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RESEARCH ARTICLE

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Specialist psychotherapy with emotion for anorexia in Kent and Sussex: An intervention development and non-randomised single arm feasibility trial

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Abstract

Objective: Anorexia nervosa (AN) is a serious eating disorder treated using psychological interventions, yet outcomes remain limited. Emotional difficulties are recognised as a treatment target. This research programme developed and evaluated feasibility of an emotion-focused therapy for adults with AN.

Methods: Phase One intervention development utilised 'intervention mapping'. Qualitative research drew on lived experience highlighting objectives for change. Empirical evidence was synthesised into hypotheses of core emotional difficulties and an associated model of change. Relevant psychotherapeutic theory-based change methods were integrated to form the Specialist Psychotherapy with Emotion for Anorexia in Kent and Sussex (SPEAKS) intervention, guidebook and clinician training package. Phase Two tested SPEAKS in a single-arm, multisite feasibility trial across two specialist services, utilising prespecified progression criteria, and embedded process evaluation.

Results: SPEAKS was 9–12 months (40 sessions) of weekly individual psychotherapy, drawing on a range of psychotherapeutic modalities, predominantly Emotion Focused Therapy and Schema Therapy. Forty-six participants consented to feasibility trial participation; 42 entered the trial and 34 completed. Thirteen of 16 feasibility criteria were met at green level and three at amber, highlighting areas for improving model adherence.

Conclusions: A randomised controlled trial is indicated. Therapist training and guidebook adjustments to improve model adherence are suggested.

KEYWORDS
anorexia, emotion, schema, SPEAKS, therapy

Highlights

- Specialist Psychotherapy with Emotion for Anorexia in Kent and Sussex is an emotion-focused intervention for adults with Anorexia nervosa following

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a proposed causal model of emotion change. Theory, tasks and techniques integrate Emotion Focused Therapy and Schema Therapy, alongside other modalities, to facilitate the proposed change processes.
- SPEAKS was developed using a clear 'intervention mapping' process, utilising mixed methods and seeking to engage and learn from those with lived experience.
- This feasibility trial suggests SPEAKS is an acceptable, engaging and clinically feasible intervention and progression to a larger randomised controlled trial is indicated.

1 | INTRODUCTION

Anorexia nervosa (AN) is a severe mental illness characterised by cognitive and behavioural patterns associated with distress regarding body image, body shape and body weight. Such patterns can persist even if body weight is restored (Other Specified Feeding or eating disorder [ED], AN type OSFED-AN; Crone et al., 2023]). Early intervention is key but AN frequently becomes a chronic illness (Steinhausen, 2002), with the highest reported mortality of psychiatric disorders (Zipfel et al., 2000).

Within the UK, National Institute for Health and Care Excellence (NICE) guidelines recommend psychotherapeutic interventions for adults with AN (NICE, 2020). Yet outpatient treatments do not out-perform one another, or control comparisons, and the best treatment option is unclear (Solmi et al., 2021; Zeeck et al., 2018). Furthermore, AN is highly valued resulting in poor treatment engagement and high drop-out rates (DeJong et al., 2012). It presents significant costs financially and emotionally offering a 'compelling case for change' in services and treatment (PricewaterhouseCoopers, 2015, p.9). Furthermore, at least 60% of those struggling with an ED have 'personality disorder' traits (e.g. emotional dysregulation, relational struggles), anxiety, depression, OCD and other Axis 1 presentations (Kaye & Bulik, 2021; Link et al., 2017; Miller et al., 2021). Standard length treatments (20–30 sessions) are less effective for those with longer illness durations (Schmidt et al., 2015). There is an urgent need to develop innovative interventions that can engage people with AN (Bulik, 2014; Solmi et al., 2021), while targeting unique development and maintenance factors (Kass et al., 2013).

Emotional experience has been recognised as a factor in the development and maintenance of AN since its earliest descriptions (Treasure & Cardi, 2017) and highlighted as a promising therapeutic target (Sala et al., 2016). It is increasingly incorporated into developments of psychotherapy interventions for adults with AN (Dolhanty & Greenberg, 2009; Hibbs et al., 2021; Schmidt & Treasure, 2014; Wildes & Marcus, 2011). However, the impact of working with emotion on therapeutic outcomes remains unclear, and it is uncertain to what extent emotional difficulties are successfully targeted.

The Specialist Psychotherapy with Emotion for Anorexia in Kent and Sussex (SPEAKS) research programme involved developing and testing in a feasibility study an emotion-focused intervention for adults with anorexia (SPEAKS intervention). Intervention development and application difficulties in mental health are argued to arise from taking an 'everything is relevant' approach, consequently lacking clarity around how desired change is achieved, or simply failing to target the identified variables (Kendler & Campbell, 2009). A lack of focus upon 'mechanistic' understandings of change in AN is argued to have impeded previous development of evidence-based interventions (Kaye & Bulik, 2021). The SPEAKS programme thus proposed focusing on a core clearly defined model with a key putative maintaining process (emotional experience in AN) following an 'interventionist-causal model approach' (Kendler & Campbell, 2009). It aimed to develop an evidence-based, acceptable and feasible emotion-focused psychotherapeutic intervention for adults with AN with a priori testable change process hypotheses.

