Self-help Therapy and Recovery Trial: evaluation of a recovery guide for psychosis

Submission date	Recruitment status	Prospectively registered
21/05/2010	No longer recruiting	☐ Protocol
Registration date 21/05/2010	Overall study status Completed	Statistical analysis plan
		[X] Results
Last Edited	Condition category	Individual participant data
11/04/2017	Mental and Behavioural Disorders	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8246

Study information

Scientific Title

An evaluation of different levels of support in using a recovery guide for people with psychosis and the impact of choice on outcomes

Acronym

STAR-T

Study objectives

This study is a partially randomised patient preference trial. The aims of the study are to:

- 1. Evaluate the feasibility and acceptability of a recovery guide for psychosis when provided with either low or high support
- 2. To assess the relative impact of the guide in relation to low and high support and no treatment on psychotic symptoms, affect, well-being and functioning

Participants will be able to choose their preferred treatment option (treatment as usual [TAU], low support or high support) or elect to be randomised to a treatment option.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West 10 REC - Greater Manchester North, 09/02/2010, ref: 09/H1011/81

Study design

Single centre randomised interventional treatment trial

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 contact Samantha Hartley (Trial Manager) on +44 (0)161 275 8497 or samantha.hartley@manchester.ac.uk to request a copy or more information

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Psychosis; Disease: Psychosis

Interventions

Therapy will consist of (in addition to TAU) either:

1. Low support: this therapy will be delivered over 9 months and will consist of the following:

- 1.1. Receive a copy of the Self Help Recovery Guide
- 1.2. Weekly CBT telephone sessions
- 1.3. Up to 5 telephone peer support sessions
- 2. High support: this will consist of all the components of low support. In addition, participants will receive group sessions.

Follow up length: 15 months Study entry: registration only

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Process of Recovery Questionnaire (QPR), measured at baseline, 9 months and 15 months

Secondary outcome measures

Subjective Experiences of Psychotic Symptoms Scale (SEPS), measured at baseline, 9 months and 15 months

Overall study start date

10/03/2010

Completion date

01/09/2011

Eligibility

Key inclusion criteria

- 1. Aged 18 65 years, either sex
- 2. In contact with mental health services
- 3. Meeting International Classification of Diseases, version 10 (ICD-10) criteria for non-affective psychosis (schizophrenia, schizophreniform disorder, schizo-affective disorder, delusional disorder)
- 4. At least one month of stabilisation if the person has experienced a symptom exacerbation in the last 6 months
- 5. Able to provide written informed consent
- 6. Able to read the Recovery Guide
- 7. Able to complete the assessments in English
- 8. Able to use the telephone

Participant type(s)

Patient

Age group

Adult

Lower age limit

Sex

Both

Target number of participants

Planned sample size: 120; UK sample size: 120

Key exclusion criteria

- 1. Do not speak/read English
- 2. Experiencing an acute exacerbation of symptoms requiring inpatient or other changes to treatment

Date of first enrolment

10/03/2010

Date of final enrolment

01/09/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre School of Psychological Sciences

Manchester United Kingdom M13 9PL

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

Oxford Road Manchester England United Kingdom M13 9PL

Sponsor type

University/education

Website

http://www.manchester.ac.uk/

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research - Programme Grant for Applied Research (PGFAR) (ref: RP-PG-0606-1086)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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

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 01/09/2015 Yes

No