BLINDED CLINICAL ASSESSMENT GUIDANCE

Getting started

- Complete this assessment when the participant **attends clinic 3 and 12 months** post randomisation
- **Only complete the assessment if you are blinded to the participant's treatment allocation**
- Complete the associated CRF directly in REDCap or use a paper cribsheet and enter the data later
- Please refer to the training video for guidance

Set up

The neurosensory assessments need to be conducted in an environment which is:

1. **Quiet** – so the participant can concentrate and attend to the sensory stimuli used in the tests
2. **Temperature controlled** – too cold will affect the participant's ability to feel stimuli

The assessment kit contains the following items:

- WEST monofilaments
- Two-point discriminators
- Shape texture identification test
- Screen
- Laminated score card of randomised trials
- Whiteboard marker
- Memory stick with guidance video

Introduction

Sit the participant at a table with their hands resting and palms facing upwards. The assessor should sit opposite, facing the participant.

Introduce the tests:

> ***The tests I will be using to assess the feeling in your injured finger are not invasive and should not cause any discomfort. If they do, please let me know.***
> ***Is it ok if I touch your hands and in particular your injured finger?***

Lightly stroke the palmar side of the hand:

> ***Do you have any discomfort or pain in your hands?***
> ***Which is the finger and side you have injured?***

Participants may have hypersensitivity in the territory of the injured nerve. If the participant cannot tolerate the neurosensory tests, indicate this on the CRF.

Identifying the correct nerve territory

Ensure that you have identified the correct digital nerve territory to assess. The clinical assessment CRF on REDCap has the hand, finger and nerve injured prepopulated. You can look at this form without the risk of unblinding.

The tests should only be performed on the distal pulp of the injured finger. The first two sensory tests – WEST and 2PD – need to be applied laterally in the territory of either the injured ulnar or radial digital nerve (look for a surgical scar proximally).

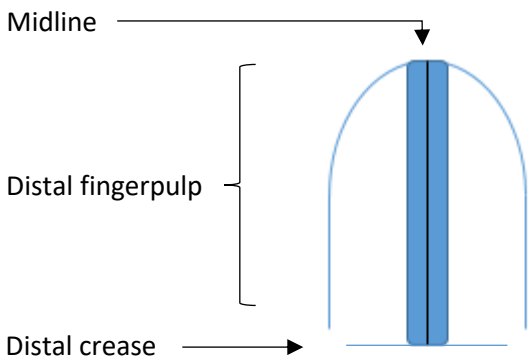

Figure 1: Testing should be done laterally, to the left or right of the blue shaded midline, depending on which digital nerve is injured.

Touch thresholds using Weinstein Enhance Sensory Test (WEST) monofilaments

The training video demonstrates WEST at 00:27

Materials

- WEST monofilaments*
- Screen
- CRF (can enter straight into REDCap or use a paper cribsheet)
- Laminated score card and whiteboard marker

**Note that the WEST monofilaments are fully calibrated and need to be handled with extreme care especially when rotating into test position.*
Avoid touching the actual filament with your fingers *as sweat from fingertips can degrade the material.*
Always rotate the filament back into the same position *as the others using the colour coded knobs and replace into carry case to avoid damage.*

Explanation and example

1. Show the WEST and explain to participant:

   In this test you will be asked to say whether you can feel being touched by a very fine nylon filament. You may not be able to feel some of these. Let me show you how this works.

2. Sit the participant at the table with both hands resting supine in front. Ensure that you have identified the correct digital nerve territory to assess. WEST needs to be applied laterally in the territory of the injured digital nerve (see **Figure 1**).

3. Rotate the lightest filament (green) into test position by rotating it 180 degrees. With the participant observing, lower the filament onto the **fingertip of an uninjured finger** until it bends. Ensure that the filament is lowered perpendicularly to the skin (at 90°) to avoid it slipping off (see **Figure 2**). **Hold it in position for 2 seconds** then lift it.

4. Ask participant to close their eyes and repeat the stimulus in the same, uninjured, location. Ask the participant to say 'yes' if they can feel it and 'no' if they cannot feel it.

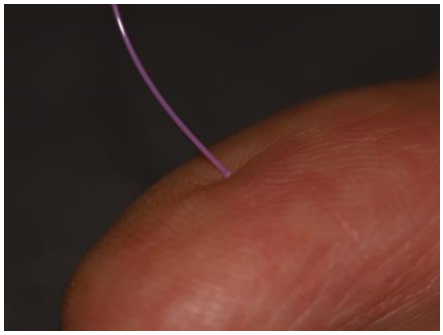

Figure 2: Example of touch threshold test using purple WEST monofilament

Test

5. Place the screen to hide the assessed hand from the participant's vision.

6. Using your fingertip, lightly stroke the area you will be assessing and say:

   I will say 'now' to prepare you for the touch, but sometimes the filament will touch you and sometimes it won't. I would like you to concentrate really hard and tell me when you feel it touching you. When you feel it, say YES, if you don't feel it, say NO. Try not to guess. Tell me if you are not sure.

7. **Conduct 5 trials with the monofilament, randomly altering between a touch and a 'sham' (where you say 'now' but do not touch with the filament – they should respond 'no').**
   a. **Use the pre-randomised order on the laminated card** ensuring that for each trial with the same filament you use 3 'touches' and 2 'shams', for example: sham, touch, touch, sham, touch. Using the whiteboard marker put a ✓ mark over each correctly identified touch or sham.
   b. **Say 'now' prior to every touch and sham** to prompt the participant to reply with 'Yes' or 'No'.
   c. **Do not give any feedback** to the participant about whether they are correct or not.
   d. **Vary the location** for each touch but ensure you remain **within the same territory** on the distal fingerpulp and laterally to the midline.

8. If the participant is unable to correctly respond to 4 of the 5 trials, then proceed to a heavier filament in ascending order and repeat the same procedure. **Stop once 4 out of 5 can be detected correctly.**

9. For each filament used, record the number of correct responses out of 5 on the CRF.

Please note

- If the sensation is poor the participant may not be able to detect when you touch, but they should not be saying 'yes' when you use a sham. Participants responding with 'Yes' to shams, may be guessing or have misunderstood the instructions. Repeat the test if necessary.

- If using the black (thickest) filament note this does not bend. Simply push it down until you can see it slightly indenting the skin or blanching the skin but do not attempt to make it bend as the pressure will be too great and may cause discomfort.

Static two-point discrimination test (2PD) using DiskCriminator

The training video demonstrates 2PD at 02:17

Materials

- Discriminators
- Screen
- CRF (can enter straight into REDCap or use a paper cribsheet)
- Laminated score card and whiteboard marker

Explanation and example

1. Show the two-point discriminators to the participant and explain:

   This test will involve distinguishing between being touched with 1 or 2 points. The tips are blunt and should not cause discomfort. The closer the 2 points are the harder it becomes to tell them apart and they may feel like 1. The test will determine the smallest distance at which you are able to tell 1 from 2 points.

2. Sit participant at table with both hands resting supine in front. Ensure that you have identified the correct digital nerve territory to assess. 2PD needs to be applied laterally in the territory of the injured digital nerve (see **Figure 1**).

3. With participant observing their hand, say:

   I want you to distinguish between when I touch you with 2 points **(demonstrate)** ***and when I touch you with 1 point*** **(demonstrate)** ***on your finger.***

