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Active Assistance for Psychological Therapy 2.0 (Actissist 2.0)

Submission date
05/02/2018

Recruitment status
No longer recruiting

Registration date
07/02/2018

Overall study status
Completed

Last Edited
08/10/2021

Condition category
Mental and Behavioural Disorders

✓ Prospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Severe mental illness (SMI) such as schizophrenia affects 24 million people worldwide, with costs to society estimated at nearly £12bn in England. It typically starts in early adulthood and up to 80% relapse within 5 years, resulting in unscheduled acute care and adverse effects on psychosocial development. The main treatment for psychosis is medication and psychosocial interventions. Currently, the delivery of psychosocial interventions for psychosis by scheduled appointment can result in indicators of relapse either being missed or treated too late. There is a need for innovative, timely, efficient and cost-effective solutions to improve the speed and quality of recovery in psychosis, over and above conventional drug and psychosocial treatments. The NHS has a clear digital agenda for addressing mental health challenges, aiming to fully harness the information technology revolution, and self-management in long-term conditions is a cornerstone of NHS policy. Smartphones offer an unprecedented opportunity to drive improvements in treatment quality, efficiency, cost, access and facilitate self-management. A user-informed, personalised, smartphone app, Actissist, has been developed which delivers a theory-driven psychological intervention that is unconstrained by traditional service settings. Patients can complete the intervention swiftly in the course of daily life over 12-weeks and this technology is feasible, safe and acceptable. The aim of this study is to refine the software and assess its effectiveness in early psychosis.

Who can participate?
Adults (16 or older) with early psychosis (within 5 years of initial episode) who are in contact with Early Intervention Services or Secondary Care Services

What does the study involve?
Participants are randomly allocated to one of two groups: the treatment group or the control group. Eighty-five people in the treatment group are asked to use the Actissist app on top of their usual treatment, and 85 people are asked to use a symptom monitoring app (ClinTouch) plus their usual care. Before using the apps, participants are asked to complete some questionnaires about their feelings and experiences. Participants also receive a training session on how to use the app and receive weekly telephone calls from a researcher to see how people are getting on with using the app. Participants using the Actissist app also meet with the

researcher to set a goal to work towards while using the app. After 12 weeks of using the apps, participants are invited to complete the same questionnaires they filled out at the start of the study and additional questions about how they felt about the app they received. Some participants are interviewed to find out what it was like being involved in the study at the end of the 12-week study period. People who do not wish to take part in the study, but who are interested in providing their views about apps for psychosis, are also interviewed. Mental health care staff are also invited to attend interviews to give their views about the implementation of apps for early psychosis in mental health services. Finally, surveys are given to participants, in addition to service users and staff who are not participants. These surveys can be completed online via a secure website or with paper-based questionnaires. Questions in the survey focus on participants' technology ownership and their interest in using technology support options for early psychosis.

What are the possible benefits and risks of participating?
It is not known whether the Actissist app will result in improvements. For this reason, participant feedback, views, experiences and input are important to help towards the development of an app that could improve access and choice over treatment options for people with experience of psychosis. Some people also enjoy completing the tasks involved in taking part in research and being given the opportunity to speak with someone about their experiences. Some people may find it difficult to answer questions about their feelings. However, in an early study and in the development of the ClinTouch app, very few people have reported feeling distressed through completing the questions.

Where is the study run from?
The study is being run from the University of Manchester, who are working with various Early Intervention and Secondary Care Services based at trusts across the North West of England

When is the study starting and how long is it expected to run for?
March 2018 to June 2020.

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

Who is the main contact?
1. Dr Sandra Bucci (PI)
sandra.bucci@manchester.ac.uk
2. Dr Alyson Williams (Project Officer)
alyson.williams@manchester.ac.uk

Study website
https://sites.manchester.ac.uk/actissist/

Contact information

Type(s)
Scientific

Contact name
Dr Sandra Bucci

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Type(s)
Public

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Dr Alyson Williams

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
36418

Study information

Scientific Title
Active Assistance for Psychological Therapy 2.0 (Actissist 2.0): digital intervention for co-producing care in psychosis

Acronym

Actissist 2.0

Study hypothesis
Onset of psychosis typically occurs in early adulthood. Up to 80% relapse within 5-years, resulting in unscheduled acute care and adverse effects on psychosocial development. The main treatment for psychosis is medication and psychosocial interventions. Currently, the delivery of psychosocial interventions for psychosis by scheduled appointment can result in psychosis relapse indicators either being missed or treated too late. The NHS has a clear digital agenda for addressing mental health challenges, aiming to fully harness the information technology revolution. Smartphones offer an unprecedented opportunity to drive improvements in treatment quality, efficiency, cost, access and facilitate self-management. Supported by MRC DPFS funding (MR/L005301/1), we have developed a user-informed, personalised, smartphone app, Actissist, that delivers a theory-driven psychological intervention over 12 weeks that is unconstrained by traditional service settings. We have shown that patients complete the intervention swiftly in the course of daily life over 12-weeks and that this technology is feasible, safe and acceptable.

