NOTTINGHAM CLINICAL TRIALS UNIT
at the University of Nottingham

Participant measured clinical outcomes: lessons learned from at-home hand measurements in the Hand-2 trial

S Harrison[1], N Rasheed[1], A Shafayat[1], L Huang[1], H Jarrett[1] & T Davis[2], on behalf of the Hand-2 trial team
1.Nottingham Clinical Trials Unit, University of Nottingham; 2.Nottingham University Hospitals NHS Trust

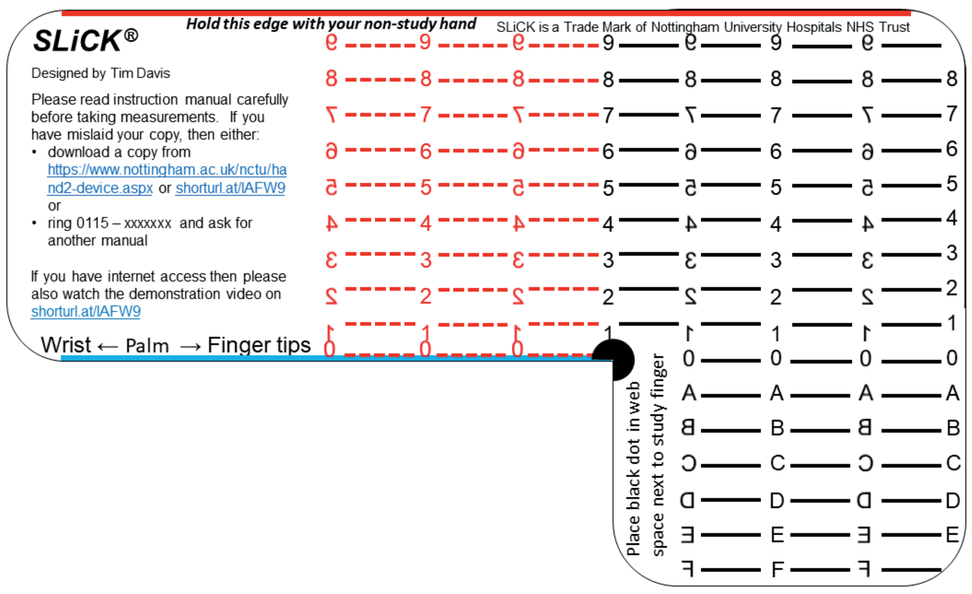
Background

- The Hand-2 trial is a non-inferiority trial comparing clinical outcomes and patient acceptability of two treatments for Dupuytren's contractures: Limited Fasciectomy and Needle Fasciotomy.
- Angle measurements are crucial for ascertaining the severity, improvement, and potential recurrence of the contractures.
- Goniometers, the tools used to take these measurements, are not suitable for self-measurement and so these measurements required participants to attend an appointment with a physiotherapist or consultant.
- Returning to clinics for research measurements is costly and burdensome on participants.

Methods

"SLiCK" measurement device

- Developed to capture finger angle measurements by an individual without requiring a physiotherapy or research appointment.
- Used in clinic at Hand-2 baseline, day of treatment, and 6-week follow-up appointments by research staff. Patients were then guided through taking the measurements themselves.
- At the 6-month follow-up, the device was posted to participants' homes with an accompanying instruction booklet.
- Video walkthroughs were available on the trial website.
- Hand-2 participants were instructed to provide SLiCK measurements at 6-, 12-, and 24-month remote study follow ups.



Results

The data capture rate for the SLiCK measurements at 6-months is 61%, and 55% at 12 months.
Data capture rates for the questionnaires at these timepoints are >82%.
This indicates that there is a low response rate for the SLiCK measurement, but this is not due to overall low retention at each timepoint, but rather difficulties with the SLiCK process itself.

Conclusion/Discussion

The use of an at-home SLiCK device reduces clinical and patient travel burden in the Hand-2 trial, but this is at the expense of data collection rates.
A number of reasons have been identified:

- Delays to Royal Mail mean that the devices sometimes arrive after the questionnaires, which are sent via email for two thirds of Hand-2's patients. This means that participants return partially-completed questionnaires, with SLiCK data missing. To combat this, we have been posting out the devices two weeks in advance of the follow-up questionnaires. This allows time for minor delays, without being so far in advance that patients may misplace the device.

- Patients have found the device difficult to use and so opt not to take measurements. Whilst participants are trained on how to use the device at their clinical appointments, there is a 4.5 month gap between follow-ups, meaning patients lose confidence during this time. Instructional videos and leaflets do little to restore their confidence in taking their own measurements. A potential solution we have implemented is allowing patients to return to clinic to have these measurements done by a research nurse, if the patient and research team are willing. This could increase data capture rates, but negates the purpose of using a tool which was developed to be used by participants themselves.

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