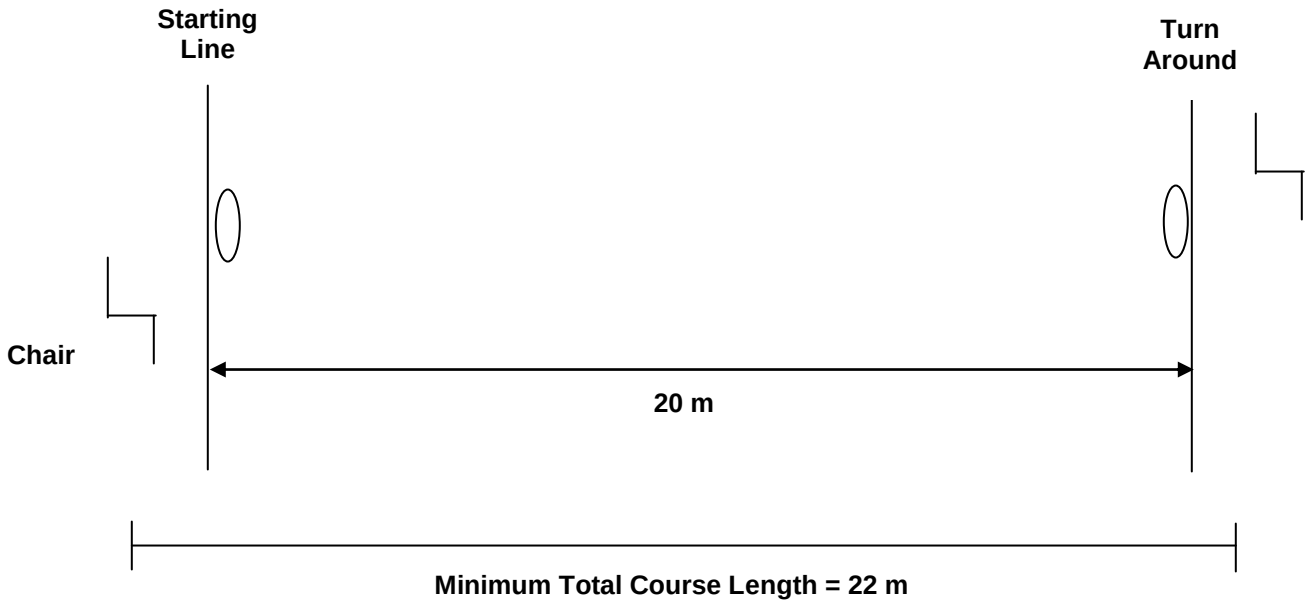
Are any medical findings suggestive of a condition that would affect the safety of this participant in a walking program? If yes, review with study physician. Items marked under Exclusions, will not allow a participant to be randomized.

16.9.15 Need for study physician review

Review all available data including the Medication Inventory, Physical Examination, 400 meter walk, telephone screening interview, blood pressure, waist circumference, radial pulse, weight, medical and hospital admission history and ECG forms. Any areas of concern should be reviewed with the study physician and documented on the form accordingly. The study physician should recommend approval, exclusion or further information collection. Further

information might include medical records or additional physical assessment by the physician or referral to the primary care provider for further evaluation and management.

