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Feasibility trial of ClinTouch-CareLoop Enhanced Management

Submission date
17/04/2014

Recruitment status
No longer recruiting

Registration date
17/04/2014

Overall study status
Completed

Last Edited
17/08/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
A new, responsive method has been developed and tested which enables people with psychosis to monitor their symptoms. This led to the development of a smartphone application, known as ClinTouch, which collects and uploads symptom information securely to a central computer server several times daily.

Who can participate?
Adults who have been diagnosed with schizophrenia or other related mental disorders can take part.

What does the study involve?
Participants are randomly allocated either to use the ClinTouch app for 12 weeks or to not use the app. The app beeps four times daily to prompt the user to respond to a simple set of symptom questions. This information is made available to a user's mental health team who can use it to tailor the support they provide (CareLoop). The computer server checks if the user is becoming unwell or if they are at increased risk of harming themselves and alerts the health team. Users may also personalise the look of the app and the way certain features work, as well as complete an accompanying personal daily diary. All participants are followed up.

What are the possible benefits and risks of participating?
Participants who take part may benefit from using a new system which helps them to keep track of their mood and symptoms, and communicate these experiences with their mental health team.

Where is the study run from?
This study is being run by the University of Manchester and the Institute of Psychiatry at King's College, London, with the help of Manchester Mental Health and Social Care, and South London and Maudsley Trusts (UK).

When is the study starting and how long is it expected to run for?
May 2014 to April 2015

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
Dr Eve Applegate
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Study website
http://www.clintouch.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2013-005471-40

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
16361

Study information

Scientific Title
Proof of Concept (PoC) feasibility trial of ClinTouch-CareLoop Enhanced Management (CEM) versus Management As Usual (MAU) in people with psychosis

Study objectives

An examination of the feasibility, utility, safety and effectiveness of the ClinTouch-CareLoop Enhanced Management (CEM) versus Management As Usual (MAU) will be undertaken. It is hypothesised that CEM will be feasible and acceptable to staff and patients. The effect of CEM on patient self-management, empowerment, clinical care, detection of Early Warning Signs (EWS) and targeting of treatment will also be examined.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/WM/0045; First MREC approval date 18/02/2014

Study design
Randomised; Interventional; Design type: Prevention, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Schizophrenia; Disease: Schizophrenia

Interventions
CareLoop Enhanced Management: Use of mobile phone app to monitor and manage existing and emerging depressive and psychotic symptoms with support from mental health workers.
Follow Up Length: 15 month(s); Study Entry : Single Randomisation only

80 service users with psychosis, deemed relapse prone, will be recruited in Manchester and London. 40 participants will be randomised to receive ClinTouch-CareLoop Enhanced Management (CEM) and 40 participants will receive Management As Usual (MAU). Randomisation will be performed by the Manchester Academic Health Sciences Centre (MAHSC) Trials Coordination Unit at the Christie Hospital via telephone according to an agreed allocation algorithm.

Participants randomised to receive CEM will use loaned handsets with the ClinTouch app installed. They will receive CareLoop enhanced support and management from mental health staff who have access to symptom information and EWS alerts via CareLoop for 12 weeks. Default ClinTouch settings will prompt and collect two datasets daily via four alerts. Each alert

will contain 10 branching items that probe positive psychotic symptoms, anxiety and mood. All service users and mental health staff will receive training and technical support throughout. Those randomised to the MAU arm of the trial will not have access to ClinTouch or CareLoop enhanced support mechanisms.

A researcher will complete the following assessments with all service user participants at baseline, 6 and 12 weeks:

1. The Structured Clinical Interview-Positive and Negative Syndrome Scale, SCI-PANSS, (Kay et al., 1987)
2. The Calgary Depression Scale for schizophrenia, CDS (Addington et al., 1990)
3. The Global Assessment of Functioning, GAF (APA, 1994)
4. EQ-5D-5L (Euroqol group, 1990)
5. Empowerment Rating Scale (Rogers et al., 1997)
6. Economic Patient Questionnaire (EPQ)

The Early Warning Signs scale, EWS (Birchwood et al., 2000), will be administered at baseline and a quantitative feedback questionnaire will be given to service users in the CEM group at the end of the study to collate views on the usefulness of the technology.

A longitudinal qualitative evaluation will run alongside the trial using multiple qualitative methods comprising:
1. Semi-structured in-depth interviews with 20 professionals, 30 service users, and nominated carers at baseline and follow-up. The semi-structured interviews will explore perceived utility for service users, perceived impact on self-care and recovery, and the nature of interaction with team staff. Interviews with staff from the two trial sites will focus on their views, expectations and experiences of the CareLoop system within the broader contextual issues regarding the organisation and delivery of care.
2. Observation of how patients and staff adopt and use the system. Observational methods will focus on professional and client interactions and participants everyday use of technology. Observation will include attention to how the system fits into the everyday routines of management and care practices for clients and professionals.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. We will assess patient, staff and service-orientated outcomes via scrutiny of:
1.1. Adoption and use of the ClinTouch and CareLoop systems by service users and staff
1.2. Effective detection of relapse or deliberate self-harm
1.3. Responsive changes in clinical management
1.4. Changes in patient views on system preference, self-efficacy, empowerment and recovery.
2. Patient-centred objectives: the proportion of eligible service users consenting; the proportion continuing for 12 weeks; the number completing greater than 33% of datapoints; the proportion indicating they would continue for a longer period at exit
3. Team-centred objectives: how frequently CareLoop data is accessed; the number of times summary data is discussed with the service user.
4. The indicative efficacy endpoints for comparing CEM vs. MAU will be:

4.1. Episodes of early warning signs of relapse or deliberate self-harm correctly detected by CareLoop
4.2. User empowerment from semi-structured qualitative interviews and Empowerment Rating Scale (Rogers et al., 1997) measured at 0, 6 and 12 weeks
4.3. Retrospectively gathered service data: service user visits brought forward, medication changes, referrals to crisis and other services, inpatient admissions, transfer between services, and Emergency Department visits.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2014

Completion date
30/04/2015

Eligibility

Key inclusion criteria
1. Diagnosis of schizophrenia or related psychotic disorders, meeting or having met the criteria for such a diagnosis
2. Aged 18 to 65 years
3. Able to provide written and witnessed informed consent; responsible medical officer will be consulted in case of uncertainly
4. Can read and write in English at a level sufficient to understand and complete study-related procedures
5. Not acutely unwell at point of study entry as defined by baseline PANSS total symptom subscale score of less than 110
6. Relapse prone as defined by one or more psychotic episodes requiring inpatient admission in past 2 years as judged from case records
Target Gender: Male & Female; Upper Age Limit 65 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
81

Key exclusion criteria
1. Diagnosis of bipolar disorder
2. Inpatient status
3. Unable or unwilling to give written informed consent
4. Unable to understand written materials relating to the study
5. PANSS total score of less than 70 or more than 110
6. Not relapse prone, as defined by fewer than one psychotic episodes requiring inpatient admission in past 2 years as judged from case records

Date of first enrolment
01/05/2014

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
Manchester Mental Health and Social Care Trust (UK)

Sponsor details
Rawnsley Building
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC); Grant Codes: MR/K015516/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2019 preprint in http://doi.org/10.2196/preprints.17019 (added 24/07/2020)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/08/2020	17/08/2020	Yes	No
HRA research summary			28/06/2023	No	No