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Feeling Safer: a guided online programme for the treatment of severe paranoia

Submission date
27/02/2024

Recruitment status
Recruiting

Registration date
28/02/2024

Overall study status
Ongoing

Last Edited
09/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Persecutory delusions (inaccurate beliefs that others intend to harm you) (e.g. “MI5 and the police are trying to torture me” “My neighbours are out to get me and are spreading nasty gossip”) are very common in severe mental health disorders such as schizophrenia. People withdraw from everyday life. This seriously affects their mental and physical health.

Existing treatments often don’t work well enough. In the UK 150,000 NHS patients experience these distressing thoughts despite treatment. This is why the Feeling Safe programme has been developed. It is the outcome of 15 years of research and clinical practice. Feeling Safe was recently tested in a clinical trial with 130 patients with persistent persecutory delusions. The treatment was delivered by clinical psychologists over 20 sessions. Half of people achieved large benefits. Another quarter made moderate gains. These results provide great cause for optimism in the treatment of delusions.

The challenge now is to make Feeling Safe widely available. So, the study team have created a 6-month guided online version that users can access whenever they choose via smartphone /computer/or tablet. A range of mental health workers can support the delivery of the treatment over 6 months (both remotely and face-to-face). Six face-to-face sessions will be reserved for a key task: going out with patients into everyday situations to relearn safety. The new programme is called Feeling Safer.

By providing Feeling Safe in an accessible version for use across the NHS, the aim is to achieve substantially improved outcomes for the large number of people with persecutory delusions who have not responded sufficiently to current treatment. The study team now wish to assess the effectiveness of Feeling Safer. There is an initial cohort study of Feeling Safer, and then the main clinical trial that this trial registration confirms.

Who can participate?

Patients (aged 16 years or older) with persecutory delusions in the context of a diagnosis of psychosis attending NHS mental health services.

What does the study involve?

Participants will complete a set of questionnaires at baseline. Participants will then be randomly allocated to one of four groups. Three groups will receive Feeling Safer supported by either a peer support worker, graduate mental health worker, or CBT therapist, in addition to their usual

care. The fourth group will continue to receive their usual care. All groups will then complete another set of questionnaires after 3, 6 and 9 months. Whether a person has Feeling Safer will be randomly decided by a computer (rather like flipping a coin).

What are the possible risks and benefits of participating?
The study team hope that using Feeling Safer will help people feel safer, happier, and to be more active. The research aims to find out whether this is the case. The study team do not anticipate any major risks from taking part. People can stop using the Feeling Safer programme if they wish. If the assessments are experienced as upsetting then it is possible to reduce the number of these or stop.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
August 2023 to May 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK) (NIHR PGfAR NIHR204013)

Who is the main contact?
1. Prof. Daniel Freeman, daniel.freeman@psy.ox.ac.uk
2. Dr Laina Rosebrock, laina.rosebrock@psy.ox.ac.uk

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
330744

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 330744, CPMS 57021

Study information

Scientific Title
Feeling Safer: a cohort study and a randomised controlled trial of a guided online programme for the treatment of persecutory delusions

Study objectives
For patients with persistent persecutory delusions in the context of a psychosis diagnosis can Feeling Safer, added to treatment as usual, delivered by either peer support workers, graduate mental health workers, or CBT therapists, compared to treatment as usual, reduce persecutory delusions? The primary time-point is 6 months (post-therapy). This is the study hypothesis for the main randomised controlled trial (RCT) test of Feeling Safer.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/11/2023, London - Harrow Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048 154; harrow.rec@hra.nhs.uk), ref: 23/LO/0951

Study design
Multi-centre four-arm single-blind interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, Other therapist office, Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Psychosis with a current persecutory delusion

Interventions
Participants will be patients (aged 16 years or older) with persecutory delusions in the context of a diagnosis of psychosis attending NHS mental health services. Participants will be randomised to one of four conditions: Feeling Safer (added to standard care) supported by peer support workers, or graduate mental health workers, or CBT therapists, or standard care. Randomisation will use a permuted blocks algorithm, with randomly varying block sizes, stratified by centre.

The treatment being tested is Feeling Safer, which is a guided online programme recommended for adults (16 years or older) attending psychosis services who have a persecutory delusion. It is

a cognitive-behavioural intervention, developed from Feeling Safe, and delivery is supported by a mental health staff member. The goal of the treatment is to reduce persecutory delusions.

There is an introductory module providing information about the programme and animations of patient accounts. Patients then complete an assessment for the programme to provide the relevant treatment modules for them (e.g. improving sleep, increasing self-confidence, reducing worry) i.e. the intervention is personalised. The patient then works through each module before going on to the next relevant module. There are up to ten modules. Each module is broken down into many 10-20-minute sections for the person to complete. There are then tasks to complete offline. Throughout there are regular assessments, with information on progress fed back to the user. Information is conveyed by voice and text, animations, and videos. There is a diary reminder section. There is also a section for people when they are having a particularly difficult day and would not want to complete a section of a module. It is expected for patients to log in two or three times a week.

Regular check-ins, typically weekly, are expected with the mental health staff member. These are conducted remotely (e.g. telephone or video call). There are in-person sessions, which are typically focussed on the staff member assisting the person in getting back into everyday activities. The level of staff support can be tailored to a patient's needs. The staff-supported provision of Feeling Safer is provided over 6 months. Patients can still have access to the programme after this period but without the staff support. If a patient does not have a suitable device to access Feeling Safer then this is provided for them.

Intervention Type
Other

Primary outcome measure
Severity of persecutory delusion measured by the Psychotic Symptoms Rating Scale (PSYRATS) at baseline, 3, 6, and 9 months. The primary endpoint is 6 months.

Secondary outcome measures
1. Depression measured using Patient Health Questionnaire-9 (PHQ-9) at baseline, 6 and 9 months
2. Anxiety measured using Generalised Anxiety Disorder Assessment (GAD-7) at baseline, 6 and 9 months
3. Insomnia measured using the Insomnia Severity Index at baseline, 6 and 9 months
4. Agoraphobia measured using the Oxford Agoraphobic Avoidance Scale at baseline, 6 and 9 months
5. Paranoia measured using the Revised Green et al Paranoid Thoughts Scale at baseline, 6 and 9 months
6. Psychological well-being measured using the Warwick-Edinburgh Mental Well-being Scale at baseline, 6 and 9 months
7. Personal recovery measured using the Process of Recovery Questionnaire at baseline, 6 and 9 months
8. Meaningful activity measured using time budget at baseline, 6 and 9 months
9. Quality of life measured using EQ-5D-L and ReQol at baseline, 6 and 9 months

Overall study start date
25/08/2023

Completion date

01/05/2027

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Aged 16 years or older
3. Attending NHS mental health services for the treatment of psychosis
4. Persistent (at least 3 months) persecutory delusion (as defined by Freeman & Garety, 2000), held with at least 50% conviction
5. No planned significant medication changes at the outset of participation

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Sex
Both

Target number of participants
484

Key exclusion criteria
1. A primary diagnosis of another mental health condition (e.g. substance use disorder) that would be the first clinical priority to treat
2. Current engagement in any other intensive individual psychological therapy or a significant change in medication.
3. In forensic settings or Psychiatric Intensive Care Unit (PICU)
4. Command of spoken English inadequate for engaging in the therapy
5. Significant learning difficulties that would prevent the completion of assessments or the therapy
6. A participant may also not enter the trial if there is another factor (for example, current active suicidal plans that need to the focus of intervention), which, in the judgement of the investigator, would preclude the participant from providing informed consent or from safely engaging with the trial procedures

Date of first enrolment
25/11/2024

Date of final enrolment
31/01/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JH

Study participating centre
Berkshire Healthcare NHS Trust Headquarters
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1LH

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital
77 London Road
Kettering
United Kingdom
NN15 7PW

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
United Kingdom
NW1 3AX

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill

Bath
United Kingdom
BA1 3QE

Study participating centre
Coventry and Warwickshire Partnership NHS Trust
Wayside House
Wilsons Lane
Coventry
United Kingdom
CV6 6NY

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Pennine Care NHS Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
Tees, Esk & Wear Valley NHS Trust
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St. Nicholas Hospital
Jubilee Road
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Newcastle upon Tyne
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Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/contacts/rgea

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Publication and dissemination plan
The trial protocol will be submitted for publication before the start of the trial. The outcome results, and tests of moderation, mediation, and cost-effectiveness, will be reported in scientific journals and conference presentations.

Intention to publish date
30/11/2027

Individual participant data (IPD) sharing plan
Requests - accompanied by a study summary - for sharing of de-identified data will be considered by the Chief Investigator (daniel.freeman@psy.ox.ac.uk) and team. The intent is to share data for reasonable requests. Data will be made available to external researchers subject to the constraints of the consent under which data were collected, with an appropriate data sharing agreement, and after publication of the main study report.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		06/06/2025	09/06/2025	Yes	No