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A smartphone app to measure day-to-day changes in hand symptoms

Submission date
31/12/2021

Recruitment status
No longer recruiting

Registration date
17/02/2022

Overall study status
Completed

Last Edited
15/09/2023

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patient-reported outcome measures (PROMs) are questionnaires that measure important elements of health. In hand surgery, PROMs are used to measure health constructs such as pain and hand function. This can be important in clinical practice, to tell whether an intervention (e.g. an operation or hand therapy) has made somebody feel better, or in research to compare how effective different interventions are. A problem with PROMs is that we usually only ask patients to complete them at infrequent and arbitrary time points (e.g. before surgery, at 6 weeks and again at 3 months). This means that day-to-day changes in symptoms are often missed. This is particularly important in arthritis and hand injuries, where symptoms can be brought on by certain activities, and even affected by the weather.

We plan to test a new technique to collect PROM responses more frequently. It is called Ecological Momentary Computerised Adaptive Testing (EMCAT). EMCAT works by using “artificial intelligence” to make PROM questionnaires much shorter and tailored to an individual, based on their previous responses. By making PROMs shorter, we think that people could complete them at frequent time points (e.g. every day) by using a smartphone application. This will help us capture day-to-day changes in symptom severity.

Who can participate?
People who have had a hand injury, and people who have hand arthritis

What does the study involve?
We are going to test a smartphone application that uses EMCAT. To see if people like using it, we will check how frequently they used it and interview them about their experience. This information will help us to make the application better, so that we can test it in a large-scale study at a later date.

What are the possible benefits and risks of participating?
There are no significant risks to taking part in this study and no direct benefits to participants, but this work may go on to help patients with a range of conditions in the future.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2020 to December 2022

Who is funding the study?
The British Society for Surgery of the Hand, the Federation of European Societies for Surgery of the Hand, and AOUK

Who is the main contact?
Conrad Harrison, conrad.harrison@medsci.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
302403

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51091, IRAS 302403

Study information

Scientific Title
The feasibility of ecological momentary computerised adaptive testing in hand surgery

Study objectives
The aim is to test Ecological Momentary Computerised Adaptive Testing (EMCAT) to take Patient-reported outcome measures (PROMs) more frequently.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2021, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 1048375; CambridgeEast.REC@hra.nhs.uk), ref: 21/EE/0261

Study design
Observational case series

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hand surgery

Interventions
We will perform a mixed-methods pilot study of the PEM EMCAT platform. This will involve 40 participants engaging with the EMCAT app on their smartphones over a 12 week period. Following this, semi-structured interviews will be conducted with a maximum diversity sample of 10 participants. These will be recorded for thematic analysis. Engagement rates will be quantified for the whole sample of 40 participants.

Sampling Strategy
Initially, we will purposively select a maximum diversity sample of 20 participants undergoing treatment for thumbbase OA and 20 participants undergoing treatment for hand trauma. These participants will be recruited from Buckinghamshire NHS Trust and the Cardiff and Vale University Health Board. We will aim to diversify samples by age, sex, ethnicity, employment status, hand dominance and type of treatment.
From each group, 5 participants will be purposefully sampled for semi-structured qualitative interviewing. We will aim to diversify these subgroups by the same variables.

Methods of Data Collection
Each of the 40 participants will be asked to download the EMCAT web-browser app onto their smartphones and enable push notifications. Where required, a member of the research team will assist with this. At pre-specified time schedules, participants will be sent a reminder to engage with the app via email and/or push notification. Three different time schedules will be tested: three notifications a day, one notification a day, and three notifications a week.
When a participant receives a notification, they can choose to engage with the EMCAT app, or

dismiss the notification. If the participant chooses to open the EMCAT app, they will be invited to complete a sample of items from the PEM part 2. We expect that participants will be asked to complete between 1 and 4 questions each time they are notified. PEM EMCAT responses will be collected for a period of 12 weeks.

In addition to the PEM EMCAT, each participant will be asked to complete the full-length PEM part 2 questionnaire (11 items) at 0, 6 and 12 weeks via the app. At 12 weeks, we will also ask participants to complete the 31 item User Engagement Scale (UES), also via the app.

Following the 12 week pilot period, we will select a maximum diversity sample of 5 participants with thumb-base OA and 5 participants with hand trauma for qualitative interviews. Semi-structured interviews will be conducted, and transcribed using the Zoom videoconferencing platform. Transcripts will then be manually de-identified. 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 EMCAT's use in remote monitoring and clinical decision support

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

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
EMCAT app

Primary outcome(s)
1. Response rates to EMCAT notifications across different scheduling regimes, measured using the app over 12 weeks
2. Attrition rate, recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 12 weeks, across different scheduling regimes

Key secondary outcome(s))
1. User engagement, as measured by the User Engagement Scale at 12 weeks
2. Agreement of EMCAT scores and full-length PEM scores over 12 weeks
3. Number of items administered and standard error of measurement in each assessment, over 12 weeks

4. Explored using semi-structured interviews:
4.1 The perceived value of the EMCAT as a data-capture platform
4.2 The acceptability of EMCAT
4.3 The perceived burden of EMCAT

4.4 Facilitators and barriers to using EMCAT
4.5 Areas for improvement within the EMCAT platform
4.6 The potential for EMCAT's use in remote monitoring and clinical decision support

Completion date
07/12/2022

Eligibility

Key inclusion criteria
1. Participant aged over 18 years and undergoing treatment for recent hand trauma or thumb-base osteoarthritis (OA)
2. Able to provide informed consent
3. Able to download and use the EMCAT app onto a personal smartphone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
40

Key exclusion criteria
The participant may not enter the study if they have any communicative or cognitive barrier that would prevent them from engaging in the interview process

Date of first enrolment
01/01/2022

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
United Kingdom

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

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
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CF14 4HH

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
The British Society for Surgery of The Hand

Funder Name
AOUK

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/09/2023	15/09/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	05/12/2021	11/01/2022	No	No
Protocol file	version 2.0	14/05/2022	19/05/2022	No	No