Study Title: The feasibility of Ecological Momentary Computerised Adaptive Testing in hand surgery

Internal Reference Number / Short title: EMCAT in hand surgery

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Sponsor:	University of Oxford
Funder:	The British Society for Surgery of the Hand, the Federation of European Societies for the Surgery of the Hand, AOUK
Chief Investigator Signature:	

None of the investigators have any conflicts of interest in relation to this work.

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

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1. KEY STUDY CONTACTS

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Funder(s)	The British Society for Surgery of the Hand, the Federation of European Societies for the Surgery of the Hand, AOUK
Academic Advisor(s) or Supervisor(s)	Jeremy Rodrigues jeremy.rodrigues@ndorms.ox.ac.uk 01865227374

2. LAY SUMMARY

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 app. This will help us capture day-to-day changes in symptom severity.

We are going to test a smartphone application that uses EMCAT in a group of 20 people who have had a hand injury, and 20 people who have hand arthritis. To see if people like using the app, we will check how frequently they used it and interview them about their experience. This information will help us to make the app better so that we can test it in a large scale study at a later date.

3. SYNOPSIS

Study Title	The feasibility of Ecological Momentary Computerised Adaptive Testing in hand surgery
Internal ref. no. / short title	EMCAT in hand surgery
Sponsor	University of Oxford Joint Research Office 1st floor, Boundary Brook House Churchill Drive, Headington

	Oxford OX3 7GB
Funder	The British Society for Surgery of the Hand, the Federation of European Societies for the Surgery of the Hand, AOUK
Study Design, including methodology	We are developing a smartphone app to administer short, frequent questionnaires to participants with hand injuries or thumb-base osteoarthritis. The app will be piloted over 12 weeks in one sample of 20 participants with hand injuries and one sample of 20 participants with thumb-base osteoarthritis. We will undertake a mixed-methods analysis which will focus on completion rates, acceptability metrics and qualitative semi-structured interviews with a subsample of each group. Interviews will be transcribed and de-identified. They will then undergo inductive thematic analysis using the NVivo software platform.
Study Participants, including sampling strategy	A purposive, diverse sample of 20 participants undergoing treatment for bony or soft tissue hand trauma, and 20 participants undergoing treatment for thumb-base osteoarthritis, will be recruited from Buckinghamshire Healthcare NHS Trust and the Cardiff and Vale University Health Board. A sub-sample of 5 participants from each group will undergo qualitative interviewing.
Sample Size	40
Planned Study Period	01/01/2022 – 01/01/2023
Planned Recruitment period	01/01/2022 – 01/06/2022
Aim/Research Questions/Objectives	
Primary	What is the feasibility of piloting EMCAT as an outcome measure in hand trauma and thumb-based osteoarthritis?
Secondary (if applicable)	

4. ABBREVIATIONS

CAT	Computerised Adaptive Test
CI	Chief Investigator
EMA	Ecological Momentary Assessment
EMCAT	Ecological Momentary Computerised Adaptive Testing
GDPR	General Data Protection Regulation
HRA	Health Research Authority
ICMJE	International Committee of Medical Journal Editors
IRT	Item Response Theory
NDORMS	Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences
NHS	National Health Service
OA	Osteoarthritis
PEM	Patient Evaluation Measure
PI	Principal Investigator
PPI	Patient and Public Involvement
PROM	Patient Reported Outcome Measure
REC	Research Ethics Committee
UES	User Engagement Scale

5. BACKGROUND AND RATIONALE

The James Lind Alliance priority setting partnership identified improving outcome measurement in hand conditions as a top ten research priority for patients and clinicians.[1] Patient-reported outcome measures (PROMs) can measure hand function from the patient's perspective. However, they are often administered as a single, one-off event, e.g. a few weeks or a year after surgery. This does not describe

the course of improvement that has taken place over time. Furthermore, people may not necessarily complete the PROM at the time of activities that are most affected by hand function. As a result, the true impact of the hand condition and its treatment may be underestimated.

We propose a novel method of collecting patient-reported data in hand conditions, which we have called Ecological Momentary Computerised Adaptive Testing (EMCAT). This combines two health-measurement techniques: ecological momentary assessment (EMA) and computerised adaptive testing (CAT). EMA involves asking people to complete a PROM at different times of day, and when they are undertaking key activities (e.g. specifically while at work or performing household tasks). This method of PROM completion minimises recall bias and can demonstrate the fluctuating impact of hand conditions.[2] A potential problem with EMA is the burden of asking people to complete full PROMs while busy with their activities. To overcome this, CAT uses psychometric algorithms to pick a small number of relevant questions from the full-length PROM. CAT algorithms learn which questions are the most relevant based on responses to previous questions. This creates shorter, personalised assessments which people are more likely to complete. The scores produced are comparable to full-length PROM scores.[3]

The EMCAT platform is under development. We plan to test this in hand trauma and thumb-base osteoarthritis (OA). These are two of the commonest hand conditions. Hand trauma accounts for 20% of Emergency Department attendances (5 million patients a year in the UK),[4,5] and thumb-base arthritis affects up to 91% of people by 80 years old.[6] The impact of these conditions on someone's health varies day-by-day, and symptoms can be triggered by a wide variety of activities including work, activities of daily living, hobbies and sports.

