



Manual 32
Physical Function and Endurance Procedures
ARIC Visit 12

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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. At Visit 8 and Visit 10, the Zeno Gait Mat (not collected at Visit 12) was implemented for participants at in-person study visits. 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 (see Section 2.6 for more information).

Existing studies have established bi-directional relationships between mobility and cognitive function,¹⁻⁶ especially executive function⁷⁻¹⁴ 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

Table 1. SPPB

Test name:	Recorded on PFX form
Usual pace 4-meter walk	X
Chair stands	X
Standing balance testing	X
Grip strength	X

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 if the test is not administered due to technical problems, staffing problems or similar unrelated issues, record "Participant refused or technical problems". 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. High heels alter a participant's gait and balance. 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 majority of participants should be able to attempt each performance test whether in the home or in the clinic exam. Walking aids may not be used for the chair stands or standing balance tests. 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 as "Other", with a text explanation in the comment field.

The decision to not assess a participant due to safety concerns can be based on the examiner's observations of the participant in the home or clinic or safety concerns expressed by the participant or proxy. However, all participants who do not have a physical function assessment should still have the PFX form completed to document the reason the test is missing. If the participant or the proxy expresses concerns about safety, the examiner should describe the test and demonstrate the test. The examiner should discuss with the participant and/or proxy their specific concerns about attempting the test, including physical problems and known disabilities. Then the examiner should ask the participant and/or proxy if they think it would be safe to do the task. If the examiner, participant, or the proxy has concerns about safety, the task should not be done. The reason for not attempting a test should be recorded as "Not attempted" and the reason not attempted should be "Safety concerns".

For the walking and balance tests, the examiner 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 is standard practice in epidemiologic observational studies of health and disease. The most 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). Masking tape, paper tape, or other tape that does not leave residue is recommended.
- 4-meter (13 feet, 1 ½ inch) measuring tape or lightweight pre-measured chain, rope, or measuring tool to mark the walking course. Use meters for measurement.

b. SPPB Component Overview

The SPPB includes three components described in the following sections:

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

A 4m Usual Pace walk will be recorded on the PFX form. Results for the 4-meter usual pace walk, standing balance testing, and chair stands are always recorded on the PFX form.

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 if the test is not administered due to technical problems, staffing problems or similar unrelated issues, record "Participant refused or technical problems". If the examiner, a proxy, or the participant considers the test unsafe, record "Not attempted" on the scoring form, go to the next question and record "Safety concerns". 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 at usual speed in the clinic should be conducted on a 5-meter (about 16 feet) path laid-out in an uncarpeted, unobstructed, low traffic corridor at least 122 cm (about 4 feet) wide. Five meters includes room on each end. See Figure 2a. The start and finish lines will be marked by tape on the floor. Allow an additional $\frac{1}{2}$ meter on each end (or at least one end for home visit) of the walking course. For the first trial, the participant starts at one end, walks past the tape on the other end. For the second trial, the participant starts where they ended the first trial and walks back..

For home visits, the course should be the same at the clinic if space allows. Low carpet, but not shag carpet, is allowed. The distance can be shortened to a 4.5-meter space (about 15 feet), allowing the participant to walk past the line of one end with the extra space (Figure 2b). For the 2nd trial, the participant would return to the same starting position as the first trial so that they have room to walk past the tape at the end of the course. Use a pre-measured lightweight chain, folding measuring stick, or other tool to measure the course.

Figure 2a. 4-Meter Usual Pace Clinic Walking Course

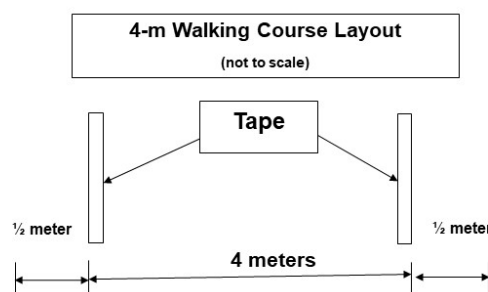
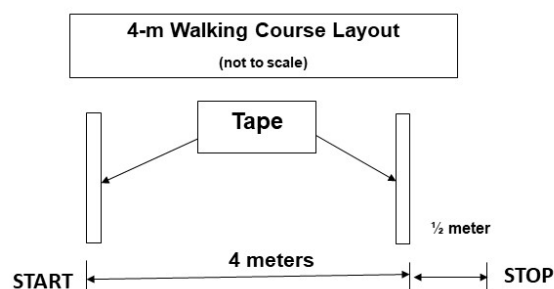


Figure 2b. 4-Meter Usual Pace Optional Home Walking Course



2.2 ADMINISTRATION OF THE SPPB SINGLE CHAIR STAND (V12 FULL CLINIC VISITS)

Results are recorded on the PFX form.

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. Correctly demonstrate a single stand, emphasizing keeping arms crossed, tight across their chest. If participants' mobility is limited primarily to transferring from bed to chair or chair to bed, ask the participant if they think they can safely attempt the task after demonstrating the single chair stand. Examiner should stand in front of the participant for safety if the participant attempts the chair stand.

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, probe for the reason to determine if the reason is due to a physical problem with weakness or balance. It is important to distinguish reasons that are related to one's ability to stand from an unrelated cause. "Participant refused or technical problems" should generally be reserved for reasons that have no relationship to what is being measured and could be lack of interest or lack of time, for example. Technical, staffing, and environmental problems that result in a participant not being assessed are included in the category with refusals.
- If the procedure was not attempted because the participant was unable to physically perform the test, or they were considered unsafe, or for other reasons, score "Not attempted", then go to the subquestion and record why the test was not attempted:
 - Participant unable due to weakness or balance (includes if the participant or proxy tells the examiner they are unable to stand without pushing or without assistance from a person or aid (such as a cane, lift chair or holding onto a support surface)). This response will be applicable to bedbound participants and some chair-bound participants who report only walking a few steps to transfer to another chair or bed.
 - Safety concerns (these can be concerns expressed by the participant or by the examiner). The examiner can demonstrate the single chair stand first, if safety is a concern, then ask "Do you feel safe doing this?"
 - Other problem (examples include recovering from fracture, sprains, amputation, cognitive problems)
- 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 (V12 FULL CLINIC VISITS)

Results are recorded on the PFX form.

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, score "Participant refused or technical problems." "Participant refused or technical problems" should generally be reserved for reasons that have no relationship to what is being measured and could be lack of interest or lack of time, for example. Technical, staffing, and environmental problems that result in a participant not being assessed are included in the category with refusals. If the procedure was not attempted because the participant was unable to physically perform the test, they were considered unsafe, or for other reasons, score "Not attempted", then go to the subquestion and record why the test was not attempted:

- Participant unable due to weakness or balance (includes if the participant or proxy tells the examiner they are unable to stand multiple times without pushing or without assistance from another person or an aid). This response will be applicable to some chair-bound participants. If participants transfer from bed to chair or chair to bed, ask the participant if they feel they can safely attempt the task. Examiner should stand in front of the participant for safety.
- Safety concerns (these can be concerns expressed by the participant or by the examiner). It is less obvious if the participant can do repeated chair stands for this response although observing the single chair stand will help inform the examiner's impression. The examiner will have demonstrated the chair stands. If the examiner has concerns about safety, they can ask "Do you feel safe doing this?"
- Other problem (examples include fracture, sprains, amputation, cognitive problems).

If the 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 (V12 FULL CLINIC VISITS)

Results are recorded on the PFX form.

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 or both) can only be used for support while the participant gets in position. If the examiner is uncertain if this is safe to attempt, he or she can ask “Do you think it would be safe to try this? I will stand here for support; you can let go of my arm [*or wall*] only when you feel ready.”

If they still feel they should not attempt it, record the appropriate response as “Not attempted”, record the reason for not doing the test, and move to the next test.

