Psychiatry Research 329 (2023) 115534

Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres

A randomised controlled trial of clinician supported vs self-help delivery of online cognitive behaviour therapy for Bulimia Nervosa☆

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ARTICLE INFO

Keywords:
Eating disorders
Cognitive behavioural therapy
Randomised controlled trial
Digital treatment
Self-help treatment
Clinician-supported self-help treatment
Online treatment
Guided self-help
Bulimia
Internet
OSFED
Disordered eating

ABSTRACT

High dropout rates and poor adherence associated with digital interventions have prompted research into modifications of these treatments to improve engagement and completion rates. This trial aimed to investigate the added benefit of clinician support when paired alongside a ten-session, online cognitive behaviour therapy (CBT) self-help intervention for bulimia nervosa (BN). As part of a three-arm, phase II randomised controlled trial, 114 participants (16 years or over) with full or subthreshold BN were randomly assigned to complete the intervention in a self-help mode (with administrative researcher contact; $n = 38$), with adjunct clinician support (weekly 30-minute videoconferencing sessions; $n = 37$), or a no-treatment waitlist control (WLC; $n = 39$). Baseline to post-treatment (12-weeks) decreases in objective binge episode frequency were significantly greater for clinician-supported participants as compared to WLC, but not for self-help when compared to WLC. However, due to continued improvements for self-help across follow-up (24-weeks), both arms outperformed WLC when analysed as an overall rate of change across three timepoints. Clinician-supported participants outperformed self-help in regards to laxative use and dietary restraint. Our results demonstrate that good clinical outcomes can be achieved with a relatively brief online CBT-based program even in the absence of structured clinical support, indicating a possible overreliance upon clinician support as a primary adherence-facilitating mechanism.

1. Introduction

Bulimia nervosa (BN) is an eating disorder (ED) associated with substantial psychological burden, chronicity, and comorbidity (Udo and Grilo, 2019; van Eeden et al., 2021). Despite there being evidence-based treatments for BN, research suggests that most individuals do not access treatment citing issues such as cost, geographical barriers, stigma around help-seeking, and health workforce limitations (Hamilton et al.,

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https://doi.org/10.1016/j.psychres.2023.115534
Received 12 August 2023; Received in revised form 2 October 2023; Accepted 6 October 2023
Available online 9 October 2023

2021; Hart et al., 2011). Digital self-help treatments present the opportunity to improve the scalability and accessibility of the evidence-based first line treatment for BN (cognitive behaviour therapy, CBT; Hay et al., 2014), allowing for dissemination to a larger number of people, at a lower cost, and in an anonymous and flexible format (Ali et al., 2017; Haderlein, 2022; Stuhldreher et al., 2012).

The field has seen exponential growth in the number digital ED interventions being developed and examined (Aardoom et al., 2013; Dölemeyer et al., 2013), with a recent meta-analytic review suggesting that the evidence base is strongest for BN of all EDs (Linardon et al., 2020). To date, four randomised controlled trials (RCTs) have examined online self-help interventions for BN, which all found moderately sized pre- to post-treatment reductions in ED symptoms in comparison to waitlist control (WLC), with improvements maintained at follow-up (Ruwaard et al., 2013; Sánchez-Ortiz et al., 2011; Strandskov et al., 2017; Wagner et al., 2013). Despite such promising findings, concerns have been raised regarding high dropout rates and low adherence in these trials when compared to face-to-face treatments (Linardon and Fuller-Tyszkiewicz, 2020; Pittock et al., 2018; Schlegl et al., 2015). It is a common critique of digital interventions that reduced human contact impedes upon the benefits of the traditional, clinician-led therapeutic environment (Cook and Doyle, 2002; Rochlen et al., 2004; Wells et al., 2007). To address these concerns, brief clinical support has been added as an adjunct to online self-help treatments for both anxiety and depression, and has been found to be effective in enhancing completion rates (Baumeister et al., 2014; Musiat et al., 2022; Richards and Richardson, 2012) and treatment efficacy (Andersson and Cuijpers, 2009; Johansson and Andersson, 2012; Spek et al., 2007).

In the field of EDs, there is strong evidence to support the added benefit of clinician support as an adjunct to *written* self-help manuals (Beintner et al., 2014), however, its role as an addition to *digital* self-help interventions is less conclusive as most evaluations have incorporated contact with a clinician (Barakat et al., 2019). One study that directly compared differing levels of clinician-support alongside a digital ED intervention, found no significant difference in either dropout rates or efficacy between independent and clinician-supported arms, including both low-intensity contact (once per week) and high-intensity contact groups (three times per week; Aardoom et al., 2016) This finding led the authors to suggest that in the presence of sophisticated and engaging digital features, clinician support may be less crucial to the success of self-help interventions than previously thought. However, evidence supporting the importance of digital design in web-based health interventions (Kelders et al., 2012) is yet to be fully translated into questions about ways in which digital interactivity may mitigate the need for clinician support, with most of the existing ED literature hindered by the use of generic, out-of-date digital features (Barakat et al., 2019). Given the cost and accessibility implications of clinical support, and the general reliance of the field upon clinician support as an adherence- and outcome-facilitating feature, further research is necessary to better elucidate the added value of such clinical expertise and time in the context of a rapidly evolving digital world.

We aimed to conduct a RCT to investigate the efficacy of a newly developed 10-session CBT-based digital program, Binge Eating eTherapy (BEeT), in a sample of participants with full or subthreshold BN when delivered with clinician support or as self-help program with brief administrative researcher contact. BEeT is an innovative, technologically-sophisticated platform, designed by an interdisciplinary team of clinicians, digital programmers and designers, which employs several engaging digital features including recorded videos of a live action therapist, lived experience videos, interactive activities, guided reviews of weekly self-monitoring records, personalized feedback and tailored automated feedback (Barakat et al., 2021; see supplementary material). In this study, we hypothesised that the two active intervention arms (self-help and clinician-supported self-help trialled in real world settings) would be more effective than waitlist control in producing clinically meaningful symptom reduction. We also hypothesised that the clinician-supported intervention arm would have a lower dropout rate, greater intervention usage, and greater efficacy as compared to the self-help intervention.

2. Methods

2.1. Study design

This three-arm, multisite, phase II RCT compared: 1) BEeT as a self-help program (with administrative researcher contact), 2) BEeT with structured clinician support and 3) waitlist control (WLC; no treatment). This research builds upon a previously conducted phase I pilot of an abridged version of BEeT (Barakat et al., 2017). The clinician-supported arm of the trial was delivered across eight trial sites (one outpatient hospital service, two community mental health services, four primary care services, and one university outpatient service) located in metropolitan and regional cities in New South Wales (NSW), Australia. Assessments took place at baseline (T_0), post-treatment (12 weeks; T_1), and follow up (24 weeks; T_2). The study was approved by the Royal Prince Alfred Hospital Human Research Ethics Review Board (HREC #X18–0486). Further details regarding the trial sites, trial design, methodology, and interventions have been published elsewhere (Barakat et al., 2021).

2.2. Participants

Participants were eligible if they were 16 years or older, met criteria for BN or other specified feeding or eating disorder (OSFED) with bulimic behaviours as defined by DSM-5 criteria (American Psychiatric Association, 2013), had a body mass index (BMI) of 20 or above, resided in Australia, had access to a digital device with both internet connection and a video camera, and provided written medical clearance from a physician. Exclusion criteria included concurrent psychological treatment for an ED, poor English literacy, severe medical instability, acute suicidality, severe comorbid psychiatric conditions, current pregnancy or breast-feeding, and/or use of stimulant medication given its common effect of appetite suppression.

Recruitment strategies have been described in detail elsewhere (Barakat et al., 2021). In brief, participants were recruited from the general Australian community either via referrals from health professionals or in response to advertisements placed in medical clinics or online platforms (e.g., social media, health websites). A trained psychologist confirmed eligibility via a screening phone call with interested individuals. Of those considered to be eligible, written informed consent was required prior to commencing the trial.

2.3. Randomisation and masking

Participants were randomly allocated to one of three arms using a permuted-block randomisation that was completed by an independent statistician. Assignment was emailed to the trial coordinator, who then onboarded the participant to their assigned treatment arm. Clinician-supported participants were assigned a clinician using a quasi-random method based upon clinician availability and participants' geographic location. Participants who lived outside of the trial site catchments were allocated to the university-based outpatient service as this was the only site approved to treat participants across all Australian jurisdictions. Masking participants and clinicians was not possible due to the nature of the intervention. All outcome measures were administered as online self-report assessments, independent of research staff.

2.4. Procedures

2.4.1. Self-help BEeT

Following completion of the baseline questionnaires, participants had a phone call with a researcher to provide login details for BEeT.

During the call, participants were advised that one session of BEeT would unlock every seven days if the previous session had been completed in full and were instructed to engage with the intervention in a self-directed manner, with the aim of completing one BEeT session per week.

2.4.2. Clinician-supported BEeT

Clinician-supported participants received access to BEeT alongside an additional ten, 30-minute weekly video-conferencing sessions with their assigned clinician. Clinician support sessions consisted of a structured review of the participants' progress with a focus upon their use of the skills taught in the online BEeT sessions. All clinicians completed an in-depth, ten session online training course, developed by the research team, to educate clinicians on how to deliver the supported BEeT program and attended monthly group supervision sessions. Clinicians had a variety of professional backgrounds and training levels including general psychologists ($n = 2$), clinical psychologists ($n = 4$), an occupational therapist ($n = 1$), a social worker ($n = 1$), and mental health nurses ($n = 2$). For participants presenting with severe ED symptomology or complex psychiatric comorbidities, for whom progress may have been delayed or hindered, an additional three support sessions were available to be used at the clinician's discretion.

2.4.3. Waitlist control

Following a 10-week delay, WLC participants received access to self-help BEeT. Participants were asked to complete a brief set of weekly questionnaires to monitor for psychiatric and medical risk across the waitlist period.

2.4.4. Adherence and discontinuation

Participants were sent an automated email notification when a new BEeT session was unlocked each week and an automatic text message in the evening if no self-monitoring entries had been logged in the previous 24-hour period. Participants also received an automated reminder via email following one week of non-completion of either their assigned BEeT session or the weekly questionnaires (for WLC). If the participants in self-help or WLC arms reached two weeks of inactivity, they received a phone call from the researcher to prompt reengagement. For clinician-supported participants, non-completion of online sessions was managed by their support clinician. Participants were discontinued from the trial if they met the disengagement criteria (i.e., three weeks of inactivity on platform or three consecutive absences from the clinician-support sessions) or in the event that medical or psychiatric instability was indicated (i.e., acute suicidality, BMI < 19). Participants were contacted by research staff to assess for medical or psychiatric risk if they indicated rapid weight loss or suicidal or self-harming thoughts and/or behaviours in their weekly self-report measures.

2.5. Outcomes

The primary outcome was the change in frequency of objective binge episodes in the preceding 28 days from baseline to post-treatment and follow-up, assessed via item 14 of the Eating Disorder Examination-Questionnaire (EDE-Q; Fairburn and Beglin, 2008). EDE-Q was also used to measure secondary outcomes including frequencies of objective overeating episodes, objective binge episode days, self-induced vomiting, laxative use and driven exercise over the past 28 days, and ED psychopathology assessed via the EDE-Q global and subscale scores (restraint, eating concern, shape concern, weight concern; range: 0 – 6; higher scores indicate greater severity of ED psychopathology; Cronbach's $\alpha = 0.82$). Given that the EDE-Q only assesses ED behaviours within a 28-day period, diagnostic subtype (i.e., DSM-5 diagnosis of BN or OSFED with bulimic behaviours) was established using a short series of items with a three-month timeframe. Other secondary outcome measures included the Kessler Psychological Distress (K10) scale (Kessler et al., 2002) and the Eating Disorder Related Quality of Life Questionnaire (EDQOL; Engel et al., 2006). The former measures are defined as follows: K10 is a 10-item measure of psychological distress in previous 30 days (range 0–50; higher scores indicate more severe distress; Cronbach's $\alpha = 0.92$). EDQOL is a 25-item measure of quality of life (range 0–4; higher scores represent greater quality of life; Cronbach's $\alpha = 0.95$). An additional self-designed survey was used to evaluate use of external health services. Intervention usage was measured automatically via the digital platform (see published study protocol; Barakat et al., 2021).

2.6. Statistical analyses

A sample size of 99 participants was required to detect an effect of the intervention with power of 0.6 using an effect size of 0.2, alpha of 0.017 and expected dropout rate of 16 %. Details regarding power calculation have been provided elsewhere (Barakat et al., 2021).

All analyses were conducted in accordance with the intention-to-treat (ITT) principle. Missing data were managed using multiple imputation by chained equations (MICE; van Buuren and Groothuis-Oudshoorn, 2011). The imputation model involved 20 imputations, each with 10 iterations, and included age, illness duration, K10 total score and EDE-Q global at their baseline values as predictor variables in the model. Data was not imputed for participants whose baseline data were not available (i.e., participants who dropped out of the trial immediately after randomisation, [$n = 5$]). For these participants, we reason that there is insufficient data for the model to impute values with an acceptable level of accuracy.

Generalised linear mixed models (GLMM) were used to assess time-by-group interaction effects for primary and secondary outcomes over the three timepoints (i.e., baseline, post-treatment and three-month follow-up) and to allow for clustering within individuals. Baseline variables of age and illness duration were added as covariates in the model. Three contrasts were conducted as part of these analyses: 1) self-help compared to WLC, 2) clinician-supported compared to WLC and 3) clinician-supported compared to self-help. An additional series of pairwise contrasts were conducted within the three timepoint models to compare change between two pairs of timepoints (i.e., baseline to post-treatment and post-treatment to follow-up) within each of the trial arms. Post-treatment to follow-up pairwise comparisons were not included for the WLC arm for whom three-month follow-up data were not available. Instead, main effects of time from post-treatment to follow-up were analysed separately for self-help and clinician self-help in addition to a time-by-group effect comparing clinician-supported and self-help arms. See supplementary material (p 4–5) for an overview of the statistical models and contrasts. Holm-Bonferroni corrections were applied to each set of contrasts to account for multiple comparisons and to reduce type I errors. Outliers ($n = 5$) were handled using the Winsorization technique (Tabachnick and Fidell, 2014). Effect sizes (Cohen's d) were calculated for the linear contrasts (i.e., baseline to post-treatment and post-treatment to follow up by dividing the unstandardised co-efficient of the time-by-group interaction effects by the pooled standard deviation of the outcome measure at baseline (Feingold, 2015). Effect sizes of 0.80 or above were considered large, between 0.20 to 0.80 moderate, and 0.20 or below small (Cohen, 1992).

Sensitivity analyses were used to assess the impact of missing data in the WLC arm at the three-month follow up (i.e., missing not at random; MNAR) on the analysis outcome. Three possible values for the WLC follow-up assessment were examined: 1) consistent change, 2) last mean carried forward (LMCF) and 3) regression to treatment (supplementary material p 4). Analyses using the LMCF method are presented as a primary set of results in the manuscript below, with the most and least conservative scenarios reported in the supplementary material. Main analyses were conducted using R (Version 4.1.0; R Core Team, 2021).

Additional exploratory analyses performed include: ANOVA to assess differences in frequency of researcher contact between trial arms, Mann-Whitney U test to compare intervention usage between the self-help and

clinician-supported arms, and both chi-squared test and ANOVA to assess group differences in external treatment service access during the intervention and follow-up periods.

