UNIVERSITY OF LINCOLN

Participant Information sheet

Research Project: **Evaluating the feasibility and acceptance of the CONSULT Decision Support System**

Before you agree to take part in this study, we would like you to understand the purpose of the research and what participation will involve.

What is the purpose of the study?

We would like to invite you to participate in a study the purpose of which is to evaluate a novel technology (a mobile application) that helps stroke survivors to monitor their health and self-manage their treatment.

This study is part of a wider programme called **CONSULT** (Collaborative mObile decisioN Support for managing mULtiple morbidiTies) which is a 5-year research project aiming to design a novel technology that harnesses the power of artificial intelligence, sensors and mobile devices and supports patient decision making, and thus actively engages patients in managing their health.

Using this mobile application, we hope that people will benefit by having better information about their health as an individual. This will help them, and their GPs, make better decisions about health and about which treatments to choose.

We are currently at the stage where we have designed version 1.0 of the mobile application and we would like to test it with real users in order to find out how easy it is for them to use and what further changes need to be made, if any, in order to improve its design and make it more relevant to their needs. Your input in this project is valuable and it will help us design novel technology for stroke survivors to better and safely self-manage their health.

Why have I been invited?

We are asking people who have had a stroke to help us. People who have had experience of stroke are best placed to use the system, since they are the immediate beneficiaries. Specifically, you can participate in the study if you meet the following criteria:

Inclusion criteria

- **You are over 18 years old**.
- **You live in London or elsewhere in the UK.**
- **You are a user of an iPhone or Android mobile device**.
- **You do NOT have implanted defibrillators or pacemakers**
- **You do NOT suffer from epileptic seizures**.
- **You are NOT pregnant or breastfeeding**.
- **You have opted in for sharing your health information for research purposes.**
- **You are a stroke survivor.** (No restrictions apply in terms of type of stroke, years since stroke, type of underlying risk factors or co-morbidities to take part in the study.)

Exclusion criteria

- **You are less than 18 years old.**
- **You have implanted defibrillators or pacemakers**.
- **You suffer from epileptic seizures.**
- **You are pregnant or breastfeeding.**

We understand that some stroke survivors may face stroke-induced mobility problems or speech difficulties. In this case you are encouraged to participate in the study along with a person who takes care of you. In many cases a carer is a family member or a person that is close to you.

In the case a stroke survivor wishes to participate in the study along with a carer, then informed consent will be sought for both to make sure that they are in agreement in taking part in the study**. Carers acting on behalf of stroke survivors who are unable to give their explicit consent for taking part in the study will not be eligible to participate.**

Do I have to take part?

No, participation is entirely voluntary.

What will I be asked to do if I take part?

- You (or your carer, in case you decide to participate in the study together) will be trained in the use of, and then asked to use over a period of 17-days, a selection of wellness sensor devices (smartwatch, blood pressure monitor/cuff and ECG patches), as well as two versions of a mobile application, stored in an android tablet device, called CONSULT.
- During the 17-day period you will be asked to use the sensor devices and the CONSULT app as many times as you like, to simulate a real-life scenario. However, you will be also given some directions that indicate a recommended level of use, for the data collected to be meaningful when processed by the CONSULT system. Specifically:
    - the smartwatch is recommended to be used by the participants as they would normally wear their own watch;
    - the wireless blood pressure cuff (which looks similar to a traditional blood pressure cuff) at least once per day;
    - the ECG VitalPatch, a lightweight device that is attached to the participant's chest like a plaster, is recommended to be used for as long as it feels alright or comfortable for you to wear during the day. **Please note that the patch contains hydrocolloid adhesive gel which may cause irritation or other adverse skin reactions. Participants with underlying skin conditions, skin allergies or sensitivity with plasters will not be asked to use the patch to avoid the risk of adverse skin reactions**. Also, women who are pregnant or breastfeeding will not be asked to use the patch due to lack of clinical testing.
- Please note, ECG, blood pressure and heart rate data used in the CONSULT App will be *synthetic* data, rather than the data collected by the wellness sensor devices (smartwatch, blood pressure monitor/cuff and ECG patches).
- Twice, during the 17-day period, we will ask you to participate in an interview and complete a set of feedback questionnaires to assess your satisfaction, experience and level of engagement with the technologies under evaluation. Interviews will be audio-video recorded. All interviews will take place remotely using Microsoft's Teams platform. Where the use of this technology is not possible, interviews will take place

over the phone or in writing via email. Interviews are expected to last approximately 30 minutes.

- The study is split into 3 phases. The first phase is an induction and training phase and lasts for 3 days. The other two phases will last seven days each. During the 17-day period you will meet remotely, via MS Teams platform or phone, with a member of the research team three times: at the beginning of phase 1 (i.e. day 1) and then at the end of phase 2 (i.e. day 10) and phase 3 (i.e. day 17). These meetings will last approximately 2 hours altogether and will involve induction, training and completion of consent forms (day 1, expected to last 1 hour); interviews and completion of questionnaires (day 10 and 17, expected to last 30 minutes each).
- All devices will be sent to the participants home address via post (pre-paid return parcel) before day 1. More details about the use of these devices will be given to the participants during the Induction. Also, these devices will be accompanied with printed manuals and further guidance. Devices should be used only by the participant in the study and not shared with other members in the household. Before posting the devices, a member of the research team, who is also an NHS GP and academic, will have all devices disinfected (except for the VitalPatches which are intended to be for single use only and then disposed).
- Throughout the 17-day period we will be collecting your personal health information, including data stored in your electronic health record and data recorded from the sensor devices (blood pressure, heart rate and ECGs). In addition, we will collect data about your experiences of using the CONSULT system through questionnaires, interviews and usage data. Usage data will be recorded automatically as you interact with the mobile app and stored in our system).
- Devices cannot be kept and must be returned at the end of the study using the pre-paid return parcel.
- As explained in the sections below on confidentiality and data privacy, any data taken by the devices will be facilitated using secure encrypted devices or networks and stored in secure computers. The team will only store and process the data removing any personal identifiable information about the individual.

Will there be any disadvantages to taking part?

We understand that some people may find it difficult to talk about life after a stroke and how the designed technology can fit in their current needs. Learning about your experiences of using these novel technologies will help us design better self-management tools for those who have a stroke in the future.

The ECG VitalPatch contains hydrocolloid adhesive gel which may cause irritation or other adverse skin reactions. **Participants with underlying skin conditions, skin allergies, or sensitivity with plasters, will not be asked to use the patch to avoid the risk of adverse skin reactions**. Also, women who are pregnant or breast feeding will not be asked to use this device.

Warnings specific to the use of the ECG VitalPatch:

- You are advised to seek medical attention if either of the following occurs:
    - A severe adverse event.
    - An allergic reaction persisting beyond 2-3 days.
- Do not use the VitalPatch device during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.

- Only place the VitalPatch device on intact skin.
- Precautions: If discomfort or irritation occurs, the VitalPatch device should be removed. If mild soreness or redness is experienced after removing the device, do not apply a new device in the same location. Choose another recommended location.

What are the possible benefits of taking part?

There may be no direct benefit to you as an individual, but you will be helping research aimed at helping others with stroke in the future. We aim to improve the technology available to stroke survivors, carers, and health professionals and help stroke survivors to better manage their health. Moreover, given the novelty of the technologies involved in this study, participants will have the opportunity to experience how the future of health care, when it comes to the self-management of chronic condition, may look like.

Will my taking part in the study be kept confidential?

The University of Lincoln (UoL) is the sponsor for this study. We will be using information from you in order to undertake 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. UoL will keep identifiable information about you (name, email address and postal address) for 3 years after the study has finished/until 2026.

In the case of video recordings, the reason we chose to use MS Teams for all video calls is because all files are stored automatically in the SharePoint service of the sponsoring universities, which complies with GDPR and accessed only by the members of the research team, with an internal university username and password. Once a video call has been concluded the researcher will produce an audio transcript of the call and the video will be immediately deleted. Since we are not collecting data related to our participants' non-verbal communication, the videos will not be used for analysis. Video will only facilitate the communication between the research team and the participants and deleted immediately after their separation from the audio. We will not store in the long-term any pictures or videos showing the participant's face or use this for analysis. Following the separation from video, audio files will be transcribed before data analysis can begin. Transcription will be conducted by the research team or in cases when this is not possible an external service, the research team has a list of approved transcription service providers. In this case, non-disclosure provisions will be in place for the sharing of confidential information. Electronic transcriptions will be stored in the SharePoint service of the sponsoring universities, which complies with GDPR and accessed only by the members of the research team, with an internal university username and password.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the researcher(s) named below.

All data collected will be kept confidential. Data collected will be stored on encrypted, secure, servers (for digital copies) that are compliant to the NHS Data Security and Protection Toolkit, and a locked cabinet (for physical copies) housed at the university. All data will be anonymized (and identifiable information like names, address and contact information will be removed) to protect your confidentiality. The research team will not discuss, present or publish data in any way that identifies individual participants. Research data will not be

shared with clinicians responsible for clinical care and responses to research questions will not in any way influence medical care or legal rights.

Following the completion of the study, an archived file with all personal data will be securely stored for up to 3 years, in accordance with the sponsoring universities' Information Governance and Compliance Policies. After this point, the data will be destroyed in a secure manner.

Am I free to withdraw at any point?

Yes. You are free to withdraw at any point without giving a reason. If you are a patient, this will not affect the standard of care that you receive.

What will happen to the results of the study?

If you would like to receive a summary of the results of the study, please contact the researcher whose contact details are given below. The results of this study will be published in academic journals.

Will I get paid for taking part in the study?

As a token of appreciation for your participation in the study you will receive a £150 voucher after the end of the study.

Will I be reimbursed for travel expenses that may occur as part of this study?

Any travel expenses, or other expenses, that may occur as part of the study, will be compensated

Who has reviewed the study?

The study has been reviewed by external independent reviewers and funded by EPSRC Pioneering research and skills. The study has been reviewed and approved by the University of Lincoln Research Ethics Committee (reference number 8822).

What happens now?

After reading this information sheet, if you agree to take part in this study, the researcher will contact you to ask for your written consent. Should you have any questions about the study, please contact the researcher whose details are shown below.

Contact details:

If you would like further information or to discuss the study please contact the researcher(s) below:

Dr Zhuoling Huang, Prof Simon Parsons or Prof Elizabeth Sklar
Lincoln Institute for Agri-food Technology
University of Lincoln
Email: ***zhuang@lincoln.ac.uk***, ***sparsons@lincoln.ac.uk***, or ***esklar@lincoln.ac.uk***

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (please see details above). In addition you can report any complaints by contacting:

UoL Research Ethics Committee
University of Lincoln,
Brayford Pool
Lincoln, LN6 7TS
Email: ***ethics@lincoln.ac.uk***

Information compliance

The University of Lincoln is the lead sponsor for this study and will be the data controller for this study. This means that we are responsible for looking after your information and using it properly.

The university's **Research Participant Privacy Notice** (https://ethics.lincoln.ac.uk/research-privacy-notice/) explains how we will be using information from you in order to undertake this study. If you feel that we have let you down in relation to your information rights then please contact the Information Compliance Team by email on compliance@lincoln.ac.uk or by post at Information Compliance, Secretariat, University of Lincoln, Brayford Pool, Lincoln, LN6 7TS.

You can also make complaints directly to the Information Commissioner's Office (ICO). The ICO is the independent authority upholding information rights for the UK. Their website is ico.org.uk and their telephone helpline number is 0303 123 1113.