Group Psychological Interventions for Individuals with Eating Disorders and their Carers.

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Chapter 1

Group Psychological Interventions for Eating Disorders: A Meta-Analysis

Prepared in accordance with the *Eating Disorders: The Journal of Treatment and Prevention (EDJTP)*

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Abstract

This meta-analysis examined the effectiveness of group psychological interventions at reducing eating disorder (ED) psychopathology compared to control groups. We also explored whether treatment effects were moderated by diagnoses, setting, control group and intervention focus. Four electronic databases; PsychINFO, Medline, EMBASE and Cochrane Clinical Trials were searched using PRISMA guidance (Pre-registration number: 42024536375). Study quality was assessed using the Effective Public Health Practice Project (EPHPP) tool. A meta-analysis with random effects model was used. Twenty-four controlled studies that compared a group psychological intervention with a control group with a total of 1627 participants were included. Group interventions were significantly more effective than control groups at reducing ED psychopathology post treatment (g=-0.27; 95% CI: -0.41 -0.13). Diagnoses, setting and control group did not moderate treatment effects. Standard CBT interventions showed a significantly higher effect size (g=-0.62, 95% CI: -1.00, -0.24) than interventions which targeted a specific mechanism (g=-0.17, 95% CI: -0.30, -0.04). Body image interventions showed a significantly higher effect size (g=-0.36, 95% CI: -0.59, -0.13) than interventions which targeted problematic exercise (g=0.10, 95% CI: -0.40, 0.61), and affect regulation (g=-0.01, 95% CI: -0.66, 0.64). Group interventions offer a modest reduction in ED psychopathology across patient groups, with strong support for CBT in targeting broad ED symptomology. Additional research is needed to evaluate the effectiveness for anorexia nervosa patients within outpatient settings. Further controlled trials and replication studies are required before strong conclusions can be drawn.

Introduction

Eating disorders (ED) are psychiatric conditions that are characterized by maladaptive eating behaviors which can lead to severe weight loss, weight gain and obesity (Fairburn & Harrison, 2003). ED's can be classified into anorexia nervosa (AN), bulimia nervosa (BN) and binge eating disorder (BED), and other specified feeding and eating disorders (OSFED) (APA, 2013). Typical age of onset across EDs is adolescence and young adult hood (Solmi et al., 2022). EDs have been deemed one of the most challenging mental illnesses to treat due to biopsychosocial aetiology and the valued nature of the illness (Fassino et al., 2013). Additionally, they are associated with high mortality rates and acute medical risks (Amiri & Khan, 2024); therefore, EDs often require a multidisciplinary approach to address both psychological and physical health components.

Treatment is typically delivered on a continuum of care; both inpatient and outpatient treatments consist of medical, nursing, dietetic and psychological care, with inpatient associated with higher medical risk (Meguerditchian et al., 2010). Current guidelines recommend cognitive behavioral guided self help for treatment of binge-eating disorder, and individual cognitive behavioral therapy for bulimia nervosa (NICE, 2017). There is currently no 'first line' psychological treatment for anorexia nervosa that has shown superiority (Solmi et al., 2021); NICE (2017) recommends CBT-ED, Maudsley Model of Anorexia treatment for adults (MANTRA) and supportive clinical management (SCM) as evidence base treatment options for adults with AN. The majority of the evidence base for psychological interventions across ED's is limited to individual therapies, with the exception of BED where group CBT is recommended as a second line treatment (NICE, 2017). There have been limited attempts to explore whether group therapeutic interventions may also be of benefit to other ED diagnoses.

Kealy & Kongerslev (2022) highlighted the current need to expand the group psychotherapy evidence-base, as group interventions can offer unique advantages over individual treatment. Beyond providing theory driven interventions and techniques, group interventions can provide an opportunity for

peer modelling, vicarious and social learning which are unable to be attained in individual treatment (Yalom & Leszcz, 2005). In addition, interpersonal difficulties are well-documented risk factors for EDs, and symptoms may arise as a result of negative self-evaluations related to challenges in navigating the social world (Rieger et al., 2010). Therefore, group interventions may provide an opportunity to foster a sense of community, enhance social skills, and reduce shame (Yalom & Leszcz, 2005).

In addition to the therapeutic benefits of group-based interventions, they may also offer economic advantages. During the COVID-19 pandemic, services saw a rise in healthcare utilization and hospital admissions for ED's (Devoe et al., 2023). Additionally, the severity and complexity of ED presentations has increased since the pandemic (Wadsworth et al., 2023). The consequence of this has been increased service pressure to meet this rising demand (Obeid et al., 2024). Existing individual psychological treatments for ED's are both costly and time-intensive (Simon et al., 2005; van den Berg et al., 2022), and it has been suggested that the limited availability of evidence base treatments is insufficient to address the growing demand (Kass et al., 2013). As such, researchers have highlighted the importance of developing scalable treatments (Cooper & Bailey-Staebler, 2015). One method of addressing these challenges may be the delivery of group psychological interventions: a more cost-effective way to increase access to evidence-based care and early intervention.

Group interventions are commonly implemented across inpatient and outpatient eating disorders services (Friedman et al., 2016; Baudinet & Simic., 2021). However, despite their widespread implementation, the evidence base supporting their effectiveness remains limited- particularly for anorexia nervosa. Previous research has been limited to bulimia and binge-eating disorder (Polnay et al., 2014; Grenon et al., 2017; O'Connor et al., 2024). While group psychological interventions have demonstrated efficacy for BN and BED, it remains unclear whether similar benefits exist for other ED diagnoses (Polnay et al., 2014; Grenon et al., 2017; O'Connor et al., 2024).

Grenon and colleagues' (2017) review aimed to evaluate the effectiveness of group therapy across all ED diagnoses. However, the review only identified one

study that included AN participants due to restrictions on inclusion criteria (RCTs) and the exclusion of inpatient studies. Conducting RCTs with individuals with AN pose significant challenge, such as ethical concerns around randomizing individuals with physical health risks to a wait list control condition. High drop-out rates further complicate intervention studies, leading to underrepresentation of AN in the literature (Fairburn, 2005; Halmi et al., 2005). Despite this, the prevalence and severity of AN continues to rise, leaving services to deliver group interventions for transdiagnostic patient groups based on evidence that does not adequately represent them.

Previous group therapy meta-analyses have focused on wait-list controls, or individual therapy as comparator groups however group interventions are commonly implemented within standard care (Friedman et al., 2016; Baudinet & Simic., 2021). Therefore, the inclusions of studies that compare group interventions to standard care may provide a more ecologically valid and clinically relevant evaluation. Additionally, it may offer insight into whether group interventions provide incremental benefits when integrated into standard treatment models, which would be of relevance for under-resourced services.

Previous meta-analyses have been limited in therapeutic approaches, therefore other forms of group psychotherapy need to be evaluated to provide more evidence-based treatment options for individuals with ED (Grenon et al., 2017). Recent controlled studies have explored the effectiveness of transdiagnostic group therapies, such as Acceptance and Commitment Therapy (ACT), Compassion-Focused Therapy (CFT), and dissonance-based interventions across eating disorder (ED) populations, including AN patient (Fogelkvist et al., 2020; Kelly et al., 2017; Stice et al., 2015). While these studies provide promising insights, they are often constrained by small sample sizes, limiting the generalizability of their findings. Given the potential for transdiagnostic approaches to enhance treatment efficacy, reduce clinical resources, and lower costs, it is critical to gain insight into their overall effectiveness.

The current study

The research remains unclear as to whether group psychological interventions are effective at reducing pathology across ED presentations, including those with Anorexia Nervosa. It is also unclear whether they offer additional benefits when compared to standard care across outpatient and inpatient settings. It is crucial that the evidence base be updated to inform service provision and address the rising demand for treatment, especially within adolescence (Madigan et al., 2025). The present study addresses this gap using meta-analysis to examine the effectiveness of group psychological interventions on reducing ED psychopathology compared to controls (waitlist/no treatment and TAU). The goals of this review are to (1): estimate the effect of group interventions for EDs compared to controls, and (2) to determine whether treatment effects are moderated by diagnoses, setting, control condition, and intervention type.

Method

This review was conducted in line with the updated Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (PRISMA, 2021). The protocol was registered on PROSPERO on the 22nd April 2024 (CRD42024536375)

This review included all studies meeting the PICOS inclusion criteria specified below, published in English in a peer-reviewed journal up until 4th May 2024.

Types of studies

Studies were included if they employed a controlled design (e.g. RCT or quasi-experimental). Observational studies without a control group were excluded. No country based exclusion criteria was set, as the multi-disciplinary treatment approach for eating disorders (TAU) is generally consistent across countries.

Types of participants

Both adolescent and adult participants, defined as over 12 years old, were included to provide an examination of effectiveness across the lifespan. Participants were required to meet diagnostic criteria for an eating disorder and/or feeding disorder according to an established classification system (e.g. DSM-5, ICD-11). This included those with AN, BN, BED, ARFID, pica, rumination disorder, and OSFED (formerly EDNOS). Participants with co-morbidities were included.

Types of interventions

We defined group psychological intervention similar to Grenon et al. (2017) study. The intervention was required to be delivered in a group face-to-face format (with 3 or more participants). The group intervention was also required to meet one of the following criteria: a) offered as a viable treatment (e.g., based on professional books or manuals), or b) contain specific treatment components based on theories of change.

Types of comparators

Studies comparing a group psychological intervention against a wait-list/ no treatment control, or treatment as usual condition were included within the review. Studies which compared group intervention with individual therapy or pharmacological treatment were excluded.

Type of outcomes

Studies were included if they used a quantitative, standardized and validated measure of global ED psychopathology. Studies were only included if they reported outcomes at baseline and post-intervention at a minimum. Studies were only included if statistics allowed for effect size estimation on ED psychopathology.

Information sources and search strategy

Articles were identified for inclusion with searches through PsychINFO, Medline, EMBASE and Cochrane Clinical Trials. Searches were conducted between 1947

and May 2024. Search terms related to three concepts; (1) feeding and eating disorders; (2) group psychological interventions and (3) controlled trials.

Study selection and data collection

After removal of duplicates, all titles and abstracts were screened by the main author and 10% were independently screened by a second reviewer to determine their relevance to this review using the eligibility criteria which found 100% agreement. The main author independently screened the full text of the remaining articles, with reasons for exclusion documented at this stage. Additionally, 10% of full text articles were screened by a second reviewer and found 84% agreement, discrepancies were resolved through discussion. The study selection process is shown in Figure 1.

Data extraction and management

Data extraction was carried out by the main author using a data extraction form created for the purposes of this review. The following data were extracted from the eligible studies:

- Study identification details- first author, publication year.
- Study design characteristics— design, sample size per group, follow-up length.
- Participant characteristics—mean age, percentage female, diagnoses and presence of co-morbidities.
- Setting- outpatient or inpatient.
- Intervention characteristics—type (e.g., CBT), number of sessions.
- Comparator(s) characteristics- wait-list/no treatment, treatment as usual.
- Outcome measure used – (e.g. Eating Disorder Examination Questionnaire- EDEQ).

We extracted means, standard deviations, and sample size at post-intervention in both the intervention and comparator groups. Wherever possible, data were extracted from intention-to-treat analyses, including the sample size at randomisation. Where completer analyses were conducted instead, we extracted the sample size of study completers.

Assessment of risk of bias in included studies

We evaluated the risk of bias in individual studies according to the Effective Public Health Practice Project (EPHPP; Thomas et al., 2004) recommendations on the domain's selection bias, study design, confounders, blinding, data collection methods, and withdrawals and dropouts. Risk was quantified as weak, moderate, or strong. Studies without areas rated as weak were deemed as "strong". One weak area led to a rating of "moderate" quality. Studies with two or more weak domains were classified as "weak". Twenty percent of studies were assessed by a co-screener, with initial 80% agreement and discrepancies were discussed among authors until a consensus was reached (100%).

Meta-analysis

SPSS was used for computing and pooling effect sizes. In view of heterogeneity among studies, a random effect model was adopted. Separate sub-group analyses were conducted that included an estimation of between-groups effect sizes of: (a) group psychological intervention compared with controls; (b) inpatient and outpatient group psychological interventions compared with controls and; (c) group psychological interventions compared with wait-list/ no treatment controls and treatment as usual; (d) standard CBT interventions and mechanism focused interventions and; (e) body image, problematic exercise and affect regulation interventions.

For outcome measures, the effect size indicating the standardised mean difference (SMD) between the two groups at post-test (Hedges' g) was calculated for each comparison. Hedges' g was chosen as it adjusts for biases caused by small sample sizes (Cuijpers, 2016). When studies provided more than one measure of outcome (e.g. four subscales of ED psychopathology), the means and standard deviations were averaged to provide a global score.

Outliers

An effect size was considered an outlier when the 95% CI did not overlap with the 95% CI of the pooled effect size (Cuijpers, 2016) and thus were removed from the analysis.

Assessment of heterogeneity

Statistical heterogeneity was examined using Cochran's Q and I^2 statistics (Higgins et al., 2003). A significant Q statistic indicates varying effect sizes across studies as well as sample or methodological differences that may contribute to variance. The I^2 statistic assesses the percentage of variability due to heterogeneity rather than to random error. A value of 0% indicates no observed heterogeneity, whereas scores of 25%, 50% and 75% indicate low, moderate and high heterogeneity, respectively (Higgins et al., 2003).

Publication bias

Studies with non-significant or negative results are less likely to be published in peer-reviewed journals (Borenstein et al., 2009). We used funnel plots and Egger's regression test (Sterne & Egger, 2005) to test publication bias.

Sensitivity analysis

To account for the potential bias of including of weak studies on treatment effects, we conducted sensitivity analysis which included estimating effect sizes with weak studies removed (Higgins et al., 2023).

Results

The PRISMA flow diagram (Fig.1) provides an overview of the search and inclusion process (Moher et al., 2009). A total of 1630 studies were identified, from which duplicate articles (n=700) were removed. The remaining titles and abstracts (n= 930) were screened against the eligibility criteria to determine their relevance to this review. Eight hundred and seventy-nine studies were excluded as they were deemed not eligible. The remaining 51 articles were screened for eligibility, of which three were unable to be retrieved, and 23 did not meet inclusion criteria. Finally, 25 studies were included within the review.

