Manual 32
Physical Function and Endurance Procedures
ARIC Visit 9

Version 2.1 – 04/06/2022

Physical Function and Endurance Procedures

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1 PHYSICAL FUNCTION, ENDURANCE, AND WEIGHT LOSS

1.1 OVERVIEW

This abbreviated objective measure of physical function is based on previous epidemiologic studies of aging, such as the Established Populations for Epidemiologic Studies of the Elderly (EPESE), Framingham Heart Study, the Cardiovascular Health Study, Women's Health and Aging Study, Health ABC, and the Baltimore Longitudinal Study of Aging, that incorporated physical function assessments. The original core battery described below includes grip strength and the Short Physical Performance Battery (SPPB) which consists of chair stands, a usual-paced 4-meter walk, and balance tests. Endurance was added at Visit 6 along with questions about weight loss. As with earlier visits, prior to SPPB training, all examiners should review this manual and the QxQ and complete the online training module for the National Institute on Aging SPPB.

Note that the video does not include training on grip strength. This video should be reviewed prior to the initial training session and every 6 months. The training video can be downloaded at: https://www.nia.nih.gov/research/labs/leps/short-physical-performance-battery-sppb. Click CD (Download). Go to the Downloads directory and click sppb_cd. This may take you to the D: or E: (or another) drive. Go to that location and click the application file labelled Start []. It should open and play the video. The file may be found under "This PC" in the directory of files. Right click on it and will either allow you to "Run"or "Open" it as a virtual disk to your computer's hard drive. If you do not have that option, you will have to burn a CD.

Existing studies have established bi-directional relationships between mobility and cognitive function,[1-6] especially executive function[7-14] and processing speed.[13,15] Some studies have shown that cognitive impairments precede mobility decline,[1,2] while others have demonstrated that impaired mobility precedes cognitive decline in older adults.[3,5] A meta-analysis review supports the hypothesis that gait speed changes likely precede cognitive changes and incident dementia, particularly for non-Alzheimer dementia.(4) In addition, even subtle changes in gait that are not visible to the eye are predictive of important clinical outcomes including mild cognitive impairment, dementia and falls.[16-18] Performance on dual tasks (concurrent physical and cognitive tasks such as walking while performing calculations) may be particularly sensitive to incident cognitive changes.[19] To date, however, the relationship of cognition with mobility is poorly understood.

ARIC and other studies have reported associations between cardiovascular risk factors and brain structural abnormalities that are also linked to cognitive and physical decline (i.e. functional decline). These risk factors are also associated with reduced cardiovascular fitness or endurance. In turn, endurance has been associated with brain structure and cognition in a small study.[20] Cardiovascular endurance may suffer substantial decline prior to the development of recognizable cognitive- or mobility-related difficulty, particularly in sedentary or cognitively impaired individuals, and may be an early indicator of impending functional limitation. The assessment of endurance in the ARIC cohort was added at Visit 6 to elucidate temporal

relations of mid-life cognitive change to late-life endurance and provide an opportunity to examine relations of late-life cardiovascular endurance with late-life cognitive outcomes in the ARIC-NCS cohort.

Although maximum treadmill-based testing with measured oxygen consumption is considered the “gold-standard” method for ascertaining endurance and cardiovascular fitness, this approach may be unsuitable for many older adults. With increasing age, the proportion of even apparently healthy ambulatory older persons who can satisfactorily complete a treadmill exercise test decreases markedly, from 30% in those aged 75 to 79 years, to 25% in persons aged 80 to 84 years, to 9% for those over 85 years.[21] This is especially problematic in longitudinal studies of the aging process in which change in fitness and exercise capacity with age and disease progression are of great interest.

The American Thoracic Society’s 6-Minute Walk Test is a widely accepted measure of submaximal level of functional capacity in clinical and research settings, but time constraints often limit its use in large studies. The Two Minute Walk is adapted from the 6-Minute Walk Test Protocol and is the recommended measure of sub-maximal cardiovascular endurance in the NIH Toolbox Endurance Domain.[22] Validation and reliability studies of the Two Minute Walk have been reported in participants aged 3-85 years of age. The distances covered during the Two Minute Walk and the 6-minute walk are reliable between sessions (intraclass correlation coefficients = 0.888 and 0.917, respectively); the distances during the Two Minute Walk and 6-minute walk are highly correlated (r=0.968).[10] The Two Minute Walk records the distance one is able to walk on a 50-foot course (out and back) in two minutes. The participant’s raw score is the distance walked in two minutes, reported in feet. This score can be used as a raw measure or converted to the Toolbox normative scale scores. Studies indicate that approximately four minutes is required to complete the Two Minute Walk, including test instructions and practice.

Unintentional weight loss is an important risk factor in older adults that may be a marker of metabolic, psychiatric, neurologic, and other medical disorders, is associated with mortality, and is also considered a component in the frailty syndrome.[23] Fifteen to twenty percent of adults 65 years or older have unintentional weight loss when followed five to ten years; rates are higher in nursing home residents.[24] The most widely used definition of frailty defined involuntary weight loss as a loss of at least 10 pounds in the prior year or, at follow-up, of 5% of body weight in prior year by direct measurement of weight.[23] Objective measures improve classification of weight loss compared to subjective reports of weight loss and will be available in the ARIC exams. Objective assessments will be repeated using previous ARIC protocols; subjective reports will reflect methods used in the Cardiovascular Health Study.

1.2 ADMINISTRATION OF SPPB

a. SPPB Administration Overview

Since motivation and level of understanding can have a significant impact on performance, each component of the exam should be administered strictly according to the protocol in the following sequence:

- Explain the procedure to the study participant making sure to adhere to the script.
- Demonstrate the procedure, using the script.
- Ask the participant if they have any questions.
- Re-explain the procedure briefly using the script.
- Ask the participant if they think it would be safe to perform the procedure.
- Begin timing with the stopwatch for the 4m usual pace walk with participant's first movement

Use the script provided to assure that all key points are covered when you describe each test and how to perform it properly. Do not provide additional description or encouragement beyond the key points provided by the standard scripts.

Demonstrate each maneuver correctly. Experience has shown that participants follow more closely what the examiner does rather than what they say. If the participant indicates they do not understand the test maneuver, demonstrate it again rather than solely relying on repeating the verbal instructions.

