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The Feeling Heard study - evaluating a novel intervention pathway for patients distressed by hearing voices

Submission date
21/02/2022

Recruitment status
No longer recruiting

Registration date
04/03/2022

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Cognitive Behaviour Therapy (CBT) has been the psychological intervention recommended for the 'positive symptoms' of psychosis (delusions and voice hearing) for the past two decades. However, CBT has experienced two barriers to progress during this time. Firstly, CBT has only been able to generate small-medium amounts of benefit (relative to control groups) for patients, and adaptations have been unable to break through the barrier. A recent response to this barrier has been to target CBT at one psychotic symptom at a time (the 'single-symptom approach') and results have been encouraging with enhanced benefits being reported. Secondly, there has been limited access to CBT with only a minority of patients being offered treatment. The reasons for limited access include a lack of resources as CBT is typically delivered by highly trained therapists who are in short supply. Our response to this barrier has been to evaluate CBT for distressing voices when offered by briefly trained therapists, with preliminary findings offering encouragement. Having made progress regarding both patient benefit from CBT and increased access to CBT, we now wish to combine these approaches to maximise access and benefits. Additionally, we want to offer patients greater choice over the length and content of CBT.

The long-term aim of this research is to increase access to effective psychological interventions for psychosis patients who are distressed by hearing voices.

The specific aim of the proposed study is to explore the feasibility and acceptability of offering choices within a pathway of brief and targeted interventions, delivered by a wider workforce of therapists.

Who can participate?
Adults over 18 years, with a diagnosis of psychosis and experiencing voice hearing.

What does the study involve?
Participants will have a baseline assessment and a pathway of interventions offered over a maximum of 20 sessions with monthly assessments.

What are the possible benefits and risks of participating?
Possible benefits - Participants will help us to learn if CBT interventions for distressing voices are more beneficial when delivered in a sequential manner. This will help mental health services to make decisions about the interventions that should be provided for people who hear distressing voices.
Possible risks - Talking about voice hearing experiences can be helpful, though it can also sometimes feel difficult or distressing. The therapists will be trained in helping people with distressing voices and will participants to cope with any temporary increases in distress, should this occur.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to August 2023

Who is funding the study?
Economic and Social Research Council (UK)

Who is the main contact?
Prof Mark Hayward, mark.hayward@spft.nhs.uk

Study website
https://www.sussexpartnership.nhs.uk/sussex-voices-clinic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
303466

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51307, IRAS 303466

Study information

Scientific Title
Targeting distress reduction for patients experiencing distressing voices: A case series evaluating a novel intervention pathway (the Feeling Heard study)

Acronym
Feeling Heard

Study objectives
The long-term aim of this research is to increase access to effective psychological interventions for psychosis patients who are distressed by hearing voices.
The specific aim of the proposed study is to explore the feasibility and acceptability of offering choices within a pathway of brief and targeted interventions, delivered by a wider workforce of therapists.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/01/2022, North West - Preston REC (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048016; preston.rec@hra.nhs.uk), ref: 21/NW/0331

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied
Psychosis - voices

Interventions
ASSESSMENT PROCESS
Assessments will be completed by participants, as follows:
- baseline assessment
- monthly assessments during treatment (maximum of 6)
- post-treatment assessment
All assessments will be conducted by a researcher either face-to-face or remotely.

ASSESSMENT MEASURES
Our measures of feasibility for this study are as follows:
• the number of patients referred
• the number of referred patients found to be eligible
• the number of consenting participants who complete an intervention(s) and offer full data sets

Clinical measures of outcome will be as follows:
• Hamilton Program for Voices Questionnaire (HPSVQ) (Van Lieshout & Goldberg, 2007)
• Voice Impact Scale (VIS) (Strauss et al., 2021)
• Choice of Outcome In Cbt for psychosES (CHOICE) (Greenwood et al., 2009)

Clinical measures of mechanisms will be as follows:
• The Brief Core Schema Scale (BCSS; Fowler et al., 2006)
• Beliefs about voices questionnaire - revised (BAVQ-R) (Chadwick et al., 2000)
• Approve-Voices (Hayward et al., 2020)
• Approve-Social
• Five-Facet Mindfulness Questionnaire – 15 (FFMQ-15) (Gu et al., 2016)

INTERVENTION PROCESS
Following the baseline assessment, all participants will receive the GiVE intervention delivered by a briefly trained therapist. Following the completion of the GiVE intervention, an expert consultation will be offered by the CI and will facilitate the selection of the next step within the intervention pathway (either leave the pathway or Relating Therapy or Person Based Cognitive Therapy). If selected, the second intervention will be delivered by a highly trained therapists. The intervention pathway will be offered over a maximum of 20 sessions, thereby adhering to recommendations within NiCE (2014) guidance for CBT to be offered to psychosis patients over a minimum of 16 sessions.

GiVE intervention
GiVE is an 8-session intervention that follows a workbook (Hazell et al., 2018) which is based upon the Overcoming Distressing Voices self-help book (Hayward et al., 2018). Participants will be given a copy of both the workbook and the self-help book at the commencement of intervention and asked to engage in some level of self-help (homework); this will take the form of reading chapters from the self-help book between sessions and engaging with the suggested activities within the workbook. Participants in the GiVE intervention will also have the opportunity to access the 'CHOICES' mobile phone application.

After an introductory session on coping, the intervention will cover three core modules: (1) beliefs about the self, (2) beliefs about voices and (3) relationships. Modules (1) and (2) draw

upon psychoeducation and cognitive behavioural strategies to help participants to re-evaluate their negative or unhelpful beliefs related to the self and voices. Module (3) additionally involves work on how to relate to others and voices more assertively.
The GiVE intervention has generated between-groups effects sizes in the medium range (relative to treatment-asusual) for voice-related distress when delivered by by briefly trained therapists (Hayward et al., 2021).

Relating Therapy
Relating Therapy (RT) is a 16-session intervention which supports patients to respond assertively within difficult relationships with voices and other people. Therapy is conducted over three phases of:
- Phase 1: socialization to RT and its implications for the interrelating between the hearer and the voice/other people. Consideration of the typical ways of responding to negative relating. Introduction of the possibility of relating differently to voices/other people.
- Phase 2: exploration of themes within the relational history of the hearer and their experience of relationships with voices, and interpersonal relating within the family and social environment (identifying any prominent themes, such as abuse, disempowerment, or rivalry). Development of connections across all forms of relating.
- Phase 3: exploration and development of assertive approaches to relating to voices/other people. Selection of a relationship to be the focus of treatment. Exploration of a current conversation within chosen relationship, responses within this conversation, identifying responses as passive, aggressive, or assertive and the generation of assertive responses. Experiential role-plays are used extensively within this phase to explore and practice relating in an assertive manner.

RT has generated between-groups effect sizes in the large range (relative to treatment-as-usual) for voice-related distress when delivered by Clinical Psychologists (Hayward et al., 2017). As the participant would have been introduced to RT within the 'relationships' module of the GiVE intervention, RT within this study will be offered over a shorter course of 12 sessions.

Person Based Cognitive Therapy
Person Based Cognitive Therapy (PBCT) is a 12-session group intervention which draws upon cognitive behavioural strategies and mindfulness principles to facilitate acceptance of distressing voices and the re-evaluation of beliefs about self and voices.
All sessions begin with mindfulness practice and discussion. Mindfulness practice in PBCT is brief (10 min) with frequent guidance that includes reference to voice hearing experiences and combines focussed attention on body and breath with open awareness. Sessions 1–3 socratically draw out participants' voice hearing experiences (onset, impact, meaning, distress and coping) and frame them using the ABC cognitive model. Sessions 4–6 explore personal control, socratically weakening voice omnipotence and enhancing autonomy. Sessions 7–12 add focus on identifying and decentring from negative schemata, and building positive schematic beliefs (including using experiential two chairwork) alongside recognition that the self is complex and changing. Participants are encouraged to practice mindfulness daily at home, using a supplied 10 min recording.
PBCT has generated between-groups effect sizes in the medium range (relative to treatment-as-usual) for voice related distress when delivered by Clinical Psychologists (Chadwick et al., 2016). A group intervention is not ideal for a pathway of interventions, as participants may be kept waiting for other participants to be ready to commence the group.
Consequently, PBCT will be offered individually over 12 sessions within this study.

