

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

<b>Submission date</b> 15/02/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/01/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

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## 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?
<a href="#">Protocol article</a>	protocol	27/06/2014		Yes	No
<a href="#">Results article</a>	results	01/06/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No