OnTrack Feasibility Study

Feasibility study of OnTrack - a digital system for upper limb rehabilitation after stroke

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Name & Role	Date	Signature

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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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This protocol describes a feasibility study for the OnTrack intervention 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 NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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KEYWORDS

Stroke, Upper Limb Rehabilitation, Sensors, Behaviour

STUDY SUMMARY

TITLE	Feasibility study of OnTrack - a digital system for upper limb rehabilitation after stroke
DESIGN & METHODS	Mixed methods
AIMS	Assess the feasibility of 'OnTrack' (a new arm rehabilitation system), for use by patients, and frontline staff in stroke rehabilitation services.
OUTCOME MEASURES	Various. (Including but not exclusive to: interviews; focus groups; usability questionnaires e.g. system usability scale; functional outcome measures e.g Fugl-Meyer; self-reported outcome measures e.g Motor Activity Log; motivational outcome measures e.g. Patient Activation Measure; and others such as e.g. Friends & Family Test, EQ-5D-5L, Modified Rankin Scale, Montreal Cognitive Assessment, etc.)
POPULATION	Stroke survivors, their family/carers, clinicians, professionals and lay people working with stroke survivors.
ELIGIBILITY	Participants will be stroke survivors, relatives/carers of stroke survivors, frontline healthcare workers who treat stroke survivors, managers responsible for stroke service provision and lay people with an involvement in stroke care/delivery. Participants will be over 18.
DURATION	1- 2 years

1. INTRODUCTION

1.1. BACKGROUND

There are over 100,000 strokes per year in the UK, and nearly 1.2 million stroke survivors, of these 25% occur in people under 65 years of age. Stroke is the leading cause of disability in the UK, and almost two thirds of stroke survivors leave hospital with a disability. Upper-limb weakness is the main cause of impairment, and significantly contributes to the loss of independence and isolation stroke survivors feel. Stroke is estimated to cost the NHS and social care in England as much as £1.7 billion per year (Stroke Association, 2017).

Repetitive rehabilitation techniques are widely accepted as the 'gold-standard' for regaining ability after stroke (Kwakkel, 2004). Nonetheless, studies suggest that the actual time patients spend exercising is minimal (Kunkel, 2014). Many current approaches to solving this problem focus on improving the prescribed rehabilitation sessions, often employing gamification techniques (Laver, 2017 and Loureiro, 2011). Whilst this is important, there is untapped potential to increase repetitive rehabilitation by targeting the 90% of the day where patients are going about life's daily activities.

1.2 RATIONALE FOR CURRENT STUDY

During the ULRAS ethnographic study we identified that patients struggle to see and keep track of improvements, this impacts their motivation and leaves them dependent on a therapist for feedback. Patient often reported they felt unsupported after leaving hospital and didn't know how to best help themselves improve their arm function. The feedback gathered from patients and clinicians during the ULRAS study was the basis for developing the OnTrack intervention.

OnTrack is a rehabilitation system that uses smart-devices to track arm movement through accelerometry. It combines principles of behaviour change with data on arm movement to provide actionable insights and motivate individuals to increase their arm activity. OnTrack therapists provide regular follow-up consultations to support individuals.

A proof-of-concept has been developed and tested with 10 individuals. A 20% mean increase of activity was observed, with one participant achieving 55% over seven weeks. Participants reported that after using OnTrack they were more aware of their impaired arm and had increased confidence in using it for new tasks.

The proof-of-concept has been developed further through a process co-design with users; therapists and stroke survivor feedback has continued to be incorporated to define the intervention.

OnTrack has the potential to be a scalable solution requiring minimal training that could be used in conjunction with NHS services to help increase the overall amount of arm rehabilitation received.

A study to assess the feasibility of conducting a definitive randomised trial of the OnTrack rehabilitation system is now warranted.

2. STUDY OBJECTIVES

Objective 1: To assess the feasibility of the study design and procedures
Objective 2. To explore implementation fidelity and acceptability of OnTrack

The feasibility study will enable the design of a definitive randomised controlled trial testing the effectiveness of OnTrack.

3. STUDY DESIGN

Feasibility study of OnTrack

A 12-15 month study to assess the feasibility of conducting a definitive randomised trial of the OnTrack rehabilitation system.

Study Design

A feasibility study and nested process evaluation. The study will be non-randomised; this is a pragmatic solution to set-up, recruitment and delivery across one site within the specified timeframe. The purpose of the study is not to measure clinical effectiveness of the intervention, this will be addressed in a future study if the system proves to be clinically feasible. The design of the study was developed through a collaborative approach between the study researchers, patients, front-line therapists, and the NIHR RDS.

A process evaluation will be completed in parallel to learn about usage and engagement mechanisms of participants, therapists and other frontline staff, providing critical information for implementation fidelity and impact mechanisms necessary for scale-up.

Outcomes

Feasibility outcomes including the percentage of patients eligible, recruited and completing the 14-week intervention.

Clinical outcomes (such as Fugl-Meyer, Motor Activity Log, Patient Activation Measure, EQ-5D-5L, Friends & Family test, Montreal Cognitive Assessment, Visual Analog Scale Pain, Rankin Scale, etc.) will be collected to identify an appropriate primary outcome, and to estimate parameters for a sample size calculation.

Feasibility assessment criteria:

1. ≥50% recruitment rate of eligible population

2. ≥50% adherence

3. ≥80% usability, measured by the System Usability Scale (SUS)

4. ≥80% implementation fidelity of OnTrack

5. Sample size estimate for a definitive RCT

6. Indication of the best way to integrate OnTrack into the current rehabilitation environment

Intervention

The OnTrack system consists of smart-devices (smartphone and smartwatch) and therapist support. Smart-devices are used to track arm movement, receive motivational messages and provide a real-time display of completed arm activity. Therapist support is provided through fortnightly consultations. Additionally, OnTrack helps therapists understand more about how and when patients use their affected arm between treatments.

Recruitment

Therapists will be responsible for identifying suitable patients. They will introduce the study to potential participants and provide information documents. Therapist will allow enough time (minimum 24 hours) for potential participants to think about the pros and cons of participating and to formulate questions. Therapists will be able to answer questions or will liaise with the research team to provide an answer. Once all questions are answered and a potential participant is happy to participate, consent will be taken by the therapist. Only at this stage will limited patient information be shared with the research team. There may be situations where a therapist is only able to take verbal consent from a participant due to time or material constraints, in such cases the researchers will be able to take written consent from the participant upon first meeting them.

We plan to recruit 50% of the total eligible stroke population at Charing Cross. Aiming for 24-38 patients to start the intervention, as advocated by feasibility literature (4). A 50% drop out rate is expected.

Participants who are subsequently discharged home will be able to continue in the study.

Frontline healthcare workers involved with patients that take part will be invited to take part in interviews and focus groups to discuss their feedback.

Inclusion: Adult stroke survivors (< 6 months) with arm impairment (including weakness, neglect, sensory deficits), who can:

- Provide informed consent
- Reliably communicate (this could be verbal or non-verbal)
- Read a short message (this is necessary as the intervention partly relies on the participants' ability to read short messages)

Exclusion: We are unable to recruit participants who at the time of recruitment are experiencing severe pain or oedema in the arm affected by their stroke. This is because their course of rehabilitation is different from a stroke survivor who isn't affected by these conditions, hence a comparison between samples would be impossible.

Dose

Participants will be involved in the study for 14 weeks.

Participants will be loaned equipment needed for the study.

Week 0: Participants will wear activity trackers on both arms to gather a baseline of activity allowing left-to-right comparison and complete outcome measures.

