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Relating differently to voice-hearing experiences in the context of anorexia

Submission date
19/12/2022

Recruitment status
No longer recruiting

Registration date
30/12/2022

Overall study status
Completed

Last Edited
09/08/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anorexia Nervosa (AN) can have a serious and severe impact on individuals and those around them. Recommended psychological interventions are typically not found to be helpful by people with AN who often have difficulties for a long time, and have regular periods of relapse. Due to this, there have been calls for new therapeutic approaches. Research suggests that voice-hearing experiences are common in those with AN and that over time, a relationship is formed with what is often called the “Anorexic Voice” (AV) or the “Eating Disorder Voice” (EDV). Individuals’ beliefs about and ways of relating to their AV may be a factor in the development and maintenance of AN. Our research aims to explore the potential for a targeted psychological therapy called Relating Therapy to reduce the distress associated with voice-hearing experiences within the context of AN. Relating Therapy targets the negative relating that can maintain voice-related distress and teaches assertiveness as an alternative response.

Who can participate?
Adult patients with AN who have reported distressing experiences with an AV

What does the study involve?
All participants will be offered Relating Therapy over a period of 24 weeks. Participants will be asked to complete different questionnaires before, during and after receiving the intervention to help us better understand the impact of receiving this therapy

What are the possible benefits and risks of participating?
Although the therapy being evaluated within this study has been found to be acceptable and effective for people with different mental health problems, it has only been delivered to a small number of people with AN before. For this reason, we do not know whether it will be helpful for people with AN. Participants will help us to learn if Relating Therapy will be helpful to people with AN, and this will help mental health services when they are planning what therapies they offer. Participants may find that talking about the AV can be helpful, though it can also sometimes feel difficult or distressing. The therapists will be trained in the treatment of AN and distressing AVs and will help participants 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?
November 2022 to April 2024

Who is funding the study?
1. Canterbury Christ Church University (UK)
2. Economic and Social Research Council (ESRC) (UK)

Who is the main contact?
Professor Mark Hayward, mark.hayward@spft.ac.uk

Study website
https://www.sussexpartnership.nhs.uk/our-research/mental-health-dementia-research/research-clinics/sussex-voices-clinic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318551

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54411, IRAS 318551

Study information

Scientific Title
Relating therapy for the anorexic voice: exploratory case series (R2AV)

Acronym
R2AV

Study objectives
Primary objective - exploring the feasibility and acceptability of relating therapy to clinicians and clients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2022, South Central - Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8253, (0)207 104 8276, (0)207 104 8276; berkshireb.rec@hra.nhs.uk), ref: 22/SC/0413

Study design
Non-randomized case series

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Eating disorders - anorexia

Interventions
The intervention will be guided by the protocol and consist of a maximum of 24 weekly sessions of individual Relating Therapy. The therapy protocol consists of three phases:
Phase 1 - socialization to Relating Theory and its implications for the inter-relating 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 - an 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 a 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. With the extension of the therapy to 24 sessions, the later sessions (approx. last 8 sessions) will focus on building on the changing relationship with the voice and applying this to changing eating behaviours.
Treatment-as-usual
All participants will be encouraged to engage in and continue with existing treatments throughout the duration of the study.
Training and supervision of therapists
Three clinical psychologists, an individual from each participating NHS site, will be trained in relating therapy, and supervision provided by Dr Matthew Pugh who has experience in providing relating therapy to this client group.

Intervention Type
Behavioural

Primary outcome measure
The feasibility and acceptability of Relating Therapy to clinicians and clients will be assessed using the following outcomes at the end of the study:
1. The number of clients referred
2. The proportion of referred clients found to be eligible
3. The proportion of consenting participants who are retained within the study and offer full datasets
4. The proportion of non-missing items for each variable
5. The proportion of consenting participants who reach the point of therapy ‘exposure’ (attend at least 16 therapy sessions)

Secondary outcome measures
Measures (quantitative): During the baseline phase, assessment data will be collected weekly and consist of three timepoints. During the intervention phase, the personal analogue measures and weight will continue to be collected weekly, and the remaining outcome measures will be collected at 4-week intervals. All assessment data will then be collected at the post-intervention timepoint and a further 4-week interval for the follow-up timepoint.
1. Disordered eating over a period of 28 days measured using the Eating Disorder Examination Questionnaire Short (EDE-QS)
2. Weight and BMI measured using calibrated weighing scales at the start of appointments. Participants' weight (kg) and height (cm) will be used to calculate Body Mass Index (BMI)
3. Hamilton Program for Voices Questionnaire (HPSVQ) - 1 item will be used from the 4-item ‘negative impact of voices’ subscale during the screening meeting
4. Frequency of depression symptoms measured using the Patient Health Questionnaire (PHQ-9)
5. Frequency of generalized anxiety symptoms measured using Generalised Anxiety Disorder Questionnaire (GAD-7)
6. Relationship between the AV and the self, measured using the Experience of an Anorexic

VoicE Questionnaire (EAVE-Q)
7. Assertive and non-assertive (passive and aggressive) relating to voices and other people; named Approve-Voices and Approve-Social respectively, measured using The Approve Questionnaires
8. Power differential that exists between the client and the voice(s) they hear, measured using the Voice Power Differential Scale
9. Personal analogue measure of distress caused by the AV, measured using a Personalised Analogue Measures Likert scale weekly during baseline and intervention phases.
10. A personal analogue measure of achievement of an identified personal goal of therapy, measured using the CHOICE questionnaire

Measures (qualitative):
Qualitative data will be generated using the Change Interview to guide discussions at the exit interview at the end of treatment

Overall study start date
01/11/2022

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Receiving care from a specialised eating disorder service (outpatients)
3. Following permission gained from the participant, a clinician-reported primary diagnosis of anorexia nervosa
4. BMI of 18.5 or less
5. Currently having experiences of the Anorexic Voice (AV); this will be operationalized by participants self-reporting at least one experience of voice-hearing within the previous week using an adapted item from the Hamilton Program for Voices Questionnaire (HPSVQ)
6. Self-reported distress by AV; this will be operationalized by participants scoring greater than or equal to 5 on the personal analogue measure of distress caused by the AV.
7. Be willing and have the capacity to provide written, informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Total final enrolment
9

Key exclusion criteria
1. Following permission gained from the participant, a clinician-reported active diagnosis for an eating disorder other than anorexia nervosa
2. Following permission gained from the participant, a clinician-reported active diagnosis of psychosis
3. Non-English speaking to the degree that the participant is unable to fully understand and answer assessment questions or give informed consent*
4. Immediate and serious risk to self or others where alternative interventions would take priority over participating in the research study (e.g being detained under the mental health act, requiring admission to hospital for refeeding)

* Funding for translation services is not available but efforts will be made where possible to use translation services from clinical resources available at the participating NHS trust services.

Date of first enrolment
19/12/2022

Date of final enrolment
19/07/2023

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

Sponsor details
Research & Development Department
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United Kingdom
BN3 7HZ
+44 (0)3003040088
researchgovernance@sussexpartnership.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Funder Name
Canterbury Christ Church University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No