If the test was not attempted because the participant or the examiner did not think the participant was physically able (see below), or the examiner, proxy, or participant thought it was unsafe, or for other reasons, score “Not attempted”, then go to the subquestion and record why the test was not attempted:

- Participant unable due to a balance problem (for example, participant or proxy might tell the examiner they are too unsteady, or examiner observes unsteady gait when participant is walking or when standing)
- Safety concerns (these can be concerns expressed by the participant or by the examiner). If scoring this response, it is less obvious if the participant can do this balance test or not. If the participant was not observed walking, for example, but the examiner is aware that the participant is not very mobile, the examiner can demonstrate the task, then ask “Do you feel safe doing this?” as a safety screen.
- Other problem (examples include fracture, sprains, amputation, cognitive problems)

The same scoring principles also apply for the more difficult balance stands. The response “Participant refused or technical problems” should be reserved for refusals that are not due to balance problems, perceived difficulty of task, or safety concerns, such as lack of interest or “not

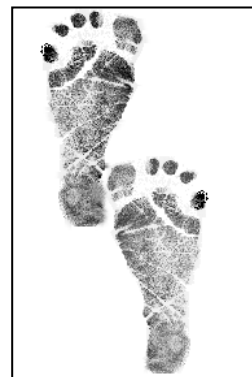
enough time". Technical, staffing, and environmental problems that result in a participant not being assessed are included in the category with refusals.

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. Administration of the Semi-Tandem Stand

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, probe for reasons and score as described above. Then 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 if the test is not administered due to technical problems, staffing problems or similar unrelated issues, score "Participant refused or technical problems." If the procedure was not attempted, go to the subquestions and record the reason for not attempting.

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 if the test is not administered due to technical problems, staffing problems or similar unrelated issues, score “Participant refused or technical problems.” If the procedure was not attempted, score “Not attempted” and go to the subquestion to record why the task was not attempted. 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 if the test is not administered due to technical problems, staffing problems or similar unrelated issues, score “Participant refused.” If the procedure was not attempted, score “Not attempted” and go to the subquestion and record the reason the test was not attempted. 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 (V12 PFX: FULL OR ABBREVIATED CLINIC AND HOME VISITS)

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 prior ARIC visits. This will be offered in home visits beginning in visit 10, continuing in visit 12.

Because the 4m usual pace walk exam may be required throughout the visits, and to ensure valid comparisons to home visits, examiners must maintain proficiency in administering the task using a stopwatch. 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. “Do you think it will be safe to walk this short distance at your own pace?” If the participant has a cane, walker, or other aid, ask “Do you think it will be safe to try this without a cane or walker?” Participants are allowed to use canes or walkers if they need one for balance or safety. If they do not feel safe walking without a cane or walker, the examiner should acknowledge that they may use a cane or walker for this task and confirm the participant feels safe walking the 4 meters with their assistive device. The examiner should assure the participant that they will walk along with the participant. For example, the examiner can say, “You may use a cane or walker if you need to. Do you think it would be safe to try this walk with your [cane / walker]?” If they do not feel safe, do not attempt the walk.

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.”

Home Visits

The physical function assessment in the ARIC exam as well as more extensive measures of physical function have been safely and successfully carried out in the homes of older adults,¹⁻³ including in disabled older women.¹ Safety protocols for functional measures assessed during ARIC home visits employ the same safety protocols as in the clinic, which include published standards^{1, 2} along with additional guidance specific for the ARIC cohort. The physical function assessment in home visits will include the 4-meter walking test and the grip strength assessment at Visit 12.

The home environment can present situations not encountered in the clinic. This section addresses some additional aspects of the physical function assessment conducted during home visits. If the assessment is not performed, the reason should be recorded. The responses on the form should be left blank.

Participants who are bedbound should not be approached for this test, but the PFX form should be completed. When “Type of Visit” is marked as a “Home Visit”, the questionnaire will skip to the usual gait speed question on the PFX form. Bedbound participants should be recorded as “Not attempted” and the reason that the test was not attempted should be marked as “Unable to walk short distance”. For other participants, examiners should observe the participant’s mobility and balance if they ambulate in the home during the visit. If the participant walks short distances in the home with or without a cane, rollator, scooter, or walker, they are generally safe to approach to assess their ability to perform the 4-meter walk test.