2 | SPEAKS INTERVENTION DEVELOPMENT AND FEASIBILITY TRIAL

The SPEAKS research programme comprised two phases: (1) Intervention development; (2) Feasibility trial. It was informed by guidance on development and testing of complex healthcare interventions (Craig et al., 2008; Eldridge et al., 2016; O'Cathain et al., 2019). Development mirrored the 'intervention mapping' process (Fernandez et al., 2019), incorporating key actions in the Framework for Intervention Development (O'Cathain et al., 2019) (see Table S1). It integrated a 'persons-based' 'bottom-up' approach, learning from lived experiences of change (Yardley, Ainsworth, et al., 2015; Yardley, Morrison, et al., 2015). A research steering group of independent researchers and experts by experience oversaw both phases.

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3 | PHASE ONE. INTERVENTION DEVELOPMENT

Intervention development ran May 2016 to May 2018 (Table S1). We first sought understanding of the presenting problem with regards emotion, culminating in our explanation of emotional processing difficulties ultimately leading to a 'lost sense of emotional self' (Oldershaw et al., 2019). We then consulted people with lived experience to develop an emotional change model associated with recovery considering *what* needed to change, and then *how* that might be best facilitated (Davies et al., in prep; Drinkwater et al., 2022). Psychotherapy theory was applied in a consensus group. Highly relevant were emotion change processes in EFT as described by Greenberg and Elliott (EFT; Elliott et al., 2004) and ST, for example, following the work of Arntz (Arntz & Jacob, 2017; Fassbinder & Arntz, 2021). Additional relevant psychotherapeutic techniques were identified (See Figure 1; Oldershaw & Startup, 2020; Oldershaw & Startup, In Press).

4 | PHASE TWO. FEASIBILITY TRIAL

4.1 | Feasibility trial methods

4.1.1 | Ethical approval and pre-registration

The trial was approved by the London–Bromley Research Ethics Committee (NHS Rec Reference REC Ref: 19/LO/1530) and pre-registered (ISRCTN11778891).

