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Mobile technology health management for patients with severe mental illness

Submission date
04/11/2019

Recruitment status
No longer recruiting

Registration date
05/11/2019

Overall study status
Completed

Last Edited
19/07/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
About 1 in 100 people experience severe mental illness (SMI) during their lifetime and about a third of patients develop a more chronic course of their illness, in particular, chronic psychosis (Schizophrenia, Schizoaffective Disorder, Bipolar Disorder). A high percentage of these patients continue to have poor outcomes, including social isolation, medical comorbidity, and poor quality of life. Current routine appointment systems do not systematically capture information suggestive of urgent care needs. In addition, those conditions result in significant costs to the NHS accounting for approximately 12% of the total budget. Due to the complexity of the illness patients require help and support from a range of health and social care professionals, resulting in problems with the coordination and timely delivery of all the care components. Many studies identified that service users with SMI struggle to comply with their treatment over time, a significant number disengage from services. In addition, most service users with SMI suffer with social isolation and poor quality of life. Current routine appointment systems do not sufficiently provide for urgent care needs and patients have little control over the care. New and cost-effective ways of delivering integrated health social care for patients with SMI are therefore required.

This pilot study is aiming to explore the clinical benefits of an enhanced community care intervention that uses an interactive simple technology (SMS text messaging) communication system. This system – called 'Florence' – is providing a user-friendly, easy to use and non-stigmatising add-on to the current care pathway at low cost. Service users can use the system free of charge on their own mobile phones. The intervention is provided in the spirit of recovery-oriented care and supports service users gaining more control over their problem monitoring as well as the necessary appointment arrangements with health professionals.

Who can participate?
Patients 18 – 65 years old who currently receive mental health care from one of the community mental health teams provided by East London NHS Foundation Trust

What does the study involve?
On a daily basis service users will receive short text messages from 'Florence' intended to help them develop their self-management skills; service users will be able to alert staff to their needs

and receive messages as reminders for appointments and to take their medication as prescribed. In addition, a simple number code will be agreed between patients and clinicians to indicate their wellbeing/early warning signs for relapses; this code will be sent as text messages and prompt a response from the patient's care coordinator as required.

Participants will be assessed at baseline and after six months. The evaluation will analyse a variety of outcomes: accounts from service user/staff and data from service provision and questionnaires regarding patient-clinician contacts, treatment adherence, relapse rates and service user satisfaction/self-management skills.

What are the possible benefits and risks of participating?
Benefits: Participants will develop their self-management skills; service users will be able to alert staff to their needs and receive messages as reminders for appointments and to take their medication as prescribed
Risks: Some service users may experience difficulties using the text messaging service on a daily basis due to problems with the technology and/or because of deficits in daily living skills in terms of processes that require daily routine. Every participant will receive a face to face introduction to the text messaging intervention and receive a detailed but easy to read /understand information leaflet for service users; the research assistant provides information events for clinicians at the beginning and as required whilst the project is live. The care coordinator will be fully trained regarding all aspects of the technology and we will train 3-5 peer support workers (with lived experience in using services) to be available for individual service users who require more assistance.
For those service users who do not want to use their private phones and or do not own one (or lost theirs) the project will be able to provide an easy to use mobile phone.
Due to the nature of their health condition (severe mental illness, including chronic psychosis) a service user might experience the daily text messaging prompts as somehow intrusive and/or as if they are meant to control their health-seeking behaviour rather than being helpful assisting and aiding tools for their stability and wellbeing. The service user will be advised that they can withdraw their participation in the study project at any moment in time and that they can immediately stop receiving text messages by sending the simple text "stop" into the system. The care coordinator (all trained health care professionals) will actively ask service users in their regular scheduled face to face meetings as to whether they experience any aspect of the text messaging intervention as stressful or as to whether they have any particular concerns and address those accordingly.
Participating service users might misunderstand the nature of the additional enhanced community care intervention as a system that will lead to immediate responses from their health professionals and help them accessing emergency care at a time of crisis. Particular emphasis will be given at the point of introducing the intervention and the Florence system to participants regarding the responses they can and cannot expect as a result of taking part, utlining the functions of the enhanced routine care intervention and emphasising that it is not replacing but extending the current care arrangements; they will be advised that the intervention is not covering any medical emergencies and that there usual contingency care plan arrangements will continue to be in place. The care coordinator will discuss any emerging concerns with participants.

Where is the study run from?
East London NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
September 2016 to March 2018

Who is funding the study?
Health Foundation, UK

Who is the main contact?
Prof. Frank Rohricht
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1.1; Date 20/01/2017

Study information

Scientific Title
Mobile technology health management for patients with severe mental illness - a randomised controlled feasibility and pilot trial

Acronym
REFRAME

Study objectives
This pilot study aims to explore the feasibility and the potential clinical benefits of an enhanced community care intervention that uses an interactive simple technology based (SMS text messaging) communication system (“Florence”)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved, London-Camden & Kings Cross Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)20 7104 8222; nrescommittee.london-camdenandkingscross@nhs.net), ref: 16/LO/1117, Protocol number: R-403-668, IRAS project ID: 205395

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Severe Mental Illness (Schizophrenia, Schizoaffective Disorder, Bipolar Disorder)

Interventions
Single-centre randomised controlled trial, comparing the impact of an enhanced community care intervention that uses interactive SMS communication tools with treatment as usual.