Examiners may not always have an opportunity to observe a participant’s mobility in the home prior to doing the walking test. In this situation, ask the participant questions about their mobility to determine how much they walk, if they use devices, if they are able to transfer out of a chair or bed, if they have unsteadiness, and so on. If participants report being able to walk across a small room, these participants are highly likely to be able to perform the 4-meter walk. For any participant whose ability to walk 4 meters is uncertain, in addition to talking to the participant and/or proxy in the home, the examiner should use the measuring tape of 4-meter chain or other measuring tool to show the distance the participant would be asked to walk. Ask the participant and/or proxy if they think it would be safe to walk this distance. Assistive devices are allowed during the 4-meter walk.

Some examples of questions that examiners could use to assess a participant’s mobility follow this paragraph and can be reworded as needed. Examiners should be cognizant of participant/proxy comfort with questions about potential physical limitations, but often questions such as these lead the participant or their proxy to disclose information about mobility or other challenges which they have never discussed with their healthcare providers. In such cases, the participant and/or proxy should be advised to discuss these with their healthcare team, who may be able to provide additional resources in the home. The following questions are not a complete list of questions, nor are they required for all home visits; rather, these should help guide examiners in gathering information that could help them assess safety related to the physical performance measures in participants for whom their mobility status is uncertain.

- “Do you ever walk outside your home?”

- o Participants who do this are usually good candidates for the 4-meter walk
- “Do you walk from room to room in your home?”
 - o Participants who do this are usually good candidates for the 4-meter walk
- “Do you use a cane or walker to get around in your home?”
 - o Participants who can walk around inside their home with or without an assistive device are usually good candidates for the 4-meter walk
- “Do you hold onto furniture or the walls for balance when you walk in your home?”
 - o Participants who do this for balance and do not have a cane (or assistive device), or are unwilling to use one could be safety risks. Do not administer the walking test. Mark the form as “Not attempted” and then “Safety concerns”.
 - o Participants who hold onto furniture or the walls for balance sometimes have a cane or other assistive device but do not always use it. Ask if they have a cane or assistive device, as even participants with balance problems who use an assistive device are usually a good candidates for the 4-meter walk. If they are not willing to use an assistive device or do not have one, do not administer the test.
- “How do you get the kitchen and bathroom?” This may be helpful for seated participants who the examiner does not observe walking in the home. If they do not go to these rooms, asking “Where do you eat?” and/or “Do you have a bedside toilet?” can provide more information about their usual mobility status.
 - o This provides information about whether a person can walk from room to room (definitely consider the 4-meter walk),
 - o If they are limited to walking a few steps from where they sit or they only transfer from one position to another, e.g. chair to bed, or if they use motorized scooters in the home, probe further about walking ability to see if the participant can walk the distance of the course. If the participant or proxy describes an inability to walk this far, the participant response should be “Not attempted” and then “Participant unable to walk short distance”. If they think they can walk the distance but are concerned about falling, the test should not be attempted and the reason recorded as “Safety Concerns”.
- “Have you fallen inside your home in the past year?” If “Yes”, ask questions such as “How many times have you fallen? When was the most recent fall? Did you trip over something?” If the participant is having recurring falls or has fallen in the past month inside the home without tripping over an object, do not perform the 4-meter walk. Mark “Not attempted” and the reason should be marked “Safety concerns”. Use the comment box to provide additional text regarding concerns.
- “Have you had any “near” falls recently?”
 - o Near falls are not an exclusion criteria for the 4-meter walk but may help the examiner determine a higher state of risk if the participant reports currently having recurring near falls. Proceed with asking the participant if they think they can walk about 13 feet; the examiner may show the distance of the course and demonstrate the task.

