Diabetes Prevention Program Outcome Study (DPPOS)

Physical Functional Assessments Manual of Operations

Background and Introduction

Type 2 diabetes is associated with increased risk of functional decline [Park et al 2007]. Recent studies have shown that hyperglycemia and obesity are associated with decreased grip strength and low physical function, which are features of frailty, a state of increased vulnerability to stressors associated with adverse health outcomes [Walston et al 2002, Blaum et al 2005, Barzilai et al 2007]. No study has evaluated whether metformin or lifestyle intervention in individuals with pre-diabetes, such as in DPPOS participants, decrease their risk of physical function decline.

Evaluation of physical performance for each participant will be based on the short-physical performance battery (SPPB) described below. The SPPB includes the grip strength test, balance test, gait speed test, and chair stand test (P09 Physical Functional Assessments).

Administration of Physical Functional Assessment (P09)

When scheduling the physical functioning tests, instruct the DPPOS participant to wear loose clothing and flat (no heels) comfortable shoes or sneakers.

<u>Grip Strength Test (Adapted from the Cardiovascular Health Study-John Hopkins)</u>: Form P09, Section B and Physical Functional Assessments Scripts and Worksheet

The grip strength test is a quick (< 5 min), practical and validated way to measure upper extremity strength in large epidemiological studies. It requires the use of a hand-dynamometer (see figure 1).

Before beginning the test, the technician may need to assess whether the participant has new symptoms of heart disease (e.g., new angina or change in angina pattern) that will contraindicate testing. Having a <u>stable</u> heart problem does NOT exclude participant from grip strength testing.

Participants with one or more of the following contraindications that affect their hands should not be tested:

- Acute flare-up of wrist/hand; for example, arthritis, tendonitis or carpal tunnel syndrome. If the problem is chronic (i.e. no improvement is expected), then you may proceed with the testing.
- Less than 13 weeks after surgery for fusion, arthroplasty, or tendon repair.



Figure 1. Jamar dynamometer

Figure 2. Testing position

Tester instructions:

- The participant should be seated in an armless chair.
- Elbow should be bent at a 90° angle and the forearm and wrist in neutral position (see figure 2).
- The dynamometer should be set at '2' strength for testing all participants
- Do not allow the participant to squeeze the dynamometer before testing.
- Once the participant is ready, begin the first attempt.
- The tester must coach the participant by saying "squeeze, squeeze" while the participant is squeezing.
- Tell the participant to stop when you see the arrow starting to go down.
- Record the results of each trial (in kilograms-force) before the next attempt.
 The dynamometer should be read at eye level (i.e., staff facing the dial for
 appropriate readings). Round down to the nearest line on the dynamometer
 (will always be an even number).
- Repeat the examination three times in the dominant hand first and then in other hand. The scores of three successive trials are recorded. Be sure to set the dynamometer dial to zero prior to each attempt.

Script for the Grip Strength Test:

Ask the participant questions according to the Grip Strength Test Script given in the Physical Functional Assessments Scripts & Worksheet form. This form supplements the P09 form and is not data entered. Record the participant's response in the space provided on the form and transfer responses to the P09 form as appropriate.

Reference values for grip strength (kg-force):

Values below the 20th percentile (see table below), by sex and body mass index, suggest reduced grip strength/frailty [Florez et al. 2008].

Sex	Normal weight	Overweight	Obese
Women	18	19	20
Men	28	31	36

<u>Balance Tests (Adapted from Dr. Guralnik et al, National Institute of Aging [NIA])</u>: Form P09, Section C and Physical Functional Assessments Scripts and Worksheet

Diabetes is associated with decreased performance on the balance tests. Impaired balance is a major cause of decreased mobility and falls.

The tests of balance provide an assessment of the participant's ability to hold three basic standing positions with the eyes open (participants may choose to focus their vision on an object in front of them). These positions are *side-by-side*, *semi-tandem*, and *full tandem* stand (or heel-to-toe) and are performed in this order. If the participant is able to complete these three initial balance tests, a *single-leg stand* will be evaluated. No equipment other than a stopwatch, script, and score sheet is needed.

