

Active Assistance for Psychological Therapy 2.0 (Actissist 2.0)

Submission date 05/02/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/02/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/04/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

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)

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2. Dr Alyson Williams (Project Officer)

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Contact information

Type(s)

Scientific

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Type(s)

Public

Contact name

Dr Alyson Williams

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Additional identifiers

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 objectives

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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

Key secondary outcome(s)

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)

Completion date

27/09/2020

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

172

Key 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

Date of first enrolment

16/02/2018

Date of final enrolment

30/11/2019

Locations

Countries of recruitment

United Kingdom

England

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

ROR
<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

Medical Research Council

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

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
Results article	Early psychosis service user views on digital remote monitoring: a qualitative study	16/04/2025	17/04/2025	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes