

# Using a computerised test to monitor and compare recovery after hand surgery

<b>Submission date</b> 13/06/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/07/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/07/2025	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Patient-reported outcome measures (PROMs) are questionnaires designed to assess various aspects of an individual's health, such as hand function, and monitor health over time. The research team has developed a smartphone app to shorten these questionnaires. Previous studies indicate that, unlike the full-length questionnaire, users are comfortable using the app daily, which could provide insights into the speed of recovery after different types of hand surgery. They aim to evaluate whether this app can effectively compare patients' recovery experiences following various hand surgeries. The study will focus on operations expected to show differences in recovery, verifying the app's ability to detect these variations.

### Who can participate?

Patients undergoing treatments for Dupuytren's contracture, trigger finger, arthritis at the base of the thumb, and carpal tunnel syndrome.

### What does the study involve?

Patients will use the app for 3-6 months post-surgery, and their recovery from different treatments will be compared. Additionally, the study will investigate if the app can facilitate remote, dynamic follow-up for carpal tunnel decompression and thumb base injections, potentially replacing routine clinic visits. The app's effectiveness will be assessed based on usage frequency and patient feedback through interviews.

### What are the possible benefits and risks of participating?

Participating in this study is unlikely to directly benefit the patients, but may do in the future, or for other patients, as more is learned and ways to use these data are developed.

It is unknown if the smartphone app being tested will make it easier to complete questionnaires regarding hand function, or whether it helps the research team to understand how people recover after treatments. This is why the study is being carried out. It is hoped that by asking shorter, more frequent questions while patients are going about their normal lives a better understanding of the condition and how to treat it will ultimately be gained.

There are no risks associated with this study. Participation does not change the medical treatment given. It is very unlikely that the questions asked will cause any distress and only relate to hand function in daily life. As the patients are being treated for a hand condition, they may find it difficult to use the app with their affected hand, but it is unlikely that this will stop them from engaging with it altogether.

Where is the study run from?

The Botnar Research Centre, University of Oxford

When is the study starting and how long is it expected to run for?

June 2024 to December 2026

Who is funding the study?

1. British Society for Surgery of the Hand
2. Oxfordshire Health Services Research Committee

Who is the main contact?

Conrad Harrison, conrad.harrison@ndorms.ox.ac.uk

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Mr Conrad Harrison

### Contact details

The Botnar Research Centre, University of Oxford

Oxford

United Kingdom

OX3 7LD

+44 (0)1865 227374

conrad.harrison@ndorms.ox.ac.uk

## Additional identifiers

Integrated Research Application System (IRAS)

332275

Central Portfolio Management System (CPMS)

62442

Protocol serial number

17695

## Study information

Scientific Title

# Ecological Momentary Computerised Adaptive Testing to monitor and compare recovery after hand surgery

## Acronym

EMCAT-2

## Study objectives

### Primary Objective

1. Compare the recovery trajectories of patients undergoing percutaneous needle fasciectomy (PNF) to patients undergoing limited fasciectomy (LF), to test whether EMCAT can detect different recovery trajectories over 12 weeks, with less severe post-treatment symptoms in the PNF group within the first 4 weeks.

### Secondary Objectives

2. Compare the recovery trajectories of other groups that are expected to differ over 12 weeks. Specifically, the study will test the following hypotheses, which are based on the researchers' clinical experience:

- Steroid injection results in less severe post-treatment symptoms than trapeziectomy, within the first 4 weeks

- Trapeziometacarpal arthroplasty results in less severe post-treatment symptoms than trapeziectomy, within the first 4 weeks

- Minimally invasive (endoscopic or percutaneous) CTD results in less severe post-treatment symptoms than open CTD, within the first 2 weeks

- The difference in the recovery of groups undergoing open release vs steroid injection for trigger finger is not clinically significant over the first 2 weeks

The objective is to test EMCAT's ability to differentiate between recovery trajectories that are expected to differ, rather than to prove or disprove that differences in recovery trajectories exist. The clinical comparisons are a vehicle for testing the measurement properties of EMCAT. Here, the threshold for clinically significant differences is approximated as half a standard deviation of baseline scores of the groups being compared. Statistical significance is taken at the 5% level. Symptom severity means PEM EMCAT scores, where a higher (poorer) score reflects more severe symptoms (a poorer level of hand health).

3. Assess the usability of the EMCAT platform

4. Assess the criterion validity of EMCAT against the full-length PEM by comparing scores at baseline, 6 weeks, and 12 weeks

### Exploratory Objectives

5. Explore whether the information provided by the EMCAT platform could have accurately predicted which patients required a change in management during open CTD follow-up

6. Explore whether the information provided by the EMCAT platform could help to time follow-up appointments for TBOA injections to coincide with patient need

7. Explore the patient and clinician perceptions of EMCAT-guided follow-up and clinical monitoring

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 07/05/2024, East Midlands - Nottingham 1 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8115; nottingham1.rec@hra.nhs.uk), ref: 24/EM/0113

## **Study design**

Observational cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic, Quality of life

## **Health condition(s) or problem(s) studied**

Dupuytren's contracture, thumb-base osteoarthritis, carpal tunnel syndrome, trigger finger

## **Interventions**

This is a mixed-methods cohort study to explore the feasibility of EMCAT for measuring between-group differences in postoperative recovery, its potential to guide follow-up type (face-to-face, telemedicine or patient-initiated) in open carpal tunnel decompression, and its potential to guide follow-up timing after steroid injection for TBOA. The study setting will be NHS hospitals in England, Scotland and Wales.