Note: In the NIA video/CD that is provided to each center (support material) the critical cutoff used for these balance tests is 10 seconds, which is the original version of the test. DPPOS will use 30 seconds as the cutoff to avoid a ceiling effect, as recently proposed by NIA investigators.

Tester instructions:

- Participants taking this test must be able to stand unassisted without using a cane or a walker.
- Do not assume that participants who arrive for testing using a cane or walker cannot stand unassisted. Ask them if they can stand without the device and are willing to try the test. If they say yes, you can assist them to assume the correct position for testing.
- For each position, the examiner first describes and then demonstrates the appropriate stand.
- The participant then assumes the correct foot position while supported by the examiner.
- Once the participant appears to be steady, ask if he or she is ready. When they say yes, the examiner relinquishes support, says "Ready, begin," and starts timing.
- The timing is continued until the participant moves his or her feet, grasps the examiner for support, or 30 seconds have elapsed.
- Record any time less than 30 seconds to the nearest hundredth of a second.
- The participant may use the arms, bend the knees, or move the body to maintain balance.

Side-by-Side Stand Feet together side-by-side for 30 sec Semi-Tandem Stand Heel of one foot against side of big toe of the other for 30 sec Tandem Stand Feet aligned heel to toe for 30 sec

The first test is the side-by-side stand:

- In this balance test, participants are requested to stand for 30 seconds with their feet together (as closer as possible) in a side-by-side position.
- Participants who are unable to hold the side-by-side stand for less than 30 seconds do not proceed further with the balance tests and are given a score of 0 for this portion of the battery.
- Participants who successfully complete the side-by-side test receive 1 point and proceed to the semitandem balance test.

The second test is the **semi-tandem balance test**:

- Each participant starts with the heel of one foot placed to the side of the big toe of the other foot. Either foot can be placed in the forward position.
- Participants who successfully hold the semi-tandem position for 30 seconds are given 1 additional point and proceed to the final balance test.
- Those who fail to hold the position for 30 seconds receive 0 points and do not perform the tandem balance test.

The third balance test is the **tandem position**:

- To assume the tandem position, the heel of one foot is placed directly in front of the toes of the other foot. Either foot can be placed in the forward position.
- Participants who hold this position for 30 seconds are awarded 2 points. Those who hold the position for 10 to 29.99 seconds are given 1 point.
- Those holding the position for less than 10 seconds will get 0 points.

Finally, if the participant is able to complete the three initial balance tests (side-by-side, semi-tandem, and full-tandem), then a **single-leg stand** will be evaluated:

• Ask the participant to try to stand on one foot for as long as he or she can (at least for 30 seconds and for a maximum of 60 seconds). Either leg can be used for this test.

Script for the Balance Tests:

Ask the participant questions according to the Balance Tests Script given in the Physical Functional Assessments Scripts & Worksheet form. This form supplements the P09 form and is not data entered.

Reference values for balance tests (adapted from the SPPB [Guralnik et al. 2000, Studenski S et al. 2003]):

- Completion of side-by-side stand for 30 sec: 1 point
- Completion of semi-tandem stand for 30 sec: 1 point
- Completion of tandem stand for ≥ 10 sec: 1 point
- Completion of tandem stand for 30 sec: 1 point (additional)
 Completion of single leg stand for 30 sec: 1 point (additional)

Balance tests scores: very poor (0), poor (1), fair (2), good (3), very good (4), excellent (5)

<u>Gait Speed Test</u> (Adapted from Dr. JM Guralnik et al, National Institute of Aging [NIA]): Form P09, Section D and Physical Functional Assessments Scripts and Worksheet

The gait speed test will assess the DPPOS participant's ability to walk 4.5 meters (15 feet).

Note: The NIA video/CD uses a shorter distance (4 meters) to test gait speed.

