



UNIVERSITY of LIMERICK

OLLSCOIL LUIMNIGH

For Office Use Only: EHSREC No: EHSREC10-RA03.

PROCEDURES INVOLVING HUMAN SUBJECTS

Title of Procedure

Name of Assessors Assessment date

Does this procedure already have ethical approval?

If so, enter ethical number and expiry date

| |
|--------------------------|
| Approval No: |
| Date expires: / / |

1

1. The subject is pre-screened according to the REC approved study protocol
2. The subject is familiarised with the testing procedures
3. The subjects undertakes a pre-assigned warm-up
4. The subject undertakes the following ADL tests as per the Standard Operating Procedures(attached)
5. The subject is supervised in the completion of the ADL tests as per the Standing Operating Procedures
6. The subject is allowed a warm-down period before leaving the laboratory

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| √ | Project Laboratory (PG034) and Biomechanics Laboratory (PG043) |
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| √ | Mature Students aged 55 to 70y |
| √ | University staff or campus personnel aged 55-70y |
| √ | Members of the general public engaged in research projects granted ethical approval aged 55-70y |

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| 4 | Potential risks. To be explained <u>before</u> obtaining consent | |
| √ | | Minimal discomfort only. Some muscle soreness and potentially joint stiffness for 1-2 day following the test |

Risk to the subject:

These procedures are well tolerated in the majority of subjects. The risk to the subject is considered to be minimal. The subject may feel some discomfort. This discomfort may include feelings of muscle soreness and joint stiffness that may persist for 2-3 days following the testing procedures.

Risk to the experimenter:

There is no perceived risk to the experimenter in the Standard Operating Procedures for this test. The following are precautions specific to this procedure:

1. All power leads and cables tracking to any instrument must be firmly secured.

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| 5 | Action to be taken in the event of a foreseeable emergency |
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Action to be taken with reference to the subject feeling unwell at any stage throughout this procedure:

1. Stop the procedure immediately and, if appropriate, remove the subject from any hazard or danger
2. Check vital signs airways, breathing and circulation (ABC). Subjects are placed supine with lower limbs raised to improve blood flow and counteract the vasovagal influence. Check blood pressure.
3. Apply CPR if required.
4. First aid personnel would be contacted, and an ambulance would be requested if necessary.
5. The University Medical Centre number is 2534 (9:00 am to 5:00 pm)
6. The University emergency number is 3333

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| 6 | Level of supervision required for procedure |
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| √ | Named researcher who is trained and experienced in the performance of this procedure |
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| 7 | Other documentation required for this assessment? |
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| √ | Standard Operating Procedures (attached) |
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Standard Operating Procedure**Activities of Daily Living (ADL)****November 2011**

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1) Background

Purpose: Standardised tests that simulate activities of daily living are useful tools to assess the functional independence of an older person. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in measurement of performance in completing these 6 separate, simulated activities of daily living.

Personnel

For the purpose of this document, a researcher is defined as a member of staff or post-graduate student of the University of Limerick fully trained in the procedures referred to in this document and competent to supervise undergraduate students in the conduct of these procedures.

The researcher is responsible for:

1. The experimental set up, conduct of the test and laboratory area in which the test is conducted.
2. Ensuring the required pre-test checks on the subject approved by the relevant REC are completed and signed off by the principal investigator or person delegated to this task.
3. The calibration and safe working of all equipment used in the ADL test battery.
4. The appropriate level of feedback to the subject (if allowed by the research design) and appropriate storage of data (as dictated by relevant REC approval).

2) The Repeated Chair Rise Test

Purpose: The purpose of the chair rise test is to assess individual's ability to rise from a chair. As one of the most important activities of daily living the chair rise test is an important component of an ADL battery. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in the repeated measurement of chair rising.

Set Up: The set-up of the chair is important to undertake a safe and effective test.

Procedure:

- 1) Having appropriately adjusted the chair for his/herself, the researcher will firstly demonstrate the test to the subject.
- 2) The researcher then adjusts the chair so the subject's feet easily touch the floor. The researcher will position the subject on the chair according to stature, a small person will not touch the backrest. The appropriate and safe set up of the subject on the chair is the responsibility of the researcher.
- 3) With the subject's feet firmly on the ground, and his/her arms crossed around the chest the researcher instructs the subject to stand and sit 5 times.
- 4) The researcher times the subject from initially standing to the standing position on the 5th stance.

3) The Sit and Reach Test

Purpose: The purpose of this test is to assess hamstrings and low back flexibility. The assessment of these muscle groups is important as tightness is a cause of lumbar lordosis and forward pelvic tilts associated with low back pain. Restriction in these areas may also inhibit general ambulation. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in the repeated measurement of flexibility.

Procedure:

- 1) Having appropriately adjusted the chair for his/herself, the researcher will firstly demonstrate the test to the subject.
- 2) The researcher positions the subject sitting on the edge of a chair with one knee bent at 90° and one leg extended fully with foot flexed.
- 3) The researcher instructs the subject to reach forward as far as possible.
- 4) If the subject reaches their toe a score of 0 is recorded by the researcher.
- 5) If the subject does not reach their toe the researcher records by how much, using a measuring tape, and records a minus value in cm.
- 6) If the subject reaches beyond their toes the researcher records by how much, using a measuring tape, and records a positive value in cm.
- 7) The researcher repeats the measure twice on each side.

4) The 10m walk test

Purpose: The 10m walk test is used to assess an individual's habitual walking speed. For example the speed they would walk to the shops. There are 5 separate components of this test. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in the repeated measurement of walking speed.