Service users with a diagnosis of Severe Mental Illness who received mental health care in Newham / London were recruited from community mental health teams (CMHTs). Once written informed consent had been obtained, patients were randomly assigned to treatment as usual (TAU) or the intervention in addition to TAU. Both conditions were delivered in the community. Masking was not possible due to the nature of the experimental intervention. Random assignment of group allocation was conducted using concealed consecutive numbers (computer-generated), provided by an independent academic unit not involved with the trial.

Intervention:
An adapted version of the ‘Florence’ Simple Telehealth system' for community care of patients with severe and/or enduring mental health problems, called "REFRAME":

The intervention utilises the potential benefits of the Florence technology for service user's treatment adherence / therapeutic engagement. The mental health care version enables service users to develop and monitor their individually agreed own wellbeing scores in collaboration with health care professionals. Simple text messaging codes are utilised to foster service user-clinician communication outside routine appointments.
The intervention consists of three elements designed for the innovation project:
1. 'Florence' sends service users four SMS text messages daily: two reminders for medication adherence or appointments and two asking service users to send their wellbeing indicators.
2. Service users develop their own wellbeing indicator based on three individually defined main issues/relapse signs (e.g. sleep, anxiety, voice-hearing intensity). Depending on the scores, automated response messages programmed into the Florence system provide positive feed-back, advice or prompt service users to contact their care coordinator to discuss problems arising as they wish.
3. At any time service users can use 'Florence' to send a message requesting support using a predefined list of codes. In response, the care coordinator is supposed to contact service users to get more detailed information regarding the nature of the problem arising and with a view to agreeing on appropriate actions to take.

The control condition was Treatment as Usual (TAU), i.e. standard community mental health care. TAU involves routine follow up as per existing Care Programme Approach with one monthly face-to-face care- coordinator contacts and 3-6 monthly medical reviews with a psychiatrist.

Intervention Type
Behavioural

Primary outcome measure
Service user satisfaction scores (subjective quality of life measured using the DIALOG scale (patient-reported outcome measure) at baseline and after six months

Secondary outcome measures
At baseline and six months:
1. Treatment adherence: compliance with medication, attendance at therapeutic/clinical appointments and Medication Adherence Rate Scale (MARS), SMS response rates and attendance rates and relapse rates (number of hospital admission, number of Crisis Resolution Team inputs, number of A&E attendances)
2. Service user satisfaction with treatment: Client's Assessment of Treatment Scale
3. Factors contributing to effective self-management skills: 1. General Self Efficacy Scale and 2. Mental Health Confidence Scale
4. Information regarding experiences using m-health technology intervention and acceptance of Florence system: semi-structured interview at follow-up with service users and clinicians

Overall study start date
01/02/2016

Completion date
30/03/2018

Eligibility

Key inclusion criteria

1. Currently receive mental health care from one of the community mental health teams provided by East London NHS Foundation Trust
2. Established diagnosis of Severe Mental Illness (Schizophrenia, Schizoaffective Disorder, Bipolar Disorder)
3. 18-65 years old
4. Currently receive care within the framework of the Care Programme Approach (be on CPA and have a care coordinator assigned to them)
5. Basic command of English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Total final enrolment
65

Key exclusion criteria
1. Lack capacity (as assessed pre consent giving by patient's clinicians)
2. Organic psychosis
3. Diagnosis of Learning Disability
4. Currently inpatient receiving acute care in hospital

Date of first enrolment
01/09/2016

Date of final enrolment
30/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East London NHS Foundation Trust
Trust Headquarter, Robert Dolan House, 9 Allie Street,
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Sponsor information

Organisation
East London NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.elft.nhs.uk

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
Charity

Funder Name
Health Foundation

Alternative Name(s)
The Health Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A project summary report was submitted to the trial funder, The Health foundation" in April 2018; subsequent qualitative (thematic) analysis was completed in 2019.
The study team has started to draft a manuscript for submission to a peer-reviewed scientific journal

Intention to publish date
30/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (Prof Frank Rohricht; frank.rohricht@nhs.net; at direct request setting out the reason for the request, as well as intended use etc.; SPSS data file; for quality assurance /monitoring purposes only, consent from participants does not extend beyond the main study purpose and corresponding data management requirements; data is pseudonymised)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.2	18/08/2016	08/11/2019	No	Yes
Protocol file	version v1.1	20/01/2017	08/11/2019	No	No
Results article		16/07/2021	19/07/2021	Yes	No
HRA research summary			28/06/2023	No	No