Usability Study of OnTrack Tools

Usability study of OnTrack Tools: a study to assess the usability of a clinician-facing software application to support arm rehabilitation after stroke.

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STUDY COORDINATION CENTRE: Helix Centre, Institute of Global Health Innovation

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Protocol authorised by:

Name & Role	Date	Signature

Study Management Group

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Clinical Queries

Clinical queries should be directed to Gianpaolo Fusari (gianpaolo@helixcentre.com / 07767 792 770) who will direct the query to the appropriate person.

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

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Funder

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This protocol describes the usability study for a clinician-facing graphical user interface (GUI) and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

GUI	Graphical user interface
ICHT	Imperial College Healthcare NHS Trust
ICL	Imperial College London
SUS	System Usability Scale
PSSUQ	Post Study System Usability Questionnaire
USE	Usefulness, Satisfaction and Ease of Use Scale

KEYWORDS

Stroke, Arm Rehabilitation, Neurology, Behaviour, Usability, Design

STUDY SUMMARY

TITLE	Usability study of OnTrack Tools: a study to assess the usability of a clinician-facing software application to support arm rehabilitation after stroke.
DESIGN	A usability study of the OnTrack Tools graphical user interface (GUI) using a combination of qualitative and quantitative methods. The evaluation of the GUI will be divided into three phases of evaluation.
AIMS	assess the usability of the OnTrack Tools GUI under simulation by therapists managing the rehabilitation of stroke survivors.
OUTCOME MEASURES	The usability of the intervention will be evaluated at each of the three phases using standardised questionnaires on usability such as the System Usability Scale (SUS), the Post-Study System Usability Questionnaire (PSSUQ), and the Usefulness, Satisfaction, and Ease of Use Scale (USE)., In addition, a focus group will be conducted at the end of each testing phase to record feedback from participants.
POPULATION	Occupational Therapists and Physiotherapists working in the stroke wards at ICHT.
ELIGIBILITY	Participants will be adult (18 years old or over) Occupational Therapists and Physiotherapists (Band 4 to Band 8) working in the stroke wards at ICHT. No exclusion criteria has been defined.
DURATION	3 months

1. INTRODUCTION

1.1. BACKGROUND

Arm disability following a stroke affects 450,000 people in the UK, equating to 77% of stroke patients with a disability. Arm recovery after stroke is a national research priority, yet a recent Cochrane review of over 500 trials failed to yield high-quality practice recommendations (Pollock, 2014).

The gold-standard of care is dose-intensive repetitive rehabilitation (CQC, 2011). However, NHS resources are limited and unable to provide this. There is untapped potential to increase repetitive rehabilitation by targeting the 90% of the day where patients are going about their daily activities and can use their arm movement (however small) to a greater extent.

The OnTrack rehabilitation system has been designed to track arm activity throughout the day and provide tailored support from clinicians. A feasibility study in the NHS has shown promising outcomes (Fusari, 2020). Participants (n=12) found OnTrack beneficial and reported improved confidence when performing activities. Preliminary results have also shown a 64% increase in arm activity and 18% increase in arm performance on average after 12 weeks of using OnTrack. Trial registration: NCT03944486.

1.2. RATIONALE FOR CURRENT STUDY

This study aims to assess the usability of the OnTrack Tools GUI under simulation. The study follows up from a study of the OnTrack system that demonstrated the feasibility and acceptability of the patient-facing component of the system by stroke survivors and therapists. The design of this study was developed through a collaborative approach between the study researchers, patients, and front-line therapists.

2. STUDY OBJECTIVES

Primary outcome: To assess the usability of the OnTrack Tools GUI under simulation by therapists managing the rehabilitation of stroke survivors.

Secondary outcomes: To understand aspects of the GUI that could improve as well as additional features that could be implemented in future development.

3. STUDY DESIGN

Usability study of OnTrack Tools: a study to assess the usability of a clinician-facing software application to support arm rehabilitation after stroke.

Study Design
A usability study of the OnTrack Tools graphical user interface (GUI) using a combination of qualitative and quantitative methods. Usability can be defined as the measure of the effectiveness of interaction between users and the system; in other words, how users perform tasks using the system.

Testing will be performed in three phases by target end-users - stroke therapists (occupational therapists and physiotherapists) - recruited from Imperial College Healthcare NHS Trust.