Appendix A. Diagram for 400 m Walk



Appendix 16.B. Course Layout for the Gait Speed Test of SPPB

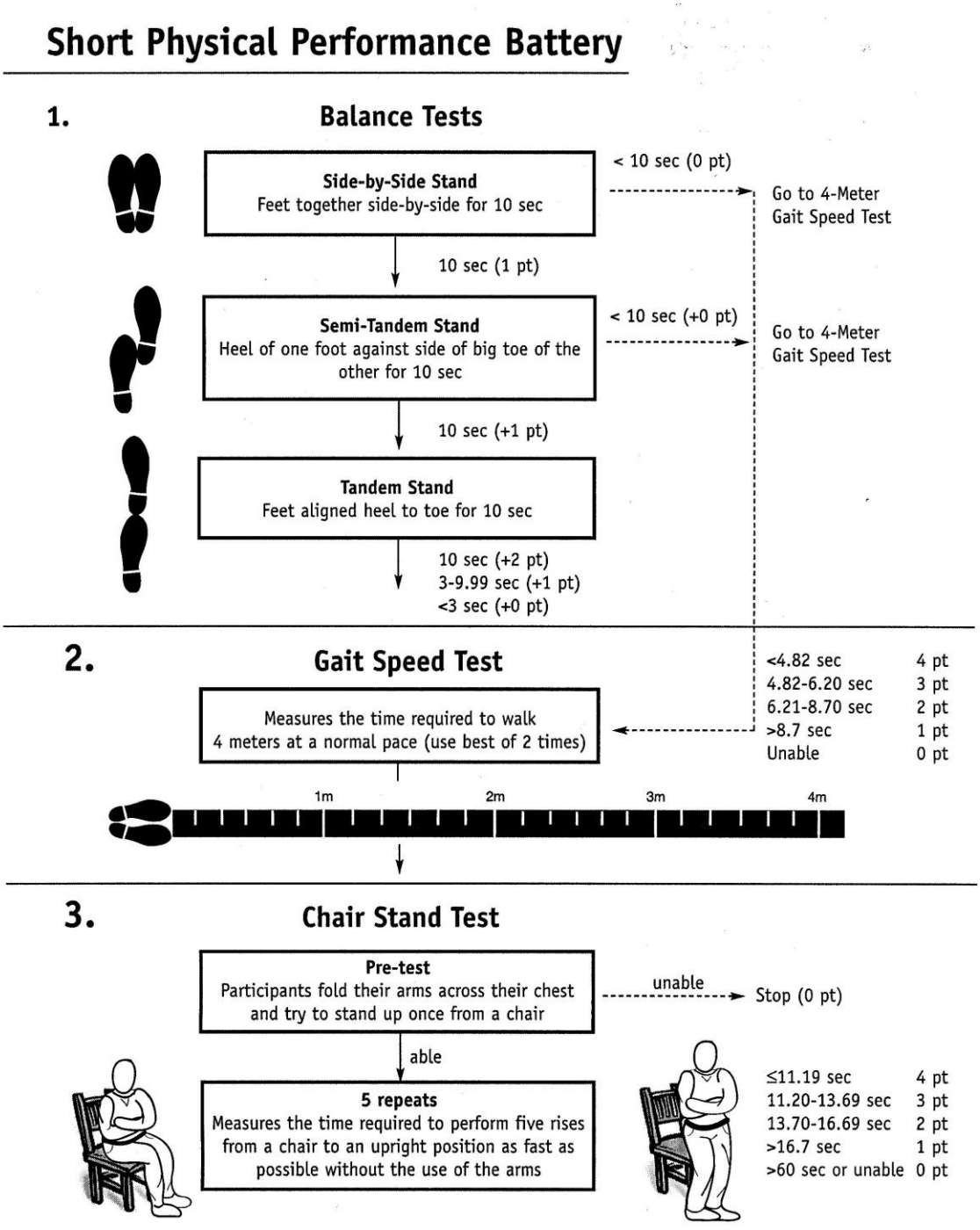
To prepare the course for the gait speed test, first obtain a length of chain with fairly fine links that is just over 4 meters long, approximately 14 feet. These can be readily obtained from a hardware store. Mark the chain with nail polish at 0, 3, and 4 meters. These marks should be the width of a piece of masking tape. The 3- and 4-meter distances should be measured from the front edge of the zero mark to the front edge of the 3- and 4-meter marks, respectively.

The course should preferably be laid out on a hard surface. A carpet is acceptable if this is the only surface available. Avoid laying the course out over the edge of a rug, a throw rug, or any irregular surface that could cause the participant to trip.

Try to find a space that is at least 5 meters long for laying out the 4-meter course. If you are in a home, you can move small furniture with the permission of the owner. If there is insufficient space for the 4-meter course, the alternate 3-meter course can be used. To check whether the available space is sufficient, tape one end of the chain to the floor with masking tape and then pull the chain tight and move around until the best course is found. Once the best course is found, tape down the other end of the tape.

Once the chains is taped down taut, tear off a 2- to 3-foot piece of masking tape and place it directly under the nail polish mark, that indicates the starting line. Place another piece of masking tape of similar length under the 3- or 4-foot mark, whichever is being used. Once the start and end lines are laid down, the chain can be removed and the course is ready for use.

Appendix 16.C. Summary of SPPB Scoring



Appendix 16.D. Scale Calibration Log

Scale Model & S/N:							
Date	20 kg	Tech. Wt.	Tech + 20 kg	20 kg	Tech. Wt.	Tech + 20 kg	Initials/Comments