For the test, you will need a stopwatch and a marked walking course. If this test is being done in a new location, then a course must be laid out on the floor. You will need to mark the start and finish lines on the floor using masking tape and a construction meter tape (or a chain that is 4.5 meters long) to measure the correct distance. The walking course for the gait speed test should be unobstructed and include at least an extra one-half meter on each end.

Tester instructions:

- Participants are instructed to walk at their usual speed, and timing is stopped when the first foot completely crosses the 4.5-meter mark.
- The faster of two timed walks is used for scoring purposes.
- When training to perform this test, it is good practice to have two or more people doing the timing so that timing can be compared for precision.
- A cane or walker may be used during the walk, but if people with such devices can walk short distances
 without them, they should be encouraged to do so. Many people with assistive devices use them only
 when they walk outdoors or for long distances indoors. Doing the test without the device provides a much
 more accurate assessment of the functional limitations of the participant.
- Ask the participant if he/she ever walks at home without the device. Then ask the participant if he/she thinks that he/she can walk a short distance for the test. Participants who normally use assistive devices should be watched particularly closely during the test to prevent falling.
- Walking bare feet is optional but some participants may feel uncomfortable. Walking in sox is not
 advisable because of potential risk of falls.
- Wait until the participant actually begins to move before starting the watch. Do not start the watch when you say "begin."
- The position of the examiner is critical for the walk. If you are too close you will set the pace. If you are too far behind you will not be in a good position if the participant falls. You also need to be in a good position to observe the foot crossing the finish line.
- The best position to maintain during the walk is to the side and slightly behind, outside of the participant's visual field.
- Record the time when the participant's first foot crosses the 4.5 -meter line. If the foot lands on the line but does not cross it, this is not the end of the test. You need to anticipate when a foot will fully cross the line and be ready to stop the watch as it crosses the line. You should imagine a plane of glass at the finish line that the foot breaks when it crosses. This is the time to stop the watch.
- Record the time to the nearest hundredth of a second.
- If you have trouble with the stopwatch or you think that the timing was not accurate, then repeat the gait speed test.

Script for the Gait Speed Tests:

Ask the participant questions according to the Gait Speed Tests Script given in the Physical Functional Assessments Scripts & Worksheet form. This form supplements the P09 form and is not data entered.

Reference values for gait speed tests (adapted from the SPPB [Miller D et al. 2008):

Unable to complete the gait speed test:

 4.5 meters in > 6.4 sec (< 0.70 meters/sec):
 4.5 meters in > 5.4 to 6.4 sec (0.71 – 0.84 meters/sec):
 4.5 meters in > 4.5 to 5.4 sec (0.85- 0.99 meters/sec):
 3 points (good)
 4.5 meters in ≤ 4.5 sec (≥ 1 meters/sec):

<u>Chair Stand Test</u> (Adapted from Dr. Guralnik, National Institute of Aging): Form P09, Section E and Physical Functional Assessments Scripts and Worksheet

Another portion of the SPPB is the chair stand test. In this test, participants are first instructed to fold their arms across their chest and to try to stand up one time from an armless chair placed against a wall.

To perform this test, you will need a stopwatch, the script, a score sheet, and a straight-backed chair with a hard seat. If this type of chair is not available, a chair with a softer seat or a chair with arms may be used as a substitute. Do not use a folding chair, a soft chair, a deep chair, or a chair on wheels. The chair should be placed next to the wall.

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

When learning to do this, it is useful for two or more people to time the test so that the times can be compared for precision.

