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Improving self-confidence in people who have worries about others

Submission date
05/09/2012

Recruitment status
No longer recruiting

Registration date
10/09/2012

Overall study status
Completed

Last Edited
12/08/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
Delusions are a key symptom of severe mental illnesses, particularly schizophrenia. Persecutory delusions are one of the most common psychotic symptoms and are frequently associated with distress, suicide and admission to psychiatric hospital. Existing treatments, pharmacological and psychological are only partially effective. A way to improve treatment is to target the mechanisms causing delusions to persist. A cognitive model of persecutory delusions indicates that negative beliefs about the self are important in the development and maintenance of persecutory delusions and this is supported by recent research. Psychological interventions based on cognitive behavioural theory and techniques have been shown to change people's negative beliefs about themselves in patients with affective disorders. Recent research also suggests that CBT interventions targeted at underlying mechanisms of delusions are effective and popular with psychosis. The evidence suggests that a cognitive behavioural intervention designed to target negative beliefs about the self in people with persecutory delusions may be effective at changing people's negative beliefs and hence their persecutory delusion. The current research will conduct a study to test this prediction.

Who can participate?
Males and females, aged 18-70. Participants will be recruited from inpatient and outpatient mental health services. They will be currently experiencing a persecutory delusion and have negative beliefs about themselves.

What does the study involve?
Participants will complete three assessments at three different time points- at 0 weeks (the beginning of their involvement in the study), at 8 weeks and at 12 weeks. These assessments will measure how participants are feeling about themselves and other people. Between the 0 week and 8 week assessments half of the participants will receive 6 sessions of cognitive behaviour therapy (CBT) designed to target the negative beliefs they have about themselves. This will be in addition to their usual treatment. The other half of the participants will continue to receive their usual treatment but with no extra therapy sessions. Who receives the therapy straight away is decided by a process called randomisation, which is like a coin toss. At the end of the study we will compare the two groups on their assessment scores to see if there is any benefit of receiving the additional therapy sessions.

What are the possible benefits and risks of participating?
The talking therapy has been designed to help with improving self-confidence. This may help to reduce anxiety and worries about others. There are not any risks in taking part. Evidence suggests that cognitive-behavioural therapy can be helpful for people who are experiencing worries about others and the therapists have previous experience of delivering cognitive-behavioural therapy to patients.

Where is the study run from?
University of Oxford in collaboration with Oxford Health NHS Foundation Trust

When is the study starting and how long is it expected to run for?
The study started in July 2012 and will be recruiting for 1 year. Participants will be involved in the study for 12 weeks.

Who is funding the study?
Medical Research Council, UK

Who is the main contact?
Dr Katherine Pugh
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12821

Study information

Scientific Title
A randomised controlled test of reducing negative beliefs about the self in people with persecutory delusions: improving self-confidence

Study objectives
It is hypothesised that a brief cognitive behavioural intervention designed to target negative beliefs about the self will reduce negative beliefs about the self and persecutory delusions in patients currently experiencing a persecutory delusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 25/07/2012 ref: 12/SC/0369

Study design
Randomised interventional 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
Schizophrenia, Psychosis

Interventions
The study will recruit 30 patients to be randomised to either 6 weeks treatment or a control condition and it is the additional receipt of the intervention to standard psychiatric treatment that will be evaluated. Measurements will be taken at three time points: pre-treatment, post-treatment and one month follow-up. Participants will be recruited from inpatient and outpatient services in Oxford Health NHS Foundation Trust.

Improving self-confidence, 6 session intervention using CBT techniques to reduce negative beliefs about the self and boost positive beliefs.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Brief Core Schema Scale measured at 0 weeks, 8 weeks and 12 weeks

Secondary outcome measures
1. Beck Anxiety Inventory measured at 0 weeks, 8 weeks, 12 weeks
2. Beck Depression Inventory measured at 0 weeks, 8 weeks, 12 weeks
3. Paranoid Thoughts Scale measured at 0 weeks, 8 weeks and 12 weeks
4. Psychotic Symptom Rating Scale - Delusions subscale measured at 0 weeks, 8 weeks and 12 weeks
5. The Robson Self-Concept Questionnaire measured at 0 weeks, 8 weeks, 12 weeks
6. Warwick-Edinburgh Mental Well-being scale measured at 0 weeks, 8 weeks, 12 weeks

Overall study start date
26/07/2012

Completion date
16/04/2013

Eligibility

Key inclusion criteria
1. A current persecutory delusion as defined by Freeman and Garety (2000)
2. Scoring at least 3 on the conviction scale of the PSYRATS (Haddock et al., 1999)
3. That the delusion has persisted for at least three months; a clinical diagnosis of schizophrenia, schizoaffective disorder or delusional disorder (i.e. a diagnosis of non-affective psychosis (F2) in the International Classification of Diseases and Diagnostic and Statistical Manual IV)
4. Negative beliefs about the self (as indicated by endorsing at least one negative schematic belief on the Brief Core Schema Scale (Fowler et al., 2006))
5. Aged between 18 and 70
6. Where major changes in medication are being made, entry to the study would not occur until at least a month after stabilisation of dosage
7. Male & female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
UK Sample Size: 30

Key exclusion criteria
1. A primary diagnosis of alcohol or substance dependency
2. Organic syndrome or learning disability
3. A command of spoken English inadequate for engaging in therapy or the assessments
4. Currently having individual CBT (though previous experience of CBT is not an exclusion)

Date of first enrolment
26/07/2012

Date of final enrolment
16/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
Oxford University (UK)

Sponsor details
Department of Psychology
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OX1 3UD

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/12/2014		Yes	No