Some participants may not be able to undergo physical function assessments in the home due to the home environment and should be distinguished from those who did not undergo

functional assessments for other reasons. Home environment reasons for not performing functional assessments include inadequate, unobstructed walking space (minimum is 4.5 meters), high-pile or shag carpeting, falls hazards such as thresholds on the floor or rugs that cannot or will not be moved, inability to place tape on the floor or participant preference to not use tape on the floor to mark the course, or clutter on the floor where the walking course would be laid out. These should be recorded as “Participant refused or technical problem”. Even though clutter is a safety concern, the safety issue is from the environment, not the participants inherent physical problem or safety risk, so environmental problems are reported in this category rather than “Safety concerns” category.

Scoring

“Participant refused or technical problems” should be reserved for refusals that are not due to walking or balance problems, perceived difficulty of task, or safety concerns; reasons such as lack of interest or “not enough time” are appropriate for the “refused” category. Technical, staffing, and environmental problems that result in a participant not being assessed are also included in the category with refusals.

If the procedure was not attempted because the participant or the examiner did not think the participant was physically able (see below), or the examiner, proxy, or participant thought it was unsafe, or for other reasons, score “Not attempted”, then go to the subquestion and record why the test was not attempted:

- Participant unable due to difficulty walking (for example, participant is bedbound, does not walk more than a couple steps to transfer to another seat/bed, participant or proxy tells the examiner they are too unsteady, or examiner observes unsteady gait when participant is walking)
- Safety concerns (these can be concerns expressed by the participant or by the examiner). It is less obvious if the participant can do this balance test for this response. If the participant was not observed walking, for example, the examiner can demonstrate the task, then ask “Do you feel safe doing this?”
- Other problem (examples include fracture, sprains, amputation, cognitive problems)

The important distinguishing factor is that **not attempted**, either because participant unable to walk short distances or participant safety concerns, indicates missingness due to mobility difficulty while **participant refused or technical problem** is unrelated to the mobility outcome.

2.6 TRAINING AND CERTIFICATION FOR SPPB

A training video for the SPPB is available online. Note that the video does not include training on grip strength. Instructions for downloading the video (“Instructions – pdf”) and the demonstration video (“CD (Download)”) can be found 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 [ 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. 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 (V12 PFX: FULL AND ABBREVIATED CLINIC AND HOME VISITS)

Results are recorded on the PFX form.

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,⁴ 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 if the test is not administered due to technical problems, staffing problems or similar unrelated issues, 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:
 - o According to protocol, as demonstrated by completed QC checklist
 - o 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

2.9 PHYSICAL FUNCTION RESULTS

Chair stand and balance results will be sent to participants as a part of the Visit 12 Summary of Results Report. The results letter template can be found in Appendix 1 (Section 6.2). The Maintaining Your Mobility handout (Section 6.3) should be provided to participants at the end of the visit.

3 TWO MINUTE WALK (TME AND TMW FORM)

Safety issues and exclusions for the TMW 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 gathered 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.

The two minute walk is not collected during home visits, but it is essential for the unintentional weight loss items on the TMW form be collected. See the TMW QxQ for more information about collecting the unintentional weight loss questions in the absence of the TME for home visits.

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. These unintentional weight loss questions should always be answered even when the participant is not eligible to complete the Two Minute Walk or in the instance where a participant is measured at home. 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

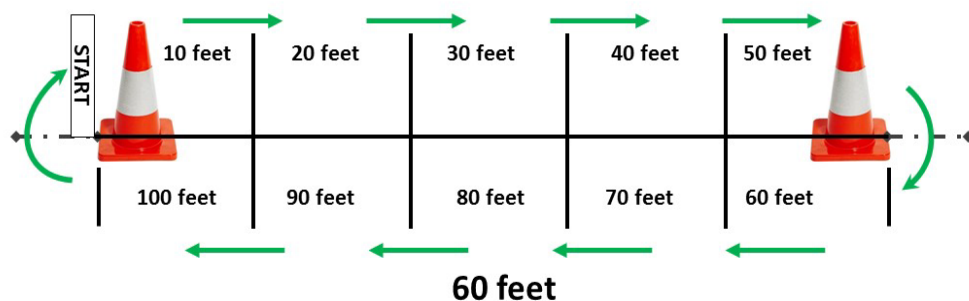
For consistency, the walking course length will be 50 feet with an additional 5 feet on each end, laid out in an unobstructed, dedicated corridor. Use traffic cones to indicate the beginning and end of the course. The cones should lie fully within the 50 foot course (see Figure 4.7).