Weeks 1-12: Participants will wear a smartwatch on their impaired arm only. They will receive real-time feedback on the amount of movement completed (measured in minutes) and daily motivational messages. Participants will receive regular consultations (approximately every two weeks) with an OnTrack researcher. During the consultation any problems will be addressed and feedback gained.

At the start of week 13 patients will be given two activity trackers to wear again for 1 week to reassess their amount of movement.

Weeks 7 and 13: Repeat outcome measures.

Week 14: Usability questionnaires and semi-structured interviews administered.

Example messages include:

- “Hello, it’s the start if a new week, let’s continue to track your arm activity. If you haven’t already, put on the watch and press the blue START button to begin tracking. Are you ok to do this now?”
- “Hi, did you know about the Stroke Association? They have a wealth of resources for you, check them out by following this link”
- “Hello, let’s keep it simple during the weekend and stick to focusing on reaching your 60 minutes of activity”

Therapist involvement

Additionally, at the start of the participant’s involvement with the study, the therapists will provide information on their goals. Therapists will also have a ‘check-in’ call or email with researchers every 1-2 weeks to update the researchers on the participant’s progress. Additionally they will be invited to take part in an interview/focus group to discuss their experience of OnTrack.

Other frontline healthcare staff

Will be invited to take part in interviews and or focus groups to discuss their experience of OnTrack.

Patients family/carer

These individuals will be invited to share their thoughts and experiences of OnTrack with the researchers.

For all participants

Sessions, interviews and focus groups may be audio recorded. Data will be anonymised as far as possible and sent to a transcription service. There may be instances where interviewees and/or session participants use someone’s name and this could be difficult to anonymise.

Analysis

Analysis will be completed on the parameters and implementation of the study in addition to the usability of OnTrack.

Data collected for the process evaluation will capture changes over time and will be a combination of qualitative data from interviews with stroke participants, physiotherapists and frontline staff to explore their experiences of using OnTrack, as well as quantitative data on usage of OnTrack and the self-reported SUS. OnTrack therapy support sessions will be monitored through a fidelity checklist and observations. Interview data will undergo thematic analysis.

Data will be analysed for any association between the feasibility of the intervention and stroke subtype, patient demographics, stroke disability, and the amount of physiotherapy patients receive during the intervention period.

Other

The list of outcome measures provided is not exhaustive and others may be used instead or in addition to the ones listed above.

Participants, with their consent, may be videoed or photographed at any point during the study. This data may be used for further development and/or dissemination (anonymised images/videos).

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 stroke survivors with arm impairment (including weakness, neglect, sensory deficits), who can:

- Cognitively able to provide informed consent (advice will be gained from the patients therapy team if researchers are in any doubt)
- Reliably communicate (advice will be gained from the patients therapy team if researchers are in any doubt)
- Read a short message

Equipment will be loaned and previous smart-device experience isn't needed.

Therapists and other frontline healthcare staff involved with patients that take part will be invited to take part in interviews and focus groups to share their thoughts. Additionally, therapists will be asked to liaise with the researchers once every 1-2 weeks via phone or email to update researchers on the patients progress (anticipated phone call duration 5-15 minutes). They may also be asked to provide researchers with the results of any outcome measures that have been completed.

Patients carers/family members will be invited to share their thoughts.

4.3 EXCLUSION CRITERIA

We are unable to recruit participants who at the time of recruitment are experiencing severe pain or oedema in the arm affected by their stroke. This is because their course of rehabilitation is different from a stroke survivor who isn't affected by these conditions, hence a comparison between samples would be impossible.

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 patient identifiable information.
- Participants will be withdrawn from the study if
    - they develop ongoing arm pain scoring 3/10 or more on the VAS or swelling in the affected arm during the study that is reported to be negatively impacted by wearing the tracker and taking part in the study.
    - Their treating therapist/medical professional in concerned about them participating.
    - Are not engaging with the process.