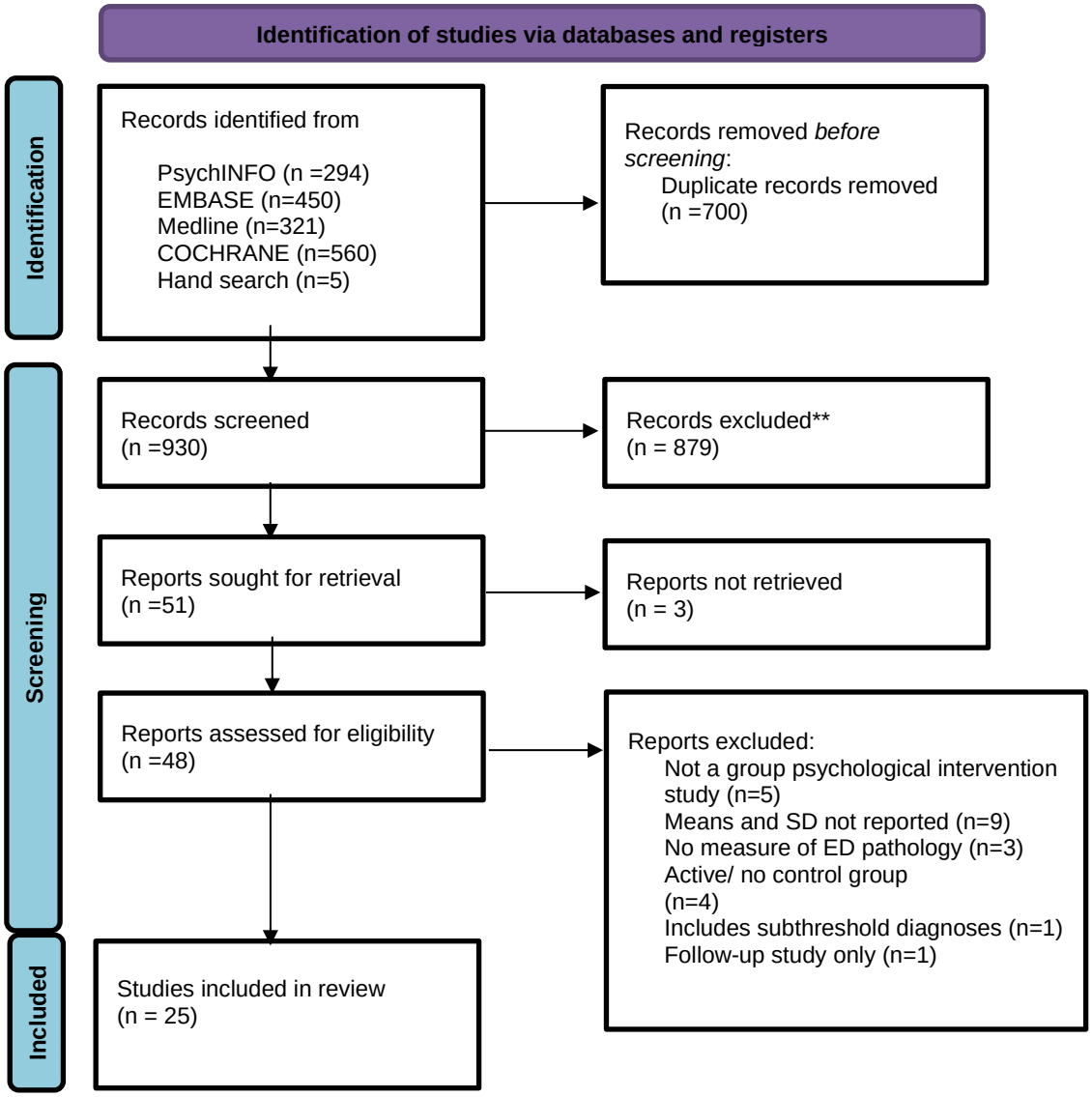
Study characteristics

Participants and treatment characteristics

Study characteristics are summarized in Table 1. The 25 studies included 1666 participants in total. Sample sizes ranged from 16 (Pegado et al., 2018) to 207 (Dittmer et al., 2020). Ten studies used a mixed diagnoses sample, two for BN, five for AN and eight for BED. The age range for the sample was 14-50 years old, with a mean of 31.5 years. Two studies included only adolescents patients (Biney et al., 2021; Pegado et al., 2018), whilst two included a mix of adult and adolescents (Meneguzzo et al.,2024; Dittmer et al., 2020). Seventeen studies consisted of 100% female participants; the remaining studies consisted of over 80% female participants. Eight studies reported co-morbidities including a range of axis 1 disorders (mood disorders, anxiety disorders, substance misuse), of which two included participants with personality disorders (Juarascio et al., 2013; Kelly et al., 2017; Zeek et al., 2020; Schag et al., 2019; Dittmer et al., 2020; Biney et al., 2022; Telch et al., 2001; Wilfey et al., 1993).

Five studies observed inpatient treatment (Dittmer et al., 2020; Biney et al., 2022; Mountford et al., 2015; Juarascio et al., 2013; Meneguzzo et al., 2024), the remaining studies were conducted in outpatient treatment settings. Intervention duration ranged from 6 sessions (Biney et al., 2022) to 24 sessions (Leitenberg et al., 1988; Pegado et al., 2018), with a mean of 12.4 sessions. Six studies used a quasi-experimental design (Mountford et al., 2015; Schlegel et al., 2015; Juarascio et al., 2013; Meneguzzo et al., 2024; Bhatnagar et al., 2013; Pegado et al., 2018), and the remaining studies employed a randomized control design.

Figure 1. PRISMA flow diagram.



Intervention types

The included studies varied in terms of therapeutic modality and focus. Treatment modalities included; CBT (n=15), behavioural therapy (n=1), exposure and response prevention (n=1), interpersonal therapy (n=1), acceptance and commitment therapy (n=2), dialectical behaviour and emotion regulation therapy (n=2), sports therapy (n=2), counter attitudinal therapy (n=1), competitive memory training (n=1) and cognitive remediation therapy (n=1) and compassion focused therapy (n=1).

Intervention focus differed across studies; some interventions evaluated broad CBT interventions to target cognitive and behavioural features associated with ED's (Agras et al., 1995; Dingemans et al., 2007; Gorin et al., 2003; Leitenberg et al., 1998a; Pegado et al., 2018; Peterson et al., 2009; Wilfey et al., 1993; Wolf et al., 1992). Others used elements of CBT, third-wave and novel approaches to target a specific maintenance mechanism, these included: body image (n=5) problematic exercise (n=3), affect regulation (n=3), low mood (n=1), impulsivity (n=1), interpersonal relationships (n=1) , experiential avoidance (n=1) and self-esteem (n=2) compassion (n=1) and purging behaviours (n=2).

Control conditions

Eleven studies compared group psychological interventions with treatment as usual (TAU). Most studies provided some description of TAU condition. Across both inpatient and outpatient studies, TAU typically involved a multi-component treatment approach which included psychiatric, individual therapy, dietetic, physiotherapy, and occupational therapy.

Table 1. Resulting study characteristics

Study	Country	Study design	Setting	Intervention(n)	N sessions	CG (n=)	Diagnosis	Age (mean, SD)	% Female	Outcome measure
Alfonsson et al. (2015)	Sweden	RCT	Outpatient	Behavioural activation (n=34)	10	WL (n=38)	BED	44.34 (10.74)	93.8%	EDE-Q
Agras et al. (1995)	USA	RCT	Outpatient	CBT (n=39)	12	WL (n=11)	BED	47.6 (10.1)	86%	Binge Eating Scale
Biney et al. (2022)	UK	RCT (pilot)	Inpatient	CBT (self esteem intervention) (n=25)	6	TAU (n=25)	AN	15.22 (1.62)	100%	EDE-Q
Bhatnagar et al. (2013)	USA	QES	Outpatient	CBT (body image intervention) (n=19)	10	WL (n=19)	AN, BN, EDNOS	27.72 (9.43)	100%	EAT-26
Dingemans et al (2007)	Netherlands	RCT	Outpatient	CBT (n=28)	15	WL (n=22)	BED	37.78 (na)	95%	EDE
Dittmer et al. (2020)	Germany	RCT	Inpatient	CBT (compulsive exercise intervention) (n=112)	8	TAU (n=95)	AN	19.25 (na)	100%	EDE-Q

Fogelkvist et al. (2020)	Sweden	RCT	Outpatient	ACT (body image intervention) (n=52)	12	TAU (n=47)	AN, Atypical AN, BN, BED, UFED, Purging	26.91 (7.50)	100%	EDE-Q
Gorin et al .(2003)	USA	RCT	Outpatient	CBT (n=32)	12	WL (n=31)	BED	45.2 (10.03)	100%	TFEQ**
Juarascio et al. (2013)	USA	QES	Inpatient	ACT (n=52)	8	TAU (n=53)	AN, BN	26.74 (9.19)	100%	EDE-Q
Kelly et al. (2017)	USA	RCT	Outpatient	CFT (n=11)	12	TAU (n=11)	AN, BN, BED, EDNOS	31.92 (na)	100%	EDE-Q
Korrelboom et al (2009)	Netherlands	RCT	Outpatient	COMET (n=26) (self-esteem)	8	TAU (n=26)	AN, BN, EDNOS	25.45 (na)	100%	EDI-II**
Leitenberg et al. (1988)	USA	RCT	Outpatient	1. CBT (n=12) 2. CBT+ERP (n=11)	24	WL (n=12)	BN	26 (6.04)	100%	EAT-26
Meneguzzo et al (2024)	Italy	QES	Inpatient	CREST (cognitive remediation and emotion skills intervention) (n=63)	8	TAU (n=53)	AN	NR Range (14-60)	100%	EDE-Q
Mountford et al. (2015)	UK	QES	Inpatient and day patient	CBT (body image intervention) (n=50)	8	TAU (n=40)	AN	27.23 (9.09)	97.7%	EDE-Q**
Pegado et al. (2018)	Brazil	QES	Outpatient	CBT (n=10)	24	TAU (n=6)	AN	14.50 (na)	100%	EDE-Q

Peterson et al. (2009)	USA	RCT	Outpatient	CBT (n=60)	15	WL (n=69)	BED	47.10 (10.4)	90%	EDE-Q
Petersson et al. (2022)	Sweden	RCT	Outpatient	Affect School (emotion regulation intervention) (n=21)	8	TAU (n=18)	AN, OSFED, BED	28.97 (na)	100%	EDE-Q
Schag et al. (2019)	Germany	RCT	Outpatient	CBT (impulsivity intervention) (n=41)	8	No treatment (n=39)	BED	40.30 (12.72)	83.75%	EDE-Q
Schlegel et al. (2015)	Germany	QES	Outpatient	Sports therapy intervention (n=18)	12	TAU (n=18)	AN, BN, EDNOS	25.45 (na)	91.6%	EDE-Q
Stice et al. (2015)	USA	RCT (pilot)	Outpatient	Counter attitudinal therapy (body image intervention) (n=66)	8	TAU (n=62)	Transdiagnostic (NR)	23.7 (7.3)	100%	EDI
Telch et al. (2001)	USA	RCT	Outpatient	DBT (emotion regulation intervention) (n=18)	20	WL (n=16)	BED	50 (9.1)	100%	EDE**
Vocks et al. (2011)	Germany	RCT	Outpatient	CBT (body image intervention) (n=17)	10	WL (n=15)	AN, BN, EDNOS	28.22 (6.73)	100%	EDE-Q**
Wilfey et al. (1993)	USA	RCT	Outpatient	CBT (n=18) IPT (n=18)	16	WL (n=20)	BED	44.3 (8.3)	100%	TFEQ**
Wolf et al (1992)	USA	RCT	Outpatient	CBT (n=15) BT (n=15)	10	WL (n=12)	BN	26 (na)	100%	EDI**

Zeeck et al (2020)	Germany	RCT	Outpatient	Sports therapy intervention(N=15)	12	WL (N=11)	AN, BN, OSFED	25.53 (na)	96.15%	EDE-Q

Notes. RCT= Randomized control trial, QES= Quasi Experimental Design, CG= control group, IG= Intervention group; WL= waitlist, TAU= treatment as usual; CBT= cognitive behavioural therapy, ACT= acceptance and commitment therapy, CFT= compassion focused therapy, DBT= dialectical behavioural therapy, IPT= interpersonal therapy, BT= behavioural therapy, ERP= exposure and response prevention, COMET= competitive memory training; AN= anorexia nervosa, BN= bulimia nervosa, BED= binge eating disorder, OSFED= other specified feeding or eating disorder, EDNOS= eating disorder not otherwise specified; EDE-Q= eating disorder examination questionnaire, EDE= eating disorder examination, EDI= eating disorder inventory, TFEQ= three factor eating questionnaire, EAT-26= eating attitudes test; (na)= SD could not be calculated due to study not providing overall mean age across groups. Outcome measure: **= subscales of ED psychopathology combined and averaged.

Quality appraisal

Assessment of overall study quality revealed that 8 studies were classified as ‘weak’ quality. Sixteen were classified as moderate, and only one was classified as ‘strong’. The primary areas for methodological shortcoming were found in blinding, selection bias, confounders and drop out.

Table 2. Quality appraisal.

Author, year	Selection bias	Study Design	Confounders	Blinding	Data collection	Drop out	Overall
Agras et al (1995)	M	M	M	W	S	M	**Moderate**
Alfonsson et al. (2015)	M	S	M	W	S	M	**Moderate**
Bhatnagar et al. (2013)	M	M	S	W	S	S	**Moderate**
Biney et al. (2022)	M	S	W	W	S	M	**Weak**
Dingemans et al (2007)	M	M	S	W	S	M	**Moderate**
Dittmer et al. (2020)	M	S	S	S	S	W	**Moderate**
Fogelkvist et al. (2020)	M	S	M	W	S	S	**Moderate**
Gorin et al., (2003)	W	M	M	W	S	M	**Weak**
Juarascio et al., (2013)	M	M	M	W	S	W	**Weak**
Kelly et al., (2017)	M	M	S	W	S	S	**Moderate**
Korrelboom et al (2009)	M	S	M	W	S	S	**Moderate**
Leitenberg et al. (1988)	M	M	S	W	S	M	**Moderate**

Meneguzzo et al (2024)	M	M	S	W	S	S	**Moderate**
Mountford et al. (2015)	M	S	M	W	S	M	**Moderate**
Pegado et al. (2018)	W	M	S	W	S	W	**Weak**
Peterson et al. (2009)	M	S	S	M	S	W	**Moderate**
Petersson et al. (2022)	W	S	M	W	S	S	**Weak**
Schag et al. (2019)	M	S	S	M	S	M	**Strong**
Schlegel et al. (2015)	M	M	M	W	S	M	**Moderate**
Stice et al. (2015)	W	S	M	M	S	M	**Moderate**
Telch et al. (2001)	W	M	W	W	S	M	**Weak**
Vocks et al. (2011)	M	S	W	W	S	W	**Weak**
Wilfey et al. (1993)	W	M	S	W	S	M	**Weak**
Wolf et al (1992)	M	M	S	W	S	S	**Moderate**
Zeek et al (2020)	W	S	M	M	S	M	**Moderate**

Note: S= strong; M= moderate; W= weak.

All studies that were classified as ‘weak’, lacked blinding of outcome assessors and participants to the study purpose. Additional weaknesses included; retention rate of less than 60% at last available follow-up (Vocks et al., 2011; Juarascio et al., 2013; Pegado et al., 2018), relying solely on newspaper advertisements for

recruitment which may have introduced selection bias (Gorin et al., 2003; Telch et al., 2001; Wilfey et al., 1993), recruitment methods unclear (Pegado et al., 2018), less than 60% participation agreement (Petersson et al., 2022), and not controlling for confounding variables (Biney et al., 2022). Our percentage of weak ratings is similar to other reviews that have used this tool within the eating disorder intervention literature. We did not exclude studies based on quality rating, which is consistent with previous eating disorder systematic reviews and meta-analysis that have used the EPHPP tool (Linardon et al., 2019; Godfrey et al., 2015; Linardon et al., 2017a;Linardon et al, 2017b; Buerger et al., 2021). Alternatively, to account for the potential bias of including these studies on treatment effects, we conducted sensitivity analysis which included estimating effect sizes with weak studies removed.

Meta-analysis results

Post-test effects

The initial meta-analysis included 25 studies. Three studies (Leitenberg et al., 1998; Wolf et al., 1992; Wilfey et al., 1993) reported results for two separate interventions (independent samples) and thus had three arms, which were analysed separately. Control arms for these studies were split to ensure that effect sizes were not inflated due to double counting participants (Higgins & Eldrige, 2022). This resulted in a total of 28 intervention arms.

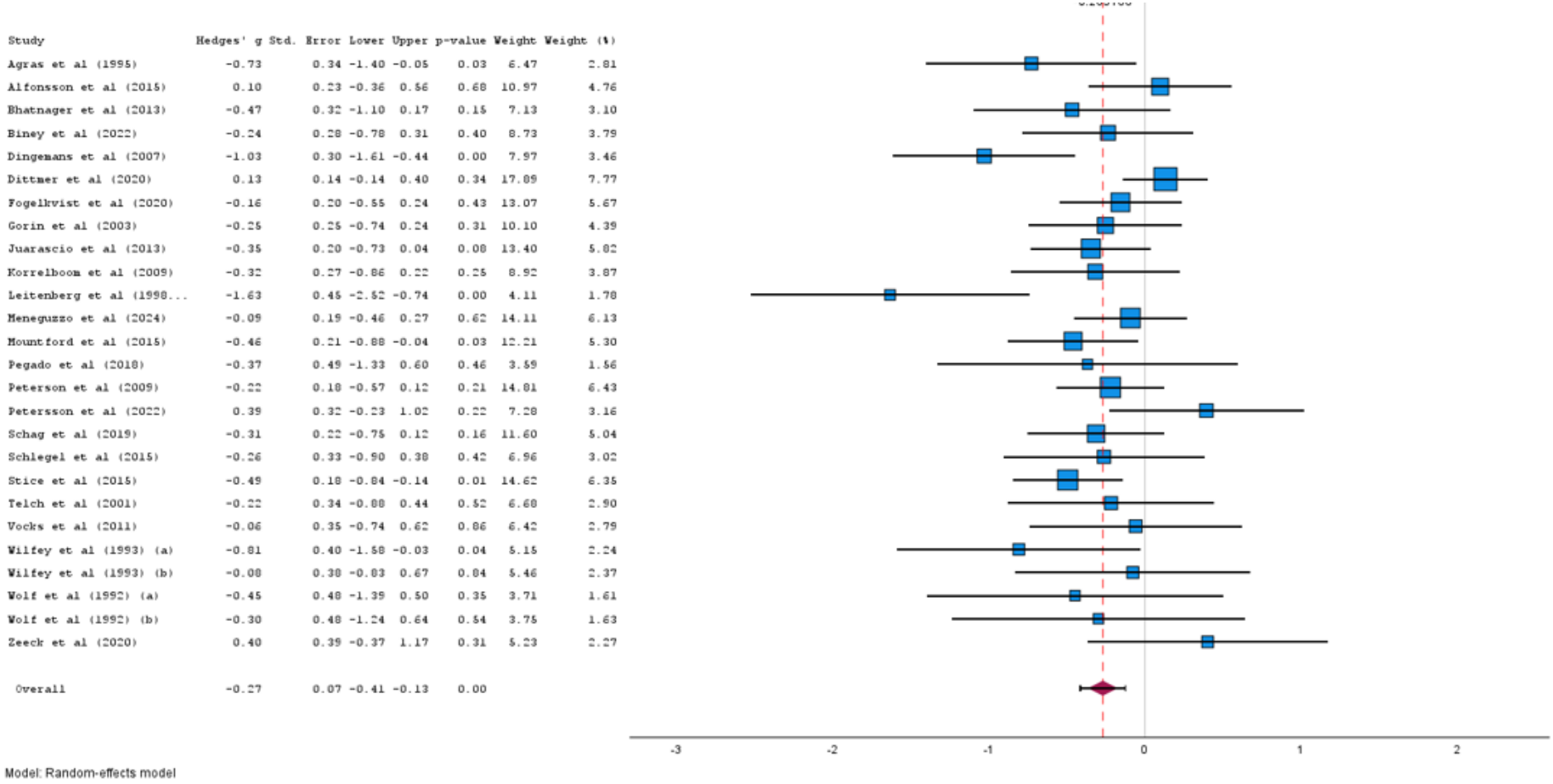
Group psychological interventions were statistically significantly more effective than wait-list and TAU controls in reducing ED psychopathology across settings. We found a small overall effect size of group psychological interventions on ED symptoms (g= -0.34; 95% CI: -0.56, -0.11, p<.001, k=28). Significant moderate heterogeneity was detected (Cochrane's Q=77.768, df=27, <.001, I^2 =54.7%). This suggests that results may be influenced by differences between studies.

Inspection of the initial forest plot revealed two outlier studies in which the 95% confidence interval did not overlap with 95% confidence interval of the pooled effect (Kelly et al., 2017; Leitenberg et al., 1998b). Once removed, heterogeneity reduced to low levels however remained significant (Q=41.835, df=25, p=.019, I^2= 35.6%). The updated overall effect size was small and significant (g=-0.27,

95% CI: -0.41 -0.13, p<.001, k=26). The results can be viewed in the forest plot presented in Figure 2.

Inspection of the funnel plot (Appendix 1.2) revealed slight asymmetry; however this was non-significant as indicated by Egger's regression test (intercept=.022, t=.109, p=.914).

Figure 2. Forest plot of effect sizes comparing group intervention with control at posttreatment



Study	Hedges' g	Std. Error	Lower	Upper	p-value	Weight	Weight (%)
Agras et al (1995)	-0.73	0.34	-1.40	-0.05	0.03	6.47	2.81
Alfonsson et al (2015)	0.10	0.23	-0.36	0.56	0.68	10.97	4.76
Bhatnager et al (2013)	-0.47	0.32	-1.10	0.17	0.15	7.13	3.10
Biney et al (2022)	-0.24	0.28	-0.78	0.31	0.40	8.73	3.79
Dingemans et al (2007)	-1.03	0.30	-1.61	-0.44	0.00	7.97	3.46
Dittmer et al (2020)	0.13	0.14	-0.14	0.40	0.34	17.89	7.77
Fogelkvist et al (2020)	-0.16	0.20	-0.55	0.24	0.43	13.07	5.67
Gorin et al (2003)	-0.25	0.25	-0.74	0.24	0.31	10.10	4.39
Juarascio et al (2013)	-0.35	0.20	-0.73	0.04	0.08	13.40	5.82
Korrelboom et al (2009)	-0.32	0.27	-0.86	0.22	0.25	8.92	3.87
Leitenberg et al (1998...	-1.63	0.45	-2.52	-0.74	0.00	4.11	1.78
Meneguzzo et al (2024)	-0.09	0.19	-0.46	0.27	0.62	14.11	6.13
Mountford et al (2015)	-0.46	0.21	-0.88	-0.04	0.03	12.21	5.30
Pegado et al (2018)	-0.37	0.49	-1.33	0.60	0.46	3.59	1.56
Peterson et al (2009)	-0.22	0.18	-0.57	0.12	0.21	14.81	6.43
Petersson et al (2022)	0.39	0.32	-0.23	1.02	0.22	7.28	3.16
Schag et al (2019)	-0.31	0.22	-0.75	0.12	0.16	11.60	5.04
Schlegel et al (2015)	-0.26	0.33	-0.90	0.38	0.42	6.96	3.02
Stice et al (2015)	-0.49	0.18	-0.84	-0.14	0.01	14.62	6.35
Telch et al (2001)	-0.22	0.34	-0.88	0.44	0.52	6.68	2.90
Vocks et al (2011)	-0.06	0.35	-0.74	0.62	0.86	6.42	2.79
Wilfey et al (1993) (a)	-0.81	0.40	-1.58	-0.03	0.04	5.15	2.24
Wilfey et al (1993) (b)	-0.00	0.38	-0.83	0.67	0.84	5.46	2.37
Wolf et al (1992) (a)	-0.45	0.48	-1.39	0.50	0.35	3.71	1.61
Wolf et al (1992) (b)	-0.30	0.48	-1.24	0.64	0.54	3.75	1.63
Zeeck et al (2020)	0.40	0.39	-0.37	1.17	0.31	5.23	2.27
Overall	-0.27	0.07	-0.41	-0.13	0.00		

Model: Random-effects model

Subgroup analysis

Subgroup analyses are presented in Table 3. We looked at the moderating effect of ED diagnosis, setting (inpatient vs outpatient), treatment focus (mechanism focused vs standard CBT) and control condition (wait-list/no treatment vs TAU).

ED diagnoses did not moderate the overall effect (p=.37). A significant small effect size was found for BED (g=-0.35, 95% CI: -0.62, -0.07, p=.02, I^2 =36.5%), and a non-significant medium effect size was found for BN (g=-0.80, 95% CI: -2.63, 1.02, p=.20, I^2 = 59.4%). A significant small effect size was found for mixed samples (g=-0.23, 95% CI: -0.45, -0.00, p=0.05, I^2 = 13.9%), and a non-significant small effect was found for AN (g=-0.14, 95% CI: -0.45, 0.17, p= 0.29, I^2 =41.3%). Test of subgroup homogeneity was not statistically significant within diagnostic subgroups.

There was no significant difference between outpatient and inpatient settings (p=.32); however, outpatient studies had a statistically significant small effect size (g=-0.31, 95% CI: -0.49, -0.13, p=<.001, I^2 = 31.2%), whilst inpatient studies did not (g=-0.17, 95% CI: -0.47, 0.14, p=0.20, I^2 =46.6%). Most inpatient studies consisted of AN sample (n=4). Test of within subgroup homogeneity was significant for outpatient settings.

There was a statistically significant small effect for studies that used a wait-list control (g=-0.36, 95% CI: -0.61, -0.11, p=.01, I^2 =43%) and for those that used treatment as usual control (g=-0.19, 95% CI: -0.37,-0.02, p=.03, I^2 =35%), there was no significant difference between groups (p=.23). Test of within subgroup homogeneity was not statistically significant for both subgroups.

We found a significant difference for intervention focus; studies that used standard CBT group interventions (g=-0.62, 95% CI: -1.00, -0.24, p=.01, I^2 =49.7%) showed a statistically significantly higher effect size than mechanism focused interventions (g=-0.17, 95% CI: -0.30, -0.04, p=.01, I^2 =22.5%), both of which were significant effects. Test of within subgroup homogeneity was not statistically significant for both subgroups.

When we explored the effects across the different mechanism focused interventions, we found body image interventions to show a statistically significant higher effect size (g=-0.36, 95% CI: -0.59, -0.13, p=.01, I^2 =0%) compared to interventions that target problematic exercise (g=0.10, 95% CI: -0.40, 0.61, p= .48, I^2 =.2%), and affect regulation groups (g=-0.01, 95% CI: -0.66, 0.64, p=.93, I^2 =.1%), the latter two not significant. Test of within subgroup homogeneity was not statistically significant for all subgroups.

Table 3. Subgroup analyses (post-test)

Criteria	**Subgroup**	K	**Hedges g (95% CI)**	**Test for subgroup differences**
Diagnoses	AN	5	-0.14 (-0.45, 0.17)ns	Q=3.18, df=3, (p=0.37)ns
	BN	3	-0.80 (-2.63, 1.02)ns	
	BED	9	-0.35 (-0.62, -0.07)**	
	Mixed	9	-0.23 (-0.45, -0.00)**	
Setting	Inpatient	5	-0.17 (-0.47, 0.14)ns	Q=0.99, df=1, (p=0.32)ns
	Outpatient	21	-0.31 (-0.49, -0.13)**	
Control	Wait-list /no treatment	15	-0.36 (-0.61, -0.11)**	Q=1.47, df= 1, (p=0.23)ns
	Treatment as usual	11	-0.19 (-0.37, -0.02)**	
Treatment focus	Standard CBT	8	-0.62 (-1.00, -0.24)**	Q=6.51, df=1, (p=.01)**
	Mechanism focused	18	-0.17 (-0.30, -0.04) **	
Type of Mechanism	Body image	5	-0.36 (-0.59, -0.13)**	Q=9.28, df=2, (p=.01)**
	Problematic exercise	3	0.10 (-0.40, 0.61)ns	
	Affect regulation	3	-0.01 (-0.66, 0.64)ns	

NS= non-significant; AN= anorexia nervosa; BN= bulimia nervosa; BED= binge eating disorder;

Sensitivity analysis

Removal of studies classified as 'weak' (k = 8) did not change the effect size or significance of the overall results (g=-0.31, 95% CI: -0.51, -0.10, p=.01). Effect sizes and significance remained stable for WL controls (g=-0.42, 95 CI: -0.80, -0.04, p=.03), effect size remained stable for TAU controls TAU (g=-0.21, 95%CI : -0.43, 0.02, p=.06), however became non-significant. Effect size and significance remained stable across settings; inpatient settings (g=-0.11, 95% CI: -0.84, 0.62, p=.58), outpatient settings (g=-0.37, 95% CI: -0.61, -0.13, p=.01). Effect sizes and significance remained stable across diagnoses, AN (g=-0.11, 95 CI: -0.84, 0.62, p=.58), BN (g=-0.81, 95 CI: -2.63, 1.02, p=.20), mixed (g=-0.29, 95% CI: -0.56, -0.03, p=.04), BED remained stable however became non-significant (g=-0.39, 95% CI: -0.92, 0.14, p=.11), which is likely due to loss of statistical power. The effect size and significance for standard CBT interventions remained stable (g=-0.75, 95% CI:-1.41, -0.09, p=.04). Mechanism focused interventions remained stable (g=-0.18, 95% CI: -0.35, -0.02, p=.03); test of subgroup difference remained significant after removal of weak studies (Q=4.90, df=1, p=.03).

Discussion

The present meta-analysis aimed to evaluate the effectiveness of group psychological interventions as a viable and effective treatment option for eating disorders. Compared to previous meta-analytic studies that explored group interventions for ED's, our results are based on a wide spectrum of evidence, including studies that used treatment as usual control conditions, different settings and ED diagnoses including Anorexia Nervosa, thereby providing a valuable update and an expanded review of intervention types across applied settings.

Our review, which focused on controlled trials, found that group psychological interventions offer a modest reduction in the psychological and behavioral features of eating disorder presentations when compared to controls (g=-0.27). This modest effect size may be interpreted in relation to the length of group interventions included within this review. On average, groups included 12 sessions which are exceedingly short compared to individual therapies; individual CBT-E for Anorexia Nervosa typically includes 40 sessions, and 20 sessions for Bulimia Nervosa (Fairburn, 2008). Additionally, the studies included participants with psychiatric co-morbidities and inpatients, which have been found to be associated with poor treatment outcomes (Eskild-Jensen et al., 2020; Simpson et al., 2022; Vall & Wade, 2015; Marzola et al., 2021). Therefore, the modest effect size may be reflective of the complexity in presentation and group duration.

