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Acceptability of the Specialist Psychotherapy with Emotion for Anorexia in Kent and Sussex psychological therapy for adults with anorexia nervosa: The SPEAKS study

Submission date
28/11/2019

Recruitment status
No longer recruiting

Registration date
20/01/2020

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anorexia nervosa (AN) is an eating disorder that causes people to lose weight and keep themselves at a very low weight by dieting, vomiting, using laxatives or excessively exercising. It affects up to 4 in 100 people at some point in their lifetime and has the highest death rate of any mental illness. People with AN currently have a high risk of long-lasting illness. This condition is associated with high costs for both the person with AN and their family in terms of burden and suffering, as well as financially to the NHS and wider economy. NICE guidelines recommend psychotherapies (talking therapies) for adults with AN; but there is a low rate of cure and effective management. No one treatment has been shown to be better than the others. Based on research and interviews with people with anorexia nervosa, the researchers propose that difficulty with experiencing emotion is a factor that promotes the development and continuation of anorexia nervosa. It is likely that targeting unique factors associated with AN and developing innovative therapies would improve treatment options.
The researchers have designed a psychotherapy that targets difficulties in emotional experience and regulation for adults with AN. The therapy is called SPEAKS (Specialist Psychotherapy with Emotion for Anorexia in Kent and Sussex). This study will investigate the effects of SPEAKS in people with AN and similar eating disorders. It is part of a programme of research to develop and test a psychotherapy for AN.

Who can participate?
Adults with AN or an AN-type eating disorder who are not extremely underweight or losing weight very rapidly.

What does the study involve?
People who are interested in participating in the research will be contacted by a research worker who works for the Kent All Age Eating Disorder Service. The research worker will answer any questions they may have about the research and their potential involvement in it. If someone is interested in taking part, the research worker will arrange to meet with them to discuss further,

and if they want to continue then the research worker will ask them to sign a consent form and complete some questionnaires. After this the participant will be allocated a SPEAKS therapist who will contact them to arrange the first appointment to begin the new SPEAKS therapy.
The SPEAKS therapy will involve meeting with a psychologist weekly for around a year to focus on difficulties with emotion. With the participant's permission, the researchers will record the therapy sessions (either audio or video). The purpose of this is to monitor what the therapist is doing and check that they are following the study guidelines and delivering therapy in accordance with the intervention guidebook. The video recordings will be reviewed during routine supervision by a senior member of the care team with the therapist. Whether or not the participant consents to video recordings, the participant's identity will be known by the supervisor as part of the care team responsible for your treatment. A person can consent to participate in the study without agreeing to have their therapy sessions recorded. Even if they do consent to these recordings, the therapist will always ask again at the start of each session and the participant is free to say no without it affecting their session that week or any of their care in the future. If the researchers wanted to use taped therapy sessions for future research, they would come back and ask participants if they would be willing for this to happen, but there would be no obligation to agree and it would not affect their participation in the current project.
After 3 months, 6 months and 9 months, participants will be asked to complete the questionnaires again at an agreed time with the research worker. None of the questionnaires completed at any point during the study will have the participant's name or any other identifying information on them; they will all be anonymous.
At the end of the 12 months, there will be further questionnaires and also a qualitative interview so the researchers can gain more detailed feedback about the participants' experience of the SPEAKS therapy. The interview will be recorded over a video call and this will be transcribed (typed up) word for word. This is to help therapists better remember everything that has been talked about. During the transcription process any identifying information will be removed and the video recordings will be destroyed after transcription.
Due to the coronavirus pandemic, SPEAKS therapy sessions were moved to delivery via an online video platform and some SPEAKS participants experienced a delay or break in their SPEAKS therapy. In order to ensure that all participants are able to access the full 9-12 months of therapy intended, therapy will be extended for those impacted by a maximum of 3 months. Where relevant, this will be discussed and agreed between therapist and participant. In order to capture end of therapy data for those affected, we will include an extra data collection timepoint at 15 months just for these participants. This data will be analysed by the research study team, which includes the research worker and clinical psychology trainees.

