ISRCTN34966555 https://doi.org/10.1186/ISRCTN34966555

Active Assistance for Psychological Therapy (Actissist): Using mobile technology to deliver cognitive behaviour therapy for psychosis

Submission date
12/06/2014

Registration date
12/06/2014

Last Edited
17/04/2025

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People who have experienced a first episode of psychosis can have more episodes of psychosis; in fact, about 80% of people will have another episode within 5 years of their first episode. Therefore, this early period of psychosis is a critical period. Factors that put people at higher risk of experiencing more episodes of psychosis include not taking medication as prescribed, feeling criticised by a significant other, misusing substances, and isolating oneself from others. National guidelines for medical care recommend a talking therapy, called Cognitive Behavioural Therapy (CBT), for the treatment of psychosis. Unfortunately, less than 10% of people with psychosis who could benefit have access to this talking therapy. To overcome this problem of getting help, we will develop a mobile phone application (Actissist). We will see if it is possible to deliver CBT through a mobile app. We will also see whether people who have experienced psychosis will like to use the app. We wish to understand whether using the app helps people feel less upset by critical comments, use substances less, reduces the distress caused by psychotic symptoms and helps people get out of the house more often.

Who can participate?
Adults with early psychosis who are in contact with Early Intervention Services.

What does the study involve?
Participants will be randomly allocated to one of two groups: the treatment group or the control group. Twenty four people in the treatment group will be asked to use the app Actissist on top their usual treatment, and 12 people to use another smartphone app (ClinTouch). ClinTouch monitors symptoms of psychosis and mood symptoms. People will use these apps for 12 weeks. Before using the app, participants will fill out some questionnaires. People who receive the Actissist app will meet with a researcher to talk about strategies that usually help them cope with upsetting symptoms. This way, we can make the app personal to the participant. Participants will also be offered a training session on how to use the app and will be phoned by a researcher weekly to see how they are getting on with using the app. After 12 weeks of using the apps, participants will be invited to fill out the same questionnaires they filled out before receiving the apps. We would like to know what it's like for people to use the Actissist app and

also what it was like for people to be involved in the study. To find this out, a small number of participants will be invited to attend an interview at the end of the 12-week study period at a convenient location and time.

What are the possible risks and benefits of participating?
We don't know if the Actissist app will improve the areas we hope it will. Our participants will be making an important contribution to the development of a new app that could improve access to treatment for people with experience of psychosis. Some people enjoy completing the tasks involved in research and the opportunity to talk to someone about their experiences. We will ask all participants if they want us to share the information we collect with their care team (participants can choose either way), which they may find useful. The Actissist app may challenge personal beliefs and values, which some people may find difficult. However, CBT is safe when delivered face-to-face and more often than not serves to help people, with little proof that it may have a negative effect. This study is very similar to previous research (e.g. in the development of ClinTouch) and very few people have reported feeling distressed by it.

Where is the study run from?
The study is being run from the University of Manchester. Working with various different Early Intervention teams based in several trusts, we aim to recruit participants from across the North West of England

When is the study starting and how long is it expected to run for?
March 2015 to June 2016

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

Who is the main contact?
Dr Sandra Bucci
sandra.bucci@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sandra Bucci

Contact details
School of Psychological Sciences
Zochonis Building
Oxford Road
Manchester
United Kingdom
M13 9PL
-
sandra.bucci@manchester.ac.uk

Additional identifiers

Protocol serial number
16617

Study information

Scientific Title
Active Assistance for Psychological Therapy (Actissist): Using mobile technology to deliver cognitive behaviour therapy for psychosis: a randomised controlled trial

Acronym
ACTISSIST

Study objectives
The ACTISSIST project seeks to develop a mobile phone application (app) to deliver a CBT intervention to people with early psychosis. In this phase of the research (phase 3 of 3) participants will be randomly assigned to one of two conditions. Over a 12-week period participants will either receive the Actissist app, or a symptom monitoring app (ClinTouch). The principal aim of this phase is to assess the feasibility and acceptability of delivering a CBT intervention via a mobile phone to people with early psychosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/WM/0118; First MREC approval date 28/04/2014

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

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

Interventions
Participants will be randomly assigned to the intervention and control groups in a ratio of 2:1, respectively (24:12).
Mobile CBT: Cognitive Behavioural Therapy administered via a mobile phone.
The control group will receive ClinTouch; a mobile phone application developed to monitor the symptoms of psychosis (Palmier-Claus et al., 2012).

Follow Up Length: 10 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Acceptability and feasibility; Timepoint(s): Uptake and drop-out rates will be assessed throughout. Patient feedback is taken at follow-up.

Key secondary outcome(s)
1. Number of social interactions, measured by the Personal and and Social Performance Scale (Morosini et al., 2000)
2. Drug use frequency, measured by the Timeline FollowBack (TLFB; Sobell & Sobell, 1992)
3. Perceived criticism, measured by the perceived criticism scale (Hooley & Teasdale, 1989)
4. Positive psychotic symptoms, measured by the Positive and Negative Syndrome Scale (PANSS; Kay,Opler & Fiszbein, 1987)

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. In current contact with Early Intervention Services
2. At least 4 week stabilisation of positive symptoms (score <3 on the PANSS items)
3. Mental capacity to provide informed consent
4. Sufficient English language proficiency to complete questionnaires and respond to written material
5. Aged 16 years or older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
48

Key exclusion criteria
1. Anyone less than 16 years old at the point of recruitment
2. Anyone incapable of giving informed consent
3. Non-English proficient
4. Score >3 on the PANSS items for positive psychotic symptoms
5. Any service user >35 years

Date of first enrolment
01/03/2015

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK); Grant Codes: R116690

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	20/08/2018		Yes	No
Results article	results	10/05/2019	29/05/2019	Yes	No
Results article	app refinement results	10/12/2020	29/12/2020	Yes	No
Results article	Early psychosis service user views on digital remote monitoring: a qualitative study	16/04/2025	17/04/2025	Yes	No
Protocol article	protocol	10/09/2015		Yes	No
HRA research summary			28/06/2023	No	No