The primary objective is to use EMCAT to compare the recovery trajectories of patients undergoing PNF and LF for Dupuytren's disease. A difference is expected in recovery trajectory over 12 weeks, with patients undergoing PNF showing less severe symptoms than those undergoing LF over the first 4 weeks. To meet this objective, the study will recruit 396 participants (198 undergoing PNF and 198 undergoing LF), who will be followed up for 12 weeks with daily EMCAT assessments.

To address our secondary objectives, the study will simultaneously recruit patients undergoing:

- Steroid injection for TBOA
- Steroid injection for trigger finger
- Trapeziectomy for TBOA
- Arthroplasty for TBOA
- Surgical release of trigger finger
- Open CTD
- Minimally invasive (endoscopic or percutaneous) CTD

It will recruit as many participants as possible in these groups, within the limits of the study timing and funding, and up to a maximum of 198 per group. All collected EMCAT data will be used to test the following hypotheses:

- Steroid injection results in less severe post-treatment symptoms than trapeziectomy, within the first 4 weeks
- Trapeziometacarpal arthroplasty results in less severe post-treatment symptoms than trapeziectomy, within the first 4 weeks

- Minimally invasive (endoscopic or percutaneous) CTD results in less severe post-treatment symptoms than open CTD, within the first 2 weeks
- The difference in the recovery of groups undergoing open release vs steroid injection for trigger finger is not clinically significant over the first 2 weeks

The objective is to test EMCAT's ability to differentiate between recovery trajectories that are expected to differ, rather than to prove or disprove that differences in recovery trajectories exist. The clinical comparisons are a vehicle for testing the measurement properties of EMCAT.

Participants undergoing open CTD or steroid injection for TBOA will be automatically entered into a second research stream. Those undergoing steroid injection for TBOA will be followed up with twice-weekly EMCAT assessments for a further 12 weeks (24 weeks total). In this stream, participants' medical records will be reviewed by members of the research team at 24 weeks. For patients with TBOA, EMCAT trajectories will be plotted as time series graphs, and follow-up appointment dates will be overlaid onto these plots. They will be inspected to see whether appointments coincide with peaks in symptom severity.

For patients undergoing open CTD, the study will record whether the participant underwent any change in management as a result of their follow-up appointment (including but not limited to antibiotic prescription, reoperation, clinical investigation, arrangement of further clinical follow-up and hand therapy referral). The study will then ask three independent clinicians to inspect de-identified EMCAT trajectories and predict whether or not the patient required a change in management at their follow-up. Then the study will calculate the accuracy of these predictions against what happened to the participant at their follow-up.

A subsample of 10 participants recruited from the first and second research streams, and 10 clinicians, will be interviewed about their experiences of the platform. Interviews will follow a schedule that covers the following topics:

- Perceived value of the EMCAT as a data-capture platform
- Acceptability of EMCAT
- Perceived burden of EMCAT
- Facilitators and barriers to using EMCAT
- Areas for improvement within the EMCAT platform
- The potential for EMCATs to guide follow-up in different scenarios (e.g. open CTD or steroid injections for TBOA)

Participants will be allowed to discuss any other aspects of the EMCAT platform they consider important.

### **Intervention Type**

Mixed

### **Primary outcome(s)**

Hand function measured using the Patient Evaluation Measure, administered via the EMCAT app daily for 12 weeks

### **Key secondary outcome(s)**

1. User engagement measured using the User Engagement Scale administered via the EMCAT app at 12 weeks
2. User engagement measured using response rates to EMCAT notifications administered via the EMCAT app over 12 weeks

**Completion date**

16/12/2026

## Eligibility

**Key inclusion criteria**

1. Willing and able to give informed consent for participation in the study
2. Aged 18 years or older
3. Will undergo one of the eligible treatments
4. Willing and able to download and engage with the EMCAT application on their own personal device

**Participant type(s)**

Patient, Health professional

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Undergoing bilateral treatments
2. Multiple treatments for the affected hand (for any condition) are planned within the study period
3. Unable to engage with the EMCAT application in the English language

**Date of first enrolment**

07/08/2024

**Date of final enrolment**

09/07/2025

## Locations

**Countries of recruitment**

United Kingdom

England

Scotland

Wales

**Study participating centre**  
**Oxford University Hospitals**  
John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**  
**Buckinghamshire Healthcare NHS Trust**  
Amersham Hospital  
Whielden Street  
Amersham  
United Kingdom  
HP7 0JD

**Study participating centre**  
**Leeds Teaching Hospitals NHS Trust**  
St. James's University Hospital  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**  
**Frimley Health NHS Foundation Trust**  
Portsmouth Road  
Frimley  
Camberley  
United Kingdom  
GU16 7UJ

**Study participating centre**

**Cardiff and Vale NHS Trust**  
Cardigan House  
University Hospital of Wales  
Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**  
**Forth Valley Royal Hospital**  
Stirling Road  
Larbert  
United Kingdom  
FK5 4WR

**Study participating centre**  
**University Hospitals Coventry and Warwickshire NHS Trust**  
Walsgrave General Hospital  
Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX

## **Sponsor information**

**Organisation**  
University of Oxford

**ROR**  
<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**  
Research organisation

**Funder Name**  
British Society for Surgery of the Hand

**Alternative Name(s)**

The British Society for Surgery of the Hand, BSSH

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Associations and societies (private and public)

### Location

United Kingdom

### Funder Name

Oxfordshire Health Services Research Committee

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets analysed during this study will be made available upon request from Conrad Harrison, [conrad.harrison@ndorms.ox.ac.uk](mailto:conrad.harrison@ndorms.ox.ac.uk)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 1-0	19/04/2024	17/06/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes