Camden and Islington NHS
NHS Foundation Trust

Participant Information Sheet

Relapse Evaluation using Smartphone Technology (REST) Feasibility study

We invite you to take part in a research study

- Please ask the study staff to explain anything that you do not understand.
- Before you decide whether to take part or not, it is important to understand why this research is being done and what it will involve.
- Please read the following information in detail, and discuss it with friends and family if you want to.
- You are free to decide whether or not to take part in this study. In either case, your care will not be affected in any way.

Important things you need to know

- We want to find out if a smartphone application (app) will help to predict relapse or a worsening of symptoms for people with mental health difficulties
- The app will passively record specific things described in this information sheet, and only requires you to use your phone as you normally would.
- All information captured by the app will be safely encrypted
- Your data will be kept confidential and processed in accordance with data protection laws and regulations.
- You can stop taking part in this study at any time

Contents

1) Why are we doing this study?

It is now possible to collect data through a smartphone that can measure someone's physical activity, sleep and social interactions. It may be possible to measure other kinds of data and find relationships with symptoms of mental health difficulties and treatment response. However, this needs to be tested in a scientific research study.

We are hoping to collect data from you and others like you to see if we can test the accuracy and potential usefulness of smartphones in measuring different aspects of mental health. This study will be undertaken as a collaboration between UCL, Mindstrong Health, and Camden and Islington NHS Foundation Trust.

2) What data will we be collecting?

The Discovery app was created by an American company called Mindstrong Health Limited (5 New Street Square, London, United Kingdom, EC4A 3TW). The company is based in the USA, but has a local office in the UK. Mindstrong Health specializes in measurement-based healthcare and has recently created this app which looks at objective, specific and continuous measurement of human cognition and mood.

Discovery by Mindstrong will be used only for the purpose of measuring smartphone data that is passively picked up during day-to-day use. The application will record the data described in the table below, and does not require you to do anything other than use your phone as you normally would.

We would like to follow each participant's smartphone use for 12 months. However, if you want to stop data collection from the application installed on your phone, you may do so at any time and have it completely removed from your phone.

If you choose to participate, you will be asked to install the app on your smartphone. We will call you once a month to ask if you have been experiencing any difficulties with your mental health and if you've visited any emergency services (this phone call will take about 10 minutes). The app will also prompt you to complete some tasks or games once a month: this is so we can track changes to things like your memory or attention, and link them to how people use their phone, and how their health is doing. The app tasks also take about 10 minutes per month.

We also ask to have access to the clinical records about your mental health, which are kept by your NHS Trust. The reason we ask for these is so that we can use it to find which smartphone patterns predict worsening of symptoms. If you consent to giving us access, you don't need to do anything else – your NHS Trust will pass the records on to us.

Here is the list of patient data which we ask to access (over the 12 months in the study):

- If you have been admitted to a crisis centre (e.g., crisis house, inpatient ward, A&E) for mental health reasons
- If you have had any police contact due to mental health (e.g., Section 136)
- If your diagnosis has changed
- If the medication that you have been prescribed for mental health reasons has changed

At the end of the study, you will be asked to uninstall the app. All the information you provide, as well as all the data collected from your smartphone, will be safely encrypted and held in a secure database that is only accessible to the research team. Data encryption means that information is transformed into another form or code that only people with access to a secret key or password can read.

Here is the list of data which the app records on your phone (over the 12 months in the study):

- Gestures (hand swipes, taps, other)
- Orientation of the smartphone (the way the phone is pointing,: up, down, sideways)
- Acceleration of the smartphone (sudden movements of the phone)
- Keyboard tapping patterns (the content is scrambled)
- Motion information without capturing location (coordinates are scrambled)
- Number of phone calls made and time and date of call
- Number of emails sent and time and date of email
- Number of text messages sent and time and date of sending

In addition, OPTIONAL data collected from your phone will include:

- Relative location information from the GPS that does not reveal the actual location of the user

All data captured by the Mindstrong app will be stored under your ID number only (e.g., "ID0657"), not your name, and in encrypted format

Pseudonymised (meaning stored using an ID number, not your name) data is kept on a secure storage site cloud infrastructure in London. The scrambled, pseudonymised data is sent for analysis to Mindstrong Health in Palo Alto, California. All files will be password protected and encrypted. When handling data, we have to comply with the General Data Protection Regulations (GDPR), which is a European Law which dictates how researchers can use data. You can ask us for more information.

We are NOT tracking <u>what</u> you are doing with your phone (the content of your text messages or phone calls, etc.), only <u>how</u> you are using it.

No information that can be used to identify you directly is collected from your smartphone (such as names, email addresses, phone numbers, location, birthdates, etc.).

We will send a letter to your GP informing them that you are taking part in the study.

3) Why am I being asked to take part?

You are invited to participate in this research study because:

- Aged 18 to 65
- You have a diagnosis of schizophrenia, bipolar disorder or non-organic psychosis
- You own a personal smartphone and are willing to install the Mindstrong Discovery application on your phone for the duration of the study
- Have been in contact with a crisis team or have been an inpatient within the past 12 weeks
- You are able to understand and comply with instructions in English

4) What will I need to do if I take part?

As a participant, you will:

- Keep the data collection application installed on your phone for the duration of the study
- Use the virtual keyboard which comes with the app for typing text.
- Otherwise use your phone as you normally would
- Answer a few questions over the phone once a month
- Complete several self-report measures on your phone once a month

- Tell the research staff if you change your mind about staying in the study

Withdrawal

You are free to withdraw from the study at any time and without having to give a reason. Your decision will not affect your ability to receive care and you will not lose any benefits to which you would otherwise be entitled. If you choose to withdraw from the study, we ask that you let the research team know about your decision. You can remove the app from your phone yourself at any time and this will stop all data collection. Removing the application is like removing any other application on your smartphone.

You might be withdrawn from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions described above
- The study is cancelled
- Administrative reasons
- Unanticipated circumstances

5) Data protection notice

UCL is the sponsor for this study based in the United Kingdom. We will be using information from you, your Medical records and your smartphone to carry out this study and UCL will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly in accordance with the General Data Protection Regulation (GDPR) (EU) 2016/679. UCL will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to adhere to principles of good quality research. 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 at https://www.ucl.ac.uk/legal-services/data-protection-overview
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.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. 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).

You can contact our Data Protection Officer at data-protection@ucl.ac.uk

Your NHS trust will, with your permission, send your clinical records to UCL for the purposes of the study. The only people who will have access to this information at UCL are members of the research team, or UCL staff whose job it is to make sure that patient rights are respected and that the research follows the necessary rules and guidelines. The research team will keep the identifiable information it has collected for 5 years after the study has finished. Other organisations may ask to see the data for research purposes – this can be universities, NHS Trusts, or health care research companies. If they do, the data the research team will give them will be anonymized, and nobody would be able to identify you from the dataset.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you,

such as insurance. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Any information participants tell us, and any data which is recorded is confidential. There are two exceptions: 1) If the participant reveals that they are going to harm themselves or someone else (in which case the research team will inform the participant's care coordinator, or a safeguarding officer) 2) If the data collected for the study becomes part of court proceedings and such disclosure is required by applicable laws or regulations.

6) Risks and benefits

There is minimal risk to you as a participant. You will be involved in one face-to-face interview during your first meeting and will complete self-report measures every month. These have been designed to be easy, short, safe and straight-forward.

In terms of data collection, there is a potential risk of loss of privacy through data transfer in the event of a breach of confidentiality or through a serious breach of data theft. However, many strict measures have been taken in order to keep this risk as small as possible.

All participant records have data encryption technology or computer passwords, as well as additional physical measures involving keeping information in locked and secure locations. Any information that leaves the possession of the research staff will be identified only by a code number —names, contact details or any other identifying information will always be omitted— and only senior research study personnel will be able to link code numbers to participant identities, which will only be done for statistical data analysis.

Additionally, the Mindstrong Discovery application is HIPAA compliant for privacy and ISO 27001 compliant for data security. It also has administrative, technical and physical safeguards for all information collected through the application.

Financial considerations

You will not be paid for taking part in the study. If the application cannot find WiFi to use to transfer the data over the course of 24 hours, the nightly transfer of data to the Mindstrong secure servers may consume up to 100MB per month of your data plan. This will cost under £1 per month and can be reimbursed. You will need to show us a bill, or a screenshot showing your data use for this.

7) Contact information

- If you have a concern that has not been adequately resolved by research staff, or a query that you would not feel comfortable speaking to our research staff about, you can contact details below for the Advice and Complaints services in your Trust:

Camden and Islington NHS Foundation Trust
Advice and Complaints Service
1st Floor
East Wing
St Pancras Hospital
4 St Pancras Way
London
NW1 0PE

Tel: 020 3317 7102
Email: feedback@candi.nhs.uk

- If you have any questions or comments, please find the contact details for the research team below:

Trial Coordinator	Clinical Studies Officer/Research Assistant
Dr. Alisa Anokhina alisa.anokhina@ucl.ac.uk	_____
	_____
	_____

The study has been reviewed and approved by the London-Dulwich Research Ethics Committee (IRAS number 245218)

- If you have a concern about the way an organisation is handling your personal information, you can contact the Information Commissioner's Office (ICO) via their live chat service ico.org.uk/livechat, or on their helpline at 0303 123 1113.