Procedure:

1. The researcher is responsible for positioning the timing gates so the subject may easily and safely walk through them along the marked walking track. The accurate and safe set up of the timing gates is the responsibility of the researcher.
2. The researcher lines up the gates opposite each other, 1m apart, at 0m and 10m. When the gates are properly aligned no noise will be heard from the monitor.
3. Having set up the timing gates, the researcher then explains and demonstrates the procedure to the subjects. Describe the habitual walking speed as their normal walking speed, for example, "the speed at which you would walk to the shops".
4. **Habitual walking speed.** The researcher positions the subject at the start of the track, marked by a black line, and instructs them to walk at their normal walking speed (e.g. when going to the shops) to the end of the track at which point the subject turns right away from the gates. This measurement is repeated TWICE.
5. **Maximal walking speed:** The researcher then instructs the subject to return to start line to measure maximal walking speed. The researcher instructs the person to walk as fast as they can through the gates without running. The subject turns right after passing through the last gate and returns on the outside of the track. This measurement is repeated TWICE.
6. The researcher then marks two lines within the speed gates a distance of 25cm apart.
7. **25 cm walk.** The researcher instructs the subject to walk 10m through the speed gates as before whilst remaining inside the 25cm band. If the subject moves outside of the band, the subject must repeat the measure. The researcher records the time taken for TWO successful trials.
8. **15 cm walk.** The researcher then marks two lines within the speed gates a distance of 15cm apart. The researcher instructs the subject to walk 10m through the speed gates as before whilst remaining inside the 15cm band. If the subject moves outside of the band, the subject must repeat the trial. The researcher records the time taken for TWO successful trials.

9. **Talking (B or C).** The research then removes all internal lines and instructs the subjects to walk the 10m as per section 4 above (normal walking speed). The researcher asks the subject to name as many animals beginning with the letter B or C (choose one) while completing the 10m walk. The researcher records the time taken for ONE successful trial.
10. **Picking up:** The researcher then places a number of small hand-held weights along the ten metre track. The researcher instructs the subject to walk along the 10m track picking up the weights as the subject progresses. The subject turns left after the speed gate and returns down the outside of the track. The researcher records the time taken for TWO successful trials.
11. **Package:** The researcher then positions the subject at the start line with a cardboard box held out in front of them. The researcher instructs the subject to walk holding the cardboard box at each side, arms straight so that the box is in front of their thighs and walks until they pass the second timing gate as per section 4 above (normal walking speed). The subject turns right after the speed gate and returns down the outside of the track. The researcher records the time taken for TWO successful trials.
12. **Obstacles:** The researcher places a number of small obstacles (hurdles) along the ten metre track. The hurdles are adjusted for the height of the subject. The researcher positions the subject in front of the black line and instructs him/her to walk down the track passing the gates without knocking any hurdles. This involves stepping over the hurdles. The researcher records the time taken for TWO successful trials.
13. **Obstacles with sunglasses:** Finally, the researcher provides the subject with sunglasses. The researcher instructs the subject to perform the same test as the previous, stepping over each hurdle along the 10m track. The researcher records the time taken for TWO successful trials.

5) Hand-grip strength

Purpose: Hand-grip strength is probably the most widely used field-based measure of a person's 'strength'. Normative data are available for most populations, male and female. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in the measurement of hand-grip strength.

Procedure:

1. The researcher is to demonstrate the procedure to the subject before giving them the dynamometer.
2. The researcher will adjust the handle width so that it is appropriate for the subject.
3. To proceed, the subject is asked to stand with the dynamometer held in the dominant hand, arms by their sides.
4. Remind the subject that the handle will not move but they need to squeeze as hard as they can for 3-4 seconds.
5. Two trials should be made with a pause of about 10-20 seconds between each trial to avoid the effects of muscle fatigue.

6) Balance and Jump Test

Purpose: Balance is an important feature in physical function, prevention of falls and related injury. Jump height is a measure of coordinated musculoskeletal functional performance involving the major locomotor muscles. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in the measurement of balance and jumping activity.

Procedure:

Balance and jump tests are done using the force plate in the Biomechanics Lab PG043

Balance Test

1. The researcher will position the subject, standing comfortably on the force plate with no shoes on looking at a fixed object (normally a pole) straight ahead.
2. The subjects are asked not to talk as the force plate is very sensitive.
3. The researcher will then take force plate records for 15s with eyes open (**ROE**) and repeat this **TWICE** within 60s.
4. A mask is then placed over the subjects eyes and the subject habituates for 60s. The researcher will then take force plate records for 15s with the mask on (**RCE**). The mask is then removed for 60s and the whole procedure repeated once more.
5. **Tandem.** The subject is asked to stand with the foot of dominant leg placed behind. Feet should be place heel to toe in a straight line in the middle of the force plate. Ask the subject what leg they would use to kick a ball. For trial 2 and 3, and T3 check which leg was the dominant leg in T1. Repeat thee test with dominant and non-dominant leg in front. Perform tests in random order

Jump Test

1. This test is performed with shoes on.
2. The researcher firstly demonstrates the countermovement jump.
3. The subject is instructed to stand with feet shoulder width apart, hands on hips. The subject is instructed to squat down as far as they can go (no lower than 90 degrees) and in one movement jump as high as they can. Remind the subject that the entire movement (including the knee bending and the subsequent jump) must be performed as fast as possible.
4. The subject is allowed to practice the jump 3-4 times with feedback from the researchers.
5. Force plate records are captured a few seconds in standing position before starting the jump and during the jump movement to landing.
6. The measurement is repeated **THREE** times.