Therapy sessions will be conducted either face-to-face (at a mental health centre) or remotely (by phone or videocall) in order to respect both patient choice and any restrictions imposed due

to the COVID-19 pandemic.
All participants will be encouraged to engage in and continue with existing treatments throughout the duration of the study.

TRAINING AND SUPERVISION OF THERAPISTS
All intervention sessions will be delivered by therapists from SVC. The briefly trained therapists have been previously trained in the delivery of the GiVE intervention by the CI. They will receive weekly supervision from the CI during the study. The highly trained therapists (including the CI) have extensive experience of delivering all the study interventions. They will offer each other weekly peer supervision during the study

Intervention Type
Behavioural

Primary outcome measure
Voice-related distress will be measured using the Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) at baseline, monthly during interventions and post-intervention

Secondary outcome measures
1. The impact of voices will be measured by the Voice Impact Scale (VIS) at baseline, monthly during interventions and post-intervention
2. Recovery will be measured by the Choice of Outcome in CBT for Psychoses (CHOICE) at baseline, monthly during interventions and post-intervention
3. Negative Core Schema will be measured by the Brief Core Schema Scale (BCSS) at baseline, monthly during interventions and post-intervention
4. Beliefs about voices will be measured by the Beliefs About Voices Questionnaire-Revised (BAVQ-R) at baseline, monthly during interventions and post-intervention
5. Relating to voices will be measured by the Approve-Voices measure at baseline, monthly during interventions and post-intervention
6. Relating to other people will be measured by the Approve-Social measure at baseline, monthly during interventions and post-intervention
7. Mindfulness will be measured by the Five-Facet Mindfulness Questionnaire (FFMQ-15) at baseline, monthly during interventions and post-intervention

Overall study start date
01/10/2021

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. 18 years or older
2. Under the care of secondary care adult services within SPFT
3. Have a clinician-reported diagnosis of psychosis
4. Are experiencing current voice hearing; this will be operationalized by participants having a score of at least 1 on item 1 (How frequently did you hear a voice or voices?) on the Hamilton Program for Schizophrenic Voices Questionnaire (HPSVQ; Van Lieshout & Goldberg, 2007) - indicating that the participant has experienced at least one episode of voice hearing in the past week

5. Distressed by hearing voices; this will be operationalized by participants scoring at least 8 out of 16 on the 'negative impact' scale of the HPSVQ
6. Willing and able to provide written/verbal, informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 14; UK Sample Size: 14

Total final enrolment
14

Key exclusion criteria
1. Established organic cause for distressing voices (e.g., brain disease or injury)
2. Primary diagnosis of substance misuse
3. Non-English speaking to the degree that the participant is unable to fully understand and answer assessment questions or give informed consent

Date of first enrolment
01/02/2022

Date of final enrolment
04/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Headquarters
Arundel Road
Worthing
United Kingdom
BN13 3EP

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.sussexpartnership.nhs.uk/

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Submission for publication in a peer reviewed academic journal, dissemination to participants and patient organizations, and presentations at patient events and at local, national and international conferences.

Intention to publish date
31/01/2024

Individual participant data (IPD) sharing plan
An anonymised dataset will be deposited within the University of Sussex Research Repository to facilitate open access for other researchers.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	03/01/2022	04/03/2022	No	Yes
HRA research summary			28/06/2023	No	No
Results article		30/05/2024	04/06/2024	Yes	No