Limit practice trials for each test to those described in the individual measurement procedures. Allow the participant to rest between tests if out of breath or fatigued. If a test is not attempted because the participant refuses or cannot understand the instructions, record "Participant refused". If you or the participant considers the test unsafe or if they cannot physically complete the test, record "Not attempted, unable, or unsafe" on the scoring form.

Footwear: To reduce effects of different footwear on test performance, the participant should wear tennis shoes or comfortable walking shoes with minimal, blunt heels or no heels. The participant may perform the tests in non-slip socks if appropriate footwear is not available.

The chair should be placed on a non-skid surface (e.g., low pile carpeting if available) with the back of the chair against a wall for stability. There should be adequate room in front and on the sides of the chair for the examiner and participant to move freely.

b. Safety Issues and Exclusions – SPPB Procedure

Safety issues and exclusions for the walking, balance, and chair stands procedures are described here. Grip and TMW safety issues and exclusions can be found in those respective sections.

The large majority of participants should be able to attempt each performance test. Walking aids may not be used for the chair stands or standing balance tests, but may be used for the timed usual pace if participants cannot walk the distance without aids. Crutches, casts or other immobilizing devices alter the participant's usual mobility; if present, do not test the participant and note the reason test was not performed. Exclusion from any performance test is also based on examiner assessment or participant concerns that the test would be unsafe. In the latter case, the examiner should describe the test and discuss with the participant his/her specific concerns about attempting the test, including physical problems and known disabilities. The reason for not attempting a test, or inability to perform a test are recorded on the data form.

For the walking and balance tests the examiner usually stands next to, and slightly behind the participant and positions his/her hands very close to either side of the participant's trunk at the hip or waist level without touching the participant. The examiner should be ready to place both hands on the participant to stabilize them if necessary. If the participant loses balance, the examiner should catch the participant with both hands at the trunk to stabilize them. If the participant begins to fall, the examiner should reach under the participant's shoulders from behind and slowly ease them down to the floor, rather than try to catch the participant while standing still. This strategy should protect both the participant and examiner from injury.

If the participant falls and is not injured, the examiner should have the participant get on their knees or on all fours, place a chair next to the participant, and have the participant support themselves on the chair as he/she helps to lift the participant under the shoulders. The examiner should not try to lift the participant from the floor by him/herself.

2 PHYSICAL FUNCTION (PFX FORM)

2.1 SHORT PHYSICAL PERFORMANCE BATTERY (SPPB)

A direct assessment of physical performance has become standard practice in epidemiologic observational studies of health and disease. The most commonly used assessments, such as the SPPB, were initially designed to differentiate function in older adults. The SPPB is a well-known and validated lower extremity performance measure that predicts adverse outcomes including mortality, falls, nursing home placement, and incident disability in older adults.

a. Equipment: SPPB

- Digital stopwatch (repeated chair stands, standing balance, short walk tests)
- Standard chair: straight back, flat, level, firm seat; seat height 45 cm at front (single and repeated chair stands).

- Colored tape to mark walking course (see drawing included in description of walking tests)

b. SPPB Component Overview

The SPPB includes three components described in the following sections:

1. Chair Stands
2. Standing Balance
3. Usual Pace Walk

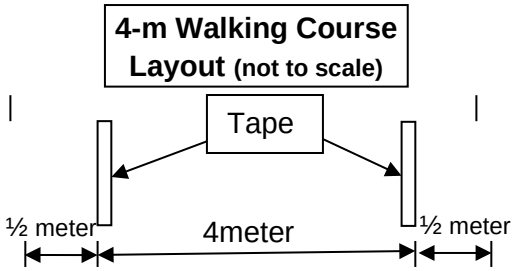
c. SPPB Administration Overview

Use the script provided to assure that all key points are covered when you describe each test and how to perform it properly. Do not provide additional description or encouragement beyond the key points provided by the standard scripts.

Limit practice trials for each test to those described in the individual measurement procedures. Allow the participant to rest between tests if out of breath or fatigued. If a test is not attempted because the participant refuses or cannot understand the instructions, record "Participant refused". If you or the participant considers the test unsafe, record "Not attempted/unable" on the scoring form. If a test is attempted, but cannot be completed or scored, record "Attempted, unable" on the scoring form.

- The chair, described in "Equipment", should be placed on a non-skid surface (e.g., low pile carpeting if available) with the back of the chair against a wall for stability. There should be adequate room in front and on the sides of the chair for the examiner and participant to move freely.
- The standing balance test should be performed with the participant standing a little less than an arm's length from a wall to provide an additional source of support should loss of balance occur.
- 4-meter Walking course: The short walks should be conducted on a 4-meter path laid-out in an uncarpeted, unobstructed, low traffic corridor at least 122 cm (about 4 feet) wide. See Figure 1. The start and finish lines will be marked by tape on the floor. Allow an additional ½ meter on each end of the walking course.

Figure 1. 4-Meter Usual Pace Walking Course



2.2 ADMINISTRATION OF THE SPPB SINGLE CHAIR STAND

This is a test of ability to stand up from a standard chair without using one's arms. This task is also used to screen for the ability to do repeated chair stands. Walking aids including canes may not be used. Although you will demonstrate the repeated chair stands, it is not necessary to demonstrate the chair stand for the single chair stand. Do, however, show the participant how to cross their arms on their chest.

Make sure the participant's feet are squarely on the floor in front of them. The participant should be seated in a position which allows them to place their feet on the floor with knees flexed slightly more than 90 degrees so that their heels are somewhat closer to the chair than the back of their knees. Feet should remain on the floor during testing. Stand in front of the participant (with arms extended, if appropriate) for the participant's safety when performing the chair stands.

Say to the participant "This is a test of strength and stability in your legs in which you stand up from a chair without using your arms. Fold your arms across your chest, like this, and stand when I say GO, keeping your arms in this position. Any questions? Ready, Go!"

If the participant's arms unfold, or they put one or both hands down on the chair to push up, or their feet come off the floor during testing, remind them to keep their arms folded snugly across their chest with feet on the floor and ask them to repeat the chair stand. It is OK for the participant to move a little forward in the chair before standing, but knees and hips should be flexed to approximately 90 degrees before standing. If the participant cannot rise without using arms, say "OK. Try to stand up using your arms to push off."

a. Scoring the SPPB Single Chair Stand

Score as follows:

- If the participant refuses to do the test or cannot understand the instructions, score "Participant refused."
- If the procedure was not attempted because the participant was unable to physically perform the test, score "Not attempted/unable".
- If the participant attempted but was unable to arise even using their arms, score as "Attempted, unable to stand."
- If the participant uses arms to stand up, score as "Rises using arms."
- If they stood up all the way without using arms, score as "Stands without using arms." Go on to Repeated Chair Stands. Skip repeated chair stand for all other responses.

2.3 ADMINISTRATION OF THE SPPB REPEATED CHAIR STANDS

Next the participant stands from a seated position five times as quickly as possible. Record the time it takes to stand five times. Say to the participant, "This time I want you to stand up five times as quickly as you can, keeping your arms folded across your chest." With the next instructions, cross your arms over your chest and then rise while emphasizing "full standing position," and sit while emphasizing "all the way down": "When you stand up, come to a full

standing position each time, and when you sit down, sit all the way down each time. I will demonstrate two chair stands to show you how it is done." Count as you stand each time. Then begin the test. "When I say GO, stand five times in a row as quickly as you can without stopping. Stand up all the way and sit all the way down each time. Ready, Go!"

Start timing as soon as you say "Go." Count: "1, 2, 3, 4, 5" as the participant straightens to standing position each time. Stop timing when the participant stands the final time.

If the participant is unable to complete the chair stands correctly (e.g., is not coming to a full stand, lifts feet off the floor), stop the procedure, repeat the demonstration, wait 1 minute, and begin the procedure again. If the participant stops before completing five stands, confirm that they cannot continue by asking: "Can you continue?" If they say yes, continue timing for up to 1 minute. Otherwise, stop the stopwatch and record the number of chair stands that were completed. If 5 stands have not been completed by 1 minute, stop the test and record "Attempted, unable to complete 5 stands" as well as the number completed.

a. Scoring the SPPB Repeated Chair Stands

If the participant refuses to do the test for non-physical reasons (e.g. not enough time) or cannot understand the instructions, score "Participant refused." If the procedure was not attempted because the participant was unable to perform the test, score "Not attempted/unable." It is acceptable to question the participant to determine if the participant refused because they thought they would have difficulty, be unable to do, or it would be unsafe due to inability to perform well; these should be coded "Not attempted/unable".

If participant attempted but was unable to complete five stands without using their arms, score as "Attempted, unable to complete five stands" and record the number completed without using arms.

If five chair stands were completed, record the number of seconds, to a hundredth of a second, required to complete five stands.

2.4 ADMINISTRATION OF THE SPPB STANDING BALANCE

This is a series of timed, progressively more difficult, static balance tests. The level of difficulty increases as the lateral base of support decreases. The time (up to 10 seconds) that the participant can hold each position (i.e., side-by-side, semi-tandem, tandem) is recorded. Walking aids such as a cane or walker may not be used.

The standing balance test should be performed with the participant standing a little less than an arm's length from a wall to provide an additional source of support should loss of balance occur.

For each stand, describe the position to the participant and then demonstrate it while facing the participant. After demonstrating, approach the participant from the front and off to the side away from the wall. The participant should use the wall for support; or, alternatively, the examiner may offer his/her arm for support if the participant is comfortable with this contact. The support

surface (wall or examiner's arm) can only be used for support while the participant gets in position.

If the participant feels it would be unsafe to try, probe for the reason, and reassure the participant that you will help them into the position and that they can use the wall for additional support. If they still feel they should not attempt it, record the appropriate response and move to the next test. The same scoring principles also apply for the more difficult balance stands. Participants who do not complete the balance test because they or the examiners feel it is unsafe should be marked as "Not attempted, unable". The response "Refused" should be reserved for refusals that are not due to balance problems, perceived difficulty of task, or safety concerns, e.g. "not enough time".

If the participant attempts the stand incorrectly, demonstrate it again. Time each stand. After 10 seconds for each stand, tell the participant to stop. If the participant loses balance before 10 seconds, record the number of seconds for which the stand was held. See figures for placement of feet for each type of stand. To maximize time allotment for testing, the balance tests begin with the semi-tandem stand. If this position cannot be held for 10 seconds, the examiner should record results of the semi-tandem stand then describe and demonstrate the side-by-side stand, which is easier, and mark the tandem stand as "Not attempted/unable." If the semi-tandem position is held for ten seconds, the side-by-side position should be marked as "held for 10 seconds" and the tandem stand should be attempted.

a. <u>Administration of the Semi-Tandem Stand</u>

Begin by introducing the balance tests: "I'm going to ask you to stand in several different positions that test your balance. I'll demonstrate each position and then ask you to try to stand in each position for 10 seconds. I'll stand next to you to provide support if you lose your balance. Do you have any questions?"

Say, "First, I would like you to try to stand with the side of the heel of one foot touching the big toe of the other foot for 10 seconds. Please watch while I demonstrate. You may put either foot in front. You can use your arms, bend your knees or move your body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step like this. Hold onto [*my arm* or *the wall*] while you get in position." Allow the participant to hold your arm or touch the wall for support to get balanced. "When you are ready, let go." If you or the participant feels this stand may be too difficult, you may start with the side-by-side stand instead (see Section 2.4.c.).

Stop the stopwatch if the participant takes a step or grabs for support, otherwise say, "STOP" after 10 seconds, record the response, then go to the Tandem stand.

If the participant is unable to hold the semi-tandem stand for at least 10 seconds, do not attempt the tandem stand, but instead perform the side-by-side stand, which is less difficult, and then go to the walking tests.

b. Scoring the SPPB Semi-Tandem Balance

If the participant refuses or cannot understand the instructions, score "Participant refused." If the procedure was not attempted because of task difficulty, the participant was unable to perform the test or the participant or examiner felt the participant was unsafe, score "Not attempted/unable."

If the participant attempted the test but could not hold the position for at least 1 second, score as "Unable to attain position or hold for one second." If the participant held the position for at least 1 second but less than 10 seconds, score as "Holds position ≥1 but less than 10 seconds" and record the time to 0.01 second on the PFX. If the participant held the semi-tandem stand for 10 seconds, score as "Holds for 10 seconds" and also score the side-by-side stand as "held for 10 seconds" on the PFX form.

c. Side-by-Side Stand

"Now, I would like you to try to stand with your feet together, side-by-side, for 10 seconds. You can use your arms, bend your knees or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. Hold on to [*my arm* or *the wall*] while you get in position." Allow the participant to hold onto your arm or the wall to get balanced. Say: "When you are ready, let go." Start timing when the participant lets go. Stop the stopwatch if they take a step or grab for support. Record to 0.01 second the time the participant could hold this position. Say, "STOP" after 10 seconds.

d. Scoring the Side-by-Side Stand

If the participant refuses or cannot understand the instructions, score "Participant refused." If the procedure was not attempted because of task difficulty, the participant was unable to perform the test or the participant or examiner felt the participant was unsafe, score "Not attempted/unable." If the participant attempted the test but could not hold the position for at least 1 second, score as "Unable to attain position or hold for one second." If the participant held the position for at least 1 second but less than 10 seconds, score as "Holds position ≥1 but less than 10 seconds" and record the time to 0.01 second. If the participant held the position for 10 seconds, score as "Holds for 10 seconds".

e. Administration of the Tandem Stand

The Tandem Stand is only administered if the participant is able to hold the Semi-Tandem stand for at least 10 seconds. "Now I would like you to try to stand with the heel of one foot in front of and touching the toes of the other foot for 10 seconds. Please watch while I demonstrate. You may put either foot in front. You can use your arms, bend your knees or move your body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step like this. Hold onto my arm while you get in position. When you are ready, let go."

Start timing when the participant lets go. Stop the stopwatch if they take a step or grab for support. Record to 0.01 second how long participant is able to hold this position. Say, “STOP” after 10 seconds.

If the participant holds the position for 10 seconds, go to the walking tests. If the participant attempts the Tandem Stand and is unable to attain the position or cannot hold it for at least one second, go to the walking test. If the participant held the position for at least 1 second but less than 10 seconds, perform a second trial of the Tandem Stand. Say “Now, let’s do the same thing one more time. Hold onto [my arm or the wall] while you get into position. When you are ready, let go.”

f. Scoring of the Tandem Stand

If the participant refuses or cannot understand the instructions, score “Participant refused.” If the procedure was not attempted due to task difficulty, because the participant was unable to perform the test, or due to safety concerns, score “Not attempted/unable.” If the participant attempted the test but could not hold the position for at least 1 second, score as “Unable to attain position or hold for one second.” If the participant held the position for at least 1 second but less than 10 seconds, score as “Holds position ≥1 but less than 10 seconds” and record the time to 0.01 second. If the participant held the position for 10 seconds, score as “Holds for 10 seconds”.

2.5 ADMINISTRATION OF USUAL WALK

a. Usual Pace 4m (PFX Form):

The 4m usual pace walk will be timed with a stopwatch following the protocol below which was employed at ARIC visits 5-7.

Because the 4m usual pace walk exam may be required throughout the visits, examiners must maintain proficiency in administering the task. The 4m walk should be administered according to the following instructions and recorded on the PFX form.

PFX Time to walk 4 meters at the participant’s usual pace is measured.

Say to the participant: “I’m going to ask you to do a short walk over this 4 meter course two times. You will walk at your normal or usual pace for two trials. I will demonstrate. Place your feet with your toes behind, but just touching the starting line, like this.”

“Walk a few steps past the finish line.” Demonstrate by walking to the other end of the course at your usual pace, making certain you walk past the finish line before slowing or stopping.

Make sure the feet are in proper position. “Do you have any questions? When I say “Go”, please walk at your normal pace. Remember to walk a few steps past the finish line.” To start the test, say, “Ready, Go.” Start timing with the participant’s first movement.

Follow along a few paces behind and a little to the side of the participant so you can see when the foot crosses the finish line. Stop timing when the first foot fully crosses an imaginary plane extending vertically up from the ending line/tape. Record the time to the nearest 0.01 second.

Have the participant repeat the usual pace walk: “Let’s try this one more time. Ready? Go.”

2.6 TRAINING AND CERTIFICATION FOR SPPB

A training video for the SPPB is available online. Instructions for downloading the video (“Instructions – pdf“) and the demonstration video (“CD (Download and Execute – (.exe)) can be found at http://www.grc.nia.nih.gov/branches/ledb/sppb/index.htm. This video should be reviewed prior to initial training session and every 6 months. Training will include:

- Watch the video for the SPPB
- Read and study the manual and the QxQ
- Attend ARIC training session on performance test administration techniques, or be trained at the ARIC field center by an experienced examiner
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

Certification will include:

- Complete training requirements
- Recite exclusions
- Conduct exam on two volunteers:
- According to protocol, as demonstrated by completed QC checklist
- Times agree within ± 0.5 second of QC officer or designated personnel for SPPB and 6 inches for 2-minute walk.

The following elements must be demonstrated successfully for certification:

CHAIR STANDS

☐ Back of chair against a wall

☐ Script correctly and clearly delivered

☐ Correctly demonstrates two stands, emphasizing full stand and return to complete sit

☐ Says “Ready? Go” for each test

☐ Records timed measure within 0.5 seconds of QC officer or designated personnel

☐ Counts each chair stand and records stand if less than 5

☐ Records and explains unusual values

☐ Starts timing with “Go”, stops with final stand or one minute

☐ If task was not performed, codes and explains reasons

STANDING BALANCE

Side-by-side stand

- ☐ Script correctly and clearly delivered
- ☐ Correctly demonstrates position
- ☐ Timing started coincident with participant release and stopped when participant takes a step or grabs for support
- ☐ Records timed measure within 0.5 seconds of QC officer or designated personnel
- ☐ If task was not performed, codes/records reasons

Semi-tandem stand

- ☐ Script correctly and clearly delivered
- ☐ Correctly demonstrates position
- ☐ Timing started coincident with participant release and stopped when participant takes a step or grabs for support
- ☐ Records timed measure within 0.5 seconds of QC officer or designated personnel
- ☐ If task was not performed, codes/records reasons

