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Worry & persecutory delusions: a brief group intervention

Submission date	Recruitment status	[ ] Prospectively registered
18/03/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2020	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims:
We are conducting a research study to evaluate a new type of therapy group. The group is for people who worry a lot and also experience paranoia and persecutory beliefs (i.e. beliefs that others are trying to harm them).The group focuses specifically on worry and lasts for 8 weeks. It aims to help participants understand more about "worry" and develop practical skills to manage worry. Research shows that this type of work can be helpful when delivered to people individually (on a one-to-one basis) and can reduce both the amount that people worry and the level of distress they feel relation to their persecutory beliefs. We are interested in discovering whether offering this type of therapy in a group setting is possible and has the same positive effects.

Who can participate?
Service-users who are open to either the Bromley Recovery West, Recovery East or Assertive Outreach and Rehabilitation Teams in Oxleas NHS Foundation Trust are being approached to take part in this study. We are specifically looking for people who have a current paranoid belief about others wanting to harm them (which they have held for at least 6 months), have high levels of worry, have a diagnosis of schizophrenia, schizoaffective disorder or delusional disorder and are aged between 18-65.

What does the study involve?
People who are suitable for the study and who agree to take part will randomly allocated to one of two groups. Group A will attend the first worry group offered. Group B will also be offered a worry group but at a later date (3 months after Group A start their group). This allows us to compare the results of people attending the worry group with those who are waiting for the group. This helps us find out if attending the group makes a difference. As well as attending their groups, participants will also be asked to complete some short questionnaires on between 3-6 different occasions over the course of the study . This allows us to measure how people's levels of worry and distress change over time, which helps us see if the groups are helping people feel better.

Where is the study run from?
The study is taking place in Oxleas NHS Foundation Trust, and patients open to the Bromley

Recovery and Assertive Outreach and Rehabilitation Teams may take part. The group itself will be run at Yeoman House in Penge.

When is study starting and how long is it expected to run for?
March 2013 to October 2015

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
148533

ClinicalTrials.gov number

Secondary identifying numbers

IRAS project ID: 148533

Study information

Scientific Title
Evaluation of a brief worry intervention for people with persecutory delusions: are groups an effective form of delivery?

Study objectives
This trial looks at the impact of a brief, 8-session "worry group" on people who have a persecutory delusion, clinically significant levels of worry, and a diagnosis of schizophrenia, schizoaffective disorder or delusional disorder. Outcomes of those in the "treatment group" (group A) will be compared to those in the waiting list control group (Group B).

Hypotheses are:
1. The treatment group (group A) will show a greater reduction in worry over time than the control group (Group B). This will meet both statistical and clinical significance.
2. The treatment group (group A) will show a greater reduction in delusional distress over time than the control group (Group B). This will meet statistical and clinical significance.
3. The treatment group (group A) will show a greater reduction in overall paranoia over time than the control group (Group B). This will meet statistical and clinical significance.
4. There will be a correlational effect such that reductions in worry are associated with reductions in paranoia, persecutory ideation and delusional distress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - London Bridge, 27/01/2015, ref: 14/LO/2055

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

We are looking at both worry and persecutory delusions in individuals with psychotic diagnoses (schizophrenia, schizoaffective disorder, and delusional disorder).

Interventions

We are utilising a waiting list control design. This means that in the initial phase of the trial, one group of participants will be randomly allocated to attend the first 8 week worry group (group A) whilst the other group will be placed on a waiting list and receive treatment as usual from their care team. Four weeks after the completion of the first worry group, the waiting list group will then commence the second worry group.

In both arms of the trial, the content of the worry group will be the same. The group will look at the process of worry, consider pros/cons of worry, and help develop strategies to manage worry.

Intervention Type

Behavioural

Primary outcome measure

1. Worry: To measure worry we will be using the Penn-State Worry questionnaire. This is a 16 item self-report questionnaire, each item rated on a five point Likert scale (rated 1 to 5). The total score on this measure will be used to identify levels of worry (NB: To be included in the study, the total at baseline must be over 45)
2. Delusional Distress: This will be measured using the Psychotic Symptom Rating Scale (PSYRATS) – delusions part, Factor 2 subscale and the The Green Paranoid Thoughts Scale (GPTS) - Part B distress subscale. The PSYRATS is a semi-structured interview comprising of 6 items, each rated on a 5 point ordinal scale (0-4). The GPTS is a 32-item self-report measure (each item rated on a 5-point Likert scale)
3. Overall Paranoia & Persecutory Ideation will be measured by the PSYRATS - delusions part (Total Score) and GPTS - Part B Total score (see above description of measures)

The key time points for measurement in this trial are as follows:
1. Recruitment
2. T0 (the time when the first worry group commences)
3. T1 (the time at which the first worry group finishes i.e. 8 weeks after T0)
4. T2 (the time at which the second worry group commences, i.e. 4 weeks after T1)
5.T3 (the time at which the second worry group finishes, i.e. 8 weeks after T2) and
6. T4 (a one-month follow up session 4 weeks after the second group finishes)

All participants will complete the PSYRATS, PSWQ and GPTS at recruitment.
For those participants randomised to receive the first worry group (i.e. group A), they will also complete the PSYRATS, GPTS, and PSWQ at T0, T1, and T2.
For those participants randomised to receive the second worry group (i.e. the waiting list control, group B), they will also complete the PSYRATS, GPTS, and PSWQ and T0, T1, T2, T3 and T4.

Secondary outcome measures

In order to control for the potential effects of demographic and IQ variables we will be collecting the following data at the recruitment stage of the trial.

1.IQ: to provide an estimate of premorbid IQ we will administer the Wechsler Test of Adult Reading (WTAR) – This measure provides an estimate of premorbid IQ

2.Demographic data: .demographic data detailing participants' age, gender, marital status, employment status. care status (i.e. open to which mental health team), diagnosis, and current medication will be obtained from the medical records at the recruitment stage of the trial.

Overall study start date
01/03/2014

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. A current persecutory delusion
2. The delusion has persisted for at least 6 months
3. A current clinical diagnosis of schizophrenia, schizoaffective disorder or delusional disorder
4. A clinically significant level of worry, as indicated by scores of 45 or more on the Penn state worry questionnaire
5 Aged between 18-65

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20 (10 in each arm of the trial)

Total final enrolment
13

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 psychological therapy
4. Judged as unable to give informed consent
5. In an acute phase of symptomatic distress such that they require inpatient admission
6. Currently in receipt of another form of Cognitive Behaviour Therapy (CBT)

Date of first enrolment

02/02/2015

Date of final enrolment
02/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxleas NHS Foundation Trust
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Sponsor information

Organisation
Oxleas NHS foundation Trust

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Sponsor type
Other

Website
www.oxleas.nhs.uk

ROR
https://ror.org/033t2dn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oxleas NHS foundation Trust

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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018	20/08/2020	Yes	No
HRA research summary			28/06/2023	No	No