ISRCTN16939126 https://doi.org/10.1186/ISRCTN16939126

Cognitive Behavioural Suicide Prevention for psychosis

Submission date	Recruitment status	[ ] Prospectively registered
21/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/09/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
6329

Study information

Scientific Title
Prevention of Suicide risk in patients with psychosis through the development of a focused and conceptually-driven intervention

Acronym
CBSPp

Study objectives
Study aims:
1. To confirm and describe the psychological architecture that drives suicide behaviour, this consists of: information processing biases, suicide schema and appraisal systems. We intend to investigate hypotheses relating to determine the role of these in suicide behaviour specifically we will use information processing tasks such as autobiographical memory tasks to investigate bias; standardised assessment to investigate appraisal and schema.
2. To derive a method of assessing this architecture through semi-structured interview that will have clinical utility
3. To formulate and develop a manualised cognitive behavioural treatment programme for suicide prevention in psychosis and to test the clinical acceptance and feasibility of this intervention. It is hypothesised that the treatment will be acceptable, feasible and reduce suicide behaviour.
4. At the end of the programme we will be in position to design a clinical trial to test the efficacy of the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stockport REC , 12/12/2008, ref: 08/H1012/97

Primary study design
Interventional

Study design
Multicentre randomised interventional treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Psychosis; Disease: Psychosis

Interventions
Those allocated to the experimental treatment will receive CBSPp as described in the manual in addition to treatment as usual (TAU). Treatment will take place over 12 weeks. Participants will be seen twice weekly. The control group will receive TAU alone. All participants will be re-assessed at 4 months and at 6 months.

Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Suicidal behaviour, measured at 4 months and 6 months

Key secondary outcome(s)
Measured at baseline, 4 months and 6 months:
1. Beck Anxiety Inventory (BAI) to assess level of anxiety
2. Beck Hopelessness Scale
3. Calagary Depression Scale for Schizophrenia
4. Global assessment of functioning (DSM-IV) to assess overall functioning
5. Positive And Negative Symptoms Scale (PANSS) to assess severity of symptoms
6. Psychotic Symptom Rating Scales (PSYRATS) to assess control over symptoms
7. Questionnaire about the Process of Recovery (QPR)
8. Self Esteem Rating Scale
9. The Subjective Experiences of Psychotic Symptoms Scale (SEPSS)

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder or psychotic disorder not otherwise specified (NOS)
2. Have had previous suicide attempts or current suicidal ideation
3. Are not currently acutely suicidal or considered a danger to themselves or others
4. Are receiving appropriate anti-psychotic medication
5. Are under the care of an appropriate clinical team and have contact with mental health service
6. Males and females aged between 18 and 65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Not providing informed consent

Date of first enrolment
01/02/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Zochonis Building
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Insititute for Health Research (NIHR) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration