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

**Submission date**
21/05/2010

**Recruitment status**
No longer recruiting

**Registration date**
21/05/2010

**Overall study status**
Completed

**Last Edited**
12/12/2013

**Condition category**
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**

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### 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: 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 measure
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).

### Secondary outcome measures
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.

### Overall study start date
01/04/2009

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned sample size: 40; UK sample size: 40

### 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
England

United Kingdom

### Study participating centre
**Royal South Hants Hospital**
Southampton
United Kingdom
SO14 0YG

## Sponsor information

### Organisation
Hampshire Partnership NHS Foundation Trust (UK)

### Sponsor details
Tatchbury Mount
Calmore
Southampton
England

United Kingdom
SO40 2RZ

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.hampshirepartnership.nhs.uk/

**ROR**
https://ror.org/03qesm017

# Funder(s)

**Funder type**
Government

**Funder Name**
Department of Health (UK) - Delivering Race Equality Programme

# 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 | 01/02/2013 | | Yes | No |