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Psychological support for fears about other people

Submission date	Recruitment status	[X] Prospectively registered
11/11/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Persecutory delusions are strong unfounded fears that others intend harm. They are very common, affecting over 70% of patients with schizophrenia (a mental health problem that affects how a person thinks, feels and behaves). These fears can be very upsetting and may cause people to become so anxious that they find it hard to cope with day-to-day life. Many patients do not show enough improvement with current treatments being offered. Therefore a new, more effective treatment is needed. One theory is that persecutory delusions stem from a belief about being “unsafe”. This belief of being “unsafe” is maintained by, for example, worrying, low self-confidence, poor sleep, biases in thinking (tendencies to think in certain ways) and avoiding other people. The fear can be reduced by targeting these factors and enabling the patient to relearn that they are safe. This study will compare two treatments which both aim to help people feel safe. The first is a new treatment which has been developed by the study team called “The Feeling Safe Programme”. The second is an existing treatment called “Befriending”. Both treatments are talking therapies which aim to help people feel safe. The Feeling Safe Programme is a targeted and personalised cognitive treatment which focuses on overcoming the key factors which maintain persecutory beliefs, allowing the patient to relearn that they are safe. The Befriending treatment is a social support treatment that simulates how a good friend would respond. Through a supportive, safe relationship it aims to help reduce isolation, provide warmth and empathy, and distract from concerns. The aim of this study is to find out if the Feeling Safe Programme will be more effective in helping people to feel safer (reduced persecutory delusions), feel happier (improved psychological wellbeing) and do more of what they want in their life (increased activity levels) compared to Befriending.

Who can participate?

Patients aged 16 or over who have persistent persecutory delusions and have a diagnosis of non-affective psychosis (e.g. schizophrenia).

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a new psychological treatment called “The Feeling Safe Programme”. Those in the second group receive an existing psychological treatment called “Befriending”. All participants continue with their usual care (e.g. taking medication). Both treatments involve around 20 meetings with a

clinical psychologist over a period of 6 months. At the start of the study and then again after 6 and 12 months, participants in both groups complete assessments in order to find out if there have been any changes.

What are the possible benefits and risks of participating?
All participants will have approximately 20 meetings with a clinical psychologist. It is hoped that this will lead to an improvement in their mental well-being. There are no notable risks of taking part in this study.

Where is the study run from?
Warneford Hospital, Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2016 to October 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Felicity Waite (Public)
2. Professor Daniel Freeman (Scientific)

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
19657

Study information

Scientific Title
Psychological support for fears about other people: A comparison of the Feeling Safe Programme to Befriending

Acronym
The Feeling Safe Study

Study objectives
The aim is to investigate whether the Feeling Safe Programme can lead to greater recovery in persecutory delusions, psychological well-being, and activity levels compared to befriending.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central-Oxford B Research Ethics Committee, 28/09/2015, ref: 15/SC/0508

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Participants are randomly allocated to receive one of two interventions: the Feeling Safe Programme (a new targeted psychological intervention for persecutory delusions) or Befriending. Both interventions are delivered by a clinical psychologist in approximately 20 sessions over 6 months.

Feeling Safe Programme: The aim of the intervention is to enable participants to relearn that they are safer than they fear. This is achieved by targeting key factors which maintain persecutory beliefs. After an assessment, the patient is offered a tailored menu of treatment

modules. Typically three to four modules are completed, based upon the assessments and patient preference. These modules are delivered in a one-to-one format, with supportive telephone calls or texts between sessions.

Befriending: This will follow a protocol devised by David Kingdon (a trial investigator), which has previously been used under his supervision in two large clinical trials for patients with psychosis. Essentially the aim is to simulate how a good friend would respond, involving: a general focus on non-threatening topics (although patients are not actively dissuaded from talking about concerns); non-confrontation; empathy; and supportiveness.

Assessments, by a rater-blind to allocation, will be conducted at 0, 6 (post-treatment) and 12 months. All main analyses will be intention to treat. (A small number of qualitative interviews will also be carried out to determine views of the intervention and implementation).

Intervention Type
Behavioural

Primary outcome(s)
Conviction in persecutory delusion will be assessed on a 0% to 100% rating scale within the Psychotic Symptoms Rating Scale - Delusions at baseline, 6 months (post-treatment) and 12 months. Both rates of recovery in the delusion (defined as conviction falling below 50%) and dimensional change in the conviction levels (0%-100%) will be tested.

Key secondary outcome(s)
1. Psychological well-being will be assessed by the Warwick-Edinburgh Mental Well-being Scale at baseline, 6 months and 12 months
2. Patient satisfaction will be assessed using the CHOICE (a service user-led outcome measure) at baseline, 6 months and 12 months
3. Activity levels will be assessed using actigraphy and a time-budget measure at baseline, 6 months and 12 months
4. Overall paranoia will be measured on the Green Paranoid Thoughts Scale (GPTS) at baseline, 6 months and 12 months
5. Overall delusion severity will be assessed by the Psychotic Symptoms Rating Scale – Delusions at baseline, 6 months and 12 months
6. Suicidal Ideation will be measured using the Columbia-Suicide Severity Rating Scale at baseline, 6 months and 12 months

Added 05/03/2021:
7. Depression will be measured using the Beck Depression Inventory at baseline, 6 months and 12 months
8. Anger will be measured using the Dimensions of Anger Reactions at baseline, 6 months and 12 months
9. Verbal auditory hallucinations will be measured using items from the Specific Psychotic Experiences Questionnaire at baseline, 6 months and 12 months
10. Anhedonia will be measured using the Temporal Experience of Pleasure Scale - Anticipatory Pleasure at baseline, 6 months and 12 months
11. Quality of life will be measured using the EQ-5D-5L and Long Term Conditions Questionnaire at baseline, 6 months and 12 months

Completion date
06/07/2020

Eligibility

Key inclusion criteria
1. Aged 16 years or above
2. Participant is willing and able to give informed consent for participation in the trial
3. Persistent (at least 3 months) persecutory delusion (as defined by Freeman & Garety, 2000), held with at least 60% conviction
4. Primary diagnosis of schizophrenia spectrum psychosis (nonaffective psychosis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
130

Key exclusion criteria
1. Current receipt of another psychological therapy
2. Insufficient comprehension of English
3. Primary diagnosis of alcohol, drug, or personality disorder
4. In forensic settings
5. Organic syndrome
6. Learning disability

Date of first enrolment
01/02/2016

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Warneford Hospital
Department of Psychiatry

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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Trial outcome data will be available upon reasonable request after the publication of the main report. For requests contact Prof Daniel Freeman (daniel.freeman@psych.ox.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2021	12/07/2021	Yes	No
Protocol article	protocol	11/03/2016		Yes	No
HRA research summary			28/06/2023	No	No
Other publications		20/09/2019	30/12/2022	Yes	No