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Cognitive behavioural therapy (CBT) for people with psychosis not taking antipsychotic medication: a randomised controlled trial

Submission date	Recruitment status
21/10/2010	No longer recruiting
Registration date	**Overall study status**
21/10/2010	Completed
Last Edited	**Condition category**
11/02/2014	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

7991

Study information

Scientific Title

Acronym
ACTION (Assessment of Cognitive Therapy Instead of Neuroleptics)

Study objectives
Comparing cognitive behavioural therapy (CBT) with treatment as usual for people with psychosis who are not taking antipsychotic medication

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 09/H1014/53)

Study design
Multicentre 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

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

Interventions
Cognitive therapy based on the cognitive model outlined by Morrison (2001).

Follow up length: 18 months
Study entry: single randomisation only

Intervention Type
Other

Phase

Phase II/III

Primary outcome measure
PANSS, measured at all assessments

Secondary outcome measures
1. Psychotic Symptom Rating Scales (PSYRATS), measured at all assessments
2. Questionnaire about the Process of Recovery (QPR), measured at all assessments

Overall study start date
15/02/2010

Completion date
15/02/2013

Eligibility

Key inclusion criteria
Participants in all phases will:
1. Be in contact with mental health services
2. Have an identified care coordinator
3. Either meet International Classification of Diseases-10 (ICD-10) criteria for schizophrenia, schizoaffective disorder or delusional disorder or meet entry criteria for an early intervention for psychosis service (operationally defined using Positive And Negative Symptom Scales [PANSS]) in order to allow for diagnostic uncertainty in early phases of psychosis
4. Either have at least 6 months without antipsychotic medication and experiencing continuing symptoms OR never have received antipsychotics and be currently refusing
5. Score at least 4 on PANSS delusions or hallucinations or, score 5 on suspiciousness /persecution, conceptual disorganisation or grandiosity
6. Aged 16 - 65 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 80; UK sample size: 80

Key exclusion criteria
1. Current receipt of antipsychotic medication
2. Moderate to severe learning disability
3. Organic impairment
4. Non-English speaking (since this would prevent the use of standardised assessment instruments)
5. Inpatient/acute psychiatric care needed

6. Previous CBT for psychosis or, previous CBT for other disorders in the last 2 years
7. Without a care coordinator
8. Any substance dependency

Date of first enrolment
15/02/2010

Date of final enrolment
15/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Psychology Department
Manchester
United Kingdom
M25 3BL

Sponsor information

Organisation
Greater Manchester West Mental Health NHS Foundation Trust (UK)

Sponsor details
Trust Headquarters
Bury New Road
Prestwich
Manchester
England
United Kingdom
M25 3BL

Sponsor type
Hospital/treatment centre

Website
http://www.gmw.nhs.uk

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF)

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	19/04/2014		Yes	No