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

Submission date	Recruitment status	[X] Prospectively registered
13/06/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/07/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2025	Injury, Occupational Diseases, Poisoning	[X] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
332275

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
17695, IRAS 332275, CPMS 62442

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
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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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1-0	19/04/2024	17/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes