Specialist Psychotherapy with Emotion for Anorexia in Kent and Sussex

RESEARCH PROTOCOL

Purpose

Anorexia nervosa (AN) is a severe mental illness with poor prognosis and the highest mortality rate of any psychiatric disorder. It is associated with high costs for both the person with AN and their families in terms of burden and suffering, as well as financially to the NHS and economy. NICE guidelines recommend psychotherapeutic interventions for adults with AN; yet outcomes are discouraging. No intervention is shown to be superior to a non-specific clinical control. Effect sizes of change following therapy are small to nil. Highlighting and targeting unique factors involved in the development and maintenance of AN is considered essential (Kass et al., 2013) and innovation in developing future effective therapies is urgently required (Bulik, 2014; NICE, 2004; Startup et al., 2015).

Even from the earliest descriptions of AN, emotional experience has been recognised as a factor in its development and maintenance. The most recently developed psychotherapy interventions recognise the importance of emotional difficulties to the development and maintenance of AN (Carter et al., 2011; Fairburn et al., 2015; Schmidt et al., 2012; Zipfel et al., 2014). However, outcomes remain limited; thus, there appears to be a discrepancy between empirical data findings and their application in clinical practice.

The present research comprises part of the SPEAKS programme (Specialist Psychotherapy with Emotion for Anorexia in Kent & Sussex) which aims to develop and test in a feasibility study an emotion focused intervention for adults with anorexia. It seeks to overcome some of the proposed difficulties with previously developed interventions. Partnering with stakeholders to develop and evaluate evidence-based interventions for adults with AN is critical (Kass et al., 2013) and consistent with MRC guidance (Craig et al., 2008). The aim of the present study is to employ a feasibility trial to investigate the intervention which has developed through the integration of empirical evidence with qualitative research and Patient and Public Involvement (PPI). This single-arm feasibility study of SPEAKS will assess:

- Validity and acceptability
- Reach and recruitment
- Adherence and compliance
- Sample size estimation
- Economic evaluation

The SPEAKS research programme is being completed in collaboration between North East London Foundation Trust, Sussex Partnership Foundation Trust, and Canterbury Christ Church University. It is funded by the National Institute of Health Research.

Design & Participants

The feasibility study will be a single armed within-group mixed-methods design. Clinical and intervention-specific measures will be completed pre- and post-intervention; qualitative interviews post-intervention. This design has been selected because, as outlined in the introduction, a focus on intervention development and refinement before large efficacy evaluations is crucial. Furthermore, as there is no 'treatment as usual' for adult outpatients with AN, completing an RCT is a significant undertaking. Most recent RCTs investigating outpatient psychological interventions for adults with AN use a standardised controlled intervention called Specialist Supportive Clinical Management (SSCM; McIntosh et al., 2006). At this stage of SPEAKS development, conducting a larger trial which involves training clinicians in two models is perceived as presumptuous and potentially an unnecessary expense.

Participants. Consecutive referrals to specialist outpatient ED services at KMPT and SPFT from primary care or community mental health teams will be assessed for inclusion and exclusion criteria.

Inclusion/exclusion criteria.

Service users are eligible to participate in the study if they:
(1) Are 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 they meet the Diagnostic and Statistical Manual V Criteria for Anorexia Nervosa or OSFED (Other Specified Feeding or Eating Disorder) of Anorexic type.
(3) Are aged 18 or above
(4) Have BMI of >15kg/m^2 or above and are currently stable in weight (i.e. not dropping more than 0.5kgs a week)
(5) Have sufficient English language abilities to complete a talking therapy

Service users are excluded from the research if they:
(1) Present with considerable physical risk or psychological risk, including active suicidal thoughts and plans.
(2) Have a comorbidity that would take priority for treatment.
(3) Have alcohol/substance dependency.
(4) Are participating in another treatment trial
(5) learning disabilities
(6) pregnancy
As indicated, because this is a feasibility study, the most severely ill referrals with BMI<15 or other severe medical risks (indicated by blood pressure, muscle strength and blood chemistry) will be excluded.

Sample size. The feasibility design precludes formal sample size calculation. Sample sizes must balance precision with unethical exposure of participants to the risks being monitored and unnecessary expense (Billingham, Whitehead & Julius, 2013). Teare et al., (2014) recommend 35

participants for sufficient feasibility data and precision of mean and variance. A sample size of 36 (40% attrition) has two-sided 80% confidence interval with a width equal to 0.411, when the standard deviation is 1.3 (standard deviation for BMI following MANTRA; Schmidt et al., 2012). Therapy attrition rates for people with AN can reach 40% (De Jong, Broadbent & Schmidt, 2012). These data suggest an approximate revised sample size of 60 participants.

Procedure and setting. Clinicians will identify all new referrals meeting criteria at assessment, provide them with an information sheet and ask if the researcher can contact them. The researcher will make contact within seven days. The potential participant will have at least 48 hours to consider and will know they may decline or withdraw consent at any point without providing reasons or affecting subsequent care. If willing to proceed, written informed consent and baseline measures will be obtained without causing treatment delay.
The researcher will maintain engagement of participants throughout the study with regular newsletters and individual letters. These engagement techniques have been used by the CI when running previous trials with this population and resulted in high levels of research follow-up rates.

Intervention. SPEAKS is an individual outpatient psychotherapy for adults with AN of approximately 12 month's duration. Participants will receive weekly individual sessions of psychotherapy for 9-12 months with two follow-up sessions within 3 months of completing therapy.

SPEAKS will be offered as direct replacement for psychotherapy as usual. Clinicians are clinical psychologists qualified to offer individual psychotherapeutic interventions employed by NELFT or SPFT ED services, with at least three year's experience of working with EDs. Therapists will receive weekly supervision by supervisors who will be trained in the supervision requirements of SPEAKS. All other usual care procedures (e.g. dietician appointments; carer's workshops) will remain, but be logged. All usual service protocols in terms of accessing additional care such as inpatient treatment will remain in place as per local and national guidance. People requiring immediate inpatient treatment at any point will be removed from the trial as applicable, but data around this will be reported.

Measures.
Validity and acceptability. Triangulation of qualitative and quantitative data will address acceptability and validity of SPEAKS to participants, therapists and supervisors.
Qualitative data. Participant's, therapist's and supervisor's lived experience of SPEAKS, its ability to address emotion regulation difficulties and its perceived validity and acceptability will be examined using post-intervention semi-structured interviews completed by the researcher. Qualitative interviews will be undertaken with all therapists and participants.
Topic guides will include:

(1) *Validity and clinical value of SPEAKS*, including perceived change; perceived impact on emotion difficulties and self-efficacy; valued psychotherapeutic targets and techniques; any unhelpful or unnecessary elements; impact on therapists; effectiveness of supervision in identifying and managing personal factors and intervention implementation; participant experiences of therapists. Specific questions will clarify any remaining ambiguity in the model.

(2) *Acceptability of SPEAKS* to participants, clinicians, and supervisors, including ease of integration into services, acceptability of a future RCT of SPEAKS including design, such as willingness to be randomised, selected measures.

Quantitative data.
Validity and clinical value of SPEAKS will be assessed using quantitative variables examining clinical and emotion regulation change collected pre-intervention, at 3, 6 and 9 months into the intervention and post-intervention. Collecting questionnaire data every three months is already standard practice in the NELFT Eating Disorder Service. These measures will include the following:
Clinical outcomes measures. *BMI* (kg/m2); *Eating Disorder Examination Schedule* (EDE; Fairburn et al., 2008); *Depression Anxiety Stress Scales 21* (Henry & Crawford, 2005)*;* and *Clinical Impairment Assessment (CIA; Bohn et al., 2008)*.
Intervention-specific measures. *Beliefs About Emotions Questionnaire* (Manser, Cooper & Trefusis, 2012), *Young's Schema Questionnaire* (Young et al., 1994), *Silencing the Self Scale* (Jack, 2017), *The Sense of Agency Scale (Tapal et al., 2017);* and *Difficulties with Emotion Regulation Scale* (Gratz & Roemer, 2004).

Acceptability of SPEAKS will be quantitatively assessed using visual analogue scales (VAS) of acceptability and of perceived value of core SPEAKS components. Participants will rate this pre-intervention, at 3, 6, and 9 months and post-intervention.

Reach and recruitment. Assessing clinicians will complete and return a checklist to researchers. Standardising this practice will help to embed into the service that everybody is approached. Where participation into the study is declined, this will include recording a reason for declining where provided (in this case data will be anonymised). This practice will enable recording of numbers and socio-demographic/clinical variables of participants approached and those agreeing or declining participation. Completeness of measures at each time-point will be recorded and reported.

Adherence and compliance. Treatment fidelity strategies will be employed consistent with the treatment fidelity checklist (Borelli et al., 2005), including a clear intervention description (guide-book) and standardised training for therapists. Assessment of adherence to SPEAKS therapy will be assessed via session recordings, where consented to by participants. It will also include assessing data regarding length of treatment, number of sessions and session content. Additional care received or breaking of study protocol will also be monitored. The researcher will review routine data entered into electronic service user notes and record these variables anonymously using specially developed record sheets. Using checklists of critical elements, therapists will anonymously self-monitor fidelity and supervisors will rate their perception of therapist's model adherence after each clinical/supervision session, which will include review of session tapes.

Sample size estimation. Primary outcome measures of BMI and EDE will be used for sample size estimation.

Economic evaluation. An adapted version of the Client Socio-demographic and Services Receipt Inventory (CSSRI, see 3.2.3) will be used to collect economic data pre- and post-intervention to assess the costs of treatment received in the six months before the intervention and during it. Cost

items including inpatient and outpatient costs, drug costs, equipment and staff costs will be assessed, as well as broader costs such as such as costs to carers and productivity loss as a consequence of AN.

Consent

The assessing clinician will give a participant information sheet to eligible referrals who are willing to hear more about the study. Informed consent will be obtained at a face to face meeting with the researcher worker. The meeting will take place at least 48 hours after the participant has been provided with the study Information Sheet, with additional time given as necessary. The study does involve recruiting participants who present with psychological and medical risk, therefore, the research worker will liaise with relevant clinicians to ensure they are aware to adjust the approach if necessary (for example, adjusting the pace at which the trial is explained, giving breaks during the meeting, and making additional efforts to assess a person's understanding). The research worker (like all other clinical staff members) will be trained in the principles of mental capacity and will hold this in mind throughout. Obtaining consent will be a focus of supervision for the research worker.

Before informed consent is given, the research worker will offer to answer any questions the potential participant may have. They will then review the information sheet with the participant, highlighting key aspects and checking the patient's understanding of what their involvement in the study will entail. The research worker will explicitly state and make clear that a decision not to participate in the study will not affect the patient's care in any way. Also, that if they decide to take part they can change their mind at any time without affecting their current or future care.

All researchers involved in this study are trained in the principles of the Mental Capacity Act (2005). If a researcher has concerns about a participant's capacity at any stage a mental capacity assessment will be completed. If the individual does not appear to have capacity to consent to the study they will not be invited to continue with the research. If a participant loses capacity to consent to participate once the study is underway, they and their associated data will be withdrawn from the study. Their data will be shredded via NELFT/SPFT confidential shredding system. A note would be appended to the participant's consent form to say that this has happened. Both the participant information sheets and the consent form explicitly state that the research is entirely voluntary and a decision to withdraw, or a decision not to participate, can be made at any time until data analysis begins, and this will not affect their care. Once data analysis has begun it will be too difficult to identify and extract individual participant data.

Ethical Considerations

The trial participants are suffering from anorexia nervosa and receiving medical care. The risks of the study are that people will be having a therapy previously untested. Therefore the potential benefits of the therapy are unknown. However, the therapeutic models employed within the SPEAKS therapy have been found to be beneficial for other complex psychological disorders (e.g. Bamelis, et al., (2014). Furthermore, SPEAKS has been developed based on extensive empirical and qualitative research data; therefore, it is grounded in the evidence base for anorexia nervosa.

It is essential to minimise risk that participants will be treated within established ED services with access to all the same medical and multidisciplinary team support as they would be when

accessing any other treatment within the service. All physical health checks will remain the same as if they were receiving treatment as usual. If a person's health deteriorates such that blood results indicate they require hospital treatment or their BMI becomes low or unstable (e.g. weight loss of >1kg/week for four consecutive weeks) then inpatient care will be considered and accessed as per usual procedure. Following discharge from hospital back to outpatient care, the multidisciplinary team (MDT) will consider what is the most appropriate treatment and whether continuing with SPEAKS will be beneficial. This is standard practise for people who have an inpatient admission during treatment. SPEAKS sessions will all be held on Trust property with senior and medical staff available to assist clinicians if required, as standard.

The inclusion and exclusion criteria have been carefully considered and agreed with the MDTs across both eating disorders services involved in the study and with the Research Steering Group which includes people with a history of anorexia. They have been designed to ensure that a representative sample of people can be recruited into the study, but also mindful of risk to ensure that the most ill people will not be included (e.g. excluding people with BMI<15).

In addition to the considerations of the SPEAKS treatment, we have also given consideration n to other aspects of the research protocol and taken the following steps:
- We have kept the number and duration of research interviews/questionnaire to a minimum.
- We will use measures that are commonly used in eating disorders research so are tried and tested. We will also ask our PPI members of the research steering group for their feedback on the suitability of measures and the interview questions.
- We will aim to conduct research interviews at a time convenient to the participant and wherever possible will seek to tie it in with a time they will already be attending the service to minimise their travel/time commitment.

Data Analysis

The data will be analysed using password protected NHS computers at NELFT. It will be analysed by the research study team, chiefly by the research worker and potentially by clinical psychology trainees as part of their doctoral theses. The qualitative analysis will rely on thematic qualitative analysis as described by Braun & Clark (2006) utilising NVivo software and quantitative data will be analysed using SPSS software.