What are the possible benefits and risks of participating?
Participants may find that they benefit from the new SPEAKS intervention. It is very different from other currently available treatments in the field of eating disorders and therefore will be a new treatment approach they have not tried before in tackling their anorexia. Their participation will also contribute to the further development and refinement of the SPEAKS therapy which may mean that those with anorexia will benefit in the future.
Therapy is a difficult process that can involve discussion of some upsetting topics. In this respect the disadvantages and risks of taking part are no different from completing any psychological therapy. As psychological therapy is in the NICE guidelines as front line treatment for adults with anorexia then talking therapy is what patients should be offered at their eating disorder service. As the SPEAKS therapy is a new intervention, however, it is unclear how much or how quickly it will help to participants to make changes. Yet, as with the provision of all psychological therapies in eating disorder services, attention will continue to be paid to any physical and psychological risk throughout their therapy. All research and therapy staff are trained to

monitor participants' safety and will follow reporting guidelines as necessary. If at any point it is considered that a change to their treatment plan is required, then this and their welfare will always be prioritised above the research.

Where is the study run from?
North East London NHS Foundation Trust (NELFT) All Age Eating Disorder Service (UK)

When is the study starting and how long is it expected to run for?
June 2019 to March 2022

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

Who is the main contact?
Dr Anna Oldershaw, SPEAKS@canterbury.ac.uk

Study website
https://www.nelft.nhs.uk/research-nelft-sponsored-studies/

Contact information

Type(s)
Public

Contact name
Dr Anna Oldershaw

ORCID ID
http://orcid.org/0000-0002-9473-5715

Contact details
NELFT All Age Eating Disorder Service
The Courtyard
Pudding Lane
Maidstone
United Kingdom
ME14 1PA
+44 (0)300 300 1980
annaoldershaw@hotmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269047

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 269047, CPMS 43351

Study information

Scientific Title
The Specialist Psychotherapy with Emotion for Anorexia in Kent and Sussex (SPEAKS) feasibility trial

Acronym
SPEAKS

Study objectives
Current hypothesis as of 09/11/2020:
This is a feasibility study to assess the SPEAKS psychological therapy with regards to validity and acceptability, reach and recruitment, adherence and compliance, and sample size and economic estimations. In addition, it aims to examine the emotional and narrative change processes hypothesised to be facilitated by the SPEAKS intervention.

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Previous hypothesis:
This is a feasibility study to assess the SPEAKS psychological therapy with regards to validity and acceptability, reach and recruitment, adherence and compliance, and sample size and economic estimations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2019, London-Bromley NRES committee (no postal address; +44 (0)207 104 8063; nrescommittee.london-bromley@nhs.net), ref: 19/LO/1530

Study design
Single-arm non-randomized feasibility study

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Anorexia nervosa or otherwise specified feeding or eating disorder (OSFED)-AN type.

Interventions
The study is a single arm feasibility study. All participants will receive the SPEAKS intervention instead of treatment as usual. SPEAKS is a weekly psychotherapy for 1 year. It focuses on working with emotion and increasing an client's understanding of themselves using an integration of psychotherapeutic modalities, but chiefly incorporating emotion-focused therapy and schema therapy. Participants are assessed pre- and post-therapy and at 3-month intervals during treatment. There is no follow-up period..

Intervention Type
Behavioural

Primary outcome measure
1. BMI calculated from measurements of height and weight taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
2. Eating disorder symptoms and behaviours assessed using the Eating Disorder Examination questionnaire at at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention

Secondary outcome measures
Current secondary outcome measures as of 01/12/2021:
1. Depression assessed using the 21-item Depression Anxiety Stress Scales (DASS-21) questionnaire taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
2. Anxiety assessed using the 21-item Depression Anxiety Stress Scales (DASS-21) questionnaire taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
3. Stress assessed using the 21-item Depression Anxiety Stress Scales (DASS-21) questionnaire taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
4. Impact of eating disorder symptoms and behaviours on quality of life assessed using the Clinical Impairment Assessment (CIA) questionnaire taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
5. Behaviour about the importance of emotions in their lives and how they should be managed assessed using the Beliefs about Emotions Scale questionnaire taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
6. Presence of particular schema assessed using the Young Schema Questionnaire taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
7. Identification of schemas in relation to eating disorder symptoms using the Schema Mode Inventory for Eating Disorders taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
8. Tendency to suppress their own emotions and to prioritise those of others assessed using the Silencing the Self Scale taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
9. Amount of agency participants feel they have in their lives assessed using the Sense of Agency Scale taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention
10. Ability to manage and regulate emotions assessed using the Difficulties with Emotion Regulation Scale (DERS) taken at pre-intervention, at 3, 6 and 9 months into the intervention and

post-intervention
11. Measures of adherence and compliance with the trial and the intervention protocol assessed using comparison of therapist-recorded session content and recorded therapy sessions against the SPEAKS guidebook throughout the intervention
12. Measures of reach and recruitment into the trial including measuring numbers of participants approached and those agreeing or declining participation during the recruitment period
13. Measures of validity and acceptability assessed using a Likert scale questionnaire (taken at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention) and semi-structured interviews of participant and therapists experience of SPEAKS post-therapy and visual analogue scales (VAS) of acceptability and of perceived value of core SPEAKS components completed every 3 months
14. Measures of economic evaluation: an adapted version of the Client Socio-demographic and Services Receipt Inventory is used to collect economic data pre-intervention, at 6 months into the intervention and post-intervention to assess the costs of treatment received in the 6 months before the intervention and during it
15. Assessment of SPEAKS emotional change process during therapy measured by applying the Classification of Affective Meaning States to video-recorded therapy sessions at around 3, 6 and 9 months into the intervention
16. Assessment of SPEAKS narrative and behavioural change measured by applying the Innovative Moments Coding System to video-recorded therapy sessions at around 3, 6 and 9 months into the intervention and through qualitative analysis of co-produced psychological formulations

Previous secondary outcome measures:
1. Depression assessed using the 21-item Depression Anxiety Stress Scales (DASS-21) questionnaire
2. Anxiety assessed using the 21-item Depression Anxiety Stress Scales (DASS-21) questionnaire
3. Impact of eating disorder symptoms and behaviours on quality of life assessed using the Clinical Impairment Assessment (CIA) questionnaire
4. Behaviour about the importance of emotions in their lives and how they should be managed assessed using the Beliefs about Emotions Scale questionnaire
5. Presence of particular schema assessed using the Young Schema Questionnaire
6. Tendency to suppress their own emotions and to prioritise those of others assessed using the Silencing the Self Scale
7. Amount of agency participants feel they have in their lives assessed using the Sense of Agency Scale
8. Ability to manage and regulate emotions assessed using the Difficulties with Emotion Regulation Scale (DERS)
All data will be collected at pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention.

Overall study start date
01/07/2019

Completion date
31/03/2022

Eligibility

Key inclusion criteria

1. Referred into the All Age Eating Disorder Service in Kent or Sussex Eating Disorder Services and meet criteria for the service (i.e. they are registered with a GP in the catchment area)
2. At assessment, meet the Diagnostic and Statistical Manual V (DSM V) criteria for anorexia nervosa or OSFED (other specified feeding or eating Disorder) of anorexic type
3. Aged 18 years or above
4. BMI >15 kg/m2 and currently stable in weight (i.e. not dropping more than 0.5 kg a week)
5. Have sufficient English language abilities to complete a talking therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36 people completing treatment

Total final enrolment
46

Key exclusion criteria
1. Presenting with considerable physical risk or psychological risk, including active suicidal thoughts and plans
2. Comorbidity that would take priority for treatment
3. Alcohol/substance dependency
4. Participating in another treatment trial
5. Have a learning disability
6. Pregnant
7. Severely ill referrals with BMI <15 kg/m2 or other severe medical risks (indicated by blood pressure, muscle strength and blood chemistry)

Date of first enrolment
12/12/2019

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NELFT Kent All Age Eating Disorder Service
The Courtyard
Pudding Lane
Maidstone
United Kingdom
ME14 1PA

Study participating centre
Sussex Eating Disorder Service
East Brighton Community Mental Health Centre
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Sponsor information

Organisation
North East London Foundation Trust

Sponsor details
Research and Development Department
1st Floor, Maggie Lilley Suite
Goodmayes Hospital
Barley Lane
Ilford
England
United Kingdom
IG3 8XJ
+44 (0)300 555 1200
Fiona.Horton@NELFT.nhs.uk

Sponsor type
Hospital/treatment centre

Website
www.NELFT.nhs.uk

ROR
https://ror.org/023e5m798

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

Publication and dissemination plan
All of our findings will be communicated to policy makers within the NHS and to people with anorexia, their families and therapists via NHS and university communications, and via local support and charity groups before the end of 31/03/2022. Findings will also be disseminated within the clinical psychology and eating disorder fields via journal publications and international conference presentations. We aim to submit our finding in the form of journal articles to open access journals.

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.0	23/08/2019	20/01/2020	No	No
Protocol file	version v3.0	30/08/2020	23/10/2020	No	No

HRA research summary			28/06/2023	No	No
Results article	Acceptability results	22/01/2024	30/01/2024	Yes	No
Results article	Feasibility trial results	10/10/2023	30/01/2024	Yes	No
Other publications	Interviews	13/01/2025	20/01/2025	Yes	No