Tester instructions:

- To ensure safety, the examiner should stand in front of the participant and be prepared to catch her if he/she falls forward. However, do not stand so close that the participant feels hemmed in and slows her pace during the chair stands.
- For this portion of the test, you would simply record whether the participant was able to rise from the chair without the use of the arms.
- If the participant successfully rises from the chair once, he/she is then asked to stand up and sit down 5 times as quickly as possible.
- Emphasize the word "quickly" and perform the demonstration quickly to further reinforce this point. The gait speed test is done at normal speed but the chair stand test should be done as quickly as possible.
- Count the stand number only after the participant has straightened up. Do not pace the test with your counting.
- Timing begins when the command to stand is given and continues until the participant straightens his/her body at the end of the fifth rise. This contrasts with the gait speed test where timing begins only when the participant begins to move.
- During the test, count out loud as the participant rises up to five times. Do not coach or encourage the
 participant during the test.
- Watch the participant closely and stop the test if the participant is tired or short of breath during the repeated chair stands.
- The test should be stopped if the participant has to use his/her arms to rise at any time or if the participant
 has not completed the five chair rises after one minute. You should also stop the test at your discretion if,
 for any reason, you are concerned about the participant's safety.
- If the participant stops before completing the five rises, you should ask him/her if he/she can continue. If the participant says yes, continue timing. If the participant says no, stop the test.

Script for the Chair Stand Test:

Ask the participant questions according to the Chair Stand Test Script given in the Physical Functional Assessments Scripts & Worksheet form. This form supplements the P09 form and is not data entered.

Reference values for chair stand tests (adapted from the SPPB [Miller et al. 2008):

Unable to complete the test (or rises in >60 sec):

Rising 5 times in >13.8 sec:

Rising 5 times in >11.4 to 13.8 sec:
Rising 5 times in 9.2 to 11.4 sec:
Rising 5 times in < 9.2 sec:

Unable to complete the test (or rises in >60 sec):

1 point (poor)
2 points (fair)
3 points (good)
4 points (very good)

Certification

For primary certification and recertification, the assessments of two volunteers are required. Recertification should be done annually.

References

- Barzilay JI, Blaum C, Moore T, Xue QL, Hirsch CH, Walston JD, Fried LP. Insulin resistance and inflammation as precursors of frailty: the Cardiovascular Health Study. Arch Intern Med 2007; 167: 635-41
- Blaum CS, Xue QL, Michelon E, Semba RD, Fried LP. The association between obesity and the frailty syndrome in older women: the Women's Health and Aging Studies. J Am Geriatr Soc.2005; 53: 927-34.
- Florez H, Gerstein H, Sherida P, Bosch J, Goldberg R. Frailty grip is associated with glucose intolerance: Results from the Epidemiological Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication Study Population. J Nutrition Health & Aging 2008; 12:421.
- Guralnik JM, Ferrucci L, Pieper CF, Leveille SG, Markides KS, Ostir GV, Studenski S, Berkman LF, Wallace RB. Lower extremity function and subsequent disability: consistency across studies, predictive models, and value of gait speed alone compared with the short physical performance battery. J Gerontol A Biol Sci Med Sci. 2000; 55: M221-31.
- Miller DK, Wolinsky FD, Andresen EM, Malmstrom TK, Miller JP. Adverse outcomes and correlates of change in the Short Physical Performance Battery over 36 months in the African American health project. J Gerontol A Biol Sci Med Sci. 2008: 63:487-94.
- Park SW, Goodpaster BH, Strotmeyer ES, Kuller LH, Broudeau R, Kammerer C, de Rekeneire N, Harris TB, Schwartz AV, Tylavsky FA, Cho YW, Newman AB; Health, Aging, and Body Composition Study. Accelerated loss of skeletal muscle strength in older adults with type 2 diabetes: the health, aging, and body composition study. Diabetes Care 2007; 30:1507-12
- Studenski S, Perera S, Wallace D, Chandler JM, Duncan PW, Rooney E, Fox M, Guralnik JM. Physical performance measures in the clinical setting. J Am Geriatr Soc. 2003; 51: 314-22.
- Walston J, McBurnie A, Newman A, Tracy RP, Kop WJ, Hirsch CH, Gottdiener J, Fried LP; Cardiovascular Health Study. Cardiovascular Health Study: Frailty and activation of the inflammation and coagulation system with and without clinical morbidities. Arch Intern Med 2002; 162: 2333-41.