Tandem stand

- ☐ Script correctly and clearly delivered
- ☐ Correctly demonstrates position
- ☐ Timing started coincident with participant release and stopped when participant takes a step or grabs for support
- ☐ Records timed measure within 0.5 seconds of QC officer or designated personnel
- ☐ If task was not performed, codes/records reasons
- ☐ Repeat (second trial), if necessary

4-METER WALK

- ☐ Script correctly and clearly delivered
- ☐ Correctly demonstrates
- ☐ Toes touching start line
- ☐ Timing started coincident with participant's first movement
- ☐ Time stopped when the first foot crosses an imaginary plane extending vertically up from the ending line/tape
- ☐ Repeat (second trial)

☐ Records timed measure within 0.5 seconds of QC officer or designated personnel

☐ If task was not performed, codes/records reasons

2.7 GRIP STRENGTH

The grip strength assessment should be performed after the SPPB components and before the TMW, providing a rest period prior to the TMW. Grip strength is a commonly used measure of upper body skeletal muscle function, has been widely used as a general indicator of frailty and, in the absence of other measures of strength, is a good marker of global muscle strength. Grip strength is often measured in the dominant hand or in both hands and the best result used in analyses. This assessment is modified slightly to accommodate time restrictions while maximizing physical function measurements; overall, it is focused on measuring maximal strength. Grip strength in the participant's preferred hand, usually the dominant hand, will be measured using an adjustable, hydraulic grip strength dynamometer. Allowing participants to choose the best side should be comparable to either testing one's dominant hand, as most will choose the dominant hand, or to choosing the best result of bilateral testing. Allowing participant preference will permit participants to choose non-dominant side if medical or other conditions, e.g. stroke, have impaired the dominant hand and testing that side would not necessarily represent global muscle mass or strength.

For grip strength, the participant should be seated at a standard height table at or just below shoulder level with the elbow extended at approximately 180 degrees or next to a table with an adjustable tray table attached.

a. Exclusions

Grip strength exclusion is limited to those who have had surgery on both hands or both wrists in the previous 3 months. If only one side is affected, test the unaffected side. The test can be performed if the participant has a current flare-up of pain in their wrist or hand, for example arthritis or tendonitis. Be sure to record this information on the data collection form.

b. Equipment

Jamar Hydraulic Hand Dynamometer, which registers maximum kilograms of force during a trial, with adjustable handgrip.

Mouse pad or small rolled towel for wrist support

Table with adjustable height (moveable tray table preferred)

c. Equipment Checks

Every six months: Check the calibration of the grip strength dynamometer by hanging 4-5 kg and 10 kg (or about 10 and 22 lb) weights across the handle using two Velcro straps, one strap on each side of the dynamometer handle, or one wide strap that covers the whole handle. Lift the weights slowly from the floor while they are strapped to the dynamometer handle and record the maximum kilograms registered. The lifting motion should be very slow and smooth, and the weight should remain evenly distributed between the two sides of the handle. Repeat the procedure three times and record each result.


Average the three calibration trials. The dynamometer should be accurate within ± 2 kgs for the average of the three calibration trials. If the result is outside the ±2 kg range after following the Troubleshooting tips below, you must send the dynamometer to the manufacturer for repair and recalibration. **DO NOT attempt to recalibrate the dynamometer yourself.** Calibration problems can be caused by dropping the dynamometer or by leaks in the hydraulic system.

Troubleshooting Tips:

If any of the measurements for any of the weights are outside of the acceptable range (±2 kg), remove the weight and turn the dynamometer position to zero. Perform the procedure again for that weight, and verify if the result is in the acceptable range. Check the positioning of the weight on the dynamometer. The position of the weight can affect the reading.

If the result is still outside of the acceptable range, take all the weights off the handle, turn the dynamometer off and then notify the PI or designated person. If readings within the acceptable range still cannot be obtained, a backup device, if available, must be used and the malfunctioning device sent to the company for repair or must be replaced. A dynamometer cannot be used if it does not calibrate properly.

d. Administration of the Grip Strength

The participant should be seated at a standard height table or on a seat with a moveable tray table attached.

"The next test I'll ask you to do is the grip strength test. This device is used to measure the strength in your hand. Even when you squeeze the grip bars as hard as you can, the bars will not feel like they are moving much at all. Before starting, I will ask you a few questions to make sure it is safe for you to do this test."

Determine if the participant has an acute or recent flare of arthritis in the hand that will be tested. Ask, "Do you have any pain or arthritis in either hand or wrist?" if participant answers "Yes", ask, "In which hand or wrist is the pain or arthritis?" Record response. Next ask, "Has the pain or arthritis in your hand(s) or wrist(s) gotten worse recently?" Record response. "Will the pain or arthritis in your hand(s) or wrist(s) keep you from squeezing as hard as you can?" Record response. Pain or arthritis that has gotten worse recently is not an exclusion for this test.

"Have you had any surgery on your hands or wrists in the past three months?" Record response. If the participant says "No", proceed with test; if they answer "Yes," ask them which hand or wrist was operated on, record response, and do not test that hand.

The examination is done with the participant seated facing a table which is at a comfortable level between the shoulder and waist while seated. Extend the arm to be tested in front of participant at or just below shoulder level with the elbow extended at approximately 180° and the elbow and forearm resting on the table (**Figure 2.2**). Place a mouse pad or comparably sized rolled towel under the wrist. The dynamometer is held perpendicular to the table in the hand to be tested, just off the table edge. Correct grip and participant positions are shown below. Demonstrate the correct grip and arm position while seated at the table.

Figure 2.2. Arm position

Figure 2.3. Arm Position

Figure 2.4. Grip Position

Figure 2.5. Mouse pad for wrist support

Ask “Which hand is your preferred or best hand to test for maximum strength?” This response determines which hand is tested unless this side was excluded in the previous screening questions. Record response on form. “Please extend that arm in front of your body and rest it on the table with your arm straight and wrist on the mouse pad. Grip the two bars in your hand like this and squeeze gently to get the feel of it.” Demonstrate proper positioning of the dynamometer then place wrist strap around the participant’s wrist and position participant. Adjust the grip size until the participant is holding the dynamometer comfortably (this will almost always be the second setting). If the handle hits the participant’s hand distal to the second knuckle the grip size should be smaller. If the participant’s natural fingernails are hitting their palm the grip size needs to be larger. “Are the bars the right distance apart for a comfortable grip?” Readjust as needed prior to starting the test until a comfortable position is attained. Allow one submaximal practice trial to determine if the participant understands the procedure and that the grip size is appropriate.

When ready for the practice trial, say, “Now try it once just to get the feel of it. For this practice, just squeeze gently. It won't feel like the bars are moving, but your strength will be recorded.” Show dial to participant after squeezing then reset to zero. “You’ll do this two times. When I say “squeeze”, squeeze as hard as you can. Ready? Squeeze! Squeeze! Squeeze! Now, stop.”

Perform two trials with 15 to 20 sec rest in between. After the first trial, reset the dial to zero, and say “Now, one more time. Squeeze as hard as you can. Ready. Squeeze! Squeeze! Squeeze! Now, stop.” Set the dynamometer to zero prior to each attempt. Record the kilograms from the dial to the nearest 2 kilograms onto the form. If the reading is exactly between two readings on the scale, round up to the next higher even number. Reset the dial to “0” after each trial.

e. Scoring of the Grip Test

Score as follows: if the participant refuses or cannot understand the instructions, score "Participant refused." If the participant was unable to perform the test, score "Unable to do." If the participant was excluded due to recent surgery, record "Excluded". If the participant completed only 1 trial, record "Did 1 trial"; if he/she completed both trials, record "Did 2 trials". Round to nearest even kg; if exactly between two readings on the dynamometer, round to the next higher even number. For example, if the reading is midway between 26 and 28, record 28. Round readings that are less than half way between two even numbers down; round readings that are more than half way round up. Reset the dial to "0" after each trial.

2.8 TRAINING AND CERTIFICATION FOR GRIP STRENGTH ASSESSMENT

Study coordinators are responsible for training new staff using certified examiners based on standardized QxQ instructions.

The examiner requires no special qualifications or experience to perform this assessment. Training will include:

- Read and study the manual
- Attend ARIC training session on performance test administration techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer
- QC officer or designated person may review video of 2 performances if necessary

Certification will include:

- Complete training requirements
- Recite exclusions
- Conduct exam on two volunteers:
    - According to protocol, as demonstrated by completed QC checklist
    - Kilograms agree within ± 2 kilograms of QC officer for grip strength

QC elements required for certification are:

- Participant is asked about recent surgery on hands
- Participant is asked about pain and arthritis in hands
- Participant is asked to place arm at or just below shoulder level with the elbow extended at approximately 180 degrees
- Recording dial reset to zero after sub maximal practice and each trial
- Appropriate hand placement and grip adjustment if needed
- Appropriate position of participant and dynamometer
- Reviews and correctly completes form

3 TWO MINUTE WALK (TME AND TMW FORM)

Safety issues and exclusions for the Two Minute Walk will be assessed on the Two Minute Walk Eligibility (TME) Form. **Staff must complete and save the TME form prior to completing the TMW form**. CDART will use the information from the TME form to determine whether a participant is eligible to complete the Two Minute Walk. This eligibility information will be displayed in the TMW form. Please see section 3.2 below for details regarding the TME form and safety and exclusions.

3.1 ADMINISTRATION OF THE TMW

a. Administration of the Unintentional Weight Loss Questions

The goal of these questions is to document unintentional weight loss that has not been regained. In the first question, the participant is asked if s/he has lost 10 pounds in the past year. If the participant has not lost more than 10 pounds, record “No” and skip to question 3a. If the participant reports s/he has lost about 10 or more pounds, the response should be coded as “Yes” and the interviewer should then ask “About how much lower is your weight now than a year ago?” This will provide an estimate of weight loss in whole numbers. Record response and go to question 3. If the response to question 1 is “unknown”, go to question 3 to ask if the participant was trying to lose weight.

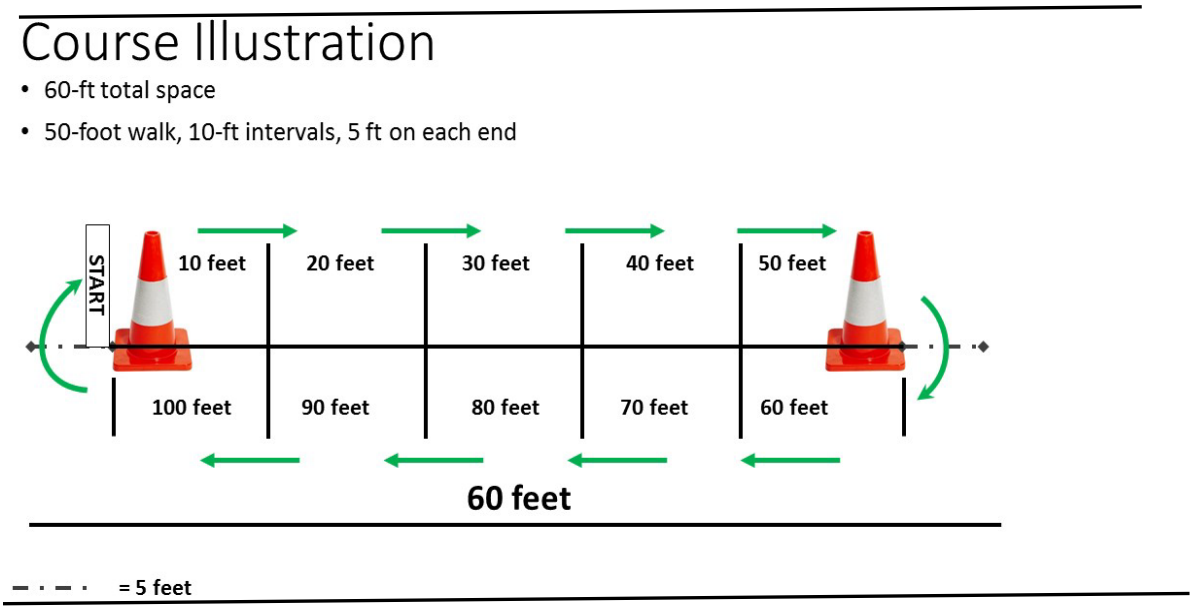
b. Footwear

To reduce the effect of different footwear on test performance, the TMW should be performed in tennis shoes or comfortable walking shoes with minimal or no heels. The participant should be instructed during the pre-visit instructions to wear or bring comfortable walking shoes to the clinic.

c. Course Set-up

For consistency, the walking course length will be 50 feet with an additional 5 feet on each end, laid out in an unobstructed, dedicated corridor. Use traffic cones to indicate the beginning and end of the course. The cones should lie fully within the 50 foot course (see Figure 4.7). Participants will walk in a clockwise direction. Place a 1.5 foot length of tape across the floor to the left of one of the cones to mark the start of the course.

Figure 4.7. Course set-up



For easy access, the examiner should wear the stopwatch around his/her neck. To use the Ultrak 410 stopwatch (pictured at right), first press the reset button at the top left so the display shows **000 00”00**. To begin timing, depress the top of the right-hand button labeled START/STOP watch and press again at the bottom right to stop. The total time will appear on the primary display as minutes’seconds”hundredths of a second.

3.2 SAFETY ISSUES AND EXCLUSIONS

The Two Minute Walk Eligibility (TME) Form is used to assess safety issues and exclusions for the Two Minute Walk. The examiner must complete and save the TME form prior to completing the TMW form and administering the Two Minute Walk test. If there is an unclear answer to an exclusion question, the final decision to test rests with the medical supervisor. Any one of the following is cause for exclusion from the TMW and must be documented on the data collection form:

- Participants unable to complete the 4-meter walk without a walking aid
- Resting heart rate < 40 or >110 beats per minute (bpm)
- Systolic blood pressure ≥180 mmHg or diastolic blood pressure ≥120 mmHg
- Cast or other immobilizing device on leg
- Self-reported angina (chest pain due to heart disease), heart attack, angioplasty, or heart surgery in the previous 3 months

- Seen or thought about seeing a health profession for new or worsening symptoms of chest pain or pressure, shortness of breath, or fainting in the previous 3 months
- Ziopatch alerts (1a, 1g) previously recorded for wide complex tachycardia >120 bpm sustained for more than 30 seconds or narrow complex tachycardia >180 bpm sustained for 60 seconds or more
- If any Ziopatch alert (1b-1e) was previously recorded for: 3rd degree (complete) heart block, Mobitz II 2nd degree AV block, pause > 6 seconds, or bradycardia < 40 bpm and sustained for > 30 seconds, then the participant must be asked if they have a pacemaker.
    - If participant response is “No” or “Uncertain”, then exclude.
- Atrial Fibrillation documented from a variety of **sources*** and displayed in the CDART Participant Snapshot Report **requires a manual heart rate check.**
    - If the manual heart rate is < 40 or > 110 bpm, this supersedes the Omron vitals and the participant is excluded. The next paragraph describes how to take a manual heart rate.

* **Sources** include the following.

- Self-reported treatment of atrial fibrillation in the past three months
- Ziopatch abnormality of atrial fibrillation or atrial flutter
- Ziopatch alert for atrial fibrillation
- Atrial fibrillation documented in ARIC by ECG or hospitalization codes

Manual heart rate check: The participant should be seated comfortably with the forearm extended and palm facing up. Place your index and third fingers in the groove between the bone and the tendon over the radial artery, which is located on the thumb side of the wrist, as shown in the pictures below, using either approach. If you can't find the pulse, try moving your fingers around a bit or press a little harder.

Perry AG, Potter PA, Ostendorf WR (Eds.) 2018. *Clinical Nursing Skills and Techniques [9th ed].* St. Louis. Elseiver. https://www.cdc.gov/physicalactivity/basics/measuring/heartrate.htm.

Using a timer, clock, or watch that counts seconds, count how many beats you feel in 20 seconds. Start the count on a beat, which is counted as “zero” as the second hand (or seconds) begins the timing cycle. The next beat is counted as “one”. Record the last beat felt when 20 seconds passes.

CDART TME Form Entry

If the participant has history of Atrial Fibrillation, then the TME form requires the examiner to determine if the manual heart rate of the participant is between 40-110 bpm.

- Mark response as “Yes” if the heart rate in 20 seconds is 14 through 36
- Mark response as “No” if the heart rate in 20 seconds is 13 or less
- Mark response as “No” if the heart rate in 20 seconds is 37 or more
- Mark response as “Uncertain” if the examiner is uncertain of the heart rate due to a weak or irregular pulse

Blood pressure: Consult blood pressure data collected earlier in the clinic visit.

Requires walking aid: Some participants who complete the short walks without a walking aid may be uncomfortable and/or unwilling to attempt a longer walk, such as the TMW, without the walking aid. Use of a walking aid is not allowed in the TMW.

For most participants, full administration of the TMW should take no longer than 4-5 minutes.

3.3 ASSESSMENT OF TEST ELIGIBILITY AND EXCLUSION CRITERIA.

1) Review exclusion criteria above and record responses on the TME and TMW forms. **Remember the TME form must be completed and saved prior to completing the TMW form**. Before beginning the Two Minute Walk test, tear off a piece of tape that will be used to mark the participant’s stopping point on the course.
2) Provide a brief, general description of the TMW to participants who have no exclusion criteria. Examiner should have participant sit in a chair near the beginning of the walking course.

Script: “This is an activity that shows how physically fit you are by seeing how far you can walk in 2 minutes. I will ask you to walk as fast as you can until I ask you to stop. I know this is hard for some people so don’t worry if you have to slow down or rest. If you do stop or slow down, start walking again as soon as you feel you are ready to do so. Is there any reason you cannot do the walk? ***[*wait for response*]*** Does anything hurt or are you in pain?***” [*wait for response*]***

If participant does not feel he or she can do this task, note this on the record sheet and continue with another measure.

Script: “You and I will not talk while you are walking because this might make you walk more slowly. I will, however, let you know how much time you have to walk and when you are almost done.**”**

While demonstrating first part of the task, say:

Script: “You will start with your feet behind this line. When I say ‘Go,’ you will walk back and forth around the cones as fast as you can without running or hurting yourself. You will begin after I say ‘Ready, 3, 2, 1, Go!’ As you pass the cone, do not stop or slow down. When I tell you to stop, stop where you are on the path until I come to you. If you stop before I say "Stop," I still need you to remain at that point if you are able.**”**

Demonstrate task and say:

Script: "Watch me as I show you what you are going to do. You see that I am walking fast but not running and that I am not slowing or stopping when I pass the cone. When I say "stop", stop in place like this.**"** (Stop where you are and stand still on the path.) "Do you have any questions?**"** Answer questions as necessary.

