

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

Submission date 21/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/10/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/02/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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