East London NHS
NHS Foundation Trust

THE REFRAME STUDY

Mobile technology health management for patients with severe mental illness – a feasibility study

(REFRAME)

PATIENT INFORMATION SHEET

We would like to invite you to take part in the REFRAME study.
Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is the REFRAME Study needed?

Previous studies suggest that mobile phone technology can be successfully used for patients with long-term medical conditions such as Asthma and Diabetes, but it has not yet been systematically tested for the care of patients with mental health conditions.

Severe mental health problems such as Psychosis or Bipolar Disorder are common (about 1% of the population). These conditions put much strain on people's lives, and patients often do not feel well enough to manage their own health, despite many years of treatment in the NHS.

The REFRAME study is a randomised controlled trial, comparing the effect of the intervention with the usual standard care. The study is needed to test if additional and new support interventions can help to improve self-management skills, and help preventing relapses through better communication with quicker response from community teams. This research will investigate if using a mobile phone text messaging systems can support patients to have better outcomes from their standard community care. The mobile phone system in this study is called "Florence".

A randomised controlled trial is when participants in a study are allocated by chance to receive the intervention under investigation, an alternative, or the usual care. Therefore half of participants will be randomly allocated to receive the mobile phone support intervention and half will receive usual standard care. Participants are randomly allocated to one of two groups because we do not know if the additional support with mobile technology is more effective than the usual standard care. The REFRAME study is a randomised controlled trial to assess the additional interventions and to find out if these can be delivered through text messages by a mobile phone, which may have the potential to help patients to have more reliable and effective care for their long-term mental health problems.

Who is organising and funding the REFRAME Study?

Professor Frank Röhricht from East London NHS Foundation Trust organizes the REFRAME study and it the project is funded by the Health Foundation. The project team is supported by research staff from the Academic Unit at the Newham Centre for Mental Health (Queen Mary University of London) and the team will collect and analyse all the data.

Why have I been asked to take part in the REFRAME Study?

You have been asked to take part in the REFRAME study because you have been diagnosed with a long-term mental health problem and because you are receiving care from a Community Mental Health Team under the Care Programme Approach (CPA).

Do I have to take part in the study?

You do not have to join the study. You are free to decide not to be in this trial, or to drop out at anytime. If you decide not to be in the study, or drop out, this will not put at risk your ordinary medical care.

What will happen if I agree to take part?

If you agree to take part, you will be asked to fill a consent form. You will automatically be assigned a Unique Trial Identification Number (UTIN); in this way the data collected will be anonymised and not linked to your personal details. You will meet with one of our Research Assistants twice for about one hour for an interview; once at the beginning and again after six months. In the interviews you will be asked a few questions about the care/support you receive and also asked to complete short questionnaires, which will help us to assess your self-management skills and routine, your satisfaction with treatment and your quality of life. After the interview it will be decided by chance if you receive treatment as before (no changes, you continue to receive care as usual) or if you receive treatment as before and in addition the mobile phone telehealth intervention called "Florence".

What will happen if I am receiving the intervention?

If you have been allocated to the intervention group, you will have time with the researcher together with your care coordinator to familiarise yourself with the text messaging system Florence ("Flo"). You will be provided with a leaflet that describes everything in writing as well.

'Florence' will send you SMS text messages daily; this will include reminders for your medication (if you are on daily medication) and asking you to send your wellbeing score. Your well-being score is a simple number between 0 and 6 based on indicators developed between you and your care coordinator (such as sleep, or anxiety, or any problems you have experienced in the past, or what indicates to you that you are doing well). Florence will send you a confirmation message when your score is received, if your well-being score is low Florence will suggest contacting your care coordinator or the crisis line and your care coordinator will try to contact you to find out if you need any help and to better understand why you are feeling not so well.

Also, at any time you can use 'Florence' to send a message requesting support using a list of codes (for example regarding your housing situation, relationships, medication, etc.). Your care coordinator will contact you to discuss your needs with you and to identify solutions.

The information from the text messages will be kept securely electronically via a computer and can only be accessed by your clinical team. Data will later be transferred to the researcher for the study analysis through a secure email service without your names attached (just using number codes so that everything remains anonymous).

Towards the end of the intervention, you may be contacted to participate in a focus group to explore your experiences of the study, which will help us in designing future studies.

Expenses and payments

Your travel expenses will be paid for; furthermore we will offer you a one-off payment for the follow-up interview that will take place six months after the first interview at the end of your participation.

What are the benefits of taking part in REFRAME Study?

The intervention offered in this study is safe and non-invasive and there are no known unwanted side effects. If the text messaging system is shown to be effective in your care and in the care of other patients with long-term mental health problems, we would like to offer this intervention to you and others as a self-management tool once the study has been completed.

Are there any risks to taking part in the study?

It is very unlikely that distress will arise from the study. Should that nevertheless occur or in case you might experience difficulties in relation to receiving or sending text messages then please contact the your clinician or the researcher.

What kind of information will be collected about me?

We will record your response to the questionnaires and document your usage of the Florence text messaging system if you are randomised into the intervention arm of the trial. We will record information from your medical records relevant to the study (anonymised).

Will my information be kept confidential?

Yes, all information and data collected during this study will be anonymous and treated confidentially. Data will be handled, stored and destroyed in accordance with the Data Protection Act (1998) and applicable laws and regulations. Your mental health care professionals involved in your clinical care, will be kept informed, but otherwise all information about you will be kept strictly confidential.

In order to look at whether the additional intervention helps to achieve more stability in comparison with standard care we will need an accurate record of your previous crisis care and hospitalisation dates and past and current treatment, and so with your permission we would like to be able to view your medical notes for this purpose.

Upon completion of the study, all collected personal data will be destroyed. Given that this is a single site study no transfer of personal data will occur during the study, all data will be handled locally only. All data will be stored with anonymised participant codes on a secure Trust network and a copy will be kept on a password protected DVD in a locked filling cabinet with access only by the principal investigator. Only the research team will have the passwords to access data on the Trust network for the duration of the study period. The anonymised paper based assessment forms will be stored in a filing cabinet in the office at the Newham Centre of Mental Health.

What if I have a question or there is a problem?

If there is anything about the study you are not sure about, just ask a member of your care team at the community mental health team.
If you are unhappy about any aspect of the study and wish to make a complaint you can do this through the NHS complaints procedure. Your hospital will be able to give you information about how to do this. You can also contact the independent Patient Advice and Liaison Service (PALS) at your hospital (Telephone number 020-75404380).

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time without giving a reason. Your care will not be affected in any way. The data we have collected about you will be analysed, unless you specify otherwise.

Involvement of the General Practitioner/Family doctor

We do not think it is necessary to inform your GP of your participation in the REFRAME study. But if you wish us to do so this will done at the beginning of your participation.

What will happen to the results of the REFRAME Study?

When the results of the REFRAME study are known, they will be published in different ways. The broad results will be presented locally to health services and on conferences; they will be published in a scientific medical journal. It is also intended to present the results at service user meetings and we will be very happy to send information to you or to arrange a meeting to discuss the results with you if and when requested. You will not be identified in any report/publication unless you have explicitly given your consent.

Who has checked the study?

All research in the NHS is looked at by an independent group of people called the Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the London – Camden & Kings Cross Research Ethics Committee.

Further information and contact details:

If you require more general or specific information about the REFRAME study you may contact Professor Frank Röhricht, Newham Centre for Mental Health, Cherry Tree Way, Glen Road Plaistow, London E13 8SP, TEL: 020 7540 6757, E-Mail: frank.rohricht@elft.nhs.uk.

For advice as to whether you should participate, you can either contact the project team or discuss this with your health care professional, who suggested to participate and that you might benefit from this project.

Thank you for taking the time to read this Participant Information Sheet.