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

Course Illustration

- 60-ft total space
- 50-foot walk, 10-ft intervals, 5 ft on each end



--- = 5 feet

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



- o Use the results of the 4-meter walk trials from the PFX form. See section 5.2.a, 'Requires walking aid,' for using the information from the PFX and the rules for completing the partial PFX for ACHIEVE-enrolled participants.
- Resting heart rate < 40 or >110 beats per minute (bpm)
 - o Use the results from the SBP form. See section 5.2.b, 'Heart rate and blood pressure,' for using results.
- Systolic blood pressure ≥ 180 or diastolic ≥ 120
 - o Use the results from the SBP form. See section 5.2.b, 'Heart rate and blood pressure,' for using results.
- 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 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.
 - o If 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.**
 - o If the manual heart rate is < 40 or > 110 bpm, this supersedes the Omron vitals and the participant is excluded. Section 5.2.c, 'Measuring heart rate' 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

a. 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. The results of the 4-meter walk trials are pre-populated in the TME form if data are entered into the PFX form for the clinic visit. If data are not entered into the PFX form, consult the PFX data and unlock the TME item 2 to answer the question about the walking aid. The PFX results **must** be collected prior to the TME/TMW and on the same day as the TME/TMW for safety concerns.

For ACHIEVE-enrolled participants, the full PFX form is completed during the ACHIEVE annual visit. The rules for the administration of the partial PFX during a participant's ARIC abbreviated visit 12 are:

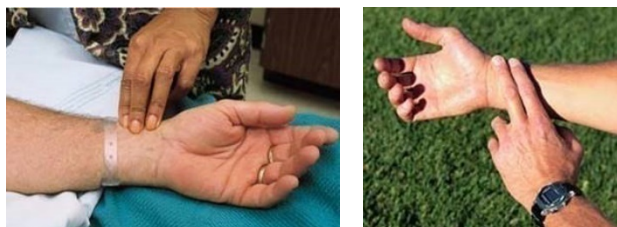
1. When the abbreviated visit 12 is on the **same** day as the ACHIEVE annual exam (and the ACHIEVE exam occurs first), the ACHIEVE staff should share the 4-meter walk results with the ARIC visit staff. The ARIC visit staff will unlock the TME item 2 and answer the 4-meter walk question.
2. When the abbreviated visit 12 is collected at **any time other than** the ACHIEVE annual visit, the 4-meter walk trials must be conducted during the ARIC visit 12. The PFX form in the "V12 / NCS" form group should be partially completed for items 0a, 0b, 0c, 7-8d.

b. Heart rate and blood pressure

Heart rate and blood pressure results are pre-populated into the TME form if data are entered into the SBP form for the clinic visit. If data are not entered into the SBP form, consult blood pressure data collected in the SBP form earlier in the clinic visit. Then unlock the TME items 3 and 4 to answer the questions about average resting heart rate, systolic blood pressure, and diastolic pressure.

c. Measuring heart rate

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/hearttrate.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". Note the last beat felt when 20 seconds passes then multiply this by 3. Use a calculator if it is too difficult to calculate by hand.

If the heart rate in 20 seconds is 13 or less, then the calculated bpm will be < 40; if the heart rate is 37 or higher, then the calculated bpm will be > 110. If the examiner is uncertain of the heart rate due to a weak or irregular pulse, make note of this finding in the comment field, mark the response for manual heart rate on the form as "Uncertain / unable to complete" and exclude the participant from the TMW test.

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.

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. 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:
 - o According to protocol, as demonstrated by completed QC checklist
 - o Distances recorded are within ± 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:
 - o Used walking aid for 4-m walk
 - o SBP >180 or DBP > 120
 - o Heart rate >110 bpm
 - o Cast or immobilizing device on leg
- 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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