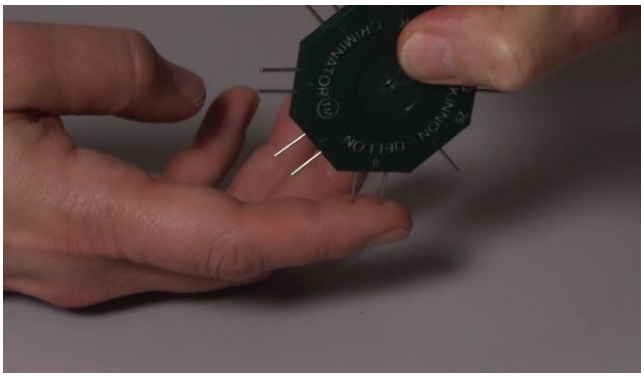

Figure 3a: discriminator touching finger with 2 points

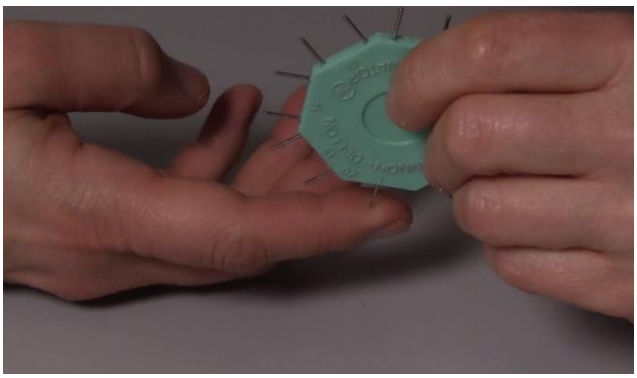

Figure 3b: discriminator touching finger with 1 point

Test

1. Place screen to hide the assessed hand from participant's vision.

2. **Starting with 9 mm calliper width, alternate 2 and 1 points randomly for 10 trials, and ask participant if they feel it as 1 or 2 points.**
   a. Hold each trial for **3 seconds**.
   b. When applying 2 points ensure these are applied synchronously and perpendicularly to fingerpulp in a longitudinal axis (see **Figure 3**)
   c. **Use a pre-randomised sequence** of 10 trials on the laminated card. Use a whiteboard marker to ✓ or X if correct or not.

3. Record on the CRF for each distance tested how many points were correctly identified out of 10.

4. Do not give any feedback to the participant.

5. Stop testing when you have found the smallest distance at which the participant can correctly identify at least 7 out of 10 trials.
   a. **If less than 7 trials are correct, increase the width by 2mm** and keep testing until 7 or more trials are identified correctly.
   b. **If 7 or more out of 10 trials are correct, reduce the width by 2mm** and keep testing until fewer than 7 trials are identified correctly.

6. Record on the CRF the number of correct trials for each distance, and the smallest distance at which at least 7 trials are correct.

Tactile gnosis using Shape and Texture Identification

The training video demonstrates STI at 03:45

Materials

- Shape and Texture Identification test
- Screen
- CRF (can enter straight into REDCap or use a paper cribsheet)
- Laminated score card and whiteboard marker

Explanation and example

Show the template disk and explain to participant:

In this test you will be asked to identify different shapes and textures of decreasing size with the tip of your injured finger.
You can see the shapes and textures on the template in front of you. There is no time limit, so take your time. When you are sure you can identify the object, tell me what it is using the letter or point to it on the template

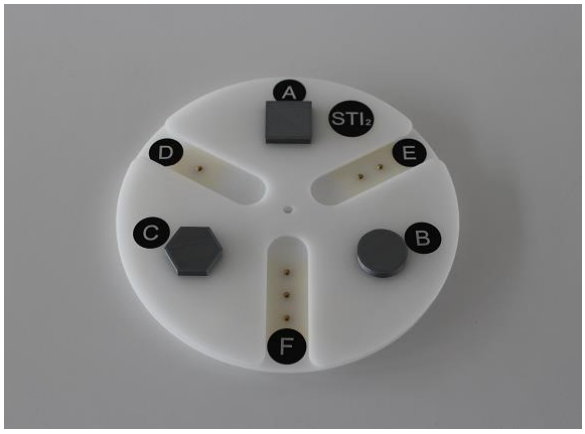

Figure 4a: Shape and Texture Identification template disc

Figure 4b: Shape Identification test in practice

Test – 15mm shapes (large)

1. Place screen to hide the assessed hand from the participant's vision.

2. Show participant the disk with 15mm shapes and explain the test.

   Let's start with the three different shapes – A, B and C. They look like this.
   I am going to place your fingertip on the shape and you need to move your finger around the shape until you are sure what it is. Don't forget that you can take as much time as you want.

3. Through the screen, place the participant's injured finger on the first shape, holding the plate in position which allows easy access and does not place the participants hand or arm in an uncomfortable position.

   Here is the first shape. When you think you can identify it, tell me what it is.

4. Record if the answer is correct or not on the CRF. Do not give the participant any feedback.

5. Now place the same finger on another shape and repeat:

   Here is another one. When you think you can identify it, tell me what it is.

6. Now place the same finger on the last shape and repeat:

   Here is another one. When you think you can identify it, tell me what it is.

7. If the participant has identified all 3 shapes correctly move onto the 8mm shapes. **If the score is 2 or less, do not continue with the smaller shapes and move onto the texture test.**

Test – 8mm shapes (medium)

1. Show the 8mm disk with shapes.

   We are going to repeat the same exercise and you will touch the same shapes but this time they will be smaller in size - 8 mm.

2. Repeat process as above and only progress to smaller disk if all 3 shapes are correct. Make sure that you do not present shapes in the exact same order.

Test – 5mm shapes (small)

1. Show the 5mm disk with shapes.

   We are going to repeat the same exercise and you will touch the same shapes but this time they will be smaller in size - 5mm.

2. Repeat process as above. Make sure that you do not present shapes in the exact same order.

Test – textures

1. Keep the screen in place to hide the assessed hand from the participant's vision.

2. Show the participant the largest disk and explain the test.

   Now let's go on to the three different textures – D, E and F. There are 1, 2 or 3 dots in a row. You are supposed to move your finger along the track all the way back and forth - as many times as you need. Use the tip of your finger and not your nail. Take as much time as you want.

3. Returning to the largest disk, take the injured finger and place it over one of the dotted 'channels', with either 1, 2 or 3 dots. Gently move the finger up and down so they can feel for all the possible dots.

4. Start with the disc with the largest dots (15mm) and choose one of the three 'channels' randomly. Place the participant's injured finger on this channel.

   Here is the first one. Slide your fingertip up and down as many times as you like until you are sure you know how many dots you can feel.

5. Record if the answer is correct or not on the CRF. Do not give the participant any feedback as to whether their answer was correct or not.

6. Repeat for the other two textures.

   Here is another one. When you think you can identify the dots, tell me how many you think there are.

7. If the participant has identified all 3 textures correctly move onto the 8mm shapes. **If the score is 2 or less, do not continue with the smaller textures.**

8. **Repeat same procedure with the 8mm distance dots and (if all three at 8mm are correctly identified) 5mm dots.** Make sure that you present the dots randomly and in different order than the previous disk.

Cold intolerance

No additional materials needed

This question has been designed by the hand therapist co-applicant and statisticians for this assessment. Please ask the question and answer options verbatim.

Elliot Neuroma Score

No additional materials needed

The Elliot neuroma score describes peripheral nerve pain in clinical terms that may not be considered appropriate or accessible for patients. Therefore we recommend using the following definitions.

Clinical term	Lay language definition
Spontaneous pain – basal	An ongoing pain that is felt most of the time.
Spontaneous pain – spikes	Spikes of worse pain with no cause (can occur every few minutes through to only a few times a day).
Pressure pain	Pain caused by pressure on the skin of the injured finger.
Movement pain	Pain caused by movement of the joints next to the injury.
Hypersensitivity	A stronger, more painful sensation than expected when the injured finger is touched.

Below is a script for how to ask the questions in the Elliot score. It can be used verbatim or as a guide.

I am now going to ask you about five different types of pain you might be feeling in your injured finger.

I will read out all the types of pain first so you know what they are. I will then read them one at a time and ask whether you have no pain, mild pain, moderate pain or severe pain for each one.

There are the following types of pain:

1. ***An ongoing pain that is felt most of the time.***
2. ***Spikes of worse pain with no cause. This could happen every few minutes or only a few times a day.***

3. ***Pain when pressure is put on the skin of the injured finger.***
4. ***Pain caused by movement of the joints next to the injury.***
5. ***A stronger, more painful sensation than expected when the injured finger is touched.***

Do you have any questions about those types of pain?

I will now ask you whether you have no pain, mild pain, moderate pain or severe pain for each one.

For pain in your injured finger that is ongoing pain and felt most of the time, do you have no pain, mild pain, moderate pain or severe pain?

For pain in your injured finger that feels like spikes of worse pain with no cause, do you have no pain, mild pain, moderate pain or severe pain?

For pain in your injured finger caused by pressure put on the skin of the injured finger, do you have no pain, mild pain, moderate pain or severe pain?

For pain in your injured finger caused by movement of the joints next to the injury, do you have no pain, mild pain, moderate pain or severe pain?

For pain in your injured finger feeling like a stronger sensation than expected when the injured finger is touched, do you have no pain, mild pain, moderate pain or severe pain?

Perception of treatment

No additional materials needed

A small study within NEON aims to evaluate how well blinding is achieved, both for participants and assessors. <u>This is not a question to complete with the participant, but to answer from your perspective.</u> The participants are asked this question separately in their follow-up questionnaires.