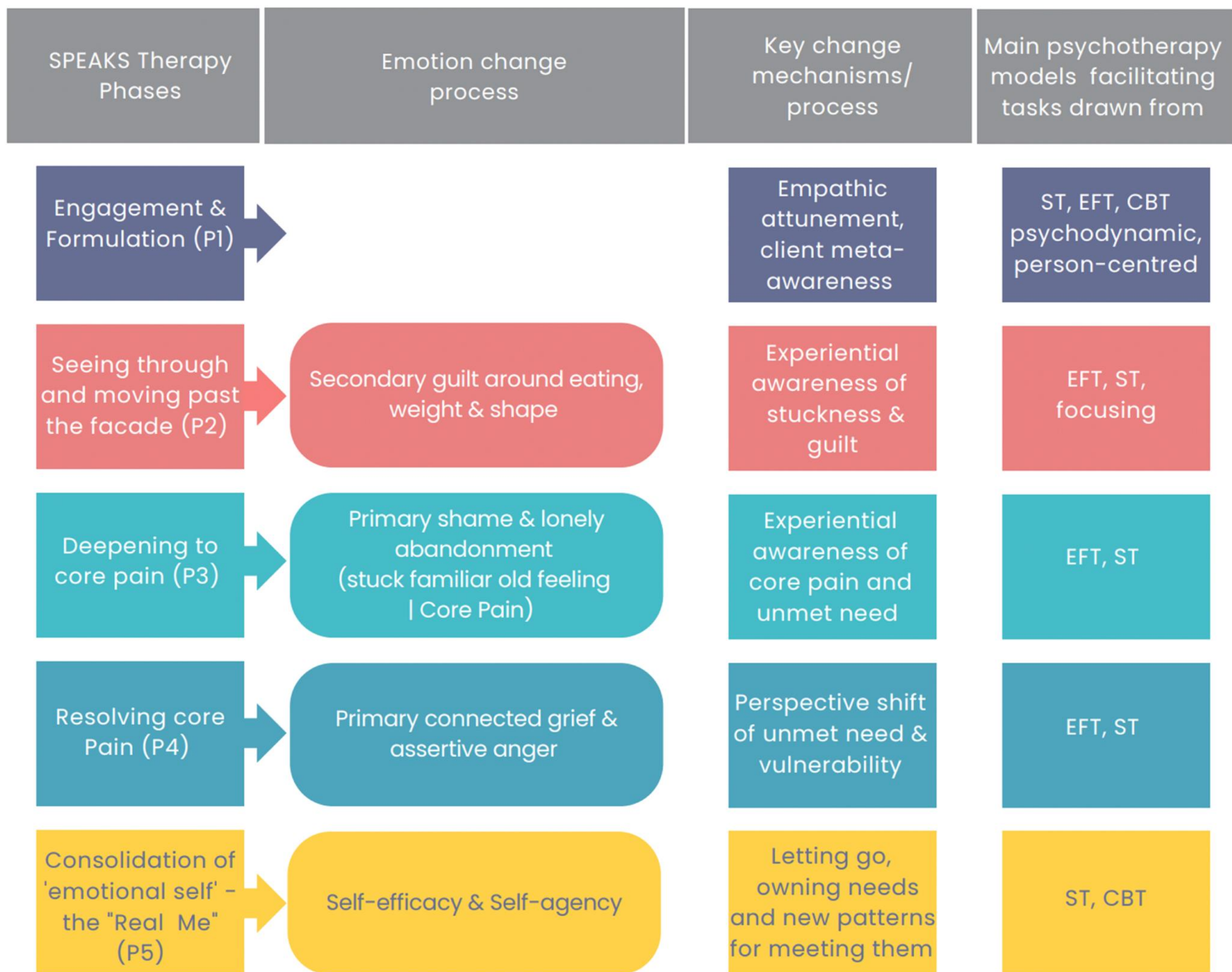

FIGURE 1 'Map' of the SPEAKS therapy process, including hypothesised change processes with associated mechanisms of change, and the main psychotherapy approaches from which tasks/techniques facilitating change were drawn. This includes hypothesised emotions and change mechanisms/processes and psychotherapy models most closely linked to causal change model, although the work is not limited to these. CBT, Cognitive Behavioural Therapy; EFT, Emotion Focused Therapy; P, phase of treatment; ST, Schema Therapy.

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4.1.2 | Study design

A multisite, single-armed, within-group mixed-methods design was employed.

4.1.3 | Setting

Two UK National Health Service (NHS) outpatient specialist eating disorders services hosted the trial: Kent and Medway All Age Eating Disorder Service, North-East London NHS Foundation Trust and Sussex Eating Disorder Service (SEDS), Sussex Partnership NHS Foundation Trust.

4.1.4 | Participants

Patients were eligible to participate if:

1. Referred into and met service criteria
2. Specialist ED psychiatrist diagnosis of AN or Atypical/OSFED-Anorexic-type (AAN) meeting DSM-5 Criteria
3. Were aged ≥18
4. Had body mass index (BMI) >15 kg/m^2
5. Had sufficient English for talking therapy

Patients were excluded if had/were:

1. Rated as 'High Risk'/'High Concern' in weight criteria on adult MARSIPAN Guidelines
2. Considerable psychological risk, including active suicidal plans
3. Comorbidity taking priority
4. Alcohol/substance use disorder
5. Participating in another treatment trial
6. Diagnosed intellectual disability impeding ability to access therapy
7. Pregnant

AAEDS/SEDS therapists were eligible to offer SPEAKS if:

1. Specialist ED therapist with ≥3 years' experience
2. Had basic training in experiential, dialogical-self chairwork model

4.1.5 | Procedure

Recruitment ran December 2019 to February 2021. Potential participants were screened from the waiting list. When SPEAKS therapist(s) had availability, patients still awaiting therapy were approached by their Health Care Practitioner for consent to be contacted by the research team. Research team contact was via telephone/email to provide additional information, answer questions, and (where relevant) arrange a consent appointment. Consent appointments took place >48 h after receiving the Participant Information Sheet.

Following informed consent provision, baseline questionnaires were completed, and therapy commenced (all online after March 2020). Questionnaires were further collected via video/telephone every 3 months until 12 months. Weight/BMI was extracted from clinical records.

Due to COVID-19 pandemic, some participants experienced a prolonged break within months 1–5 of therapy whilst services adapted, and online therapy procedures were established. To ensure access to 9–12 months of therapy, those impacted ($n = 7$) had therapy extended to match time lost, up to a maximum of 3 months. End of therapy data for those affected was captured by adding an extra data collection timepoint at 15-months. The 15-months data point was considered equivalent to 12-months timepoint of unaffected participants, and 6-month assessment equivalent to 3-month assessment as this most accurately captured 3 months of completed therapy.

4.1.6 | Intervention

SPEAKS intervention was organised into five phases in a process-oriented approach incorporating a hypothesised sequential model of emotional processing (Oldershaw & Startup, 2020; Pascual-Leone, 2018), with associated mechanisms of change and suggested useful therapeutic 'tasks' identified, to be flexibly used in targeting key processes (see Figure 1; Oldershaw & Startup, 2020; Oldershaw & Startup, In Press). This was written into a guidebook for therapists following requirements of preliminary feasibility evaluation manuals (Carroll & Nuro, 2002).

Phase 1 (Engagement & Formulation) establishes the groundwork for therapy with key consideration to building a warm and safe therapeutic relationship seen as central to change, including the use of 'limited reparenting' (Gülüm & Soygüt, 2022) and empathic responding techniques (Greenberg, 2014). Initial behaviour change with regards ED behaviours and reducing physical risk is sought, such as by establishing regular eating patterns. From early on, the therapist attunes to expression of emotion and parts of self as they arise and an idiosyncratic 'whole self' mode map is collaboratively developed. This incorporates coping modes, the critic and

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vulnerable child (Little Self). The heterogeneity of AN is such that there may be common, but also diverse schema modes of relevance to reflect an individual's presenting difficulties (Oldershaw & Startup, 2020). Building the Healthy Adult who can take in good emotional information and direct the client to meet needs in healthy ways is considered crucial to the SPEAKS model of change. This part is added to the map and explored, however under-developed and unintegrated currently (Oldershaw & Startup, 2020). SPEAKS seeks to be experiential and playful and this map can use toys and other objects to represent parts, as appropriate for the client. From the outset, clients are encouraged to develop meta-awareness of modes, mode shifts and associated emotions, behaviours and cognitions. Over therapy, a goal is that alternative behaviours are encouraged, such as offering soothing to the vulnerable child, standing up to the ED critic or reducing 'people pleasing' (compliant surrenderer) in relationships, thereby establishing new Healthy Adult patterns.