Outcomes
The usability of the OnTrack Tools system will be evaluated at each of the three phases using standardised questionnaires on usability such as the System Usability Scale (SUS), the Post-Study System Usability Questionnaire (PSSUQ), and the Usefulness, Satisfaction, and Ease of Use Scale (USE). Questionnaires will be administered online using Qualtrics on the devices that will be loaned to the participants for the study. In addition, a focus group will be conducted at the end of each testing phase to record feedback from participants. Focus groups will be face-to-face wherever possible and will take place at Charing Cross Hospital in the CNRU or ASU gyms, both of which are on the 9th floor and accessible to all therapists. Covid guidance will be followed. If a session needs to be moved online, it will be done using Microsoft Teams. Focus group sessions may be audio recorded using a recording device and photos/video may be taken with participant consent. Audio recordings may be sent to an external party (PageSix Transcription Services Ltd) for transcription, recordings will be deleted after transcription.

Intervention
The intervention is the OnTrack Tools system consisting of a GUI used to manage patients who are users of the OnTrack rehabilitation system. Participants will be asked to complete clinical and non-clinical tasks in simulation using OnTrack Tools. The themes for the scenarios of use presented in each of the three phases are summarised below:

Phase 1 - Account creation, system onboarding and general system navigation.
Phase 2 - Individual patient management.
Phase 3 - Content and data management.

Recruitment
Occupational Therapists and Physiotherapists will be recruited from Imperial College Healthcare NHS Trust (ICHT). A Research Therapist (RT) working on site will be responsible

for identifying and recruiting participants. They will introduce the study to potential participants and provide information documents allowing a minimum of 24 hours for potential participants to formulate questions. The RT will be able to answer questions or will liaise with the project lead to provide an answer. Once all questions are answered and a potential participant is happy to participate, consent will be taken by the RT. The study aims to recruit 5-10 therapists per evaluation phase, this equates to 30-50% of Band 4 to Band 8 therapists at ICHT. Given the rotational nature of therapist work at ICHT, we expect different participants taking part at each of the three phases of evaluation.

Study duration
3 months

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

There will be no pre-registration evaluations necessary for eligible participants to be included in the study.

4.2. INCLUSION CRITERIA

Adult (18 years old or over) Occupational Therapists and Physiotherapists (Band 4 to Band 8) working in the stroke wards at ICHT.

4.3. EXCLUSION CRITERIA

No exclusion criteria has been defined.

4.4. WITHDRAWAL CRITERIA

Participants are free to withdraw from the study at any time. However, anonymised activity data collected may still be used for data analysis as this is unlinked of any participant identifiable information.

Participants will be able to withdraw from the study by contacting the research team in person or in writing via the contact details provided in the participant information sheet.

5. ASSESSMENT AND FOLLOW-UP

There will be no follow-up after the third round of evaluation. Data collection for the study and participants' involvement will end at this point.

6. STATISTICS AND DATA ANALYSIS

Sample size
15 participants over three cycles of evaluation.

Nielsen, et.al. (1993) advocate that a sample size of 5 participants over 3 rounds of testing will be able to uncover close to 100% of all usability problems. Taking into consideration the staffing numbers at ICHT, we anticipate being able to recruit a

maximum of 10 participants per round and expect a 50% drop out or non-completion rate.

Data analysis
Analysis will be completed on the parameters of usability of the intervention, including the quantitative results of outcome measures and the qualitative outputs from focus groups.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study.

7. REGULATORY ISSUES

7.1. ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the Health Regulatory Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

7.2. CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time from the study without giving reasons and without affecting their role as a member of staff.

7.3. CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Data will be pseudonymised.

Researchers will have participants' names, contact numbers, and/or emails for the purposes of managing the study. This information will be stored securely as per Imperial College London data policy.

Participants will be assigned an identification number that will be used in place of their name wherever possible.

The document that links the participant's name to their ID number will be stored on a password protected university computer.

Images, videos and audio recordings may be taken at any stage of the study with the participants' consent. Media will be stored securely on a password protected device owned by the sponsor. Audio recordings may be transcribed by an external service (with contractual

arrangements with the sponsor) - with participant identifiable information removed ahead of this, recordings will be deleted after transcription. Photographs taken will be anonymised as soon as possible. Videos will exclude participants' faces.

Direct quotes may be used alongside a participant characteristic (e.g. Occupational Therapist, Band 5) however participant identifiable information will not be used alongside quotes.

There will be a combination of participant information stored on paper (e.g. consent forms) and electronically (e.g. contact details). Paper documentation will be stored in a locked cupboard inside a locked office at ICL or ICHT only accessible to the researchers. Electronic information will be stored on password protected university computers.

7.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

7.5. SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

7.6. FUNDING

SBRI Healthcare is funding this study. No participant payments or incentives will be provided.

7.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

8. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through the Helix Centre by Gianpaolo Fusari (contact details above).

9. PUBLICATION POLICY

The researchers will seek to publish their work through publications in peer-reviewed journals.

10. REFERENCES

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