We did not find treatment setting, control group or diagnoses to moderate treatment effect; however, trends within the data are consistent with previous research. A negligible non-significant effect was found for anorexia nervosa patients which is consistent with previous research that has documented the challenges in achieving positive psychotherapy outcomes for this population (Solmi et al., 2021). The majority of these studies included were conducted within inpatient settings, which often represent a severe manifestation of the illness, with many individuals detained under the Mental Health Act (2007) (Clausen et al., 2020). Therefore, this may reflect higher co-morbidity and motivation to engage in any type of therapy whether group or individual (Elzakkers et al., 2014). The evidence base would be enhanced from prioritizing controlled group interventions studies for those with anorexia nervosa within outpatient settings.

We also found a small yet significant effect for group interventions studies that used a Binge Eating Disorder (BED) sample. The findings are in line with theoretical expectations such as the interpersonal model of BED; which propose that interpersonal difficulties perpetuate symptoms for this population and therefore they may be particularly well-suited to the interpersonal nature of group based interventions (Wilfey et al., 2003). Additionally, we found a small significant effect for mixed diagnostic groups, in which group interventions typically targeted a shared symptom; this may suggest potential utility in

delivering such interventions, within under-resourced services, where grouping patients is more practical.

We found a large effect for Bulimia Nervosa (g=-0.80), however this was not statistically significant. This effect is comparable in size to findings from Grenon et al (2017) study which also found a moderate effect (g=0.73). Our study was limited to two bulimia studies, comprising of three arms, therefore may have been underpowered to detect a statistically significant effect. The bulimia studies included in the present meta-analysis date back to 1988 and 1992. Previous meta-analysis have failed to identify group interventions studies for this population published within the past nine years. This is notable as those with bulimia nervosa are commonly treated in groups (Von Ranson & Robinson, 2006; Rosenvinge & Klusmeier, 2000). Therefore, there is an urgent need for updated controlled trials to validate the continued use of group therapy for this population.

We did not find a moderating effect of setting on outcome. Though not a significant moderator, outpatient settings yielded a significant small effect (g=-0.31) compared to non-significant negligible effect for inpatient settings(g=-0.17). This disparity may reflect overlap between diagnosis and setting; as most inpatient studies focused on severe anorexia presentations, whereas outpatient studies included bulimia, binge eating disorder and mixed samples. This disparity complicates the interpretation of findings as it is challenging to determine whether differences are attributable to treatment setting, diagnoses or an interaction of both. Future research and replication studies are needed to explore the effectiveness' of group interventions across diagnoses in-outpatient settings.

We did not find control condition to be a significant moderator, however studies that used a wait-list control condition showed a larger effect (g=-0.36) than TAU (g=-0.19), both of which were significant. This is unsurprising, as wait-list groups typically receive no active intervention therefore the benefits of group therapy are highlighted more clearly. In contrast, TAU conditions included multi-disciplinary care which may have attenuated the unique contribution of group interventions.

We found intervention focus to be a significant moderator of treatment effect. That is, standard CBT group interventions produced a moderate effect (g=-0.62) compared to interventions that targeted a specific mechanism which showed a

small effect (g=-0.17), of which both were significant. These findings suggest that standard CBT delivered in a group format can offer reductions in ED psychopathology. CBT interventions target multiple cognitive and behavioral symptoms associated with EDs, and individual CBT has an established evidence base across EDs (Linardon et al., 2017), which may account for the smaller effects seen within mechanism focused interventions.

Additionally, standard CBT interventions algin more closely with the primary outcome measure of ED psychopathology, which likely accounts for stronger effects. However, mechanism focused interventions may yield stronger effects on secondary outcomes related to intervention target (self-esteem, body image, emotion regulation, problematic exercise), which could be explored in further reviews. When we investigated the effect of different mechanism focused interventions on ED psychopathology, we found that body image interventions had significantly larger effects (g=-0.36) than those that targeted problematic exercise (g=0.10), and affect regulation (g=-0.01). This aligns with previous research which shows body image disturbance is linked with the onset and maintenance of eating disorders (Fairburn, 2008; Farrel et al., 2006). Therefore, this may indicate body image as a promising mechanism that is amendable through group treatment for ED's.

Limitations

The present meta-analysis included important limitations. First, the included studies varied in intervention duration, focus and modality, with limited replication studies. We attempted to explore this by using sub-group analysis, however there is likely to be other sources of heterogeneity within subgroups. Our treatment as usual conditions were not standardised across studies, varied considerably, and were poorly described in most studies; therefore we cannot rule out the confounding effect of additional treatments on effects. The number of studies in some subgroups was small, which may have influenced our ability to detect statistically significant differences between groups. Our inclusion criteria likely restricted our sample size for bulimia studies as we required a waitlist/no treatment or TAU control, whereas previous reviews have shown that a large proportion of the bulimia literature compare group interventions with an

individual intervention or active control (Polnay et al., 2014; Grenon et al., 2017). This may have influenced our ability to detect a significant effect for this sample. We did not analyse follow-up data, as this was not available for most studies. When this information was presented, it varied in length and often only reported for the intervention group. While the results from the sensitivity analysis show that removal of studies classified as 'weak' quality highlight overall robustness of findings, future research should prioritise high quality research to allow for reliable subgroup comparisons. Additionally, the included studies were unevenly distributed with the majority of anorexia studies carried out in inpatient settings and used adapted/ novel interventions, whilst studies for Bulimia and Binge Eating Disorder were carried out in outpatient settings, using standard CBT and compared with wait-list controls. Therefore, it is challenging to disentangle the effect of these on overall treatment effect. Finally, the majority of the studies included an adult population, with limited studies on adolescents which precluded subgroup analyses for developmental differences on treatment effects.

Conclusions and clinical implications

This meta-analysis adds to the previous literature by extending our understanding of the effectiveness of group interventions across diagnoses and settings. The study benefits from the inclusion of participants with AN, psychiatric co-morbidities, and standard care conditions, which reflects the complexity of presentations seen within clinical practice. The findings suggest that group psychological interventions offer modest improvement in eating disorder psychopathology across ED presentations, although some of the effects may vary across ED's and settings (inpatient and outpatient). Standard CBT group interventions, and body image interventions appear to show the greatest clinical utility in terms of reduction in overall ED psychopathology.

Conflicts of interest

The authors declare that they have no conflicts of interest to declare.

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Chapter 2

An evaluation of a program for carers of people with anorexia nervosa: a feasibility study

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Plain Language Summary

Background: Caring for someone with an eating disorder can negatively impact on carer wellbeing, which can lead to challenging relational dynamics. Currently, there is limited evidence on effective of interventions for carers of adults with moderate-severe anorexia nervosa (AN-MS). This study explored the feasibility of running an intervention based on schema therapy for carers of adults with AN, and will inform a future study to assess its effectiveness.

Aims and questions:

- How successful is recruitment and retention of the intervention?
- Can the intervention be delivered with adequate treatment fidelity?
- How acceptable are outcome measures?
- What are the main characteristics of the sample recruited on the domains of caregiver burden, expressed emotion, distress, healthy adult schema and family functioning?

Methods

Participants: Carers of adults with anorexia nervosa were included in the study. Patients with AN-MS were invited to complete questionnaires alongside their carer (although they did not receive direct intervention).

Recruitment: We aimed to recruit 8-10 carers of adults with AN to two cycles of the intervention. Carers were invited to take part in the study by clinicians at NHS sites and social media advertising.

Design: The study used an uncontrolled feasibility design.

Data collection: Carers who agreed to take part completed online questionnaires at baseline, mid-intervention (6 weeks), post intervention (12 weeks) and at 3-month follow-up. Carers also completed two short weekly questionnaires across the 12 weeks.

Main findings: We successfully recruited 8-10 carers per group; however we were only able to retain 50% of these at the end of the intervention, and 44.4% at follow-up. Only 3 patients with AN agreed to participate. Male carers and spouses/partners appeared to drop out at a higher rate than other carers. Most carers returned questionnaires, and they were generally completed in full. The intervention was delivered with good treatment fidelity. The characteristics of the sample were similar to previous carer intervention studies.

Conclusion: Overall, the study found that it is feasible to recruit and deliver the present intervention to carers of adults with AN, however retention was challenging, and only half of carers remained on study at the endpoint. We found that recruiting through clinical sites worked well, and most participants accepted the outcome measures. More research is needed to understand why people dropped out to improve retention in future trials.

Abstract

Objectives: There is currently a lack of evidence base for interventions for carers of adults with moderate-severe anorexia nervosa (AN-MS). This study aimed to evaluate the feasibility of running a 12-week intervention, informed by schema therapy, for this population.

Methods: A repeated-measures uncontrolled feasibility design was used. The intervention was delivered online across 12 weekly sessions. Two consecutive cycles of the group were delivered over seven months. Feasibility was assessed based on recruitment, retention, treatment fidelity and acceptability of outcome measures. The study also described the sample using psychological and clinical characteristics.

Results: Each intervention cycle successfully recruited nine carers. Of those recruited, 50% remained on study and provided endpoint data, and 44.4% completed assessments at 3-month follow-up. Outcome measures were generally completed in full, and the intervention was delivered with adequate fidelity.

Conclusions: The study demonstrates promising feasibility outcomes; however, retention was challenging, and only half of carers remained on study and provided end point data. Qualitative research is needed to further enhance our understanding of the acceptability of the intervention and inform strategies for improving retention in future trials.

Introduction

Anorexia nervosa and the impact on family functioning

Anorexia nervosa is an eating disorder characterized by low body weight, food restriction and an intense fear of weight gain (American Psychiatric Association, 2013). Moderate to severe presentations (AN-MS) are associated with poor treatment response, longer duration of illness, and psychiatric co-morbidities (Broomfield et al., 2017). In addition, research has shown high rates for co-morbid personality disorders and PTSD within AN (Martinussen et al., 2017; Sjögren et al., 2023), which has been shown to complicate treatment outcomes and predict poor prognosis and longevity of the illness (Simpson et al., 2022; Rodríguez et al., 2005). Often, informal carers like family members and spouses provide long term care for individuals with AN-MS; the demanding nature of this care has been associated with adverse outcomes on interpersonal relationships, quality of life, and psychological distress for caregivers (Surgenor, 2022; Treasure & Nazar, 2016; Coomber & King, 2012). Research has found that carers of patients with EDs report unmet needs such as lack of information, and a need for support from a professional (Pehlivan et al., 2024; Graap et al., 2007). These needs can be met using evidence-based interventions, which may offer carers the opportunity to gain the knowledge and skills required to navigate the complexity of illness.

Carer models and Interventions within eating disorders

The current empirical evidence for carers of people with EDs includes psychoeducational interventions (Dimitripoulos et al., 2018; Uehara et al., 2001), systemic CBT interventions (Grover et al., 2011) and the New Maudsley Method (Hibbs et al., 2015; McEvoy et al., 2019; Pepin et al., 2013; Quiles et al., 2018; Sepulveda et al., 2008). Interventions based on the New Maudsley Method include “The collaborative care workshops” and various online/DVD adaptions (*for review see*; Mihaljevic, 2020; Hibbs et al., 2015). The New Maudsley Method is based on the cognitive interpersonal model of EDs (Goddard et al., 2011). The model states that carers experience psychological distress which is expressed

in unhelpful ways (e.g. criticism, hostility or over protection), which can inadvertently maintain the illness via unhelpful communication strategies and accommodating behavior patterns (Rienecke, 2018; Kyriacou et al., 2008; Zabala et al, 2009). These interventions aim to target caregiver burden and expressed emotion through teaching communication and coping skills (Treasure et al., 2015).

Findings from preliminary studies have been promising, and have found significant improvements in expressed emotion, self-efficacy and carer skills post intervention (Sepulveda et al., 2008, 2010; Pepin et al., 2013). These findings were replicated in an RCT which compared a brief version of the workshop to a wait-list control (McEvoy et al., 2019). Studies which compared this intervention to a psychoeducational program revealed both groups showed improvements in levels of distress, caregiving appraisal and expressed emotion (Quiles Marco et al., 2018; Sepulveda et al., 2018), however no significant differences were found between groups.

Whilst previous carer workshop interventions have received empirical support, they are predominantly skills based, limited to 6 sessions and primarily focused on addressing maintaining factors (Sepulveda et al., 2008, 2010; Pepin et al., 2013*).* There remains a lack of evidence base interventions tailored for carers of adults with anorexia nervosa, particularly with complex presentations and co-morbidities. Existing carer interventions place a strong emphasis on enhancing communication skills with a focus on meal-time support (Treasure et al., 2016). These interventions give limited attention to the relational dynamics between the carer and loved one, which has been found to be an important factor for recovery (Hay & Cho, 2013). In contrast, research in the field of personality disorders has shown that carer interventions with longer duration, and a focus on enhancing understanding of etiology, interpersonal relationships and emotion validation skills can significantly improve carer distress and quality of life (Guillen et al., 2022).

Given the complexities of AN-MS, carers of adults with complex AN may also benefit from deeper level approaches which allow carers to understand the

complex belief systems that underline the anorexic behaviors. One approach that may be useful for carers of someone with AN-MS and/or co-morbid personality disorders is schema therapy. AN-MS has been linked to greater complexity and comorbidity, associated with deeply entrenched beliefs (schemas) about oneself, others and the world (Young et al., 2003). In turn, maladaptive schemas have been linked to the development of AN, and are associated with higher levels of ambivalence and treatment resistance (Joshua et al., 2022). Schema therapy has been evidenced as a useful approach for treating patients with complex ED presentations (for reviews of the evidence see Joshua et al., 2023; Pugh, 2015), therefore, it is likely to be of particular relevance to carers of this population.

Schema Model

According to the schema therapy model, consistent unmet emotional needs and/or early adverse experiences with caregivers and others can contribute to the development of maladaptive schemas (e.g. continuous criticism can give rise to schemas of failure and defectiveness; Young et al., 2003). These schemas operate as emotional wounds, which can be activated in adulthood by situations that in some way resemble those early events (e.g. criticism, making mistakes), resulting in high levels of distressing emotion (fear, shame, anger, loneliness or a combination of these) (Young et al., 2003).

Schema therapy for EDs place a strong emphasis on coping ‘modes’ which are patterns of thinking, feeling and behaving that emerge in response to activation of schema beliefs, often shaped by early life experiences (Jacob & Arntz, 2013). At the core of schema therapy, is an understanding that whilst everyone has schemas and modes, these can become problematic as a result of adverse childhood experiences. The ‘child modes’ refer to emotional temperament-based states that are common to all humans: Vulnerable, Impulsive, Angry and Contented. It has been suggested that these states are commonly rejected within EDs and often overshadowed by inner critic modes (self-blame and shame) and other maladaptive coping modes (e.g. overcontrol, emotional detachment or excessive compliance) (Simpson et al., 2012; Pugh et al., 2015; Marney et al., 2024). The goal of schema therapy is to support an individual to develop their own “Healthy Adult” mode to care for their child modes and reduce the impact of

avoidant coping modes in order to meet their needs in more helpful ways. It has been suggested that functional and adaptive coping with schema activation is attributed to the healthy adult mode, which tends to be weak in cases of severe psychopathology (Yakin & Arntz et al., 2023).

Within the schema model, anorexia nervosa is not externalized or given negative connotations, instead it is conceptualized as 'solution' to avoid overwhelming emotional distress associated with the activation of maladaptive schema (Simpson & Smith, 2019). Applying this model to a carer intervention, schema therapy may help carers understand the underlying emotional struggles that drive their loved ones' ED behaviours, which may allow them to respond with empathy rather than frustration. In addition, carers' behaviours are likely to operate from their own schema modes. By identifying and understanding their own schema modes, and that of their loved one, it is expected the carers may learn to set healthier boundaries, reduce distress and influence interpersonal and relation dynamics within the caregiving context.

The present intervention

The present intervention goes beyond standard skills-based approaches and has an emphasis on supporting carers of adults with AN-MS by helping them to consider their own innate temperament and schema modes, and those of their loved ones, and how these may influence interactions. The CAREFREE (Carers program for Fluency in Resonance, and Empowerment in Eating Disorders) programme was originally developed for carers of adolescents with AN (Seifi et al., Submitted), and adapted in this study for carers of adults with AN. The intervention was delivered in an online group format as previous carer studies have found that online platforms are preferred to reduce geographical constraints (Batchelor et al., 2022).

The current study

Given the novelty of the intervention and lack of established evidence-based, a feasibility study was deemed necessary to help plan for a larger efficacy trial (NIHR, 2021). The present study represents the first phase of a two-part

feasibility evaluation (*Phase 1*) which involved establishing early-stage feasibility from running two cycles of the intervention based on specified indicators; including recruitment and retention, treatment fidelity, acceptability of outcome measures, and resulting sample characteristics (Teresi et al., 2022; Orsmond & Cohn, 2015). *Phase 2* will involve running a further three groups, which will explore the acceptability of the intervention using qualitative methods, and potential signs of intervention effectiveness. Together, these will provide a comprehensive evaluation to inform the design of a future efficacy trial.

Aims and research questions

The primary aim of *Phase 1* was to assess the feasibility of running a novel 12-week group program, informed by schema therapy for carers, partners and family members of individuals with AN-MS and/or co-morbidities. Best practice guidelines for feasibility studies were used to inform our primary research questions (Teresi et al., 2022; Orsmond & Cohn, 2015):

- How successful is recruitment and retention of the intervention?
- Can the intervention be delivered with adequate treatment fidelity?
- How acceptable are outcome measures?
- What are the main psychological or clinical characteristics of the sample recruited on the domains of caregiver burden, expressed emotion, distress, family functioning, and levels of adaptive schema mode (healthy adult mode).

Method

Design

The study employed an uncontrolled repeated measures feasibility design informed by conceptual feasibility frameworks (Teresi et al., 2022; Orsmond & Chon, 2015). These frameworks guided the identification of key feasibility domains assessed within this study. Feasibility domains such as recruitment, retention, treatment fidelity and acceptability of outcome measures were selected for their direct relevance to early-stage preliminary work in *Phase 1.* Phase 1

included running two consecutive cycles of the intervention, which was delivered over seven months.

Participants

Carers

Carer participants were eligible if they had a family member, partner or spouse with AN-MS or Complex AN which was defined as: (1) BMI between 13-15; or 15-17 and ≥1 previous treatment for ED, and/or has a co-morbid psychiatric diagnosis, and/or duration of ED is greater than 4 years. The BMI qualifier was removed as a protocol amendment for Group 2 to be in line with current ICD-11 definition of Anorexia Nervosa (WHO, 2019).

Carers were required to be over 17 years old, can speak and read English, were not experiencing an acute psychotic mental health state and had access to the internet and were comfortable using an online meeting platform. Participation of the family member who has AN was not necessary.

Patients

The patient sample, adults with AN-MS/complex AN, were eligible if their carer had consented to take part in the study. The patient sample continued treatment as usual and did not receive any direct intervention in the study. They were invited to complete outcome assessments across the four timepoints.

Patients were eligible if they had AN-MS/complex AN, were over 17 years old, could speak and read English and were not experiencing an acute psychotic mental health state.

Procedure

Recruitment

The feasibility study aimed to run two cycles of the intervention and recruit 8-10 carers per cycle. Participants were recruited from collaborating NHS Scotland Inpatient and Outpatient Eating Disorder Services. Clinicians at NHS sites 'pre-screened' potential participants (carers associated with patients within the

service) based on the eligibility criteria. Clinicians provided the patient with a study flyer and invited them to offer their carer the opportunity to take part in the study. In some instances, when the carer was present at the site, clinicians were able to provide the carer with study information directly. Additionally, study flyers were shared nationwide via social media by BEAT Eating Disorder Charity and posters within the NHS sites.

Carers and/or patients registered their interest by contacting the research team via email. Interested participants were emailed a participant information sheet and invited to attend an eligibility screening call with the lead clinician and research assistant via online platform Microsoft Teams. Participants were screened for eligibility, provided further details of the study and offered the opportunity to address any questions regarding participation.

Eligible participants were provided with an online link to review the information sheet, consent form and completion of baseline assessment measures. Carers were advised that participation is entirely voluntary and that they can take part with or without participation of the family member with AN.

Intervention

The intervention consisted of twelve weekly online sessions (1.5 hours) delivered via videoconferencing platform Zoom© in the evening. Participants accessed the platform from their own personal devices. Two consecutive cycles of the intervention were delivered across 7 months *(Group 1;* 4th September 2023- 20th November 2023, *Group 2*; 6th December 2023- 6th March 2024). The intervention was delivered by two clinical psychologists trained in schema therapy with experience of working with individuals with Anorexia Nervosa and their families. The intervention included a mix of psychoeducation, skills based and experiential techniques; topics covered in the sessions are outlined below and in Table 4.

Initial sessions (Modules 1-4)

The early sessions focused on introducing the schema therapy framework for understanding anorexia nervosa. These modules helped carers conceptualise

anorexia in terms of schema modes, explore temperament/trait-based factors, and view anorexia as a 'solution' to accessing unmet emotional needs. Cultural and familial influences on the development of AN was also introduced to aid carers in contextualizing difficulties.

Middle sessions (Module 5-8)

This phase helped carers identify and manage relational dynamics; particularly around conflict, self-criticism and individuation. These modules explored the role of the 'inner critic' and related schema modes in both carers and loved ones, by helping them to recognise and navigate interactions through the lens of 'mode clashes'. Additionally, culturally shaped expressions of anger were discussed, and the protective function of anger was discussed in the context of anorexia. Carers were taught strategies for bypassing coping modes and anger, and to attune to the underlying emotional needs and reconnect with their loved one. A dedicated module on individuation and autonomy explored the unspoken fears associated with recovery (for both carer and loved one) and provided skills for supporting the development of healthy levels of autonomy.

Later sessions (Module 9-12)

The final phase explored the impact of guilt and shame in both the carer and their loved one, and included experiential exercises which aimed to support carers to learn how to model their 'healthy adult mode' and practice self-compassion. These sessions included guided compassionate imagery, communication strategies to facilitate emotional attunement and reflective exercises.

Table 4. Overview of session topics.

Module	**Content**	**Module**	**Content**
Module 1	Introductions & expectations	Module 7	Managing anger and conflict
Module 2	Thinking of anorexia as parts of self – "Modes"	Module 8	Negotiating Individuation

Module 3	Temperament and traits	Module 9	Understanding and Managing Shame & Guilt
Module 4	Emotional needs	Module 10	The role of modelling – healthy self-care and self-compassion
Module 5	Fighting the inner critic	Module 11	Carer self-compassion
Module 6	Mode clashes between you and the person with anorexia	Module 12	Strengthening Healthy Adult & strategies for managing modes

Data collection

Carers received an e-mail link to complete outcome measures at baseline (prior to session 1), midpoint (6 weeks), endpoint (12 weeks), and follow-up (24 weeks) via an online survey platform JISC©. Additionally, carers completed short pre and post session questionnaires across the 12 weeks. Patients completed measures across the four timepoints. Carers were regularly prompted by the research assistant via e-mail to complete outcome measures.

Ethical approval

Ethical approval for the study was obtained from the Southeast Scotland Research Committee 01 on the 24th February 2023.

Measures

Feasibility measures

Primary feasibility indicators were recruitment, retention, acceptability of outcome measures and treatment fidelity.

Recruitment. Recruitment was measured by the proportion of participants approached, opted in, and successfully recruited to the study.

Completion rate of intervention. Completion rate of intervention was measured as proportion of recruited carers who remained on study at Week 12.

Study retention. Study retention was measured as proportion of recruited participants who remained on study and provided outcome data at endpoint and 3-month follow-up.

Intervention adherence. Intervention adherence was measured as proportion of sessions attended by carers who remained on study at week 12.

Acceptability of outcome measures. Response rate to questionnaires (>70% was deemed acceptable based on previous carer studies (Sepulveda et al., 2008; Grover et al., 2011). Data completion was measured as the proportion of fully completed outcome assessments across the four time-points.

Treatment fidelity. Fidelity in Group 1 was assessed by the author on two occasions and fidelity in Group 2 was assessed by a different assessor (trainee clinical psychologist) on one occasion. Fidelity was measured using an adapted version of the Group Schema Therapy Assessment Scale (GSTRS-R) (Zarbock et al., 2014), which is a 28-item instrument for group schema therapy. The measure contained assessment of adherence to key therapeutic elements involved in delivering group schema therapy and a 7-point rating scale for delivery of each element (0= very poor, 1= poor, 2= unsatisfactory, 3= adequate, 4= good, 5= very good and 6= excellent). The indicators used to assess therapist competence are detailed in the fidelity manual which offers a structured rating system with clear behavioral examples for each rating (Appendix 2.1). Fifteen Items were selected from the scale based on their relevance to the content delivered within the carer intervention. Adherence scores are calculated by summing adherence to key therapeutic elements (number of present elements) and calculating the

average rating of delivery. Two additional items were included for the purposes of this study; this included the therapists' ability to deliver all of the main learning points/content and style of delivery (dyadic vs didactic balance), which were also rated on the same 7-point scale.

Demographics

A demographic questionnaire was developed to capture participant (carer and patient) sociodemographic information (Appendix 2.2). Due to an administrative error, age and ethnicity were inadvertently omitted from the initial questionnaire. However, efforts were made to subsequently collect this data.

Outcome measures

The primary outcome (caregiver burden) and measures related to the main psychological domains of interest were used to characterize the sample and were administered across the four time-points. Details of all outcome measures included can be found in Appendix 2.11.

Primary outcome measure

The Eating Disorder Impact Scale (EDIS; Sepulveda et al., 2008) measures caregiver burden related to symptoms that are specific to the eating disorder within the past month. The scale contains 24-items that are rated on a 5-point scale. Total scores are computed by adding the raw scores on all items (0-96) with higher scores reflecting higher burden severity. No clinical cut-offs were available.

Secondary outcome measures

SCORE-15 Index of Family Functioning and Change (Stratton et al., 2010): is a 15-item measure designed to assess family functioning and indications of useful therapeutic change in family functioning. Items are rated on a 5-point Likert scale. The clinical cut-off for the average scale is ≥ 2.72 (Miller et al., 2022).

Schema Mode Inventory (Healthy Adult Subscale) (Young et al., 2007): is a is a 10-item scale that measures the strength of healthy adult schema mode using a 6-point Likert scale. Higher scores reflect higher

levels of this mode. The clinical cut-off for the average score is ≤4.60 (Lobbestael et al., 2012).

Family Questionnaire (FQ) (Wiedemann et al, 2002) is a 20-item questionnaire that measures levels of expressed emotion (criticism and emotional-overinvolvement) of relatives with psychiatric disorders. Items are rated on a 4-point Likert scale. Cut-off score for the criticism subscale is ≥23; and ≥27 for emotional overinvolvement.

Depression, anxiety and stress scale (DASS-10) (Halford et al., 2021) is a 10-item measure assessing depression, anxiety and stress over the past seven days using a 4-point Likert scale. All items are summed to provide a total score for psychological distress. Severity scores of 0-4 are classified as subclinical, 5-6 = mild, 7-12= moderate, 13-20= severe, and 21-30 = extremely severe.

Weekly outcome measures

World Health Organisation Quality of Life Assessment (WHOQOL-BREF) (WhoQol Group, 1998): one item from WHOQOL-BREF was used to assess quality of life: "How would you rate your quality of life?" which is rated on a 5-point Likert scale.

SCORE-15 Index of Family Functioning and Change (Stratton et al., 2010): One item from the SCORE-15 was selected to assess family functioning: "How are you managing as a family?" which is rated on a 5-point Likert scale.

Session Rating Scale (SRS) (Johnson, Miller and Duncan, 2000): A short-four item visual analogue scale which measures aspects of therapeutic alliance including; relationships, goals and topics, approach and method and overall. Items were rated on a 7-point Likert scale, in this study.

Patient outcome measure

EDEQ-7 (Jenkins et al., 2020): is a 7-item brief version of the gold standard EDE-Q (Fairburn et al., 2008), designed to measure eating disorder psychopathology. Items were derived from the original EDE-Q, retaining the same response scale (0–6) referencing the past 28 days.

The scale provides an overall global score, and three subscale scores (Dietary Restraint, Shape/Weight Overvaluation, Body Dissatisfaction). The average clinical cut-off for global score is 3.64 (Bang et al., 2023).

Data analysis

The data were organized and stored using SPSS V-29. Recruitment, retention and outcome measure completion rates were calculated using proportional analysis using Microsoft Excel. Descriptive statistics were generated using SPSS to characterize baseline demographic and psychological profiles of participants. Means and Standard deviations were used for continuous outcome measure scores as recommended by feasibility study guidance (Teresi et al., 2022). When clinical cut off scores are available for outcome measures, those were used to characterize the proportion of the sample meeting clinical levels. Total scores were not calculated when the scale contained a missing item. No formal sample size or power calculations were required as only descriptive statistics were used.

Results

Recruitment and retention

During the period from 3rd May 2023 to 30th November 2023, a total for 87 carers and/or patients were approached to take part (Figure 3. Consolidated Standard of Reporting Trials (CONSORT diagram), of whom 36 opted in (carers=30, patients=6). Non-participation at this stage was attributed to no response (n=38), declined to take part (n=12), and inability to commit to sessions (n=1).

Eligibility and enrollment

Of the 36 participants who opted in (30 carers, 6 patients), 34 (94%) were informed about the study from collaborating NHS sites and two participants had unknown recruitment sources. Twenty-one participants (18 carers, 3 patients) were successfully recruited and enrolled onto the study, resulting in an enrollment rate of 58%.

Allocation

Eighteen carers were allocated to receive the intervention, with 3 patients consenting to provide parallel outcome data (no intervention). All successfully recruited participants were from collaborating NHS sites.

Study retention

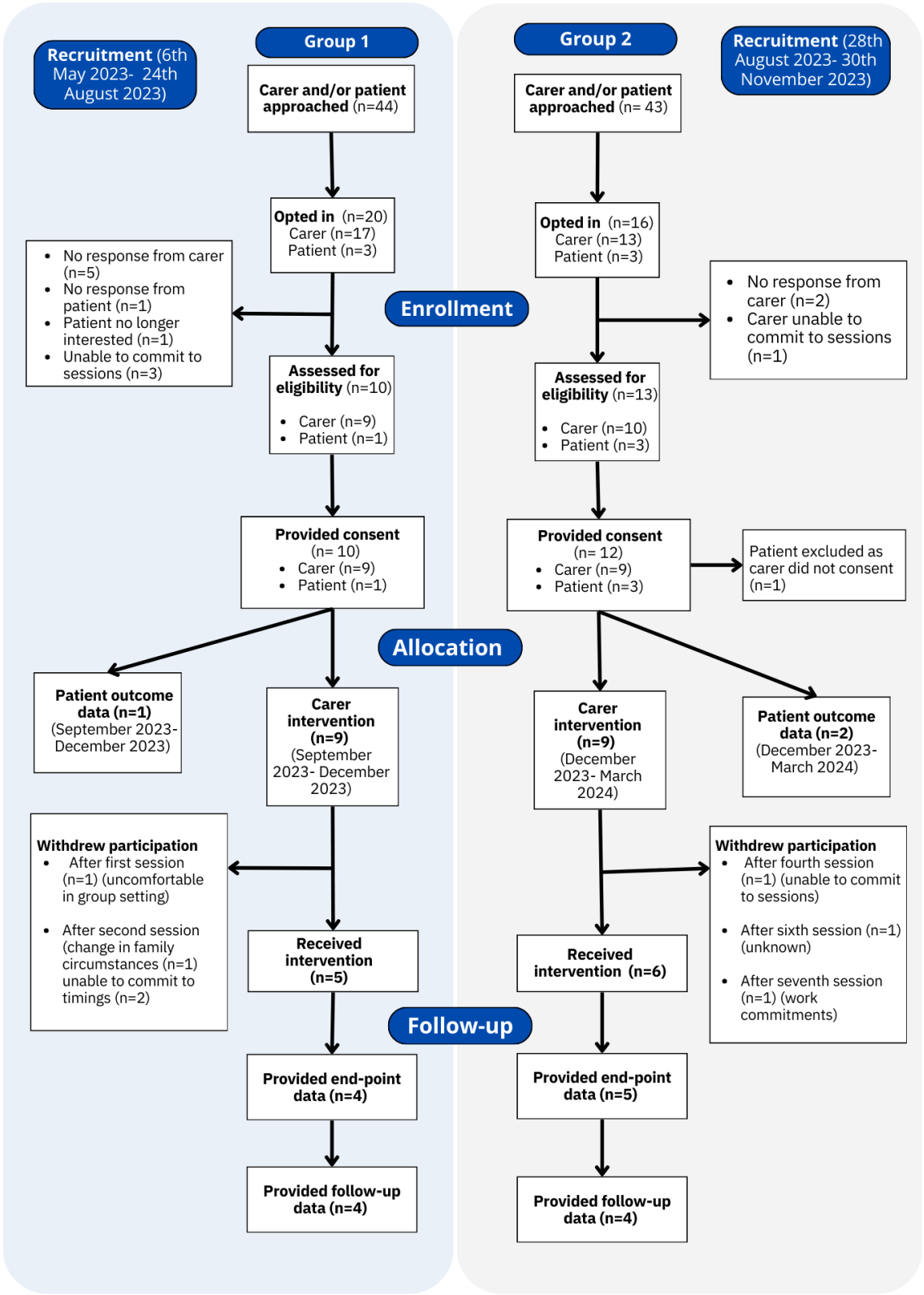
Of 18 carers recruited and provided baseline data, 9 (50%) remained on study and provided outcome data at endpoint, and 8 (44.4%) at 3 month follow up. All patients recruited were retained from baseline to follow-up.

Intervention completion and adherence

No formal attendance threshold was required for continued study enrollment. Participants were classified as 'treatment completers' if they remained on study at the end of the intervention period (Week 12), and did not formally drop-out. Seven participants formally dropped out during the intervention phase (38.9%). Eleven (61%) carers completed treatment (Group 1: 5 (56%), Group 2: 6 (67%).

For treatment completers (n=11); 8 participants attended at least 80% of sessions offered, two attended 67% of sessions and one only attended 41% of sessions offered. The mean number of sessions attended was 9.6 sessions for both groups. Carers who withdrew participation from the study before the midpoint (session 6, n=4) attended between 1 to 2 sessions. Those who withdrew participation after midpoint (session 6-12, n=3) attended between 3 to 5 sessions. Four carers reported that their reason for drop-out was other competing commitments (57%).

Figure 3. CONSORT Diagram depicting recruitment and retention.



Demographics of the sample

Carer reported demographics

Demographic information reported by carers is presented in Table 5. The majority of the sample of carers across both groups consisted of parents. Group 1 included two parents from the same family, along with a mother/ partner dyad from the same family. Group 2 included two parent dyads from the same family.

The majority of the carers sample were female, in employment, had attended further education, and were married. No carers received carer benefits. The majority of the sample were in a parenting role for the person with AN.

With regards to the person they care for, the majority were aged between 18-29 years old. The mean duration of illness overall was 7.14 years, with group 1 reporting a longer illness duration (7.6 years) than group 2 (6.3 years), however missing data may have impacted the accuracy of these estimates. In terms of living arrangements, a higher percentage of carers were living with the person with AN in Group 1 (88.9%) compared to Group 2 (44.4%).

Table 5. Demographic information for carers.

Variable	**Total sample**	**Group 1**	**Group 2**
Carer age (M, SD)	**(n=14)**	**(n=7)**	**(n=7)**
	53.1 (9.4))	49.6 (10.4)	56.6(7.5)
Ethnicity	**(n=11)**	**(n=6)**	**(n=5)**
	White (100%)	White (100%)	White (100%)
Carer gender	**(n=18)**	**(n=9)**	**(n=9)**
Female	11 (61.1%)	5 (55.6%)	6 (66.7%)
Male	7 (38.9%)	4 (44.4%)	3 (33.3%)
Relationship with person with AN	**(n=18)**	**(n=9)**	**(n=9)**
Parent	14 (77.8%)	6 (66.7%)	8 (88.9%)
Spouse	2 (11.1%)	2 (22.2%)	
Partner	2 (11.1%)	1 (11.1%)	1 (11.1%)
Age of person with AN	**(n=17)**	**(n=9)**	**(n=8)**
18-19	5 (29.4%)	3 (33.3%)	2 (25%)

20-29	8 (47.1%)	4 (44.4%)	4 (50%)
30-39	2 (11.8%)		2 (25%)
40-49	2 (11.8%)	2 (22.2%)	
Illness duration	**(n=14)**	**(n=8)**	**(n=6)**
Years (Mean, SD)	7.14 (7.7)	7.62 (7.37)	6.25 (8.76)
Gender of person with AN	**(n=18)**	**(n=9)**	**(n=9)**
Female	9 (100%)	9 (100%)	9 (100%)
Currently living with person with AN	**(n=18)**	**(n=9)**	**(n=9)**
Yes	12 (66.7%)	8 (88.9%)	4 (44.4%)
No	6 (33.3%)	1 (11.1%)	5 (55.6%)
Carer employment status	**(n=17)**	**(n=9)**	**(n=8)**
Employed	13 (76.5%)	6 (66.7%)	7 (87.5%)
Unemployed	2 (11.8%)	1 (11.1%)	1 (12.5%)
Retired	2 (11.8%)	2 (22.2%)	
Carer Educational attainment	**(n=18)**	**(n=9)**	**(n=9)**
Secondary school (<16 years)	2 (11.1%)	1 (11.1%)	1 (11.1%)
Further secondary school (higher, A-levels)	3 (16.7%)	1 (11.1%)	2 (22.2%)
Further education	13 (72.2%)	7 (77.8%)	6 (66.7%)
Carer Relationship status	**(n=18)**	**(n=9)**	**(n=9)**
Married	16 (88.9%)	9 (100%)	7 (77.8%)
Single	1 (5.6%)		1 (11.1%)
Divorced	1 (5.6%)		1 (11.1%)
In receipt of carer benefits	**(n=18)**	**(n=9)**	**(n=9)**
No	18 (100%)	9 (100%)	9 (100%)

Patient demographics

As the patient sample consisted of only 3 participants, demographic data have been combined and reported together. All patients were female, and aged 18, 30 and 23. Two reported an illness duration of 4 years, and one reported 11 years. All patients were daughters of carers in the study. Two were employed and one was unemployed. One patient reported completing further secondary school, whilst another had pursued further education, and one patient omitted this data. Two reported that they did not live with their carer, and one currently resided with their carer. Two reported that they were single, and one was married.

Features of carers who dropped out

Dropout was defined as a carer who formally withdrew participation from the study during the intervention phase. Dropout rates and reasons have been previously provided in Figure 3. A higher proportion of male carers dropped out (n=4, 57.1%) compared to female carers (n=3, 27.3%). Additionally, a higher proportion of spouses/partners dropped out (n=2, 50%), compared to parents (n=5, 35%). Dropout rates were higher among carers supporting individuals with a shorter duration of illness (<5 years; n=4, 50%) compared to those caring for individuals with a longer duration of illness (> 5 years, n= 1, 16.7%).

Acceptability of outcome measures

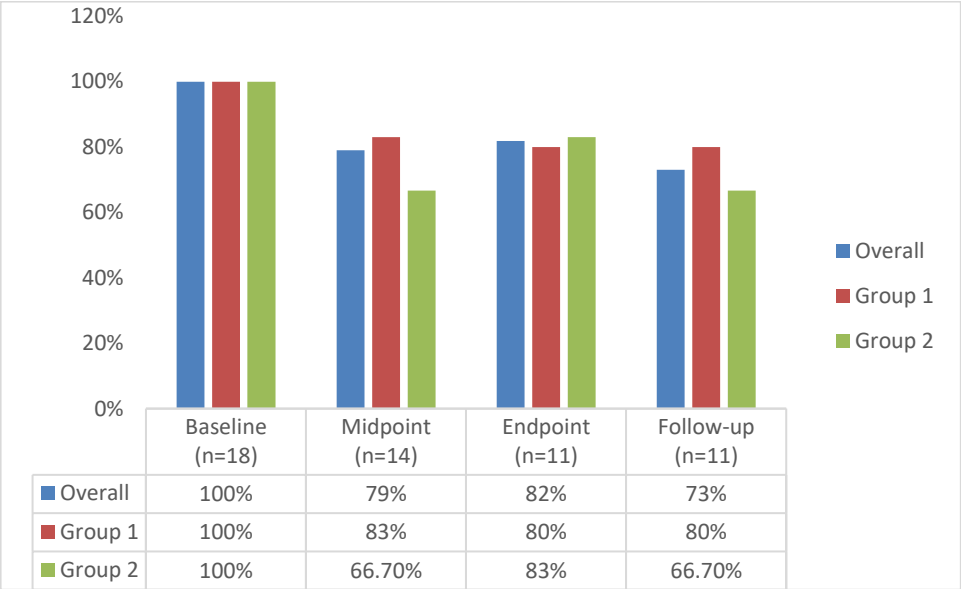
Response rate

The response rate for carer questionnaires at all time points are detailed in Figure 4. We considered a response rate of 70% to be sufficient, based on previous carer intervention response rates for post and follow up timepoints (Grover et al., 2011; Sepvuleda et al., 2008). Response rate is defined as the proportion of participants (on study) who responded to the questionnaire and provided data. Overall, 11 (79%) of participants returned the midpoint measure, 9 (82%) returned the endpoint measures and 8 (73%) returned follow-up measures. See Figure 4. for a breakdown per group.

Overall, a higher proportion of participants returned baseline, and end-point questionnaires, compared to mid-point and follow-up. Group 2 had a poor

response (<70%) rate for mid-point and follow-up questionnaires. All patient participants responded to all questionnaires across all time-points.

Figure 4. Carer Questionnaire Response Rate.



	Baseline (n=18)	Midpoint (n=14)	Endpoint (n=11)	Follow-up (n=11)
Overall	100%	79%	82%	73%
Group 1	100%	83%	80%	80%
Group 2	100%	66.70%	83%	66.70%

Completion of outcome measures

We assessed completion levels for each outcome measure within the returned questionnaire to evaluate its acceptability. Completion was defined as having no missing items, and is reported as the percentage of fully completed measures across four timepoints.

Outcome measures were generally completed in full, and all questions generally complete. Of the total returned carer questionnaires across baseline, midpoint, endpoint, and follow-up (n=46), the Eating Disorder Impact Scale had a completion rate of 96%, the SCORE-15 had 98% completion, the Family Questionnaire (Criticism) had 93% completion, the Family Questionnaire (Emotional Over-Involvement) had 96% completion, the Schema Mode Inventory- Health Adult Subscale had 98% completion, DASS-10 had 98% completion, the Interpersonal Guilt Rating Scale had 89%, the Experience in Close relationships- revised has 95%, the Young Parenting Inventory (mother subscale) had 84%, and the father subscale had 76%. The EDEQ-7, the HRQOL and the Score-15 outcome measures had 100% completion by all patient

participants (n=3). The ANSOCQ had 44% completion rate, and only one patient provided fully complete data for this across timepoints.

Weekly questionnaires

Pre-session questionnaires had an overall higher completion rate than post-session questionnaires. Overall, treatment completers (n=11) completed 75% of total pre-session questionnaires issued and 48% of total post session questionnaires. Therefore, weekly questionnaires issued before the session had a higher completion rate.

Treatment fidelity

Across both groups, evidence of all key therapeutic elements were present (100%) in all sessions rated (n=3), indicating that the intervention was delivered with adequate fidelity to the group schema therapy model. All key learning points were covered in all three sessions rated. The mean competence rating score for Group 1 on the first session was rated as ‘good’ (M=4.93, SD=1.03) and ‘very good’ for the second session (M=5.13, SD= 0.92). In Group 2 the session was rated as ‘very good’ (M=5.3, SD=0.1).

Psychological and clinical characteristics of the recruited sample.

Carer sample characteristics

Carers’ baseline level of caregiver burden, family dysfunction, expressed emotion, levels of healthy adult schema mode, and psychological distress are presented in Table 6. Scores were only calculated for participants who had no missing data on any items. Scores suggested that most participants reported low levels of family dysfunction, with only 29.4% of carers scoring above the clinical cut-off. In relation to expressed emotion, 33.3% of carers reported high levels of criticism and this was similar for both groups. In comparison, a high proportion of carers reported high levels of emotional over-involvement (82.4%). Over half of carers scored within the moderate-severe range for psychological distress, with a higher proportion in Group 2. The majority of carers reported levels of healthy adult mode schema similar to the general population (77.8%), whilst 22.2%

reported clinical levels similar to those found in an Axis 1 population (anxiety, mood disorder, substance abuse, eating disorders and somatoform disorder) (Lobbestael et al., 2012)

Table 6. Baseline carer and patient characteristics

Measure	**Total**	**Group 1**	**Group 2**
Eating disorder Impact Scale (EDIS)	**(n=17)**	**(n=9)**	**(n=8)**
Eating Disorder Caregiver Burden (mean, SD) Severity (0-96)	40 (14.8)	43 (14.6)	36.9 (15.4)
SCORE-15	**(n=17)**	**(n=9)**	**(n=8)**
Family dysfunction	**Above clinical cut off:** 29.4% (n=5)	**Above clinical cut off:** 22.2%(n=2)	**Above clinical off** : 37.5% (n=3)
	Below clinical cut off: 70.6% (n=12)	**Below clinical cut off:** 77.7%(n=7)	**Below cut off:** 62.5%(n=5)
Family Questionnaire (FQ)	**(n=18)**	**(n=9)**	**(n=9)**
Criticism	**High criticism**: 33.3% (n=6)	**High criticism:** 33.3% (n=3)	**High criticism:** 33.3% (n=3)
	(n=17)	**(n=8)**	**(n=9)**
Emotional overinvolvement	**High emotional overinvolvement:** 82.4% (n=14)	**High emotional overinvolvement:** 87.5% (n=7)	**High emotional overinvolvement:** 77.8% (n=7)
Schema Mode Inventory (Healthy Adult Subscale)	**(n=18)**	**(n=9)**	**(n=9)**
Healthy Adult Mode	**Average (non-clinical):** 77.8% (n=14)	**Average (non-clinical):** 77.8% (n=7)	**Average (non-clinical):** 77.8% (n=7)

(Level of Adaptive Coping Mode)	**Clinical level:** 22.2%(n=4)	**Clinical level:** 22.2% (n=2)	**Clinical level:** 22.2% (n=2)

DASS-10	**(n=18)**	**(n=9)**	**(n=9)**
Depression, and anxiety and stress	**Severe:** 22.2% (n=4) **Moderate:** 44.4% (n=8) **Mild:** 11.1% (n=2) **Subclinical:** 22.2%(n=4)	**Severe:** 11.1% (n=1) **Moderate:** 44.4%(n=4) **Mild:** 22.2% (n=2) **Subclinical:** 22.2% (n=2)	**Severe:** 33.3% (n=3) **Moderate:** 44.4% (n=4) **Subclinical:** (n=2)

Patient Characteristics

EDEQ-7	**Total (n=3)**	**Group 1 (n=1)**	**Group 2 (n=2)**
Eating Disorder Severity	**Above clinical cut-off**: 66.7% (n=2) **Below clinical cut off**: 33.3% (n=1)	**Below clinical cut-off**: 100% (n=1)	**Above clinical cut-off**: 100%(n=2)

Discussion

The present study aimed to assess the initial feasibility of running a novel 12-week group program, informed by schema therapy for carers, partners and family members of individuals with AN-MS, and/or co-morbidities. *Phase 1* of the feasibility study demonstrated that the current protocol is sufficient to recruit a relevant sample of carer participants to the study, however retention was challenging. Outcome measures were deemed acceptable by participants, and the intervention was delivered with adequate fidelity. Considerations for future trials in relation to these feasibility domains are discussed below.

Can we recruit participants?

The findings from this study indicated that it is feasible to recruit 8-10 carers per intervention cycle over the course of 3 months respectively. All successfully recruited carers were identified by clinicians at collaborating NHS sites, which

indicates that this is a productive recruitment method. This is in line with previous research that has found that establishing personal contact and explaining the relevance of the research is a key component for successful recruitment (Axen et al., 2021).

It was challenging to recruit patients to the study, and only three agreed to participate. Other studies that have collected patient data alongside a carer intervention reported that 57% and 63% of patients (individuals with ED) agreed to participate (Quiles Marcos et al., 2018; Sepulveda et al., 2018). However, patients in these studies were excluded if they were presented with co-morbid personality disorder and included other ED diagnoses in addition to AN. In contrast, the current study required the inclusion of AN-MS and/or co-morbidities, which may in part have impacted on the low participation rates. This patient group is likely to present with low motivation and increased barriers to treatment which may also impact on research participation (Robinson et al., 2024). Therefore, future trials would benefit from consideration of additional recruitment/engagement efforts to evaluate the impact of the intervention on patient outcomes.

Of carers recruited to the study, the majority were female and in a parental role for the person with AN. This is similar to previous carer intervention studies (Uehara et al., 2001; Sepulveda et al., 2008; Grover et al., 2011; Jenkins et al., 2018). Our sample consisted of 22.2% partners/spouses, this is a high proportion compared to previous studies, with most recruiting under 10% partners and spouses (*for review see;* Mihaljevic, 2020). These findings align with previous research that have found high caregiver burden in spouses, thus, highlighting a need for support for this group (Pehlivan et al., 2024).

Can we retain participants?

Intervention retention rate was 50%, which is relatively low compared to previous carer workshop-based interventions which have reported between 70-100% retention rates post intervention (Uehara et al., 2001; Sepulveda et al., 2008; Sepulveda et al., 2010; Gisladotter et al., 2016). The most frequently reported reason for the drop-out was other competing commitments. It is noteworthy that the present intervention was delivered over 12 sessions compared to 6 sessions

(at most) in previous carer intervention studies; therefore, it required increased commitment from carers. One study which delivered a virtual peer support group for carers found that delivering 12 sessions over 6 months resulted in a 77% retention rate (Nicula et al., 2023). Future trials could consider bi-weekly sessions as a method of reducing burden and maintaining retention. Alternatively, the intervention could be offered as a 'Phase-based group' which would enable carers to opt in for Part-1, which would involve a shorter number of sessions to start with (e.g. 4 or 5), and following this they could either opt-in or opt-out of Part-2. This may be a method of meeting carers needs based on the different stage they are at in their own journey as well as their capacity to commit to attend and do the work.

With regards to adherence, we did not specify a minimum session adherence for carers to remain on study which might have influenced attendance rates. Of those who completed treatment, 8 attended at least 80% of sessions offered, and 2 attended 67% of sessions offered. Previous 12-week carer interventions studies have used 80% as a drop out criterion (Guillen et al., 2022). Therefore, future trials would benefit from pre-specifying a drop-out criterion with regards to session attendance and intervention completion.

We observed a higher proportion of male carers who dropped out of the intervention (57.1%) than female carers (27.3%). This is in line with findings from family-based treatment for adolescents with AN which found that 75% of mothers attended all sessions compared to 33% of fathers (Hughes et al., 2018). This may be attributed to differences in coping styles, as females have been shown to display emotional coping compared to males who display problem solving coping (Matud, 2004; Ptacek et al., 1994). Therefore, it may be that the present intervention aligned more comfortably with female coping styles than males. Additionally, 50% of carers of individuals with a shorter illness duration (<5 years) dropped out, compared to 16.7% of those caring for someone with a longer illness duration. This finding is unsurprising, as the content of the intervention was tailored to AN individuals with entrenched maladaptive beliefs, commonly seen in severe and enduring forms of illness. We also observed a higher proportion of spouses/partners (n=2, 50%) dropped out compared to parents (n=5, 35%), which may suggest this was less acceptable for this group. However,

the small sample size limit the generalizability of conclusions at this stage. The qualitative research that will follow this study should aim to focus on understanding their unique experience and perspectives.

Can the intervention be delivered with adequate fidelity?

The intervention was assessed as adhering to the group schema therapy model. Notably, there was evidence of all key therapeutic elements in both sessions. Group facilitators were rated as 'good' or 'very good' in their delivery. This indicates a strong alignment with schema therapy principles and is supportive of overall fidelity of the intervention. It is important to note that both group facilitators were trained in schema therapy. Therefore, for large-scale trials it would be essential to either recruit trained facilitators or account for and allocate resources for additional training to maintain fidelity and consistent delivery. The cost effectiveness of these additional resources will need to be taken into account in future trials.

How acceptable are outcome measures?

The small amount of missing data within outcome measures suggest that these are acceptable to participants. Completions rates are similar or higher to previous carer feasibility studies (Nicula et al., 2023; Bjornstad et al., 2021; Grover et al., 2011). This suggests that these measures are feasible and appropriate for this population and should be retained in future trials. Although overall response rates reduced from baseline, the response rate across timepoints remained above 70% for the two groups together which algins with previous carer studies (Goddard et al., 2011; Sepulveda et al., 2008; Flynn et al., 2017). Future trials could utilise e-mail reminders from the end of intervention to follow-up to further increase response rates (Whitebird et al., 2011; Svensson et al., 2012).

What are the main psychological or clinical characteristics of those recruited?

The sample reported similar levels of eating disorder caregiver burden to previous carer intervention studies (Pepin et al., 2013; Lefkovtis et al., 2024). It is notable that our sample reported low levels of family dysfunction, albeit in keeping with previous research. Studies have shown that despite the challenges

of caring for someone with AN, family cohesion, closeness and emotional expression are similar to community samples (Sim et al., 2009). However, this may also reflect that families with lower levels of dysfunction are more motivated or have greater capacity to take part in research. At the same time, whilst family cohesion, closeness and emotional expression are supportive for recovery, they may create an environment which is conducive to enmeshment and emotional over-involvement, which has been shown to negatively impact carer wellbeing (Zabala et al., 2009). Our sample reported high levels of emotional over-involvement, and 66.6% reported psychological distress within the moderate-severe range. These findings are similar to what has been found in previous carer samples (Pepin et al., 2013; Hibbs et al., 2015; Lefkovits et al., 2024). These findings confirm the need for targeted interventions for carers of adults with AN, and the similarity of the sample indicates that the present recruitment strategy is effective at reaching carers who may benefit from this intervention.

When exploring the schema specific measure (healthy adult mode) we found that 77.8% of carers reported levels similar to the general population (Lobbestael et al., 2012). This suggests that, in general, carers recruited into this study report average levels of psychological flexibility and healthy coping. (Yakin & Arntz, 2023). We could not contextualize these findings as previous studies have not examined schema modes present in carer samples. Nonetheless, this may suggest that this schema mode is not necessarily uniquely informative in carers of patients with moderate-severe AN. However, maladaptive coping strategies have been shown to predict carer burden and distress (Coomber & King, 2011), therefore future trials could include measures of maladaptive coping modes to better characterize the sample and treatment effectiveness.

With regards to the patient sample, one patient scored below the global clinical cut-off point on the EDEQ-7 (<3.64), despite all patients identified for this study identified through NHS clinicians due to their moderate-severe AN. The EDEQ-7 has a higher cut-off score than the full version of the EDE-Q (2.72) (Bang et al., 2023), and validation studies have shown that 80% of patient samples were correctly classified using this measure, thus highlighting potential for false negatives (Bang et al., 2023). Whilst the EDE-Q7 reduces questionnaire burden,

the full 28 item version is likely to be more beneficial for use in clinical samples and future studies (Aardoom et al., 2012).

Limitations

Whilst our sample was similar to previous carer intervention studies, there is still a need to identify recruitment and engagement strategies for spouses and partners. This is likely to be challenging, as the spouse/partner population for individuals is relatively small. Research has suggested that individuals with AN are less likely to have support from a spouse or partner and demonstrated significantly less positive attitudes towards romantic relationships (Schmidt et al., 1995; Tiller et al., 1995). Additionally, it is possible that partners/spouses may be less likely to identify themselves as a carer and eligible for the study. Nonetheless, future trials may increase engagement by tailoring information sheets to reflect the eligibility of partners/ spouses.

In relation to treatment fidelity, the assessors had no formal schema therapy training, which may introduce bias or inaccuracy in fidelity ratings. Whilst the assessors followed the framework outlined within the Group Schema Therapy Assessment Scale Manual (GSTRS-R) (Zarbock et al., 2014), their lack of expertise may have limited their ability to detect nuances in facilitators' adherence and competence. The assessors nonetheless had the opportunity to familiarize themselves with the intervention manual and administration guidelines and have appropriate clinical experience with a broad range of presentations, including AN. Future trials could consider including trained schema therapy assessors to enhance the reliability of fidelity ratings. Additionally, inter-rater reliability was not assessed. Therefore, it is unclear whether ratings would be consistent across different assessors. Future trials should include an assessment of inter-rater reliability to ensure consistency and objectivity in fidelity ratings.

The present study used self-report questionnaires as outcome measures, which may have introduced self-report bias. Research has shown that carers of people with EDs experience high levels of stigma and shame, which could influence the accuracy of reporting on self-assessments (Fox et al., 2017). This potential bias

should be considered when interpreting findings and accompanying clinician rated scales may be considered in future trials.

Conclusions

The findings from this feasibility study indicate that it is feasible to recruit relevant carer participants to two cycles of intervention over seven months, whereas recruitment of patient participants remained challenging, requiring consideration of further engagement strategies. Notably, recruitment from clinical sites appears to be a productive recruitment method for this type of intervention and outcome measures were generally accepted. Retention is a critical consideration for Phase 2, as the high dropout rate may threaten the validity and reliability of outcomes. It will be important to ensure consistent participation in order to assess potential signs of intervention effectiveness. The qualitative research that will follow this study should focus on the acceptability of the intervention for carers, with particular attention paid to males and spouses' experiences. Additionally, adaptations to the timing, length or structure of the intervention should be considered and assessed in future trials.

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Project Title: Evaluation of a Skills-Based Program for Carers & Families of patients with Moderate to Severe Anorexia Nervosa**.**

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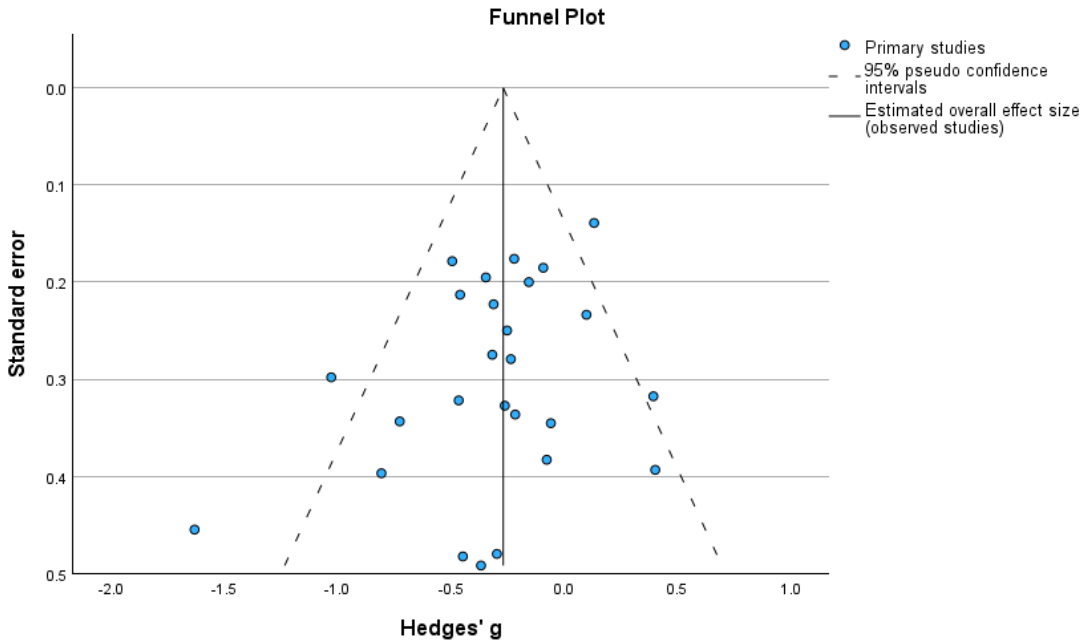
Appendices

Appendix 1.1. Search Strategy
https://osf.io/jf7zt

Appendix 1.2. Funnel plot



Appendix 1.3. PRISMA CHECKLIST

PRISMA CHECKLIST			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
TITLE			
Title	1	Identify the report as a systematic review.	Pg 7
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Pg 8
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pg 9-11
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Pg 12
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pg 12-13
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pg13-14
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Pg87
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pg14
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Pg 14
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time	Pg 14-15

PRISMA CHECKLIST			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
		points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Pg 14
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Pg 15
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Pg 15
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Pg 15
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Pg 15-16
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	NA
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Pg 15
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Pg 16
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Pg 16
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Pg 15

PRISMA CHECKLIST			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	NA
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pg 18
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	NA
Study characteristics	17	Cite each included study and present its characteristics.	Pg 20-23
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Pg 24-25
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Pg 28
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Pg 20-22,28-29
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pg 26-27
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Pg 29-30
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Pg 31
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Pg 31
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Pg 26-31
DISCUSSION			

PRISMA CHECKLIST			
Section and Topic	**Item #**	**Checklist item**	**Location where item is reported**
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pg 31-35
	23b	Discuss any limitations of the evidence included in the review.	Pg 31-35
	23c	Discuss any limitations of the review processes used.	Pg 31-35
	23d	Discuss implications of the results for practice, policy, and future research.	Pg 31-35
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Pg 12
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Pg 12
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Pg 12
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Pg 35
Competing interests	26	Declare any competing interests of review authors.	Pg 35
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Pg14

Appendix 2.1. Fidelity rating Scale.
https://osf.io/ysf5m

Appendix 2.2. Demographics
https://osf.io/s6xyq

Appendix 2.3. MRP Proposal
https://osf.io/e2p3h

Appendix 2.4 Data analysis plan and process

Descriptive statistics and proportional analysis (%) was used to answer feasibility research questions and describe the sample characteristics using the outcome measures.

Data analysis process

Recruitment process

Step 1) Data collection

- Participant data for those approached between 1st May 2023- 30th of November 2023) were anonymized and extracted from EDGE system. Monthly screening records from each recruitment site was examined (carer or patient approached). Data was recorded on an Excel Spreadsheet (including approached (date), opted in (date), off study reason/ successful recruited outcome.

Separate spreadsheets were created for:

- Group 1 (Recruitment period; 6th May 2023 to August 2023)
- Group 2 (Recruitment period; 28th August 2023- November 30th 2023)

Recruitment numbers:

- Group 1; Approached; 22 patients, 22 carers.
- Group 2; Approached; 18 carers, 25 patients.

Step 2) Initial outcomes tracking

Outcomes recorded and calculated using Pivot Tables (drop-off after initial approach, e.g. no response, declined etc)

- **Group 1: 24 off study**
- **Group 2: 27 off study**

Step 3) Opt in Outcomes calculated (e.g. no response following opt in etc).

- **Group 1: 10 off study**
- **Group 2: 3 off study**

Enrolment rate calculation:

number of participants successfully recruited/ number who opted in X 100.

Step 4) Successful recruitment outcomes recorded using PIVOT Table.

- Group 1; 9 carers, 1 patients.
- Group 2; 9 carers, 2 patients.

Study retention

Data was inputted into an Excel Spreadsheet on participant attendance at each session across both groups. E-mail correspondence was examined and used to collate reasons for drop-out.

Retention calculation:

number of carer participants on study & endpoint data / number of carer recruited X 100

Treatment completion = N (on study at week 12) / N (recruited) X 100

Follow-up data was recorded on an excel spreadsheet:

- Recorded as returned/ did not return.
- Follow up rate = N (returned FU Qs) / N (recruited) X 100

Demographics

- Proportional analysis used for demographic calculations.
- Formula: Total N (provided data) / N (demographic subgroup) X 100

Example: Gender (n=18): (female=11) → 11/18X100= 61.1%.

Features of carers who dropped out

Formula: Total N (demographic of drop out) / Total N (recruited demographic) X 100

e.g. Gender= Total Male Dropouts / Total Recruited Males X 100

Response rate

Data inputted onto spreadsheet for total returned questionnaires.

Response rate was calculated as number of returned questionnaires/total on study at timepoint X 100

This was also calculated for both groups separately.

Completions of outcome measures

- Each outcome measure within total returned questionnaires were inspected for missing items.
- Data on outcome measures with missing items was recorded.
- Completion rate calculation: total complete (no missing items) / total returned X 100.

Weekly session questionnaire

- Treatment completers (n=11)
- Total pre/post session weekly questionnaires issued to treatment completers (n=11 X 12) = 132 pre session & 132 post-session issued.
- Data for each returned weekly session questionnaire (pre and post) were inputted into Excel Spreadsheet for treatment completers (n=11).
- Total returned pre session (n=99), and post (n=64)

Returned questionnaires:

Pre-session: 99/132 X 100

Post-session: 64/132 X 100

Sample characteristics

Eating Disorder Impact Questionnaire – descriptives syntax.

```
DATASET ACTIVATE DataSet4.

DESCRIPTIVES VARIABLES=EDIS_TOTAL /STATISTICS=MEAN SUM STDDEV
VARIANCE RANGE MIN MAX SEMEAN.
```

Illness duration

```
DESCRIPTIVES VARIABLES=ilnessduration

 /STATISTICS=MEAN SUM STDDEV VARIANCE RANGE MIN MAX SEMEAN.
```

Frequency tables generated for DASS-10, SCORE-15, FAMILY Questionnaire, Healthy Adult Subscale.

```
FREQUENCIES VARIABLES=healthy_adult1 dass_10 ilnessduration FAMILY_CC
FAMILY_EOI SCORE15_STEP4

  /NTILES=4

  /NTILES=10

  /STATISTICS=STDDEV VARIANCE RANGE MINIMUM MAXIMUM SEMEAN MEAN
MEDIAN MODE SUM

  /ORDER=ANALYSIS.
```

Appendix 2.5. CONSORT2010 statement: extension to randomised pilot and feasibility trials

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Pg 44
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Pg 47
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Pg 48-51
	2b	Specific objectives or research questions for pilot trial	Pg 52
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Pg 52-53
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Pg 53
Participants	4a	Eligibility criteria for participants	Pg 53
	4b	Settings and locations where the data were collected	Pg 53-54
	4c	How participants were identified and consented	Pg 53-53
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Pg 54-55
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Pg 56-59
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	NA

	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Pg 60
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Pg 62
	13b	For each group, losses and exclusions after randomisation, together with reasons	Pg62
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Pg 60-62
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Pg 63-64, Pg 68-69
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	NA

Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Pg 65,
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Pg 76-75
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Pg 76-75
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Pg 76-75
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Pg 76-75
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Pg 75
Protocol	24	Where the pilot trial protocol can be accessed, if available	Pg92
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Pg75
	26	Ethical approval or approval by research review committee, confirmed with reference number	Pg56

Appendix 2.6. University Approval Letter

University of Glasgow
School of Health & Wellbeing

BC/PR

31 October 2023

Johanna Johnstone
xxxxxxxx@student.gla.ac.uk

Dear Johanna,

Major Research Project Proposal

Evaluation of a Program for Carers of People with Anorexia: A feasibility study

The above project has been reviewed by your University Research Supervisor and by a member of staff not involved in your project and has now been deemed fit to proceed to ethics.

Congratulations and good luck with the study.

Yours sincerely

Dr Breda Cullen
Senior Lecturer in Clinical Psychology
DClinPsy Research Director

School of Health & Wellbeing
College of Medical, Veterinary and Life Sciences
University of Glasgow
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Appendix 2.7. Ethical Approval Letter

Lothian NHS Board

South East Scotland Research Ethics Committee 01

2nd Floor, Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
www.hra.nhs.uk

Enquiries to: Sandra Wyllie
Mobile: 07814 764241
Email: sandra.wyllie@nhslothian.scot.nhs.uk

24 February 2023

Dr Susan G. Simpson
Eating Disorders Service
Livilands Resource Centre
Stirling Health & Care Village
Stirling
FK8 2AU

Dear Dr Simpson

Study title:	**Evaluation of a Skills-Based Program for Carers & Families of patients with Anorexia Nervosa**
REC reference:	**22/SS/0108**
Protocol number:	**TCS/22/05**
IRAS project ID:	**320250**

Thank you for your letter of 13 February 2023, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Carer recruitment flyer]	1	01 November 2022
GP/consultant information sheets or letters [GP letter]	1	19 December 2022
IRAS Application Form [IRAS_Form_21022023]		21 February 2023
Letter from funder [Funder letter]	1	01 November 2022
Other [Informed Consent form for Patient with Anorexia]	2	19 December 2022
Other [Referrer letter]	1	26 September 2022
Other [Carer Questionnaires]	2	19 December 2022
Other [Summary of recruitment & burden of participation]	1	19 December 2022
Other [Response to REC PO table]		
Other [PIS Information Sheet for Carers]	2	19 December 2022
Other [CARER INFORMED CONSENT FINAL]	2	19 December 2022
Other [PIS FOR INDIVIDUAL WITH AN FINAL]	2	19 December 2022
Research protocol or project proposal [Study protocol]	1	23 November 2022
Summary CV for Chief Investigator (CI) [Lead Investigator CV]	1	01 November 2022
Summary CV for student		
Summary CV for supervisor (student research)		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [research flowchart]	1	22 November 2022
Validated questionnaire [Patient Questionnaires (TC)]	2	19 December 2022

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

Appendix 2.8. Consent Forms and Participant Information Sheets

Consent form (carer) : https://osf.io/zy5qv

Consent form (patient): https://osf.io/k9m36

Participant Information sheet (carer): https://osf.io/f2jvd

Participant information sheet (patient): https://osf.io/f2jvd

Appendix 2.9. Data Availability Statement

Once our study is complete, we will make all anonymised data freely available via the DataShare service within The University of Stirling, which you can access via this link: https://datastorre.stir.ac.uk/ To find data specific to this study, please type the name of the Lead Researcher into the search bar on the webpage (e.g. Susan Simpson).

Appendix 2.10 Recruitment Screening Log
https://osf.io/echgw

Appendix 2.11 List of outcome measures

Outcome measures included:

Carers:

Primary outcome measure

The Eating Disorder Impact Scale (EDIS; Sepulveda et al., 2008) measures caregiver burden related to symptoms that are specific to the eating disorder within the past month. The scale contains 24-items that are rated on a 5-point scale. Total scores are computed by adding the raw scores on all items (0-96) with higher scores reflecting higher burden severity. No clinical cut-offs were available.

Secondary outcome measures

SCORE-15 Index of Family Functioning and Change (Stratton et al., 2010): is a 15-item measure designed to assess family functioning and indications of useful therapeutic change in family functioning. Items are rated on a 5-point Likert scale. The clinical cut-off for the average scale is ≥ 2.72 (Miller et al., 2022).

Schema Mode Inventory (Healthy Adult Subscale) (Young et al., 2007): is a is a 10-item scale that measures the strength of healthy adult schema mode using a 6-point Likert scale. Higher scores reflect higher levels of this mode. The clinical cut-off for the average score is ≤4.60 (Lobbestael et al., 2012).

Family Questionnaire (FQ) (Wiedemann et al, 2002) is a 20-item questionnaire that measures levels of expressed emotion (criticism and emotional-overinvolvement) of relatives with psychiatric disorders. Items are rated on a 4-point Likert scale. Cut-off score for the criticism subscale is ≥23; and ≥27 for emotional overinvolvement.

Depression, anxiety and stress scale (DASS-10) (Halford et al., 2021) is a 10-item measure assessing depression, anxiety and stress over the past seven days using a 4-point Likert scale. All items are summed to provide a total score for psychological distress. Severity scores of 0-4 are

classified as subclinical, 5-6 = mild, 7-12= moderate, 13-20= severe, and 21-30 = extremely severe.

Young Parenting Inventory-revised (YPI-R2; Louis, Wood & Lockwood, 2018) is a 36-item questionnaire measuring parenting styles, namely: Competitiveness and Status seeking; Degradation and Rejection; Emotional Inhibition and Deprivation; Overprotection and Overindulgence; Punitiveness; Controlling. Subscale scores are calculated as mean scores with higher scores indicating stronger perceived unhelpful parenting.

Experiences in Close Relationships Revised (ECR-R; Fraley et al., 2000; 36 items) is a self-reported questionnaire designed to assess individual differences regarding attachment-related anxiety and attachment-related avoidance.

The Interpersonal Guilt Rating Scale (IGRS-15) (Gazillo et al, 2017)**:** is a validated 15 item self-report questionnaire that measures distress caused by feelings of guilt.

Weekly outcome measures

World Health Organisation Quality of Life Assessment (WHOQOL-BREF) (WhoQol Group, 1998): one item from WHOQOL-BREF was used to assess quality of life: "How would you rate your quality of life?" which is rated on a 5-point Likert scale.

SCORE-15 Index of Family Functioning and Change (Stratton et al., 2010): One item from the SCORE-15 was selected to assess family functioning: "How are you managing as a family?" which is rated on a 5-point Likert scale.

Session Rating Scale (SRS) (Johnson, Miller and Duncan, 2000): A short-four item visual analogue scale which measures aspects of therapeutic alliance including; relationships, goals and topics, approach and method and overall. Items were rated on a 7-point Likert scale, in this study.

Patient outcome measure

EDEQ-7 (Jenkins et al., 2020): is a 7-item brief version of the gold standard EDE-Q (Fairburn et al., 2008), designed to measure eating

disorder psychopathology. Items were derived from the original EDE-Q, retaining the same response scale (0–6) referencing the past 28 days. The scale provides an overall global score, and three subscale scores (Dietary Restraint, Shape/Weight Overvaluation, Body Dissatisfaction). The average clinical cut-off for global score is 3.64 (Bang et al., 2023).

Eating Disorder Quality of Life (EDQoL; Engel et al., 2006) questionnaire. It has 25 items comprising four subscales (Psychological, Physical/Cognitive, Work/ School, and Financial). Each item is coded on a five-point scale and assesses the degree to which the participant perceives their ED to impact a specific area of their QoL.

Anorexia Nervosa Stages of Change Questionnaire (ANSOCQ; Rieger et al., 2002) is a 20 item self report questionnaire designed to measure motivation to recovery. Each item is rated on a 6 point scale, and are averaged to provide a total classification score. Higher scores indicate higher levels of motivation.

SCORE-15 Index of Family Functioning and Change (Stratton et al., 2010): is a 15-item measure designed to assess family functioning and indications of useful therapeutic change in family functioning. Items are rated on a 5-point Likert scale. The clinical cut-off for the average scale is ≥ 2.72 (Miller et al., 2022).