AIM / RESEARCH QUESTIONS / OBJECTIVES

Aim / Research Questions / Objectives
Aim: To explore to feasibility of EMCAT as an outcome measure in hand trauma and thumb-base OA
Objectives: 1. Determine the feasibility of PEM EMCAT deployment in a sample of 20 participants undergoing treatment for hand trauma and 20 participants undergoing treatment for thumb-base OA

2. Explore the user experience of EMCAT through semi-structure qualitative interviewing in a subsample of 5 participants with each condition

6. STUDY DESIGN

6.1 Methodology

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.

6.2 Sampling Strategy

Initially, we will purposively select a maximum diversity sample of 20 participants undergoing treatment for thumb-base 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.

6.3 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 using the Zoom videoconferencing platform and interviews transcribed using a secure transcription service (Appen) which has been approved for this purpose by the information security team at the University of Oxford. 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.

6.4 Methods of Data Analysis

The primary outcome measure will be PEM EMCAT completion rates (number of completed response sets divided by number of invitations) stratified by sampling schedule. These will be calculated and tabulated. We do not aim to compare these through hypothesis testing.

Subscale scores of the UES will form a secondary outcome measure. The UES was originally intended to measure 6 user engagement constructs, but a number of subsequent studies have suggested that it follows a 4-factor structure. Items of the UES will be grouped into the 4 subscales described by O'Brein et al, to measure: focused attention, aesthetic appeal, perceived usability and reward.[7] Responses to

individual items and subscale scores will be interpreted in the context of other measures. We will not perform comparative statistical analyses with these data.

We will perform an inductive thematic analysis with the de-identified interview transcripts.[8] We have chosen an inductive (data-driven) approach as there is relatively little evidence to support an *a priori* theoretical framework with which to classify themes relating to EMCAT engagement. This will involve reading and re-reading transcripts, using the Nvivo platform to generate codes for elements of the transcript, and grouping these into themes. Each time a theme is generated, previous transcripts will be reviewed to identify data that could be categorised into the new theme. Themes will be named and structured (if appropriate) into a framework that aids their interpretation.

6.5 Study Sequence and Duration

1. Potential participants will be identified by clinical members of the research team during routine care at Buckinghamshire Healthcare NHS Trust and Cardiff and Vale University Health Board.
2. The investigator will invite potential participants to participate at the end of their clinic appointment
3. Potential participants will be provided with a written information pack, and given time to read this and discuss it
4. The investigator will take informed consent from the participant at that point, if the participant feels they have had sufficient time to consider taking part
5. If the potential participant does not feel they have had long enough to consider participating in the study, they will be free to contact a member of the research team should they later wish to participate
6. At the point of recruitment, a member of the research team will assist the participant in downloading the EMCAT app and enabling push notifications
7. At the point of recruitment, the participant will also complete the full-length (11 item) PEM part 2 via the app
8. Over the next 12 weeks, participants will complete PEM EMCAT questionnaires (if they choose to) when prompted by email or push notification
9. In addition, at 6 and 12 weeks, participants will be asked to complete the full-length PEM part 2 via the app
10. At 12 weeks, participants will also be asked to complete the 31 item UES via the app

11. At 12 weeks, we will identify and approach 10 participants with invitations to take part in semi-structured interviews, this will happen either in clinic or remotely via telephone or the Zoom videoconferencing platform
12. Interview participants will be provided with additional written information and time to consider their involvement in the interviews, a member of the research team will then take informed consent for participation in the interviews
13. Participants will not be followed up after interview
14. We will notify all participants when the results of this study have been made available in the public domain
15. Personal data will be held securely for a three year period, and then destroyed, research data will be held securely for a seven year period, and the destroyed

7. PARTICIPANT IDENTIFICATION

7.1 Study Participants

We will recruit 20 participants undergoing treatment for clinically diagnosed thumb-base OA. Treatments may be non surgical or surgical.

We will also recruit 20 participants undergoing treatment for hand trauma. Again, treatments may be non surgical or surgical. The participant will be recruited at the start of treatment. For conservative treatments (e.g. splinting) this will be at the first clinic appointment following the injury. For procedural treatments (e.g. an operation) this will be the day of their procedure.

