

Feasibility study of Culturally adapted Cognitive Behaviour Therapy for psychosis for ethnic minority groups

Submission date 21/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/12/2013	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

Protocol serial number
7499

Study information

Scientific Title

A multicentre randomised interventional treatment trial to develop culturally sensitive Cognitive Behaviour Therapy (CBT) for psychosis for ethnic minority patients

Acronym

CaCBTp

Study objectives

This study follows on from a recently conducted qualitative study using semi-structured interviews and focus groups to develop culturally sensitive cognitive behaviour therapy (CBT) for psychosis for ethnic minority patients by exploration and incorporation of service users' and health professionals' views and opinions.

The project has been funded by delivering race equality (Department of Health) Clinical trailblazers group. We will now conduct a pilot randomised controlled trial (RCT) with an intervention (CaCBTp) in black and ethnic minority populations. Participants will be randomised to two groups: intervention or treatment as usual.

Those in the intervention group will receive 16 sessions of CaCBTp over a 4 month period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton & South West Hampshire Research Ethics Committee (B) approved on the 28th January 2009 (ref: 09/H0504/4)

Study design

Multicentre randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Schizophrenia, Psychosis; Disease: Schizophrenia, Psychosis

Interventions

Control group (TAU): Treatment as usual as provided by mental health services

Treatment group (CaCBTp): 16 sessions of CaCBTp with a trained therapist over a four month period

Follow up length: 6 months

Study entry: single randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Reduction in overall Comprehensive Psychopathological Rating Scale (CPRS) scores post-therapy. Outcome is assessed at baseline, the end of the intervention period (4 months) and the end of the follow up period (6 months).

Key secondary outcome(s)

Acceptability of intervention as assessed by satisfaction, number of sessions attended and drop-out rate. Outcome is assessed at the end of the intervention period and the end of the follow up period.

Completion date

31/07/2010

Eligibility

Key inclusion criteria

1. Diagnosis of schizophrenia using International Classification of Disease, version 10 (ICD-10) criteria
2. Belong to an ethnic minority community
3. Willingness to participate in the interview and have notes made and/or be tape recorded
4. Have capacity to consent and understand the interview
5. Able to speak English or willing to participate with the assistance of interpreters
5. Male and female, lower age limit of 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Severe illness which may affect capacity or markedly affect their ability to participate in the interviews
2. Lacks capacity or not giving consent
3. Those patients who in the opinion of the key worker would be thought to be distressed by the interview due to low insight

Date of first enrolment

01/04/2009

Date of final enrolment

31/07/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal South Hants Hospital

Southampton

United Kingdom

SO14 0YG

Sponsor information

Organisation

Hampshire Partnership NHS Foundation Trust (UK)

ROR

<https://ror.org/03qesm017>

Funder(s)

Funder type

Government

Funder Name

Department of Health (UK) - Delivering Race Equality Programme

Results and Publications

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	01/02/2013		Yes	No