A clinical trial monitoring committee was established to review any adverse events occurring during the trial. The trial was pre-registered with the Australia New Zealand Clinical Trials Registry (ANZCTR Registration Number: ACTRN12619000123145p).

2.7. Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

3. Results

3.1. Study participants

Participants were recruited between May 2020 and October 2021. Of the 310 individuals screened, 114 were considered eligible and randomly assigned to either self-help (n = 38 [33 %]), clinician-supported (n = 37 [32 %]) or WLC (n = 39 [34 %]; Fig. 1). Participants had a mean age of 31·1 years (SD=10·2; range 16·0–65·0), were predominately female (96·3 %), and had a mean BMI of 25·7 kg/m^2 (SD=6·0; range 19·1–48·4). Baseline characteristics were not significantly different between arms (Table 1). The number of non-completers (i.e., participants randomised to a trial arm but disengaged prior to post-intervention assessment) did not significantly differ between clinician-supported (n = 13 [34·7 %]) and self-help (n = 12 [31·6 %]; χ^2 = 0·11; p = 0·74). The results of the logistic regression showed there were fewer non-completers in WLC condition (n = 7 [17·9 %]) as compared to both the clinician-supported (OR=8·8; p = 0·012; supplementary material p 6) and self-help arms (OR=7·1; p = 0·024). Non-completers were more likely to be younger (OR=0·80, p = 0·033), have a greater illness duration (OR=1·2; p = 0·028) and experience greater psychological distress at baseline (OR=1.1; p = 0·018). Across the intervention period the frequency of research contact differed significantly between the trial arms (F[2111]=35·1; p<0·001), such that participants assigned to self-help were contacted more often than those who were assigned to clinician-supported (p<0·001) or WLC (p<0·001; Table 2). Note, this does not include clinician support contact which was distinct from researcher contact. The number of retention contacts (i.e., contacts to follow up disengagement from intervention) was significantly different between groups (F[2111]=40·4, p<0·001) with greater contacts for self-help as compared to both clinician supported (p<0·001) and WLC (p<0·001). However, the frequency of contact made by research staff in regards to psychiatric or medical risk did not differ between arms (F([2111]=2·7, p = 0·072).

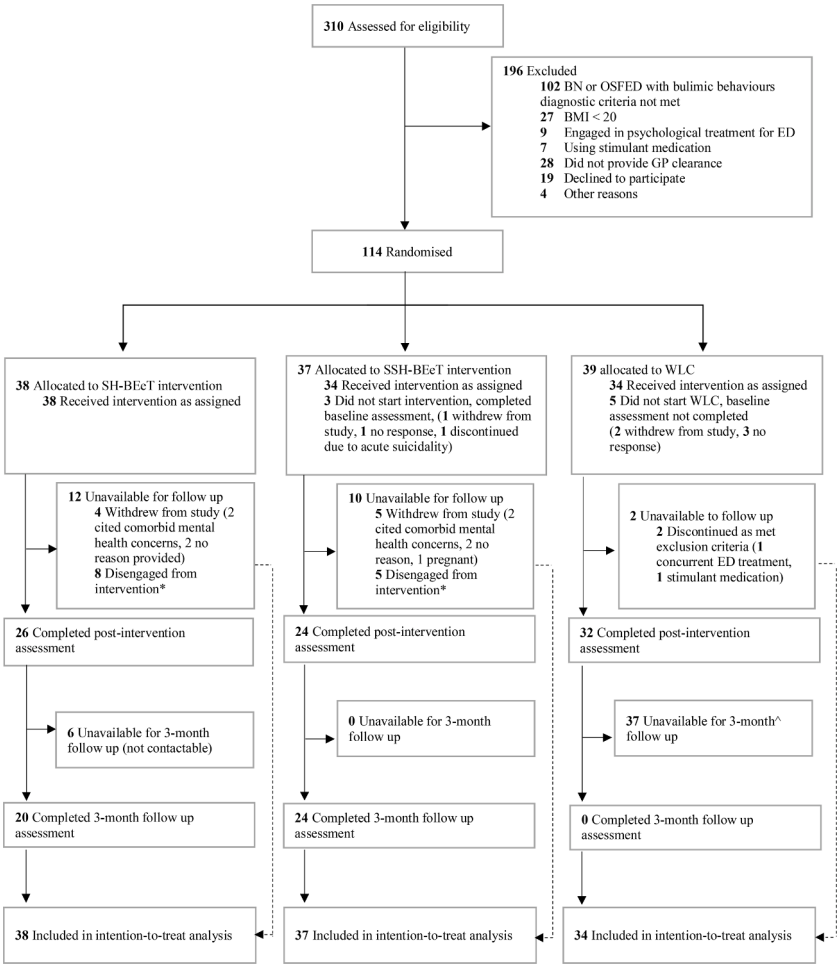

Fig. 1. *Trial profile*
Abbreviations: BN, bulimia nervosa; OSFED, other specified feeding or eating disorder; BMI, body mass index; ED, eating disorder; GP, general practitioner, SH-BEeT, self-help Binge Eating eTherapy; SSH-BEeT, clinician-supported Binge Eating eTherapy; WLC, waitlist control. *Disengagement criteria include three weeks of inactivity on BEeT platform or three consecutive absences from the clinician-support sessions. ^WLC participants received intervention directly following completion of post-intervention assessment.

Table 1
Baseline participant characteristics.

Characteristic	Self-help BEeT (n = 38)	Clinician-supported BEeT (n = 37)	Waitlist control (n = 34)	Total sample (n = 109^)
Female, n (%)	35 (92·1)	37 (100·0)	33 (97·1)	105 (96·3)
Age				
Mean (SD), y	30·2 (10.0)	30.0 (7·5)	33·2 (12·5)	31.1 (10·2)
Range, y	17·0–59·0	17·00–50·0	16·0–65·0	16·0–65·0
Marital status, n (%)				
Single	21 (55·2)	20 (54·0)	14 (41·1)	55 (50·5)
Married or living together	9 (23·7)	7 (18·9)	8 (23·5)	24 (22·0)
In a relationship	6 (15·8)	6 (16·2)	9 (26·5)	21 (19·3)
Other	2 (5·3)	4 (10·8)	3 (8·8)	9 (8·3)
Employed, n (%)	31 (81·6)	30 (81·1)	30 (88·2)	91 (83·5)
Education level ≥ 12 y of school attendance, n (%)	32 (84·2)	31 (83·8)	31 (91·2)	94 (86·2)
Metropolitan area of residence, n (%)	28 (73·7)	29 (78·4)	21 (61·8)	78 (71·5)
Eating disorder diagnosis (%)				
BN	38 (100)	36 (97·3)	33 (97·1)	107 (98·2)
OSFED with bulimic behaviours	0 (0)	1 (2·7)	1 (2·9)	2 (1·8)
Illness duration, mean (min, max), y	14·1 (1, 39)	13·6 (3, 34)	15·6 (1, 48)	14·4 (1, 48)
Self-reported secondary mental health concern, n (%)				
Anxiety	7 (18·4)	13 (35·1)	14 (41·2)	34 (31·2)
Depression	19 (50·0)	5 (13·5)	9 (26·4)	33 (30·3)
Antidepressant medication, n (%)	13 (34·2)	8 (21·6)	10 (29·4)	31 (28·4)
Body mass index				
Mean (SD)	25·9 (5·8)	26·1 (6·6)	25·0 (5·6)	25·7 (6·0)
Range	19·9–47·2	19·1–48·4	19·4–47·0	19·1–48·4
Average number of OBEs (in the past 28 d), mean (SD)	14·0 (7·3)	15·9 (11·3)	14·9 (9·8)	14·9 (9·5)
Average number of self-induced vomiting episodes (in past 28 d), mean (SD)	9·6 (10·6)	11·3 (13·0)	11·2 (13·2)*	10·6 (12·1)
Average number of laxative episodes (in past 28 d), mean (SD)	1·1 (4·8)	3·1 (6·6)	3·1 (7·7)	2·4 (6·4)
Average number of driven exercise episodes (in past 28 d), mean (SD)	8·4 (9·3)	5·6 (8·5)	6·9 (7·8)	7.0 (8·6)
EDE-Q global score, mean (SD)	4·3 (1·0)	4·2 (1·1)	4·3 (1·0)	4·2 (1·0)
K10 total score, mean (SD)	25·9 (8·8)	26·0 (7·9)	26·2 (7·8)	26·0 (8·1)