Phase 2 (Seeing Through and Moving Past the Facade) aims to further reduce ED behaviours and enhance motivation for change. Chairwork with the 'ED critic' to de-centre and understand its motivations, as well as encourage the emergence of underlying feelings and needs, highlights its impact on the client and relationships. The goal is partly to support the 'softening' of the ED critic (Elliott et al., 2004) and to reduce the 'noise' it generates, freeing the client to make further initial change and access emotional work later in therapy. Suggested other tasks/techniques include: chairwork with conflicting parts (the part that wants to change and the part that doesn't), or with future recovered/unrecovered selves (Pugh & Salter, 2018); Imagery to conceptualise 'stuckness', associated emotions and unmet needs in the present and how they might be met in/outside of therapy; Chairwork with coping modes aims to de-centre from and enable bypassing them in order to better understand and reduce these blocks to deeper therapy processes.

Phases 3 (Deepening to Core Pain) and 4 (Resolving Core Pain) reflect the core emotional change process to support the emergence and strengthening of the client's 'Healthy Adult'. Working with the ED critic is seen as a means to reveal and connect with an underlying 'broader critic' whose origins and functions can be explored. This enables connection to and work with primary emotional experiences ('core pain') and past unmet needs. Through a series of tasks/techniques, the client is sensitively supported by the therapist in a process of emotional processing (Pascual-Leone, 2018), transforming stuck old emotional and relational patterns, leading to new emotional experiences of acceptance, self-efficacy and self-agency; core features of the Healthy Adult (Oldershaw & Startup, 2020; Pascual-Leone, 2018). Suggested techniques/tasks include: Chairwork with 'broader' critic; 'empty chair', focusing, imagery, float back and float back with imagery rescripting, and visual flashcards to support emerging shifts and strengthen the Healthy Adult. Additional tasks support emotion regulation and compassionate self-soothing, such as grounding or 'safe bubble' exercises and chairwork with the Vulnerable Child. It is recognised that clients will move backwards and forwards between phases (e.g. continuing work to de-centre from the ED critic and coping modes), and that tolerance for emotion work will vary, with clients accessing emotional processing in different ways (Pascual-Leone, 2018), some more deeply or experientially than others. Clinicians are encouraged to be sensitive and flexible and both 'follow and guide' the client (Oldershaw & Startup, 2020), moving between tasks with a more emotional, cognitive or behavioural basis, and maintaining their therapeutic stance of empathy and 'limited reparenting'.

Phase 5 (Consolidation of the 'Real Me') seeks to further consolidate the 'Real Me' (Drinkwater et al., 2022) and work towards ending. The 'Real Me' is a reconfigured, resilient and integrated sense of self (Pos & Greenberg, 2007), with the Healthy Adult able to take in good emotional information in order to act with self-agency and self-efficacy in getting needs met in healthy ways. This phase includes further encouraging, testing and prizing of new Healthy Adult ways of being in the world, including regarding ED behaviours, but also more broadly in inter- and intrapersonal relationships, such as boundary setting. Chairwork such as with the ED critic is revisited to consolidate the Healthy Adult and highlight shifts in this intrapersonal relationship, as well as point to any further work that might need to be considered before ending. Ending tasks include visual and written remapping of the mode map to reflect changes made, consider how these might be maintained and how to respond if things slip into old patterns (e.g. 'finding your way back to the Healthy Adult'). Ending letters are shared between therapist and client in the penultimate session to reflect on and summarise the changes made, highlight any remaining difficulties and encourage expression of emotion from both therapist and client on the ending and their unique relationship. Transitional objects can be given as a reminder of the time spent together and of key shifts made (e.g. gifting the formulation object used to represent the Healthy Adult).

Delivery was weekly, estimated to be delivered over 9–12 months, including up to two final sessions

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delivered at a wider interval to taper the ending as appropriate to client needs and mindful of their attachment relationship. It directly replaced treatment as usual with physical health, risk and monitoring procedures, and other appointments (e.g. dietetic support) continued as per usual guidelines/practice. This involved regular weighing and other monitoring of physical health (e.g. blood tests) which were discussed in therapy. Links were made between continuing ED behaviours and the mode map formulation and blocks to making relevant changes considered through the use of tasks as described above.

Therapists received four initial days of SPEAKS training, with two further days to develop and maintain skill. Ongoing fortnightly supervision was delivered by two SPEAKS developers (AO&HS). Where participants consented, therapy sessions were video recorded for purposes of supervision which is common practice in supervision of many therapeutic approaches, including ST and EFT. Part of the feasibility trial was to consider whether SPEAKS could be delivered by ED specialist therapists even if not ST/EFT trained and videos were used to assess adherence and for continued skill development. Additional consent was sought for change process analysis of emotional, cognitive and behavioural change across videoed sessions (Dunstan et al., in prep; Malik-Smith et al., in prep). Reflective practice groups for therapists were offered every 16 weeks by the third SPEAKS developer (TL).

4.1.7 | Outcomes

Feasibility of the SPEAKS intervention
This was assessed via acceptability, engagement, clinical feasibility, intervention fidelity and health economics indicators summarised in Table 1.

Feasibility of the study methods
This was assessed through targets for reach and recruitment, research engagement, sample representativeness, qualitative process evaluation of study method acceptability and protocol fidelity (Table 1).

Change in clinical variables
Clinical change from pre- and post-SPEAKS therapy to inform sample size estimation for future trials utilised EDEQ-Global Score v6.0 (Fairburn, 2008) and BMI (primary outcomes measures), Clinical Impairment Assessment (CIA) (Bohn & Fairburn, 2008) and Depression Anxiety and Stress subscales (Lovibond & Lovibond, 1995) (secondary outcomes).

4.1.8 | Sample size

Thirty-five participants are recommended for sufficient feasibility data and precision of mean/variance (Teare et al., 2014) according with proposals that 20–40 participants are sufficient for pilot/feasibility studies (Hertzog, 2008). AN therapy attrition rates can reach 40% (DeJong et al., 2012). We aimed for 36 people completing therapy, thus inflated the proposed sample size to maximum 60 (Oldershaw et al., 2022).

4.1.9 | Analyses

Qualitative acceptability and process data were analysed using Braun and Clarke's 6-stage thematic analysis model (Braun & Clarke, 2012). Participant characteristics and clinical outcomes were summarised using descriptive statistics. Progression criteria were prespecified and a traffic light system indicated these were fully (green), partially (amber) or not met (red) (Avery et al., 2017).

All statistical analyses were conducted in STATA (version 17). Unpaired *t*-tests (or non-parametric equivalents) examined group differences between those who completed and who did not complete therapy. Outcome analysis was conducted on a 'completer'/per-protocol basis. A Generalised Linear Model was employed to allow for missing data with timepoint (categorical variable) as fixed effect. Data assumed to be missing at random. Effects size of change (omega-squared,) were calculated for clinical variable change, defined as small (0.01), medium (0.06) and large (0.14). Remission was defined as BMI >18.5, EDEQ-global <2.77 and absence of binging/purging (Byrne et al., 2017; Mond et al., 2006) and applied to those underweight at baseline.

4.2 | Feasibility trial results

4.2.1 | Participants

Participants were predominantly White British (73.5%) females (97.0%), age 29.1 years at recruitment (see Table 2). Mean baseline EDEQ-global score was 4.1 (sd = 1.1). Average age of AN onset was 19.7 years and illness duration 9.0 years. Three fifths (61.7%) were underweight at admission into the trial meeting criteria for AN; the remainder met criteria for AAN. Four fifths (80.3%) had received previous psychological therapy and 15.6% an inpatient admission. Depression, Anxiety and Stress Scale scores fell within the 'severe' range across

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TABLE 1 Summary of progression criteria set for the feasibility of the SPEAKS intervention and feasibility of the study methods, and whether these were met.

Criteria	Measurement	Target	Achieved	Progression criteria (green = met; amber = partially met; red = not met)
Feasibility of the SPEAKS intervention				
Acceptability of SPEAKS intervention				
Acceptability	Qualitative interview analysis	Most find intervention and techniques acceptable	All found elements acceptable (Rennick et al., submitted)	Met
	Visual analogue scale	>5	6.3	Met
Clinical engagement & feasibility				
Clinical engagement	% of people who dropped out due to lack of therapy engagement	≤40%	0.0%	Met
Clinical feasibility	% of people who required inpatient ED care	2%–3%	2.9%	Met
Clinical feasibility	% of people who died while receiving the intervention	0%	0.0%	Met
Intervention fidelity & adherence				
Treatment fidelity	Score of fidelity strategies used divided number of relevant strategies	0.8	0.9	Met
Adherence of therapists to the model	% of sessions following change processes and tasks	>80%	87.2% (range 62.5%–95.8%)	Average met, but some adherence below requirements
Adherence to treatment duration	Average number of months of therapy	Average within 9–12 months	11 months, 1 day (range 9 months, 1 day–13 months, 10 days)	Overall met criterion, but some participants beyond range
Economic estimation				
Health service use	% of people who visit accident & emergency or general practitioner	Rates during SPEAKS do not exceed those prior to SPEAKS	Rates during SPEAKS were lower	Met
Feasibility of the study methods				
Reach and recruitment				
Eligibility rates	% of people who were eligible of those who were screened	>50%	67%	Met
Recruitment rates	% of eligible people who were approached and agreed to participate	75%	85%	Met
Total recruitment	*n* recruited who completed treatment	36	34 (94%)	Total *n* slightly under target, but appropriate range

(Continues)

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TABLE 1 (Continued)

Criteria	Measurement	Target	Achieved	Progression criteria (green = met; amber = partially met; red = not met)
Research engagement				
Research follow-up rates	% of research follow-up appointments attended	>70%	88.1%	Met
Sample representativeness				
Sample representativeness	Lack of baseline differences between people who completed and did not complete the intervention (on variables: Age, illness duration, EDEQ global score, BMI, CIA, DASS)	all $p > 0.05$	all $p > 0.05$	Met
Process evaluation of study method acceptability				
Acceptability of research procedures, including measures	Qualitative process evaluation	Most participants find procedures and measures acceptable	Acceptable, although measures could be shortened	Met
Acceptability of a proposed future RCT	Qualitative process evaluation	Most participants feel larger trial with randomisation acceptable	All participants supportive of a larger trial. No suggested changes to intervention or study methods, beside shorter questionnaires (Rennick et al., submitted)	Met

Abbreviations: BMI, Body Mass Index; CIA, Clinical Impairment Assessment; DASS, Depression, Anxiety and Stress Scale; EDEQ, Eating Disorder Examination Questionnaire.

depression, anxiety and stress. Around half of participants (51.6%) reported taking psychotropic medication. Sixteen participants (47.1%) and six of seven eligible therapists participated in qualitative interviews following therapy completion.