    - They become unable to participate due to a change in their health or any other force majeure circumstances.
- If at any point the researchers become concerned about a participant's cognition or communication then the researchers will, in the first instance, discuss this with the participant's therapist, or if this is not possible, the participant will be withdrawn from the study.

Participants will be responsible for reporting a change in symptoms (pain, swelling, etc.) to researchers during the study.

4.5 DISTRESS PROTOCOL

Users (patients, staff, family/carer)

- In the event that a participant communicates (verbally or body language) that they are becoming distressed the session will be temporarily stopped and participant given a moment and then asked if they would like to continue.
    - If the response is that they would like the session to finish it will stop immediately. The researchers will ask the participant what they would like to do. (e.g. If they would like to be left alone, have a family/friend called, or stay with the researchers or in the case of staff have a colleague or manager contacted.)
    - If the response is that they would like the session to continue it will do so. However, if on a second occasion the participant becomes distressed the session will stop immediately. At this point the participant will be asked what they would like the researchers to do. (e.g. If they would like to be left alone, have a family/friend called, or stay with the researchers or in the case of staff have a colleague or manager contacted.)

Researchers

- The researchers will consider the number of patient facing sessions that they complete per day/week to take into consideration the exposure to potentially distressing information.
- If the researchers at any point become distressed during a session then they will look to stop the interview and seek the necessary support (discussion with a colleague, line manager, etc.).

5. ASSESSMENT AND FOLLOW-UP

Participants will be involved in the study described above, their involvement lasting typically 14 weeks. No follow up after this point is planned.

6. STATISTICS AND DATA ANALYSIS

Sample Size

24-38 patients.

Literature advocates a sample size of 12-30 participants at the completion of a feasibility study. A 50% drop out rate is expected. We have taken these two points into consideration in addition to what is realistic within our time frame/budget to come to our current sample size.

Data Analysis
Analysis will be completed on the parameters and implementation of the study in addition to the usability of OnTrack.

Data collected for the process evaluation will capture changes over time and will be a combination of qualitative data from interviews with stroke participants, therapists and frontline staff to explore their experiences of using OnTrack, as well as quantitative data on usage of OnTrack and the self-reported SUS. OnTrack therapy support sessions will be monitored through a fidelity checklist and observations. Interview data will undergo thematic analysis.

Data will be analysed for any association between the feasibility of the intervention and stroke subtype, patient demographics, stroke disability, and the amount of physiotherapy patients receive during the intervention period.

7. REGULATORY ISSUES

7.1 ETHICS APPROVAL

The Chief Investigator will seek ethical approval from the NHS Research Ethics Committee and the Health Research Authority. 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.

For patients:

Verbal consent will be provided to the therapists and then the researchers will obtain written consent.

For family/carer: Written consent will be sought.

For therapist and frontline healthcare staff: Written consent will be sought.

The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

7.3 CONFIDENTIALITY

The Chief Investigator is responsible for preserving the confidentiality of participants taking part in the study.

Researchers will have patients' names, contact numbers, emails and home addresses for the purposes of arranging visits. This information will be stored securely on Imperial College computers.

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

The documents that links the patient's name to the 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. Audio recordings maybe transcribed by an external service - with patient identifiable information removed ahead of this. 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. Patient (M/F) had a stroke 6 weeks ago and could not use his arm) however participant identifiable information will not be used alongside quotes.

There will be a combination of patient information stored on paper (e.g. consent forms) and electronically (e.g. patients address). Paper documentation will be stored in a locked cupboard inside a locked office at Imperial College London only accessible to the researchers. Electronic information will be stored on University computers that are also password protected.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study in line with Imperial College London policy.

7.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies that 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

This project is funded by the Helix Centre and NIHR Imperial Biomedical Research Council No participant payments or incentives will be given.

7.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the NHS Research Governance Framework for Health and Social Care (2nd edition).

8. STUDY MANAGEMENT

The day-to-day management of the study will be coordinated through the Helix Centre by My 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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