Within these groups, we will aim for diversity by: age, gender, ethnicity, employment status, hand dominance (i.e. whether the participant is undergoing treatment for their dominant hand, non-dominant hand or both hands), and treatment type.

From these groups, we will recruit 5 participants who have undergone treatment for thumb-base OA and 5 participants who have undergone treatment for hand trauma to take part in qualitative interviews. This will represent a maximum diversity sample by the variables listed above.

7.2 Inclusion Criteria

- Participant aged over 18 and undergoing treatment for recent hand trauma or thumb-base OA
- Willing and able to provide informed consent
- Able to download and use the EMCAT app onto a personal smartphone

7.3 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

7.4 Welsh Language Act

In line with the Welsh Language Act 1993 all clinical appointments in Wales have to be available in Welsh.

The PEM questionnaire does not have an official Welsh language version and has not been validated in any language other than English.

Where needed during routine clinical use, the questionnaire is translated for the patient by a Welsh speaker. However, for the purposes of this study we consider the lack of a validated Welsh language version to be a reasonable exclusion criteria for potential participants unable to comprehend the English language.

8. STUDY ACTIVITIES

8.1 Recruitment

This is a two centre study. Eligible participants will be identified by Jeremy Rodrigues and Ryan Trickett during clinic appointments at the Buckinghamshire Healthcare NHS Trust and Cardiff and Vale University Health Board. Jeremy Rodrigues and Ryan Trickett are consultant hand surgeons at these sites and have routine access to the data which will be used to identify potentially eligible participants.

At the end of the appointment, Jeremy Rodrigues or Ryan Trickett will approach potential participants, discuss the study with them and invite them to partake. Written information will be provided to the potential participant, and they will be offered time alone to read the material and consider taking part. It

will be made explicitly clear that participants are free to decline without reason, and this will not affect the care they receive in future.

We anticipate that most people will be able to make an informed and considered decision about taking part on the same day as their clinic appointment. If the participant accepts the invitation, written consent will be taken on the same day as their appointment. Participants will be provided with a research team member's email address, and are free to withdraw consent at any time by emailing them.

If a participant feels they need more time to decide whether or not to take part, they will be provided with a research team member's email address on the day of clinic, and asked to contact them should they decide to participate. We will not approach someone a second time in this case.

8.2 Informed Consent

Written and verbal versions of the appropriate participant information and informed consent forms will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed to consider the information, and the opportunity to question the investigator, their GP or other independent parties to decide whether they will participate in the study. Written informed consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the informed consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed informed consent form will be given to the participant. The original signed form will be retained at the study site – this will be kept securely locked in a locked office.

8.3 Screening and Eligibility Assessment

All information required to screen participants (nature of hand condition, age, gender, ethnicity, employment status, hand dominance and treatment type) will already be known to Jeremy Rodrigues or Ryan Trickett as part of their role in the participant's routine care.

On the basis of this information, Jeremy Rodrigues or Ryan Trickett will identify prospective participants during clinics at Buckinghamshire Healthcare NHS Trust and Cardiff and Vale University Health Board

respectively. One of these researchers will approach prospective participants and invite them to participate. If the participant accepts the invitation, they will be screened for the other eligibility criteria:

- Able to provide informed consent
- Able to download the EMCAT app onto a personal smartphone
- No communicative or cognitive barrier that would prevent them from engaging in the interview process

8.4 Subsequent Visits

From the point of recruitment, all follow-up will occur remotely via the app. This includes completion of the PEM part 2 at weeks 6 and 12, and the completion of the UES at week 12. Participants identified for recruitment to interviews will be contacted by telephone or the Zoom videoconferencing platform.

6.14 Discontinuation/Withdrawal of Participants from Study

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

- Response fatigue from the EMCAT app
- The occurrence of significant distress during study interviews
- Inability to comply with study procedures
- Participant decision

Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely.

Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. In this case, no further data would be collected after withdrawal.

Participants can withdraw completely from the study and withdraw the data collected up until the thematic analysis of qualitative interviews has begun. In that case, the data already collected would not be used in the final study analysis. Patients will be identifiable through a study number that they are

assigned at recruitment. Once thematic analysis has begun, participants will not be able to withdraw interview data – this will be made clear in written participant information.

In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including, but not limited to:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- Significant protocol deviation
- Significant non-compliance with study requirements

In this case, withdrawal from the study would exclude that participant's data from the analysis if it has not already begun.

Where a participant has withdrawn, or been withdrawn, from the study, we will aim to replace that participant.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in the study file.

6.14 Definition of End of Study

The end of study date is the date of the interview of the last participant.

