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The GOALS study: evaluation of a brief cognitive-behavioural therapy (CBT) treatment to support people with psychosis to reach personal goals

Submission date
15/02/2013

Recruitment status
No longer recruiting

Registration date
20/02/2013

Overall study status
Completed

Last Edited
31/01/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The aim of the study is to run a small trial of a new, recovery-focused, brief cognitive behavioural therapy (CBT) treatment for people with psychosis: the GOALS study (Getting On top of Anxiety and Low mood and So achieving your goals). The therapy will be delivered by frontline mental health staff over eight weekly sessions, following brief training and ongoing supervision with a clinical psychologist. The intervention (treatment) aims to improve recovery, social inclusion and social functioning and reduce distress, and in this study, will be evaluated in comparison to a treatment as usual control group. The will inform the further development of the treatment and training and will provide information for a larger multi-centre trial.

Who can participate?
The GOALS study aims to recruit around 65 adults with a diagnosis of psychosis and who have difficulties in their daily functioning due to anxiety-related avoidance and/or depression. Participants will be recruited from early intervention and recovery teams within the local National Health Service Trust.

What does the study involve?
Participants who give their consent to take part in the study will meet with a researcher three times to complete a number of questionnaires asking about thoughts, feelings, beliefs and experiences. Each meeting will last around 1.5 hours and will be at the beginning of the study, 8 weeks later and 16 weeks later.
After the first meeting, half of the people taking part will be randomly chosen to receive the therapy straight away and half will be offered therapy in four months. Everybody will be asked to complete all of the questionnaires in order to compare the therapy with usual treatment. Those who have therapy straight away will meet with a trained staff member at their clinical team for 8 weekly one-to-one meetings and one follow-up meeting a month later. The therapy aims to support participants to work towards a personal goal which they are finding difficult to complete due to anxiety or depression.

Those who are allocated to the control group will continue to receive their usual care, but will be offered the therapy once they have completed all of the questionnaires.
In addition we will ask a quarter of people taking part to give some additional feedback on how they found the meetings with staff and how they could be improved.

What are the possible benefits and risks of participating?
In a pilot study almost all participants achieved their goals and many showed improvements in mood and wellbeing. All participants will be offered the intervention including those allocated to the treatment as usual group should they wish, after completion of the measures. It is not expected that participation in the study has any risks. The staff who will be delivering the therapy are trained in managing patient distress and will be working within participants clinical teams. Participants will be free to take a break at any point during the meetings and are free to withdraw from the study at any point.

Where is the study run from?
The study has been set up by the Institute of Psychiatry and will be conducted within the South London and Maudsley NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
The study is due to begin in February 2013 and the end date for the project is August 2015.

Who is funding the study?
The study is funded by the National Institute for Health Research, Research for Patient Benefit funding stream.

Who is the main contact?
Dr Helen Waller
helen.waller@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Helen Waller

Contact details
16 De Crespigny Park
London
United Kingdom
SE5 8AF
-
helen.waller@slam.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13538

Study information

Scientific Title
The GOALS Study: a randomised controlled trial of a brief CBT intervention to promote recovery in psychosis

Acronym
GOALS

Study objectives
It is hypothesised that, in comparison to those receiving treatment as usual, people who receive the brief CBT treatment will reach their personal goal and show improvements in their levels of activities, symptoms of anxiety and depression, and general well-being. In addition it is hypothesised that the brief CBT treatment will be cost-effective. Although the treatment is not aimed at directly intervening with psychotic symptoms, it is hypothesised that the intervention will also have a beneficial indirect impact on delusions and hallucinations.

Those who have therapy straight away will meet with a trained staff member at their clinical team for 8 weekly one-to-one meetings and one follow-up meeting a month later. The therapy aims to support participants to work towards a personal goal.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London, 19/12/2012, ref:12/LO/1523

Study design
Randomised interventional; Design type: Screening

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Psychosis early intervention and recovery

Interventions
Treatment as Usual Group: Participants in the TAU group will continue to receive all the treatment and support they currently receive, including input from their GP and psychiatrist and will be seen by their care co-ordinator at least monthly.

Treatment Group: Participants allocated to the treatment group will receive the brief CBT intervention. The manualised intervention comprises two evidence-based CBT interventions, which have been adapted for people with psychosis graded exposure (GE) for anxious avoidance and behavioural activation (BA) for depression. Participants will meet with a trained member of staff for nine hour-long sessions (8 weekly sessions and 1 booster session at 1 month post-intervention). The intervention aims to support participants to achieve personal recovery goals (increasing activity and social engagement), through targeting symptoms of depression or anxiety.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Levels of daily activity, measured by the Time Budget Measure (Jolley et al., 2006) at the end of treatment and follow-up

Secondary outcome measures
1. Global distress (Clinical Outcomes in Routine Evaluation - Outcome Measure, Evans et al., 2000); Timepoint(s): 0, 8 and 16 weeks
2. Patient-reported outcomes (CHOICE Measure, Greenwood et al., 2010); Timepoint(s): 0, 8 and 16 weeks
3. Psychotic symptoms (Positive and Negative Syndromes Scale, Kay et al., 1987; Psychotic Rating Scal; Timepoint(s): 0, 8 and 16 weeks
4. Symptoms of anxiety and depression (Hospital Anxiety and Depression Scale, Zigmond & Snaith, 2003); Timepoint(s): 0, 8 and 16 weeks
5. Well-being (Warwick-Edinburgh Mental Well-being Scale, Tennant et al., 2007); Timepoint(s): 0, 8 and 16 weeks
6. Anxious avoidance (Mobility Inventory, Chambless et al., 1985); Timepoint(s): 0, 8 and 16 weeks

Overall study start date
01/02/2013

Completion date
01/08/2015

Eligibility

Key inclusion criteria

1. Male & Female; Upper Age Limit 65 years ; Lower Age Limit 18 years
2. Diagnosis of a Schizophrenia Spectrum Disorder or currently experiencing positive psychotic symptoms (e.g. with diagnosis of personality disorder, bipolar affective disorder or psychotic depression)
3. Accessing adult community mental health services (both early intervention or longer-term)
4. Symptoms of anxiety-related avoidance and / or depression (above clinical cut-offs)
5. Sufficient command of the English language to complete questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 65; Description: Randomised 1:1, therapy and control group

Key exclusion criteria
1. Currently refusing all medication
2. Currently or recently (in last 3 months) receiving psychological therapy (CBT)
3. Primary diagnosis of an organic mental health problem
4. Primary diagnosis of substance dependency
5. Clients under the care of staff who are trained in the intervention will be excluded in order to reduce the potential for leakage of delivery of the intervention to the treatment of usual condition, should they be allocated to the control group. However, we will ensure that any eligible clients are offered access to the intervention following completion of the trial follow-up should they wish

Date of first enrolment
01/02/2013

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

16 De Crespigny Park
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Institute Of Psychiatry
16 De Crespigny Park
London
England
United Kingdom
SE5 8AF

Sponsor type
University/education

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

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme; Grant Codes: PB-PG-0711-25010

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

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?
Protocol article	protocol	27/06/2014		Yes	No
Results article	results	01/06/2018		Yes	No
HRA research summary			28/06/2023	No	No