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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

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)

Primary study design
Interventional

Study design
Multicentre randomised interventional treatment trial

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