Abbreviations: BEeT, Binge Eating eTherapy; SD, standard deviation; BN, bulimia nervosa; OSFED, other specified feeding and eating disorder; OBE, objective binge episode; EDE-Q, Eating Disorder Examination-Questionnaire.
Note. Percentages are based upon non-missing data.
^ Data are not available for five participants who disengaged from the research trial prior to completing the baseline assessment.
* One participant was identified as a statistically significant outlier on this measure and Winsorised data was included in this statistic for this participant.

3.2. Primary outcome

Participants in the clinician-supported arm reported a greater reduction in objective binge episode frequency from baseline to post-treatment as compared to the WLC arm (d = 0·74; p = 0·004; Fig. 2; supplementary material p 7–8). Baseline to post-treatment change in objective binge episodes did not differ significantly for self-help in comparison to WLC (d = 0·40, p = 0·35). However, when assessed across the three timepoints (baseline vs post-treatment vs follow-up), both self-help (b=−3·97; SE=1·78; p = 0·027) and clinician-supported (b=−6·05; SE=1·73; p = 0·001) displayed a greater reduction in objective binge episodes as compared to WLC (Table 3). No significant differences in objective binge episode frequency were found between self-help and clinician-supported arms for both the baseline to post-treatment and three timepoint analyses (all ps ≥ 0·16; Table 3; supplementary material p 7–8).

Table 2
ANOVA Results Showing Differences in Frequency of Researcher Contact Between Trial Arms.

Variable	Self-help BEeT M (SD)	Clinician-supported BEeT M (SD)	Waitlist control	F	p	Post-hoc
Total contact researcher	16.05 (8.80)	4.51 (4.04)	5.13 (6.50)	35.09	<0.001	PSH > SSH PSH > WLC
Type of contact						
Frequency of phone contact (spoken)	4.42 (4.18)	1.08 (1.26)	1.79 (2.28)	14.37	<0.001	PSH > SSH PSH > WLC
Frequency of phone contact (attempted)	6.37 (5.55)	1.54 (2.04)	2.18 (3.56)	16.57	<0.001	PSH > SSH PSH > WLC
Frequency of SMS contact	4.13 (3.53)	0.57 (1.12)	0.64 (1.11)	31.66	<0.001	PSH > SSH PSH > WLC
Frequency of email contact	1.26 (2.01)	1.00 (1.67)	0.38 (0.96)	3.06	.051	–
Reason for contact						
Total clinical contacts	5.13 (8.31)	1.84 (2.58)	4.05 (6.38)	2.70	.072	–
Total retention contacts	10.63 (8.04)	2.35 (3.13)	0.90 (1.97)	40.40	<0.001	PSH > SSH PSH > WLC

Abbreviations: BEeT, Binge Eating eTherapy; M, mean; SD, standard deviation; SH, self-help; SSH, clinician supported self-help; WLC, waitlist control.

3.3. Secondary outcomes

Both treatment arms improved over time (in both baseline vs post-treatment and three timepoint analyses) in comparison to WLC with respect to overeating episodes, objective binge days, EDE-Q global score, and all four EDE-Q subscales (all ps ≤ 0·049; Table 3; supplementary material p 7–8). Findings were less consistent in terms of compensatory behaviours. Although clinician-supported participants experienced a greater baseline to post-treatment reduction in laxative use as compared to WLC (d = 0·33; p = 0·021), this was not significant for self-help participants (d=−0·03; p = 0·97). Also, self-help participants displayed significantly greater baseline to post-treatment reductions in self-induced vomiting frequency in comparison to WLC (d = 0·53; p = 0·033), however this was not significant for the clinician-supported arm (d = 0·37; p = 0·16). Clinician-supported participants did outperform

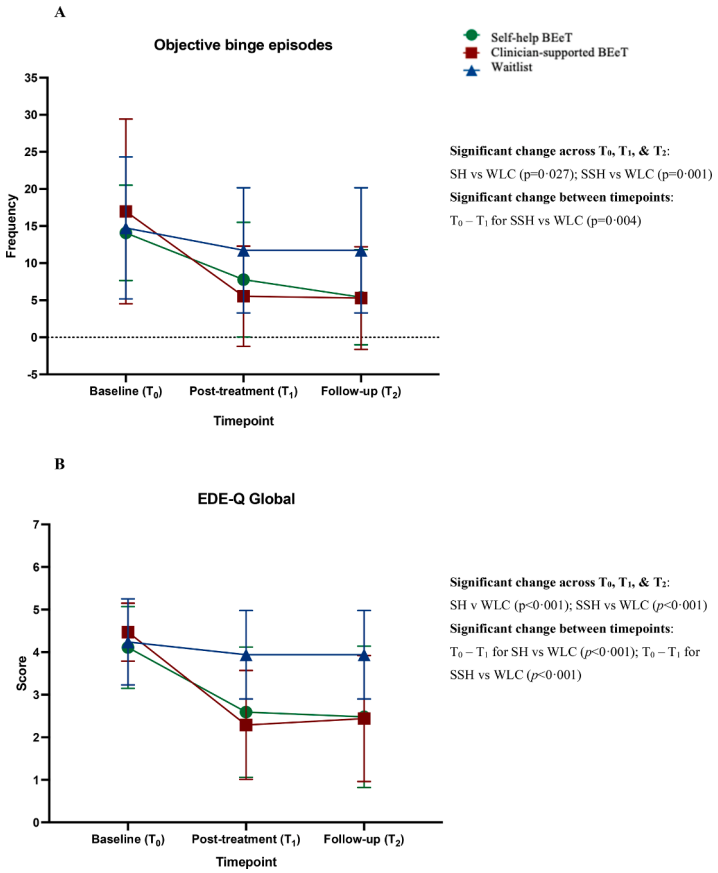

Fig. 2. *Pooled Results of Generalised Linear Mixed Model Analyses*
(A) Change in frequency of objective binge episodes. (B) Change in EDE-Q global score.
Abbreviations: SH, self-help; SSH, supported self-help; WLC, waitlist control; EDE-Q, Eating Disorder Examination-Questionnaire. *Note*. Mean and standard deviation are derived from intention-to-treat (ITT) analysis ($n = 109$) using multiple imputation. The three-month follow up timepoint for the waitlist control group is based upon imputed data using the carry forward method. Error bars represent standard deviations.

WLC in the reduction of self-induced vomiting when analysed across three timepoints (b=−5·39; SE=1·67; $p = 0·001$). No significant differences in driven exercise were found between all treatment arms and across all analyses (all ps ≥0·076).

Baseline to post-treatment changes in ED quality of life scores were not significant for both clinician-supported and self-help arms, however, when assessed over three timepoints, both arms displayed a statistically significant improvement in the EDQOL total score in comparison to WLC ([b=−0·54; SE=0·15; p<0·001] and [b=−0.48; SE=0.15; p<0·001], respectively). Psychological distress (i.e., K10 score) was observed to decrease for clinician-supported participants from baseline to post-treatment when compared to WLC ($d = 0.65$; $p = 0·011$). A main effect was also observed for clinician-supported participants who experienced a significant increase in psychological distress from post-treatment to follow-up ($d = 0·39$; $p = 0·040$). Self-help participants did not report any significant changes in psychological distress at either post-treatment or follow-up (all ps≥0·42). Post-treatment to follow-up effects were not significant for the remaining outcomes for all groups (all ps≥0·087; supplementary material p 9–10).

When comparing secondary outcomes between the clinician-supported and self-help arms, differences emerged with respect to laxative use and dietary restraint, such that clinician-supported participants reported significantly greater reduction over time (in both baseline vs post-treatment and three timepoint analyses) as compared to self-help participants (all ps≤0·050; Table 3; supplementary material p 7–8). No other significant differences were apparent between clinician-supported and self-help arms (all ps≥0·076).

3.4. Sensitivity analyses

Overall, the pattern of results in the three timepoint analyses were consistent across the sensitivity analyses, excluding two variables: objective binge episode frequency (b=−3·47; SE=2·04; $p = 0·091$) and EDE-Q weight concern (b=−0·42; SE=0·29; $p = 0·15$) for which the time-by-group effects comparing self-help vs WLC were not significant in the consistent change scenario (supplementary material p 11–13).

3.5. Diagnosis and abstinence rates

Across both intervention arms, approximately half of the participants no longer met criteria for BN at the post-treatment assessment (53·8 % for self-help; 95 % CI [34·6 %, 73·0 %]; 51·5 % for clinician-supported; 95 % CI [31·5 %, 71·5 %]), with most participants moving into the subclinical diagnostic category of OSFED (38·5 % for self-help; 95 % CI [19·8 %, 57·2 %]; 54·2 % for clinician-supported; 95 % CI [34·3 %, 74·1 %]; Fig. 3). Two participants (7·7 %, 95 % CI [1·1 %, 25·5 %]) in self-help displayed full remission (i.e., no longer met criteria for an ED) at the post-treatment assessment. This increased to three participants (15·0 %, 95 % CI [4·6 %, 37·0 %]) at follow-up. None of the participants in clinician-supported entered remission by post-treatment, however two participants (8·3 %, 95 % CI [1·3 %, 27·3 %]) no longer met criteria for an ED at follow-up. Of the participants assigned to self-help, 15·4 % achieved abstinence from binge eating post-treatment (i.e., no episodes in previous 28 days; 95 % CI [1·5 %, 29·3 %]), which increased to 25·0 % at follow-up (95 % CI [6·0 %, 44·0 %]). Abstinence rates remained stable for clinician-supported participants across the same time period (post-

Table 3
Results of Generalised Linear Mixed Model Analyses of Time-by-Group Effects as Three-Timepoint Analysis.

Descriptive statistics				Time-by-group interaction effects											
M (SD)				SH – control				SSH – control				SH – SSH *			
Outcome	SH (n = 38)	SSH (n = 37)	WLC (n = 39)	b (SE)	t	p	95 % CI	b (SE)	t	p	95 % CI	b (SE)	t	p	95 % CI
Objective binge episode frequency															
Baseline	14·1 (6·4)	17·0 (12·5)	14·8 (9·6)	−3·97 (1·78)	−2·23	0·027	−7·48, −0·46	−6·05 (1·73)	−3·50	0·001	−9·45, −2·65	−2·07 (1·89)	−1·10	0·27	−5·80, 1·65
Post-Tx	7·8 (7·7)	5·5 (6·8)	11·7 (8·4)												
Follow-up	5·4 (6·4)	5·3 (6·9)	11·7 (8·4)^												
Objective overeating episode frequency															
Baseline	16·4 (7·3)	17·9 (13·8)	15·2 (9·4)	−5·55 (1·77)	−3·13	0·002	−9·05, −2·06	−6·54 (1·77)	−3·70	<0·001	−10·02, −3·05	−0·97 (1·89)	−0·51	0·607	−4·71, 2·76
Post-Tx	7·3 (7·8)	5·7 (6·2)	12·6 (9·0)												
Follow-up	5·9 (6·7)	6·0 (6·7)	12·6 (9·0)^												
Objective binge episode days															
Baseline	14·4 (7·2)	13·7 (9·0)	13·9 (7·4)	−5·17 (1·43)	−3·63	<0·001	−7·98, −2·36	−4·19 (1·40)	−3·00	0·003	−6·94, −1·43	1·02 (1·53)	0·67	0·506	−2·00, 4·04
Post-Tx	7·4 (7·3)	5·0 (5·9)	11·9 (8·3)												
Follow-up	5·0 (5·3)	5·7 (7·6)	11·9 (8·3)^												
Self-induced vomiting frequency															
Baseline	9·5 (10·5)	12·7 (13·2)	10·2 (12·5)	−4·25 (1·68)	−2·54	0·011	−7·55, −0·95	−5·39 (1·67)	−3·23	0.001	−8·68, −2·10	−1·16 (1·79)	−0·65	0·517	−4·69, 2·37
Post-Tx	2·7 (5·5)	6·8 (10·6)	9·7 (11·9)												
Follow-up	2·9 (5·4)	4·2 (7·1)	9·7 (11·9)^												
Laxative use frequency															
Baseline	1·6 (5·7)	3·9 (7·4)	2·6 (7·0)	0·15 (0·60)	0·24	0·809	−1·05, 1·34	−1·23 (0·61)	−2·01	0·045	−2·43, −0·03	−1·37 (0·65)	−2·12	0·035	−2·65, −0·10
Post-Tx	1·3 (5·3)	1·0 (5·0)	2·1 (6·8)												
Follow-up	1·3 (5·2)	1·7 (5·3)	2·1 (6·8)^												
Driven exercise frequency															
Baseline	9·0 (10·1)	5·5 (8·2)	7·3 (7·7)	−1·33 (1·23)	−1·08	0·282	−3·77, 1·10	1·04 (1·22)	0·85	0·396	−1·37, 3·44	2·35 (1·32)	1·78	0·076	−0·25, 4·94
Post-Tx	3·4 (7·8)	2·3 (5·6)	4·2 (5·8)												
Follow-up	4·0 (7·6)	3·7 (7·0)	4·2 (5·8)^												
EDE-Q Eating Concern Subscale															
Baseline	4·2 (1·1)	4·4 (1·0)	4·2 (1·1)	−1·18 (0·25)	−4·69	<0·001	−1·67, −0·68	−1·17 (0·24)	−4·89	<0·001	−1·64, −0·70	0·01 (0·26)	0·03	0·974	−0·51, 0·53
Post-Tx	2·2 (1·6)	1·9 (1·4)	3·9 (1·1)												
Follow-up	2·1 (1·6)	2·3 (1·8)	3·9 (1·1)^												
EDE-Q Restraint Subscale															
Baseline	3·6 (1·7)	4·0 (1·1)	3·4 (1·6)	−0·87 (0·23)	−3·74	<0·001	−1·33, −0·41	−1·37 (0·23)	−6·04	<0·001	−1·82, −092	−0·49 (0·25)	−1·98	0·050	−0·98, 0·00
Post-Tx	2·1 (1·8)	1·5 (1·3)	3·4 (1·6)												
Follow-up	2·2 (1·9)	1·9 (1·8)	3·4 (1·6)^												
EDE-Q Shape Concern Subscale															
Baseline	4·5 (1·0)	4·9 (0·8)	4·8 (1·1)	−0·77 (0·25)	−3·12	<0·001	−1·25, −0·28	−1·02 (0·23)	−4·38	<0·001	−1·48, −0·56	−0·25 (0·26)	−0·96	0·34	−0·77, 0·27
Post-Tx	3·3 (1·7)	3·0 (1·6)	4·5 (1·3)												
Follow-up	3·0 (1·8)	2·9 (1·5)	4·5 (1·3)^												
EDE-Q Weight Concern Subscale															
Baseline	4·2 (1·1)	4·6 (1·0)	4·5 (1·1)	−0·65 (0·26)	−2·53	0·012	−1·15, −0·14	−0·82 (0·25)	−3·32	0·001	−1·30, −0·33	−0·16 (0·28)	−0·59	0·56	−0·71, 0·38
Post-Tx	2·8 (1·7)	2·7 (1·7)	4·1 (1·3)												

(*continued on next page*)

Table 3 (*continued*)

Descriptive statistics				Time-by-group interaction effects											
	M (SD)			SH – control				SSH – control				SH – SSH *			
Outcome	SH (n = 38)	SSH (n = 37)	WLC (n = 39)	b (SE)	t	p	95 % CI	b (SE)	t	p	95 % CI	b (SE)	t	p	95 % CI
Follow-up	2·8 (1·8)	2·7 (1·6)	4·1 (1·3)^												
EDE-Q Global Score															
Baseline	4·1 (1·0)	4·5 (0·7)	4·2 (1·0)	0·91 (0·20)	−4·54	<0·001	−1·30, −0·51	−1·10 (0·19)	−5·70	<0·001	−1·48, −0·72	−0·19 (0·21)	−0.89	0·38	−0·61, 0·23
Post-Tx	2·6 (1·5)	2·3 (1·3)	3·9 (1·0)												
Follow-up	2·5 (1·7)	2·4 (1·5)	3·9 (1·0)^												
EDQOL Total															
Baseline	1·5 (0·7)	1·8 (0·5)	1·6 (0·7)	−0·21 (0·09)	−2·26	0·025	−0·39, −0·03	−0·24 (0·09)	−2·61	0·010	−0·42, −0·06	−0·03 (0·10)	−0·31	0·76	−0·23, 0·16
Post-Tx	1·1 (0·8)	1·4 (0·6)	1·7 (0·6)												
Follow-up	1·2 (0·9)	1·4 (0·9)	1·7 (0·6)^												
K10															
Baseline	23·5 (8·3)	25·5 (8·1)	25·8 (7·5)	−0·80 (1·21)	−0·66	0·507	−3·18, 1·58	−1·69 (1·19)	−1·43	0·16	−4·03, 0·64	−0·83 (1·30)	−0·64	0·52	−3·40, 1·74
Post-Tx	21·1 (8·0)	19·3 (6·8)	24·7 (8·2)												
Follow-up	21·2 (9·0)	22·0 (8·0)	24·7 (8·2)^												

Abbreviations: SH, self-help; SSH, supported self-help; WLC, waitlist control; EDE-Q, Eating Disorder Examination-Questionnaire; EDQOL, Eating Disorder Quality of Life questionnaire; TFEQ, Three Factor Eating Questionnaire; BMI, body mass index, K10; Kessler Psychological Distress Scale.
Note. Mean and standard deviation are derived from intention-to-treat (ITT) analysis (n = 109) using multiple imputation.
* PSH – SSH refers to a separate model whereby the reference group was changed from waitlist control to self-help BEeT.
^ The three-month follow up timepoint for the waitlist control group is based upon imputed data using the carry forward method.

treatment: 33·3 %; 95 % CI [14·4 %, 52·2 %]); follow-up: 33·3 %; 95 % CI [14·4 %, 52·2 %]). Rates of abstinence from self-induced vomiting for self-help participants increased from 28·9 % at baseline (95 % CI [14·5 %, 43·3 %]) to 65·4 % at post-treatment (95 % CI [47·1 %, 83·7 %]) and continued increase to 70·0 % at follow-up (95 % CI [49·9 %, 90·1 %]). Clinician-supported participants also reported an increase in abstinence across the intervention period from 29·7 % (95 % CI [15·0 %, 44·4 %]) to 50·0 % (95 % CI [30·0 %, 70·0 %]), followed by a decrease to 45·8 % (95 % CI [25·9 %, 65·7 %]) at follow-up. A similar pattern was found for laxative use and excessive exercise (see supplementary material p 14 for abstinence rates for remaining behaviours).

3.6. Participant engagement

The number of sessions completed by participants did not differ between self-help (M = 8·7; SD=2·7) and clinician-supported arms (M = 8·1; SD=3·4; F[1,70]=0·51, p = 0·70). The average length of time between session completion was 14.8 days for self-help (SD=9·9, range 2–67) and 10.9 days for clinician-supported (SD=8·0, range 0–44). Clinician-supported participants attended an average of 8·4 support sessions (SD=4·3, range 0–13), with an average length of 36·2 min (SD=9·7, range 14·6–60·0). Ten participants (27 %) attended a total of ten clinician-support sessions as per study protocol. Fourteen participants (37 %) required additional sessions beyond the ten. Of these 14 participants, four participants attended 11 sessions, five participants attended 12 sessions and five participants attended 13 sessions. Table 4 displays intervention usage metrics for the self-help and clinician-supported arms. Clinician-supported participants recorded a significantly greater number of food monitoring entries as compared to self-help (U = 451.00, p = 0·028). No other significant differences in intervention usage metrics were observed between trial arms (all ps≥0·055).

3.7. Health service use

No significant differences were apparent between trial arms in terms of the number of participants who accessed external psychological, psychiatric, and dietetic treatment services or the number of health service appointments attended during the intervention or follow-up periods (all ps≥0·10; supplementary material p 15).

There were no study-related adverse events reported.

4. Discussion

This study is the first RCT to our knowledge to compare clinically meaningful outcomes of a digital intervention for EDs delivered in a clinician-supported format vs self-help (with administrative researcher contact) within existing treatment pathways in the Australian healthcare system. As expected, the two intervention arms outperformed WLC in the reduction of key disordered eating behaviours and psychopathology associated with BN, with the exception of two variables – objective binge episodes for the self-help arm and self-induced vomiting for the clinician-supported arm. Despite displaying non-significant reductions at the end of treatment, both arms outperformed WLC when analysed as an overall rate of change across the three time points from baseline to post-treatment and follow up. Direct comparisons between the self-help and clinician-supported arms revealed that the addition of clinician support had an isolated effect upon two outcome measures. Namely, improvements in laxative use and dietary restraint were significantly greater for those who received clinician support compared to no clinician support. Contrary to our hypotheses, dropout rates were similar between self-help (31.6 %) and clinician-supported (34.7 %), as was participant engagement with the intervention. Only frequency of food monitoring differed between treatment arms, favouring the clinician-supported arm.

Post-treatment effect sizes found in this trial compare favourably with those reported in meta-analyses of digital ED interventions

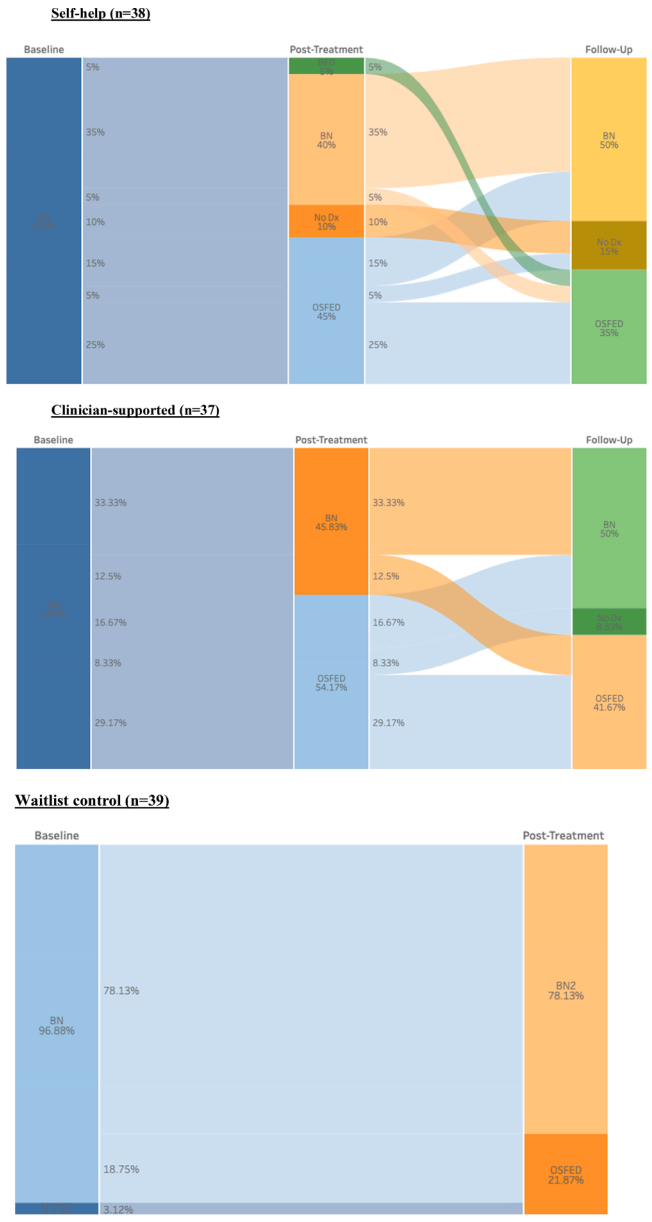

Fig. 3. *Sankey Chart Displaying Movement Between Diagnostic Categories Across Timepoints*
Self-help ($n = 38$)
Clinician-supported ($n = 37$)
Waitlist control ($n = 39$)
N.B. *Values are expressed a proportion of the total sample size in each arm (self-help, $n = 38$; supported self-help, $n = 37$; waitlist control, $n = 39$). Dropouts were accounted for in the proportion calculations, however, were omitted from graphic presentation.*

(Hedges' g 0.51 to 1.06; Aardoom et al., 2013; Barakat et al., 2019; Dölemeyer et al., 2013; Linardon et al., 2020). The current study found moderate to large effect sizes across several primary and secondary outcomes of ED symptomology, including objective binge days, overeating episodes, eating, weight, and shape concerns, and dietary restraint. Consistent with other trials of digital ED treatments, improvements were found across compensatory behaviours, including moderately sized post-treatment reductions in self-induced vomiting and laxative use for the self-help and clinician supported arms, respectively (Aardoom et al., 2016; Ruwaard et al., 2013; Sánchez-Ortiz et al., 2011; Wagner et al., 2013). Engagement with the intervention was high and usage metrics across both intervention arms were impressive.

Table 4
Intervention Usage Metrics.

Intervention Use Metric Median (IRQ) [range]	Self-help BEeT ($n = 38$)	Clinician-supported BEeT ($n = 34$)	Total sample ($n = 72$)	Mann-Whitney U Test Statistic	*P* Value
Total unique days using intervention	39 (25–71) [3–131]	55 (32–79) [12–129]	51 (12–69) [3–131]	549·50	0·28
Total unique days of self-monitoring	24 (11–65) [0–119]	42 (21–71) [2–118]	37 (12–69) [0–119]	521·00	0·19
Average number of self-monitoring entries per login	4 (3–5) [0–10]	5 (3–7) [2–11]	4 (3–6) [0–11]	497·50	0·094
Total number of self-monitoring entries	144 (68–517) [0–1009]	359 (67–524) [0–1034]	268 (68–514) [0–1034]	522·50	0·16

Abbreviations: BEeT, Binge Eating eTherapy. *Note*. Median, interquartile range (IQR), and range were used due to the skewed nature of app usage.

Dropout rates compared favourably to those reported in trials of other online ED interventions (range: 8 % to 49 %; Dölemeyer et al., 2013; Pittock et al., 2018) and face-to-face, therapist-led treatments (24 %; Linardon et al., 2018). These findings may reflect our use of a live action therapist in the program rather than cartoons or static imagery (as is often used) to enhance engagement, along with attempts to bolster the interactivity and personalised features of the BEeT digital platform. This body of research sought to advance ongoing technological advancements, which to date, have been integrated into existing ED digital interventions to a lesser extent (Barakat et al., 2019). Therefore, it is possible that high quality, credible interactive digital features embedded in the platform facilitated engagement by replicating the personalised experience typically associated with human contact (e.g., live action therapist, tailored automated feedback according to one's progress; Andersson and Titov, 2014). Future research would benefit from direct experimental comparison of personalised experience and interactive technologies to better understand their impact on adherence and outcome and to investigate how they relate to key mechanisms of change in web-based interventions.

Consistent with the findings of Aardoom et al. (2016) and the wider mental health literature (Berger et al., 2011; Dear et al., 2015; Levin et al., 2021; Titov et al., 2016), the current trial found clinician-supported and self-help arms to be largely similar in their capacity to treat core psychopathology and behaviours, challenging the previous understanding of the importance of clinician support in the delivery of online mental health treatments (Andersson and Cuijpers, 2009; Johansson and Andersson, 2012; Richards and Richardson, 2012; Spek et al., 2007). Clinically significant changes in ED diagnosis were high across both intervention arms, such that more than half of participants no longer met diagnostic criteria for full-threshold BN at post-treatment and moved into sub-threshold category of OSFED. Clinician support was found to enhance the impact of the intervention upon laxative use and dietary restraint as compared to independent engagement. However, the exact clinical benefit of this finding is unclear given that self-help were still able to achieve significant improvements in dietary restraint (albeit a smaller effect size) and the difference in laxative use was likely driven by a floor effect for self-help participants who reported low rates of laxative use at baseline.

Not only do our findings demonstrate that good clinical outcomes can be achieved without clinical support, but they also indicate there may be an advantage to completing the program in a self-directed manner. In the absence of a significant post-treatment reduction in binge episode frequency, self-help participants continued to improve

across the follow-up period, whereas clinician-supported participants showed no further change after completing treatment. Whilst binge eating abstinence rates remained consistently high for clinician-supported participants at 33.3 % both at post-treatment and follow-up, self-help arm increased from 15.4 % at post-treatment to 25 % at follow-up. Despite not reaching the same magnitude of change as the clinician-supported arm, self-help participants did achieve abstinence rates which compare well with average estimates from other studies with greater levels of clinician support, including other CBT-based online and written self-help interventions (20 % – 30 %; Hay et al., 2004; Sánchez-Ortiz et al., 2011) and some face-to-face CBT programs (22.5 % – 44 %; Atwood and Friedman, 2020; Linardon et al., 2018). A similar trend was observed for compensatory behaviours such that abstinence rates increased from post-treatment to follow-up for self-help, however clinician-supported participants also experienced a regression across the same time period. These results are consistent with two recent meta-analyses of internet-based CBT treatments for anxiety and depression which both found that differences in outcome between clinician-supported and self-help interventions at post-treatment (in favour of clinician-supported) were no longer significant at follow-up (Karyotaki et al., 2021; Oey et al., 2023). Taken together, this emerging body of evidence appears to suggest that whilst it may take longer for self-help to achieve its treatment effect, there may be a unique benefit in fostering self-efficacy and autonomy to engage with the skills even once formal treatment has ceased.

Another noteworthy finding relates to the distinct impact of the two interventions upon psychological distress. In absence of change for the self-help participants, those receiving clinician-support reported a reduction in distress at post-treatment followed by an increase at follow up. Whilst it is difficult to know what these changes represent, their sequencing may indicate that the experience of human connection, inclusive of empathy, interest and understanding from another individual, is instrumental in alleviating some level of distress and may contribute to the overall wellbeing of the participants. This hypothesis is consistent with evidence of lower treatment satisfaction associated with unsupported vs supported use of digital ED interventions (Aardoom et al., 2016; Rohrbach et al., 2022) as well as feelings of abandonment and concern about relapse reported by participants after completing a clinician-supported online CBT program for BN (McClay et al., 2013). More research is needed to better understand how to incorporate aspects of clinician support which are central to the patient's experience and their overall wellbeing, without creating an unhelpful reliance on external motivation and support in the longer term.

Overall, our findings suggest that both self-help and clinician-supported formats of BEeT can reliably produce clinically meaningful improvements in key symptomology of BN. However, there are some important contextual factors which need to be considered. Of particular interest is researcher-initiated contact of participants who were observed to disengage from the intervention. Although controlled for in the outcome analyses, it is possible that more frequent contact between research staff and self-help participants may have improved retention rates for this arm. Our results showed that the average length of time between sessions for self-help participants was 14.8 days compared to 10.9 days for clinician-supported, which may be indicative of the helpfulness of the researcher prompts to re-engage (which were made after two weeks). Researcher contact involved strictly no guidance around intervention content and was designed to be a purely administrative, ethics-mandated brief touchpoint, as is the nature of RCTs of any kind (Ebert and Baumeister, 2017; Mohr et al., 2015). However, it may be that this contact created a minimum dose of accountability or human connectedness such that less added benefit was gained from structured inclusion of clinician support. Whilst it is difficult to determine the degree to which researcher prompts influenced engagement in the current trial, it is important to note that the number of actual spoken phone calls was relatively low. Even though the number of total researcher contacts was higher for self-help participants, the majority of these contacts were either attempted phone calls or asynchronous contact (SMS and email), meaning that the participant rarely engaged in meaningful, dyadic communication with the research staff.

Similar methodological considerations have been noted across the field as a whole, with evidence to suggest that the relatively high degree of research attention and structuring found in clinical trials may be responsible for the higher rates of engagement the higher rates of engagement with self-help interventions observed in these trials as compared to use outside of research settings (e.g., via open-access websites; Baumel et al., 2019; Christensen et al., 2009; Fleming et al., 2018). Whilst a scientific design limitation itself, this could also yield important information about the optimal trade off of between type and frequency of human contact and treatment outcome, with emerging evidence to suggest that very light touch contact from a researcher or technician (which may in some way resemble the researcher contact in our trial) may be the optimal form of contact for digital for self-help programs (Andrews et al., 2010; Robinson et al., 2010; Shim et al., 2017; Titov et al., 2010). Future studies should be aimed towards advance our understanding of subgroups for whom brief researcher contact is most impactful. For example, Newman et al. (2011) found optimal amount of guidance differed according to diagnostic category, such that self-guided interventions were most effective for motivated patients with anxiety disorders, whilst patients with clinical levels of depression responded better to treatments delivered with therapist support. Similar research is needed in the field of EDs to understand the role of clinical indicators such as illness severity or comorbidity as potential mediators of the need for more human involvement.

From a public health perspective, these insights pose important implications for the design of innovative cost- and time-effective models of healthcare that are capable of titrating very valuable and costly human contact in a targeted, evidence-based manner. With evidence to support both clinician-supported and self-help options, it is important to recognise that self-help delivery does not negate the need for clinician-support. Rather, we need a strong understanding of for whom human support is crucial and for whom outcomes are the same, or even improved, with fewer contacts. This will allow patients to be triaged in a safe and efficient manner, with the capacity to "step-up" the intensity of human support, if clinically indicated (Straten et al., 2015).

There are further methodological limitations that need to be considered. First, due to the study design, follow-up data were not available for WLC. We aimed to minimise this limitation by conducting sensitivity analyses highlighting the best, worst and average case scenarios for this WLC condition. Next, the absence of a longer follow-up period for the treatment arms (e.g., six or 12 months) means we cannot be sure that the self-help arm would have continued to improve over time or whether there was a maximum treatment effect associated with the program which clinician-supported participants achieved at a faster rate. The design of the eligibility and onboarding process, including contact with a physician and research staff, may have imposed barriers to participation for some individuals (e.g., anonymity, cost of medical appointments). However, as discussed above, it is equally possible that researcher contact inflated our adherence metrics, with evidence to suggest that telephone screening is associated with higher attrition than online enrolment (Berger et al., 2011; Farrer et al., 2011; Linardon and Fuller-Tyszkiewicz, 2020). Even though clinicians attended monthly supervision sessions and completed a standardised training package, the absence of a fidelity assessment for the clinician support sessions limits our understanding of the degree to which clinicians adhered to the protocol. We also note that the trial was conducted during the height of the COVID-19 pandemic, an optimal time for self-help treatment due to limited availability of face-to-face treatment options. Taken together with the well-evidenced increase in ED symptoms during the prolonged lockdown periods (Lin et al., 2021; Miskovic-Wheatley et al., 2022; Taquet et al., 2021; Zipfel et al., 2022), it is possible that participants' motivation to engage with non-traditional treatment pathways was heightened in the current sample. This holds

important implications when interpreting the fairly low dropout rates observed in this trial as it may be participants were more engaged with the self-help intervention as consequence of having fewer clinician-led psychological treatments at their disposal. Finally, although the sample size exceeded the pre-determined minimum of 99 participants, it is possible that the study was not adequately powered to detect small effect sizes for some of the contrasts considered.

This trial has successfully demonstrated the efficacy of a novel, online intervention integrated into existing health services in a clinical sample of individuals with DSM-5 diagnoses of BN or OSFED with bulimic behaviours. To inform successful delivery of this model of care, future research is needed to understand the mechanisms underlying response patterns with different intensities of support and how these may interact with modern digital capabilities designed to mimic the connectedness and personalisation typically associated with human contact. Reflecting the need for innovative treatments and delivery methods, an immediate impact of this research is the scalability of a low-resource, relatively brief treatment with the capacity to provide accessible and effective mental healthcare in real life settings, improve recovery rates for the illness and reduce burden on the health system, individuals and their carers.

Data sharing

Deidentified data and a data dictionary may be made available for meta-analyses, after approval of a proposal and signed data access agreement (contact SB).

Author contributions

SMaguire and SB contributed to study conception and design. SB was the trial coordinator and took the lead role in managing ethics approval, recruitment, data collection and storage, and implementation at trial sites. MS, JLH, MK, and SB conducted the statistical analyses with support from SL. SMaguire, ST, DM, JR, PH, SMadden, MC, JMW, and SL attended quarterly investigator meetings and provided input regarding study design and progress. DR managed the design and development of the digital platform. AB assisted with study recruitment and provided feedback on the manuscript. SM was the lead investigator, obtained funding and supervised the study. SB wrote the first draft of the manuscript with extensive input from SMaguire and AB. All co-authors revised the manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. All authors have seen and approved the final version of the manuscript being submitted. The manuscript is the authors' original work, hasn't received prior publication and isn't under consideration for publication elsewhere. SB and MS have directly accessed and verified the underlying data reported in the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

We would like to recognise the funding body, NSW Health, for the Translational Research Grants Scheme (TRGS). We would also like to thank the following individuals who contributed to the design and development of BEeT and supported the project throughout: Jessica Aradas, Gabriella Barclay, Claire Diffey, Brooke Donnelly, Carmel Flemming, Belinda Green, Blake Hamilton, Tessa Heinonen, Caroline Hill, Sarah Horsfield, Jessie Kilcourse, Linda Lazar, Martin Lumetzberger, Ang Li, Hugo Muecke, Vicki Radford, Jessica Ross, Helen Rydge, Beth Shelton, Rachel Simeone, Emma Spiel, Shane Thomas, Kate Tolley, Cindy Tran and Meg Vickery. Finally, we would like to thank all participants for their willingness to be involved in the research and share their lived experience.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2023.115534.

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