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OnTrack Tools - Participant Information Sheet

Study title

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

Study management group

Principal Investigator: Professor Ara Darzi

Co-investigators: Gianpaolo Fusari, Clare McCrudden, Brian Quan, Simone Welch

Research invitation

You are invited to take part in a study by researchers from the Helix Centre, part of Imperial College London. Before you decide if you'd like to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information and discuss it with others if you wish. This will help you decide whether or not you wish to take part. Feel free to come back to us if there is anything that is not clear or if you would like more information.

Thank you for considering this study.

What is the purpose of the study?

The study aims to assess the usability of a clinician-facing software, part of the OnTrack rehabilitation system.

The OnTrack rehabilitation system aims to help stroke survivors keep track of their arm activity and increase opportunities for repetitive rehabilitation. The system was developed by the research team at Imperial College London. Its patient-facing component was recently tested in a feasibility trial by stroke patients in the NHS.

This study will assess the graphical user interface (GUI) of the system's clinician-facing component using simulation data.

By testing the usability of the software, we can ensure that clinicians are able to use the system to its full potential and make sure stroke survivors have a better experience when using OnTrack for their recovery.

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Why have I been chosen?

You have been invited because you are a therapist working in one of the stroke and/or neuro rehabilitation wards at ICHT.

We aim to invite about 15 therapists to take part in this study.

Do I have to take part?

No. It is entirely up to you to decide if you want to take part. If you do take part, you can withdraw at any time without giving a reason by informing any of the researchers in person or using the contact details included in this Participant Information Sheet. If you withdraw, your personal data will be deleted but we may still use your anonymised responses from questionnaires or insights gathered during focus groups.

What will happen to me if I take part?

By being involved in this study you will be asked to:

- Attend a 30 minute briefing session to explain the task(s) that you will be completing as part of your usability session.
- Undertake a usability session (at a time of your choice) not lasting more than 30 minutes, including responding to simple questionnaires.
- Take part in a 60 minute focus group with other therapists who completed a usability session.

Please note that the three activities described above will not be taking place on the same day, it is likely that they will happen over a period of one or two weeks, with the briefing session and focus group session bookending this period of time.

Briefing sessions and focus groups will be held in person at Charing Cross Hospital, however it is possible that they may need to be conducted online. If this is the case, they will be held using Microsoft Teams.

Usability sessions will also be held individually at Charing Cross Hospital and all software and hardware will be provided by the researchers.

Sessions will be fully facilitated by the research team and are designed to fit around your clinical commitments, you do not need to prepare in any way to take part.

If you decide to take part, the research team will inform you about the time and place of the briefing and focus group sessions.

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You will then be able complete your usability session at any time between these two sessions by using one of the tablets provided by the researchers.

The research team may ask if they can take photographs or videos of some sessions, in addition, focus group sessions may be audio recorded to enable us to capture your feedback more efficiently. Audio recordings will be transcribed by an external service (PageSix Transcription Services Ltd) and recordings will be deleted once transcribed. All data collected for the study will be pseudonymised, we may use quotes from your feedback but your identity will not be linked to the quote.

Your participation will help us build a better user interface that can benefit OnTrack Tools users and their patients.

What are the possible disadvantages and risks of taking part?

We have planned the study carefully together with therapists and team managers to make sure the impact on your workload is minimised, however it is possible that due to a busy caseload this additional work may seem overwhelming.

If you decide to participate in the study and suddenly realise you cannot commit to one of the fixed sessions, please talk to one of the researchers who may be able to offer some flexibility in the planning of sessions.

What are the possible benefits of taking part?

There is no immediate benefit for taking part, however by being involved in this research you are contributing towards the development of a rehabilitation system that has shown potential to improve arm rehabilitation after stroke.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Professor Ara Darzi at a.darzi@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you.

How will we use information about you?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

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- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you for this research project.
This information will include:

- your initials,
- name,
- contact details (e.g. NHS email address).

People will use this information to do the research or to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Legal Basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing your information with others

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For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

- PageSix Transcription Services Ltd – audio recordings from focus group sessions will be shared with PageSix for transcription. Recordings will be deleted as soon as they are transcribed.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your data in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to OnTrackRehab@helixcentre.com

Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

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What will happen to the results of the research study?

The results of the research will be collated in a study report and may be sent for publication in peer-reviewed journals. The full report and a lay summary will be made available to study participants upon request.

Who is organising and funding the research?

Imperial College London is organising the research, and SBRI Healthcare is the funder.

Who has reviewed the study?

This study has been reviewed by Imperial College London as the sponsor, and Health Research Authority (HRA).

Contact for Further Information

For any further information you can contact the researchers of this study:

Gianpaolo Fusari: gianpaolo@helixcentre.com

Clare McCrudden: clare@helixcentre.com

Brian Quan: brian@helixcentre.com

Simone Welch: simone.welch1@nhs.net

Thank you for considering taking part on this study!

A copy of this Participant Information Sheet and signed Informed Consent Form will be provided for you to keep.

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OnTrack Tools – Consent Form

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

Name of Principal Investigator:
Professor the Lord Ara Darzi

Research Team:
Gianpaolo Fusari, Clare McCrudden, Brian Quan, Simone Welch

		Please initial box
1.	I confirm that I have read and understand the subject information sheet dated ..... version ..... for the above study and have had the opportunity to ask questions which have been answered fully.	☐
2.	I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason. I understand that sections of any of my research notes may be looked at by responsible individuals from Imperial College London, from NHS Trust or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research.	☐
3.	I understand that photographs and videos may be taken and then anonymised to be used in public facing documentation.	☐
4.	I understand sessions may be audio recorded and sent to external transcription services.	☐
5.	I understand that all information will be kept confidential (quotes may be published but my name will not be given).	☐
6.	I understand that results of this study will likely be used for publication and shared amongst various academic and public facing groups.	☐
7.	I understand there may be a requirement to transfer information to countries outside the UK (for example, to a research partner)	☐
8.	I give/do not give **(delete as applicable)** consent for information collected about me to be used to support other research in the future, including those outside of the UK.	☐
9.	I consent to take part in the above study.	☐ ☐
10.	I give/do not give **(delete as applicable)** consent to being contacted to potentially taking part in other research studies.	☐

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_____	_____	_____
Name of Subject	Signature	Date
_____	_____	_____
Name of Person taking consent	Signature	Date

An original copy of the Participant Information Sheet and completed informed consent form (this form) is to be given to the participant, in addition to the original copy that is filed in the investigator file