9. ANALYSIS

9.1 Description of Analytical Methods

Anonymised demographic data will be tabulated. This will include, age, ethnicity, gender, employment status, hand dominance, condition and treatment.

Response rates will be calculated and compared across demographic groups and sampling schedules. EMCAT scores will be plotted against time and area under the curve will be calculated. These measurements will be compared to full-length PEM part 2 scores at a group and individual level.

Responses to the UES will be evaluated with descriptive statistics at the item and subscale level.

Audio recordings will be transcribed verbatim using a secure transcription service (Appen) which has been approved for transcribing research interviews by the University of Oxford Information Security team, under a third party security assessment. Audio recordings will be held on a secure University of Oxford cloud server until they have been transcribed. Once transcribed, audio recordings will be deleted. Transcripts will be read, re-read, and coded using Nvivo (QSR International 2021) and an inductive approach, which is appropriate for exploratory studies. Data will be categorised into themes, and as each new theme emerges previous transcripts will be reviewed to identify data described by that theme. Themes will be organised into a descriptive framework and presented narratively, with direct, anonymised participant quotes.

10. DATA MANAGEMENT

10.1 Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Members of the research team will have access to participants' personal data for study purposes (e.g. to inform participants that the research has been published). In addition, members of the app development team at the Psychometrics Centre, University of Cambridge, may have access to participants' personal data for app administration (e.g. to upload email addresses for study notifications). This will be detailed in participant information sheets.

10.2 Data Recording and Record Keeping

Informed consent forms will be kept in the site file, which will be securely stored in a locked office at the recruitment site. The participants will be identified by a unique study specific number and/or code. Study numbers will be linked to participants and their email address with a password-protected excel spreadsheet, uploaded to Conrad Harrison's Oxford University Nexus 365 OneDrive for Business account, using the University's encrypted cloud service. It is necessary to include the email address in this

document as it will be used to inform participants once the results of the study have appeared in the public domain. Email addresses will also be uploaded to the EMCAT web-platform, which will securely store these on an AWS server.

The EMCAT platform will collect pseudonymised responses to the PEM EMCAT questionnaire which will be stored on an AWS server.

Names and any other identifying details will not be included in any study data electronic file. Anonymised study data (de-identified transcripts, demographics and questionnaire responses) will be analysed on a password-protected personal device.

Personal data will be held securely for a three year period following publication of this research, and then destroyed. Research data will be held securely for a seven year period following publication of this research, and the destroyed. Consent forms will be stored in the site files as described, the spreadsheet that links participants to their study numbers will be stored on the University's encrypted cloud service, and de-identified research data will be stored on a password-protected, encrypted memory stick.

11. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, relevant regulations and standard operating procedures.

12. ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

12.2 Approvals

Following sponsor approval the protocol, informed consent form and participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), and host institution(s) for written approval.

The investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

12.3 Other Ethical Considerations

The interviews will focus on the use of the EMCAT app. There is a chance that these interviews remind participants of health concerns addressed by the EMCAT app, such as pain and disability.

If a participant discloses illegal activity to a researcher during the study, this information will be reported to a law enforcement agency in line with UK law. This will be made explicit in written study information.

In the unlikely event that they arise, we will recommend any medical or psychiatric red flags are discussed with a medical professional in an appropriate context.

12.4 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

12.5 Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s), with the exception of consent forms, the spreadsheet that identifies a participant from their reference number. These will be kept separately from the pseudonymised study data, on the University of Oxford's encrypted cloud service.

All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

12.6 Expenses and Benefits

Funding for this study does not permit the payment of expenses or benefits. This will be made explicit on written participant information sheets.

13. FINANCE AND INSURANCE

13.1 Funding

This study will be funded by a pump priming grants from the British Society for Surgery of the Hand, the Federation of European Societies for the Surgery of the Hand, and AOUK.

13.2 Insurance

The University of Oxford maintains Public Liability and Professional Liability insurance which will operate in this respect.

13.3 Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

14. PUBLICATION POLICY

The investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the British Society for Surgery of the Hand, the Federation of European Societies for the Surgery of the

Hand, AOUK. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. Study participants will be notified by email once the results of this study appear in the public domain.

7. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the study.

8. ARCHIVING

All study data will be retained for three years following publication of this research, in keeping with local data protection policy.

Consent forms will be stored in a site files as described. The spreadsheet that links participants to their study numbers will be stored on University's encrypted cloud service. De-identified research data will be stored on a password-protected, memory stick encrypted to 256-bit Advanced Encryption Standard.

9. REFERENCES

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APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.1	05/12/2021	Conrad Harrison	Clarification regarding the storing of audio recordings.