The primary aim of the current proposal, Actissist 2.0, is to refine the software and conduct an efficacy study in an psychosis group. The randomized controlled trial will be carried out over 36 months and involves an initial period of app refinement, followed by an evaluation of the efficacy and usability of the app in a randomized controlled trial.

Primary hypothesis: participants allocated to the Actissist group will have a lower mean PANSS total score compared to those allocated to the control (symptom monitoring) group at 12 week follow-up (T2)
Secondary hypothesis: participants allocated to the Actissist group will have a higher mean score on secondary outcomes compared to those allocated to the control (symptom monitoring) group (or lower score, if lower indicates improvement on the scale) at 12 week follow-up (T2)

Updated 23/04/2018: The primary outcome will be determined at the 12-week (post randomisation) follow-up timepoint

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee 4, West of Scotland, 14/11/2017, ref: 17/WS/0221

Study design
Randomised; Both; Design type: Treatment, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

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

Condition
Psychosis

Interventions
Participants will be randomly assigned on a 1:1 ratio to either the intervention (Actissist plus TAU) or control (ClinTouch plus TAU) groups.

Actissist intervention: Theoretically-informed content administered via a mobile phone app. The control group will receive ClinTouch, which is a mobile phone application developed to monitor mood and symptoms of psychosis (Palmier-Claus et al., 2012).

Intervention length: 12 weeks; Follow-up: 12 weeks post randomisation and 24 weeks post randomisation; Study Entry: Single Randomisation only.

Intervention Type
Other

Primary outcome measure
Psychotic symptoms are measured using the Positive and Negative Syndrome Scale (PANSS) at baseline, 12 weeks post randomisation and 24 weeks post randomisation

Updated 23/04/2018: The primary outcome will be determined at the 12-week (post-randomisation) follow-up timepoint

Secondary outcome measures
All outcomes measured at baseline, 12 weeks post randomisation, and 24 weeks post randomisation:

1. Symptom distress is measured using the Psychotic Symptoms Rating Scales (PSYRATS)
2. Mood is measured using the Calgary Depression Scale (CDSS) for Schizophrenia
3. Social functioning is measured using the Personal and Social Performance Scale (PSP)
4. Perceived criticism and perceived warmth is measured using the Perceived Criticism and Perceived Warmth Scale (PCPW)
5. Recovery is measured using the Questionnaire about the Process of Recovery (QPR)
6. Well-being is measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWEBS)
7. Internalised stigma is measured using the Internalised Stigma of Mental Illness Inventory (ISMI)
8. Cannabis use frequency is measured using the Time Line Follow Back for drugs and alcohol (TLFB) and the DUDIT/DUDIT-E
9. Empowerment is measured using the Empowerment Scale (ERS)
10. Health economics is measured using Euro-Qol Five Dimension (EQ-5D-5L) and Client Service Receipt Inventory (CSRI)

Updated 20/03/2018:
8. Substance use is measured using the Alcohol Use Disorders Inventory (AUDIT; past 3 months), Cannabis Use Disorders Inventory-Revised (CUDIT-R; past 3 months), Alcohol, Smoking and

Substance Involvement Screening Test (ASSIST), Drug Use Disorder Identification Test-Extended (cannabis only). Cannabis use frequency is measured using the Time Line Follow Back for drugs and alcohol (TLFB)

Overall study start date
01/10/2017

Overall study end date
27/09/2020

Eligibility

Participant inclusion criteria
Current inclusion criteria as of 20/03/2018:
1. Meet ICD-10 criteria for a schizophrenia-spectrum diagnosis (ICD codes F20, F22, F23, F25, F28, F29) as confirmed by the treating clinician or Early Intervention for Psychosis Service entry criteria, operationally defined using the Positive and Negative Syndrome Scale (PANSS) and/or the psychosis transition criteria of the Comprehensive Assessment of At-Risk Mental States
2. In contact with mental health services
3. Within 5 years from onset of first psychotic episode, deemed by the treating clinician
4. Meet a criterion level of positive symptoms severity, indicated by a score of >3 (symptom present) on any PANSS positive item and a score of >3 (symptom present) on any PANSS negative or PANSS general items
5. English speaking
6. Aged 16 years or older
7. Capacity and willingness to provide informed consent
8. Not currently participating in another trial

Previous inclusion criteria:
1. Early psychosis (within 5 years of initial episode), deemed by the treating clinician
2. In current contact with either an early intervention service or a secondary mental health service
3. PANSS total score 65 or more
4. English speaking
5. Aged 16 years or older
6. Capacity to provide informed consent
7. Not currently participating in another trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 170; UK Sample Size: 170

Total final enrolment
172

Participant exclusion criteria
Current inclusion criteria as of 20/03/2018:
1. Anyone with psychosis not in contact with a NHS mental health service
2. Anyone less than 16 years old at the point of recruitment
3. Anyone not capable of giving informed consent
4. Non-English proficient
5. Score <3 on all PANSS positive, negative and general items

Previous inclusion criteria:
1. Anyone with psychosis not in contact with a NHS mental health service
2. Anyone less than 16 years old at the point of recruitment
3. Anyone not capable of giving informed consent
4. Non-English proficient
5. Score <65 on PANSS total
6. Current participation in another trial

Recruitment start date
16/02/2018

Recruitment end date
30/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust (Lead Centre)
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Bolton Early Intervention Service
Bentley House
Viking Works
Weston Street

Bolton
United Kingdom
BL3 2RX

Study participating centre
Bolton North Function Team
Bentley and Barnett House
Viking Works
Weston Street
Bolton
United Kingdom
BL3 2RX

Study participating centre
Bolton South Function Team
Barnett House
Viking Works
Weston Street
Bolton
United Kingdom
BL3 2RX

Study participating centre
Salford Early Intervention Team
Broadwalk Centre
51 Belvedere Road
Salford
United Kingdom
M6 5EJ

Study participating centre
Cromwell House CMHT
Cromwell Road
Eccles
Salford
United Kingdom
M30 0GT

Study participating centre
Prescott House CMHT
Little Hulton

Salford
United Kingdom
M28 0ZA

Study participating centre
Ramsgate House CMHT
Ramsgate Street
Lower Broughton
Salford
United Kingdom
M7 2YL

Study participating centre
Trafford Early Intervention Service
Crossgate House
Cross Street
Sale
United Kingdom
M33 7FT

Study participating centre
Trafford - North CMHT
Crossgate House
Cross Street
Sale
United Kingdom
M33 7FT

Study participating centre
Trafford – South CMHT
2A Craven Drive
Brook Heys
Broadheath
Altrincham
United Kingdom
WA14 5JF

Study participating centre
North Manchester Early Intervention Service
Wilson’s Park
Monsall Road

Manchester
United Kingdom
M40 8WN

Study participating centre
South Manchester Early Intervention Service
Wilson's Park
Monsall Road
Manchester
United Kingdom
M40 8WN

Study participating centre
Manchester – North West Area Team CMHT
Macartney House
Beech Mount
Harpurhey
United Kingdom
M9 5XS

Study participating centre
Manchester – North East Area Team CMHT
Moston Lane
Harpurhey District Offices
Manchester
United Kingdom
M9 4AD

Study participating centre
Manchester – Central West Area Team
Kath Locke Centre
123 Moss Lane East
Manchester
United Kingdom
M15 5DD

Study participating centre
Manchester – Central East Area Team
Rawnsley Building
Manchester Royal Infirmary
Manchester

United Kingdom
M13 9WL

Study participating centre
Manchester – North Mersey Area Team
Kingslea House
Francis Road
Withington
United Kingdom
M20 4XP

Study participating centre
Manchester – South Mersey Area Team
Brian Hore Unit
West Didsbury
United Kingdom
M20 2LR

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-Under-Lyne
United Kingdom
OL6 7SR

Study participating centre
Oldham Early Intervention Team
5 Waterloo Street
Oldham
United Kingdom
OL1 1 SP

Study participating centre
West Oldham CMHT
Maple House
Hamilton Street
Oldham
United Kingdom
OL4 1DB

Study participating centre
East Oldham CMHT
Maple House
Hamilton Street
Oldham
United Kingdom
OL4 1DB

Study participating centre
Bury Early Intervention Service
Humphrey House
Angouleme Way
Bury
United Kingdom
BL9 0BQ

Study participating centre
Bury CMHT
Humphrey House
4 Angouleme Way
Bury
United Kingdom
BL9 0BQ

Study participating centre
Heywood, Middleton & Rochdale Early Intervention Service
John Elliot Unit
Birch Hill Hospital
Rochdale
United Kingdom
OL12 9QB

Study participating centre
Heywood, Middleton & Rochdale CMHT
Hanson Corner
Hanson Street
Middleton
United Kingdom
M24 2HW

Study participating centre
Stockport Early Intervention Service
Councillor Lane Resource Centre
Councillor Lane
Cheadle
United Kingdom
SK8 2JF

Study participating centre
Sector 1 Stockport CMHT
21 Heaton Moor Road
York House
Stockport
United Kingdom
SK4 4LT

Study participating centre
Sector 2 Stockport CMHT
Councillor Lane Resource Centre
Councillor Lane
Cheadle
United Kingdom
SK8 2JF

Study participating centre
Tameside and Glossop Early Intervention Team
225 Old Street
Ashton-under-Lyne
United Kingdom
OL6 7SR

Study participating centre
Tameside South CMHT
Outram Road
Dunkinfield
United Kingdom
SK16 4XE

Study participating centre
Tameside North CMHT
Haughton House

Stamford Street East
Ashton-Under-Lyne
United Kingdom
OL6 6QQ

Sponsor information

Organisation
The University of Manchester

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
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

The study protocol is in the process of being prepared for publication. The study protocol will be made available once published. Planned publication of the study results in a high impact peer-reviewed journal, with the intent to submit the outcome paper for publication January 2021. Planned presentations at public engagement events and national and international conferences, presenting to audiences working in the field of psychosis and/or technology.

Intention to publish date

30/12/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	app refinement results	10/12/2020	29/12/2020	Yes	No
HRA research summary			28/06/2023	No	No