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

Submission date	Recruitment status
21/05/2010	No longer recruiting
Registration date	**Overall study status**
21/05/2010	Completed
Last Edited	**Condition category**
11/04/2017	Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

18 Years

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
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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