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ARIES: App to support Recovery in Early Intervention Services

Submission date
16/05/2018

Recruitment status
No longer recruiting

Registration date
25/05/2018

Overall study status
Completed

Last Edited
19/06/2023

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
Psychosis is a mental health problem that causes people to perceive or interpret things differently to those around them. People with psychosis have been found to benefit from self-management programmes. Aims of these programmes include learning to look out for early warning signs of a relapse and to respond to them, and to work towards important life goals. Research suggests that the internet and mobile phones may be an acceptable of providing additional support for people with psychosis. Smartphones may be a way of helping people with self-management, perhaps especially beneficial for young people in the early stages of psychosis. We have developed a Smartphone app (My Journey 3), which includes materials from paper tools already used in the NHS for the self-management of psychosis.
Previously as part of the ARIES study six EIS service user participants have used My Journey 3 in a lab setting and talked us through how they found it. This enabled us to improve its design. A further six participants then used the improved app in their everyday lives with support from EIS staff in a small field study.
The main aims of the current study we are now carrying out are:
1. To find out how EIS service users and staff get on with the My Journey 3 app. Do they find it easy to use and do they think it will be helpful? We plan to identify any changes that need to be made for it to become more useable.
2. To carry out a small trial of the app, using methods that we hope later to use for a large scale test. This allows us to try out procedures for testing the app, including ways of recruiting participants, of allocating them to the app or to a control group, and of measuring how they get on with the app. We are also be able to assess how many centres we would need to include in a large-scale trial to get high quality evidence on whether the app is helpful.

Who can participate?
Adults aged 16 or older with psychosis, currently in contact with one of the Early Intervention Services taking part.

What does the study involve?
Participants are randomly allocated to one of two groups. One of these groups is given the My Journey 3 app to use throughout the study period of a year. The other group do not receive the MyJourney3 app. Both groups are continuing to receive usual EIS care and support. The My

Journey 3 app is based on existing paper-and-pen self-management intervention components used in NHS services.
All participants are followed-up by a study researcher to find out whether the app has had any impact on their progress and what they thought of it.

What are the possible benefits and risks of participating?
Participants who take part in the study may benefit from using the My Journey 3 app on their Smartphone, which aims to help users manage their illness, monitor related symptoms, set and track personal goals and plan for mental health crises and preventing relapse. There are no anticipated significant risks for participants taking part in the study, although people sometimes find it upsetting to talk about past experiences of psychosis.

Where is the study run from?
1. Islington Early Intervention Service (UK)
2. Camden Early Intervention Service (UK)
3. Tower Hamlets Early Intervention Service (UK)
4. EQUIP Team (Early Intervention City and Hackney) (UK)
5. Early Intervention in Psychosis Service: East Surrey (UK)
6. Early Intervention in Psychosis Service: West Surrey & NE Hants (UK)

When is the study starting and how long is it expected to run for?
September 2015 to November 2018

Who is funding the study?
National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care North Thames (UK)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
182553

Study information

Scientific Title
App to support Recovery In Early intervention Services (the ARIES study): feasibility trial of a supported self-management Smartphone application for psychosis

Acronym
ARIES

Study objectives
The aim of this study is to test the feasibility and acceptability of a Smartphone app for people with psychosis who use NHS Early Intervention Services for Psychosis.

Further aims include:
1. To identify if any modifications to the content, design or delivery of the My Journey 3 Smartphone app is necessary.
2. To test the feasibility and acceptability of trial procedures, including eligibility criteria, assessment, randomisation and allocation procedures for a definitive randomised controlled trial.

3. To assess recruitment and retention rates to inform planning of a definitive randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London - Brent, 02/10/2015, ref: 15/LO/1453. Amendment approved 29/07/2017.

Study design
12 month multi-centre randomised controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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
First-episode psychosis

Interventions
The study is un-blinded and features a 1:1 allocation to the treatment group and the control group.
All 20 participants randomised to the treatment group receive access to My Journey 3, a smartphone application, on their Android Smartphones. The My Journey 3 app has been designed from existing paper-and-pen self-management intervention components used widely in NHS services and features four main intervention components: information and advice about psychosis, mental health, and mental health services; self-monitoring of symptoms and medication adherence; identifying things to do to keep well and setting and tracking personal recovery goals; and relapse prevention and crisis planning. Participants in the treatment group first get access to My Journey 3 on their Smartphone at an app training session with a study researcher and a supporting clinician. Participants have access to My Journey 3 from the training session until the end of the study, and their use is supported by EIS clinical staff.

All participants in both the control (n=20) and treatment groups (n=20) receive treatment as usual for first-episode psychosis.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
My Journey 3 app

Primary outcome measure
Relapse as indicated by admission to acute care (inpatient wards, crisis resolution teams, crisis houses and acute day services) during the 12-month follow-up period. Data on admissions to acute care during the trial period is collected from patient records at the 12-month follow-up.

Secondary outcome measures
1. Social outcomes are measured using The Social Outcomes Index (Priebe, Watzke, Hansson & Burns, 2008) at the study baseline meeting, at a 4-month follow-up meeting and at a 12-month follow-up meeting
2. Mental wellbeing is assessed using The Mental Health Confidence Scale (Carpinello et al., 2000) and The Warwick-Edinburgh Mental Well-Being Scale (NHS Health Scotland, University of Warwick & University of Edinburgh, 2007) at the study baseline meeting, at a 4-month follow-up meeting and at a 12-month follow-up meeting
3. Recovery in psychosis is assessed using The Process of Recovery Questionnaire (Neil et al., 2009) at the study baseline meeting, at a 4-month follow-up meeting and at a 12-month follow-up meeting
4. Quality of life and satisfaction with treatment is assessed using The DIALOG scale (Priebe et al., 2007) at the study baseline meeting, at a 4-month follow-up meeting and at a 12-month follow-up meeting
5. Positive, negative and general psychopathology symptoms are assessed using the PANSS (Kat et al., 1987) at the study baseline meeting, at a 4-month follow-up meeting and at a 12-month follow-up meeting
6. Participants' engagement with Early Intervention Services during the study period is obtained using the Service Engagement Scale (SES; Tait et al., 2002) completed by participants' clinicians at baseline and at the 12-month follow-up.
7. The following patient information is collected from patient records at baseline and one year after entry into the study:
7.1. Current diagnosis
7.2. Current care cluster
7.3. Care plan approach status
8. The usability and acceptability of My Journey 3 for service users and clinicians is assessed from semi-structured qualitative conducted at the 4-month follow-up meeting.

Overall study start date
01/09/2015

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Currently on the caseload of an Early Intervention Service and in contact with clinicians
2. Aged 16 or older

3. Have a diagnosis of psychosis
4. Own an Android Smartphone

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Lack capacity to provide consent to take part in the study
2. Unable to communicate and understand English sufficiently to understand trial procedures and use the app
3. In the view of their EIS team, pose such a high risk to others that it would be unsafe to conduct research meetings even on NHS premises

Date of first enrolment
09/03/2017

Date of final enrolment
06/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Islington Early Intervention Service
London
United Kingdom
NW1 0AS

Study participating centre
Camden Early Intervention Service
London
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NW1 0AS

Study participating centre
Tower Hamlets Early Intervention Service
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Study participating centre
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Study participating centre
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care North Thames

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available two years after the trial end.

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?
Protocol article	protocol	20/03/2019	01/04/2020	Yes	No
Results article	results	26/08/2020	02/09/2020	Yes	No
Participant information sheet	version 3	11/04/2016	19/06/2023	No	Yes
HRA research summary			28/06/2023	No	No