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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Suicidal behaviour, measured at 4 months and 6 months

Secondary outcome measures
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)

Overall study start date
01/02/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 60; UK sample size: 60

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
England

United Kingdom

Study participating centre
Zochonis Building
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Oxford Road
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England
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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 Insititute for Health Research (NIHR) (UK)

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