FIGURE 1. Stopwatch at 0:00:00 seconds

Script: "Stand with your toes at the starting line. Ready, 3, 2, 1, Go!"

Start timing the participant when the first foot crosses the start line, before making first footfall. Examiner should begin marking off the number of cones on the data form as they are completed; all turns around the cone away from the start line should be odd numbers and all turns around the cone nearest the start line should be even numbers. The examiner should walk with the participant, slightly behind and just to the side of the participant.

The examiner should provide the following feedback: After 1 minute* say:

Script: "You are doing well. You have 1 minute to go."

*If participant is resting at one-minute reminder, encourage him/her to continue and change statement to:

Script: "You have only 1 minute left. Rest as long as you need; start walking again as soon as you feel able to do so."

When time reads 1:45, tell the participant:

Script: In a moment, I'm going to ask you to stop. When I do, just stop right where you are and I will come to you.

When five seconds remain, examiner should count down:

Script: "5, 4, 3, 2, 1, stop."

Stop the stopwatch, put a piece of tape on the floor behind the participant's heel that is on the floor at the end of the two minutes, and, if the walk was done on the Zeno mat, press "End Walk". Save as "TMW". Measure distance from the last cone passed to the edge of the tape that touched the participant's heel. Record the distance in feet on the data form. If the distance is 6 inches or more beyond a foot marker, round up. Otherwise, round down. If the participant stopped for a rest, mark this on the data collection form.

a. Scoring Process

The participant's raw score is the distance walked in two minutes, reported in feet or meters (and fractions thereof). This score can be used as a raw measure or converted to the Toolbox normative scale scores.

b. Interpretation

Cardiorespiratory and muscle endurance are important components of physical fitness and contribute to both performance and health status. Greater distance walked in the TMW is

suggestive of better endurance. Normative scale scores are provided in the NIH Toolbox: (http://www.nihtoolbox.org/WhatAndWhy/Motor/Endurance/Pages/default.aspx).

For the endurance component of the NIH Toolbox Motor assessment, the fully adjusted scale score can be used in the interpretation of normative scores, because it takes into account gender, age, ethnicity and education differences. Thus, it provides a level playing field for evaluating participants' performance since differences in performance may exist as a function of some of these demographic variables (most notably, gender and age). When interpreting endurance normative scale scores, higher performance is indicative of better endurance. A fully adjusted scale score that is 2 SDs below the mean (scale score of 70 or below) is suggestive of motor dysfunction; further evaluation by a physician or physical therapist may be warranted. People with better endurance are able to complete daily tasks and are more physically fit to pursue leisure activities and accomplish higher-intensity workloads. The clinical significance of endurance, as measured by timed walk tests, to morbidity and mortality outcomes has been reported in healthy and clinical populations across the age span.

c. Symptoms during/after the TMW

Participants could experience symptoms during the walk. Mild symptoms could include feeling tired or flushed, dizziness, muscle soreness, cramping, or have other muscle or joint irritation. If mild symptoms occur, tell the participant to slow down. If chest pain/pressure/tightness occurs, quickly approach the participant, mark the stopping distance and record the time and distance. Assist the participant to a chair, or if necessary take a chair to the participant. If the participant confirms chest pain or pressure/tightness after resting for 5 minutes notify the nursing or medical staff on site. Symptoms of chest pain, tightness, or pressure with walking that do not resolve with rest are considered a medical emergency. Even if the symptoms resolve with rest this should be reported to the participant and with the participant's authorization to the physician of record as an alert. If the reason for stopping is chest pain, tightness, or pressure, discontinue the test and do not resume.

Except for chest pain/pressure/tightness, the test should not be stopped cold. Participants may resume walking from the marked stopping location if symptoms such as flushing, shortness of breath, cramping, or fatigue resolve and they are willing. Participants can resume walking at the faster pace or continue with the slower pace during the remainder of the walk after a rest period. Always record the reason for stopping the walk on the data collection form.

3.4 TRAINING AND CERTIFICATION FOR THE TMW

Study coordinators are responsible for training new staff using certified examiners based on standardized QxQ instructions.

The examiner requires no special qualifications or experience to perform this assessment. Training will include:

- Read and study the manual
- Questions regarding unintentional weight loss questions will be addressed during central training and certification for the TMW will include administering these questions.

- Attend ARIC training session on performance test administration techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer
- QC officer or designated person may review video of 2 performances if necessary

Certification will include:

- Complete training requirements
- Recite exclusions
- Conduct exam on two volunteers:
    - According to protocol, as demonstrated by completed QC checklist
    - Distances recorded are within $\pm$ 1 foot of QC officer measurement

3.5 QUALITY CONTROL

The data collected by each interviewer are periodically reviewed by the QCC from quality control analyses performed by the CC. Data patterns suggestive of deviations from protocol are brought to the attention of the field center principal investigator and study coordinator. Observation of the assessments then follows, with discussion of possible remedial actions with staff. Major deviations are brought to the attention of the QC Committee.

3.6 QUALITY ASSURANCE/CERTIFICATION CHECKLIST

Preparation

- Checks blood pressure and heart rate using vitals previously taken
- Reviews exclusion criteria:
    - Used walking aid for 4-m walk
    - SBP $\geq$180 or DBP $\geq$ 120
    - Heart rate >110 bpm
    - Cast or immobilizing device on leg
    - Arrhythmia alerts
    - Checks manual heart rate as indicated for specific conditions
    - When indicated, asks if the participant has a pacemaker
- Clearly delivers key points from script for each test
- Correctly describes the test
- Correctly demonstrates walking the course (around the cone)

- Explains stop protocol
- Prepares a piece of tape to mark where participant stops

2-Minute Walk

- Instructs participant to walk as quickly as they can
- Encourages participant every lap
- Gives 1 minute warning
- Marks and records number of cones passed
- Offers rest period if needed and encourages resting participant to resume when ready
- Gives participant notice when 1:45 time elapsed and walks to participant at 2 minutes
- Places tape behind participant's heel
- Records whether or not the participant completed the walk and if not, why
- Reviews form for completeness
- Accurately measures and records distance
- Describes appropriate responses to symptomatic participants during TMW

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