4.2.2 | Feasibility of the SPEAKS intervention

Table 1 summarises criteria set and ratings. Progression criteria targets were met across acceptability, clinical engagement and clinical feasibility, intervention fidelity and health economics evaluation.

Amber ratings of 'partially met' were assigned for model adherence of therapists and adherence to treatment length. Session notes indicated that, on average, 87.2% of sessions (range 62.5%–95.8%) aligned with SPEAKS model change processes/tasks, thus a small number of sessions fell below requirements. Treatment duration ranged from 9 months, 1 day to 15 months, 18 days. Average treatment duration fell within the expected range (11 months, 10 days), as did average number of sessions of 40.42 (sd = 12.08), but four people exceeded 12 months, three by less than 1 month.

4.2.3 | Feasibility of the study methods

Feasibility of study methods progression criteria were met across Reach and recruitment (Figure 2), Research engagement, Protocol fidelity, Sample representativeness and qualitative process evaluation.

The trial aimed for 36 people completing therapy and 34 completed (Figure 2) marking this criterion 'partially met' (amber). Four adverse events were registered. There were two self-harming incidents by overdose. Neither were assessed by the panel as being related to SPEAKS

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TABLE 2 Baseline demographic & clinical characteristics of SPEAKS participants.

Demographic Characteristics		
	Mean	***sd***
Age at baseline	28.7	7.9
	N	**%**
Gender		
Female	33	97.0
Male	0	0.0
Non-binary	1	3.0
Ethnicity		
Mixed–white & black	1	2.9
Mixed–any other mixed	2	5.9
Not stated	3	8.8
White–any other background	2	5.9
White british	25	73.5
White–mixed	1	2.9
Employment at baseline		
Homemaker	1	2.9
Paid/self-employed	19	55.9
Student	7	20.6
Unemployed	6	17.7
Volunteer	1	2.9
Clinical characteristics[a]		
	Mean	***sd***
BMI at start of therapy for those with AN	17.2	0.7
BMI at start of therapy for those with AAN	19.2	2.0
Age of AN onset (years)	19.8	8.1
Illness duration (years)	9.0	7.9
Lowest ever BMI	16.4	1.9
	N	**%**
Previous psychological treatment	26	80.3
Previous admission to hospital for ED	5	15.6
Lifetime history of self-harm/suicidal ideation	14	43.8

Abbreviations: AAN, atypical anorexia/Other Specified Feeding or Eating Disorder, AN type; AN, anorexia nervosa.

[a]Missing data for 2 participants.

therapy per se, one being a participant already in process of withdrawal due to unaccessibility following covid-19 pandemic measures. The third was short general hospital admission due to risk of refeeding syndrome. The fourth was an inpatient ED admission.

4.2.4 | Change in clinical variables

EDEQ-global scores significantly decreased from 4.14 pre-therapy (sd = 1.11) to 2.90 post-therapy (sd = 1.74), ($z = -3.51$, 95% CI −1.52 to −0.34, $p = 0.000$) with medium effect (omega-squared = 0.054) (Table 3; $n = 34$). For those underweight at the start of therapy ($n = 21$), BMI significantly increased from pre- to post-therapy ($z = 3.41$, 95% CI 0.70–2.60, $p = 0.001$), with medium effect (omega-squared = 0.075). Significant reductions pre to post-therapy were observed for anxiety ($z = -3.61$, 95% CI −15.96 to −4.74, $p = 0.000$), depression ($z = -3.60$, 95% CI −17.89 to −5.27, $p = 0.000$) and stress ($z = -4.56$, 95% CI −14.52 to −5.78, $p = 0.000$), ranging from medium to large effect (anxiety omega-squared = 0.065, depression omega-squared = 0.072 and stress omega-squared = 0.12), putting each average category from 'severe' at pre-therapy to 'mild' at post-therapy. Quality of life scores on the CIA significantly improved ($z = -4.93$, 95% CI −1.20 to −0.52, $p = 0.000$), with large effect (omega-squared = 0.15). For those underweight at the start of therapy, 43% were in remission at 12-months.

5 | DISCUSSION

The overarching goal of the SPEAKS research programme was to develop a process-oriented intervention for adults with AN utilising a causal model of emotion change and to test it in a feasibility trial. This was achieved across two phases: (1) A 'bottom-up' approach to intervention development following six 'intervention mapping' steps; (2) Feasibility testing of the SPEAKS intervention in two real-world NHS ED services to consider both intervention and research feasibility.

5.1 | Feasibility of SPEAKS therapy and study methods

Feasibility criteria were largely met indicating that SPEAKS was an acceptable, engaging and clinically feasible intervention. Effect size analyses demonstrated clinical change with medium-large effect in the context of complexity and severity. Participants started from a higher average baseline EDEQ-global score than other studies, with EDEQ-global score change from pre-post therapy lower than reported elsewhere for MANTRA, CBT-E and SSCM, whilst change in BMI was larger than that reported for MANTRA and SSCM, but not CBT-E (Byrne et al., 2017; Fairburn et al., 2013). Depression

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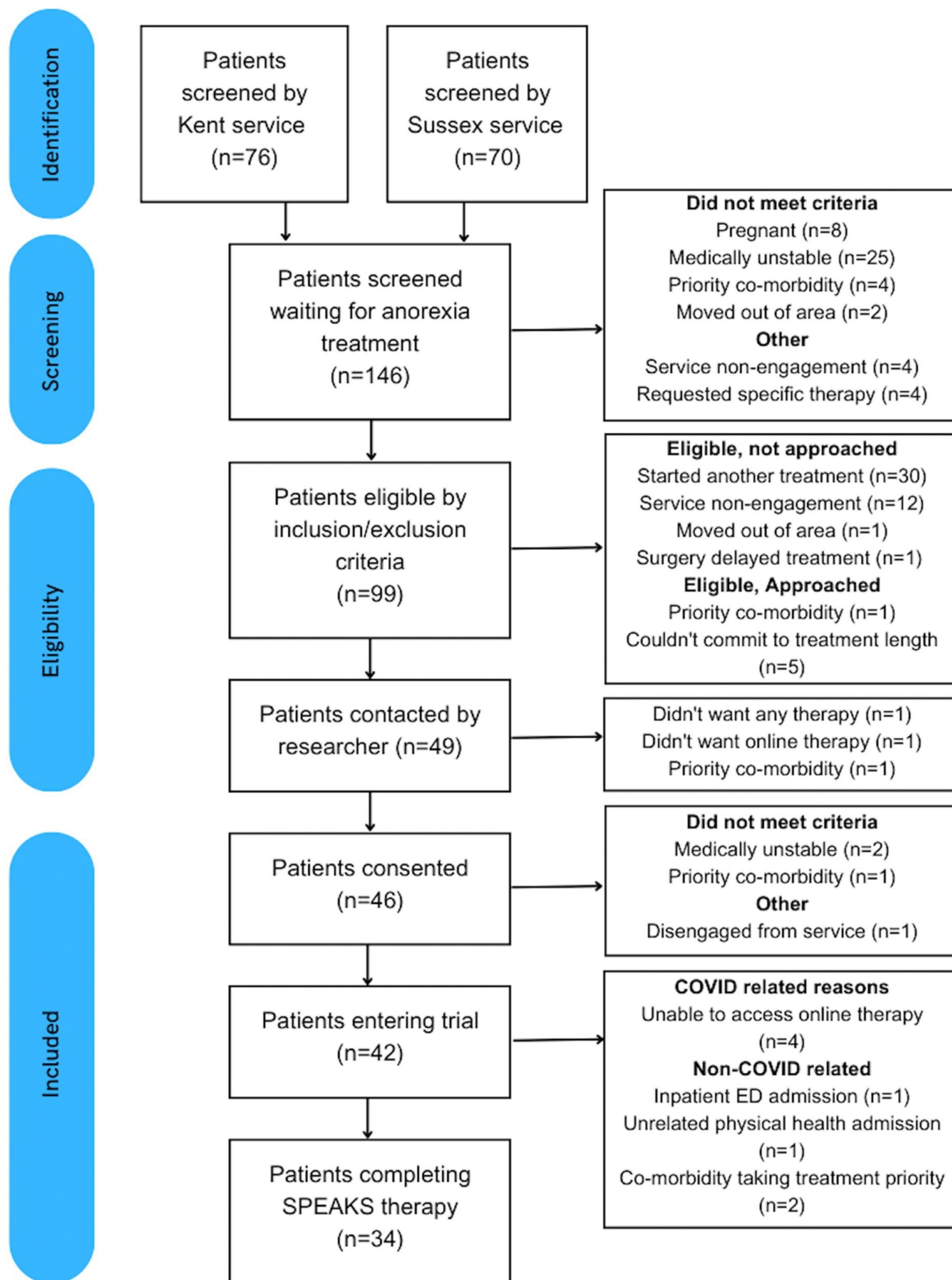

FIGURE 2 SPEAKS feasibility trial CONSORT diagram.

and anxiety change scores exceeded those reported for MANTRA, SSCM and CBT-E (Byrne et al., 2017), perhaps reflecting the 'whole self' focus of SPEAKS on a wider range of symptoms. Remission rate for those underweight was 43% compared with SSCM (33.5%), MANTRA (22%) and CBT-E (30.8%) (Byrne et al., 2017).

Illness duration exceeded expected length for people with 'Severe and Enduring AN' (SE-AN) (Broomfield

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TABLE 3 Scores over time on key clinical variables of eating disorder examination questionnaire, BMI, depression, anxiety and quality of life for participants who competed therapy ($N = 34$) at baseline, 3, 6, 9, and 12 months follow-ups.

	Baseline		3 months		6 months		9 months		12 months	
***N* = 34**	**Mean**	***sd***	**Mean**	***sd***	**Mean**	***sd***	**Mean**	***sd***	**Mean**	***sd***
EDEQ										
Restraint	3.9	1.5	3.2	1.6	3.0	1.6	2.8	1.8	2.4	1.9
Eating Concern	3.2	1.0	2.9	1.3	2.7	1.4	2.8	1.4	2.2	1.7
Weight Concern	4.5	1.3	3.8	1.4	3.6	1.6	3.7	1.6	3.2	1.9
Shape Concern	4.8	1.2	4.3	1.4	4.0	1.6	4.0	1.6	3.4	1.9
Global score	4.1	1.1	3.7	1.2	3.4	1.4	3.5	1.4	2.9	1.7
Depression	24.3	11.9	20.2	11.4	17.2	13.2	16.2	11.5	12.7	12.7
Anxiety	18.9	11.8	14.8	10.5	12.8	9.6	13	11.3	8.6	10.4
Stress	23.0	9.0	20.0	7.2	17.3	8.6	16.8	8.1	12.9	8.6
Clinical impairment assessment	33.5	8.9	27.4	8.1	24.3	10.3	23.3	11.5	19.5	13.9
BMI of those underweight at start of treatment ($n = 21$)	17.2	0.7	17.9	1.1	18.1	1.6	18.3	1.9	18.9	2.1
BMI not underweight at start of treatment ($n = 13$)[a]	19.2	2.0	20.4	2.2	20.0	1.4	20.2	1.4	21.3	1.6

[a]These weights not included in analysis of BMI change as weight gain was not a goal for these clients.
Abbreviations: BMI, Body Mass Index; EDEQ, Eating Disorder Examination Questionnaire.

et al., 2017; Hay & Touyz, 2015), although this may not have a bearing on outcomes (Raykos et al., 2018). Other severity factors such as psychotropic medication use, anxiety/depression symptoms and baseline Eating Disorder Examination Questionnaire scores were greater than other trial participants, including trials conducted for SE-AN (Touyz et al., 2013). Furthermore, disengagement with therapy was zero; an important finding for this group where disengagement can reach 40% and designing interventions to optimise therapeutic engagement is necessary (Wonderlich et al., 2020). Even accounting for all reason trial withdrawals–including unrelated factors pertaining to the COVID-19 pandemic–of those who started SPEAKS, 81% completed. This is similar to Touyz et al. (2013) and compares favourably with 58%, 56% and 67% for SSCM, MANTRA and CBT-E respectively (Byrne et al., 2017). Although, it should be noted that retention in itself is not indicative of positive outcomes.

Study methods were deemed acceptable, with strong reach and recruitment. This is a useful feasibility finding, given that SPEAKS focused explicitly on emotion; thus high potential emotional avoidance (Lavender et al., 2015; Oldershaw et al., 2015) was not an impediment to engagement.

Three criteria were partially met. Two related to adherence and duration. This highlights that clarity over SPEAKS model and delivery should be improved, including edits to clinician training and guidebook. The third partially met requirement was sample size, reflecting the impact of the covid-19 pandemic. Recruitment delays and trial timelines commonly affected trials conducted during the pandemic, as did diminished data integrity (Sathian et al., 2020; Shiely et al., 2021). This trial maintained good data integrity and overall recruitment was within the recommended range for feasibility trials (Hertzog, 2008; Teare et al., 2014).

5.2 | Strengths and limitations

This study followed a systematic intervention development approach utilising mixed methods, seeking to learn from those with lived experience at multiple time-points; an approach considered essential in ED treatment and service provision (Lewis & Foye, 2022). It was conducted in a real-world setting across two research naïve services. SPEAKS clearly articulates testable change process hypotheses which were studied within the trial, to be published elsewhere. Scrutiny of change processes is considered crucial in development and refinement of complex interventions (Craig & Petticrew, 2013; Skivington et al., 2021) and will inform further SPEAKS development.

There were limitations inherent in the feasibility design, such as small sample, single-arm and complete-

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case analysis. Outcomes and any comparisons of effectiveness should be interpreted cautiously. Such a trial is open to selection bias, particularly given the limited availability of SPEAKS trained therapists meaning that not all eligible participants could be offered SPEAKS. Furthermore, the trial was impacted by the covid-19 pandemic. As is common in clinical trials for people with AN, and reflecting demographics of those accessing UK ED services (Sinha & Warfa, 2013), participants were largely white British and findings may not extend to those from other ethnicities. Similarly, participants were predominantly female limiting generalisation with regards gender.

6 | CONCLUSIONS

SPEAKS is a process-oriented psychotherapeutic approach following a causal model of emotional change that is acceptable and feasible for adults with AN, including those with established or complex AN. Following strengthening of the therapist training and guidebook, progression to a larger randomised controlled trial is indicated.

AUTHOR CONTRIBUTIONS

Conceptualisation & study design: Anna Oldershaw, Helen Startup, Tony Lavender; Data collection: Randeep Basra; Performed analysis: Anna Oldershaw, Randeep Basra; Writing - original draft preparation: Anna Oldershaw, Randeep Basra; Writing - review and editing: Tony Lavender, Helen Startup; All authors read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

None to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

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