The impact of floatation therapy on body image and anxiety in anorexia nervosa: a randomised clinical efficacy trial

Emily M. Choquette,[a,e] Michael C. Flux,[a,e] Scott E. Moseman,[b] Sheridan Chappelle,[a] Jessyca Naegele,[a] Valerie Upshaw,[a] Alexa Morton,[a] Martin P. Paulus,[a,c] Justin S. Feinstein,[a,d] and Sahib S. Khalsa[a,c,*]

[a]Laureate Institute for Brain Research, Tulsa, Oklahoma, USA
[b]Laureate Eating Disorders Program, Saint Francis Health System, Tulsa, Oklahoma, USA
[c]Oxley College of Health Sciences, University of Tulsa, Tulsa, Oklahoma, USA
[d]Float Research Collective, Kihei, Hawaii, USA

eClinicalMedicine 2023;■: 102173

Published Online XXX https://doi.org/10.1016/j.eclinm.2023.102173

Summary

Background Body image disturbance and anxiety are core features of anorexia nervosa (AN), a psychiatric disorder with one of the highest mortality rates. This study examined the efficacy of a novel non-pharmacological treatment, floatation-REST (Reduced Environmental Stimulation Therapy) on body image disturbance and anxiety in inpatients with AN.

Methods This parallel group randomised controlled trial compared floatation-REST vs. care as usual in women and girls hospitalised for treatment of AN in Tulsa, Oklahoma, USA. Participants were randomised on a 2:1 ratio to receive eight, twice-weekly, 60-min floatation-REST sessions for 4 weeks, in addition to care as usual, or to receive care as usual. The primary outcome was the average change in body dissatisfaction from pre- to post-float as measured by the Photographic Figure Rating Scale. The secondary outcome was the average change in anxiety from pre- to post-float as measured by the state version of the State Trait Anxiety Inventory. Longitudinal effects of floatation-REST on body dissatisfaction were also examined. All analyses were conducted using the intention-to-treat principle. Planned linear mixed models tested the effect of floatation-REST vs. care as usual. The trial was preregistered (clinicaltrials.gov NCT03610451).

Findings Between March 16, 2018 and February 25, 2021, 133 participants were screened for eligibility, and 86 were consented. Eighteen were excluded after consent, for a final randomisation sample of 68 participants (45 floatation-REST; 23 care as usual). There were two session by condition interactions on body dissatisfaction ($p = 0.00026$) and state anxiety ($p < 0.0001$), such that the floatation-REST group exhibited acute (i.e., pre- to post-session) reductions in body dissatisfaction (floatation-REST group mean change (Δm) = –0.43; 95% CI –0.56 to –0.30, $p < 0.0001$, Cohen's $d = 0.23$), and acute reductions in anxiety (floatation-REST group Δm = –15.75; 95% CI –17.95 to –13.56, $p < 0.0001$, Cohen's $d = 1.52$); however, the care as usual group exhibited no significant changes. With regard to longitudinal results, there was a significant time by treatment interaction between baseline and immediately post intervention ($p = 0.012$) and baseline and six-month follow up ($p = 0.0019$). At immediately post intervention, there was a trending reduction in body dissatisfaction for the floatation-REST group (Δm = –0.41, 95% CI –0.86 to 0.03, $p = 0.068$) and care as usual group (Δm = 0.61; 95% CI –0.04 to 1.27, $p = 0.070$). At six-months post-intervention, the floatation-REST group exhibited lower body dissatisfaction (Δm = –0.91; 95% CI –1.37 to –0.45, $p = 0.0020$, Cohen's $d = 0.53$) whereas the care as usual group reported no change in body dissatisfaction (Δm = 0.35; 95% CI –0.28 to 0.98, $p = 0.96$) relative to baseline. There were no adverse events related to the trial during the study.

Interpretation Our findings suggest that Floatation-REST decreased body dissatisfaction compared to care as usual acutely after each float session and at six-month follow-up. Floatation-REST has potential utility for the treatment of body image disturbance and anxiety in AN. These results may be limited by some generalisability concerns given the recruitment of a modest sample receiving inpatient treatment at a single site.

Funding The William K. Warren Foundation.

*Corresponding author. 6655 S Yale Avenue, Tulsa, Oklahoma 74136, USA.
E-mail address: skhalsa@laureateinstitute.org (S.S. Khalsa).
[e]Equal contribution.

Keywords: Eating disorders; Body image; Anxiety disorder; Stress; Behavioral treatment

Research in context

Evidence before this study

Reduced Environmental Stimulation Therapy via floatation (floatation-REST) has been investigated for potential clinical utility in individuals with psychiatric or medical conditions. Between August 18, 2022 and September 1, 2022, we searched the titles and abstracts in PsycINFO, PubMed, and Web of Science using the search terms ("reduced environmental stimulation therapy") OR ("floatation therapy") OR ("flotation therapy") OR ("floatation-REST") OR ("flotation-REST") OR ("restricted environmental stimulation"). Sixty-eight unique articles were identified using the following search criteria: original research articles published in a peer reviewed journal, and those utilising human participants.

For this review, articles that were not relevant to the current study topic were excluded including those related to athletic and/or strength conditioning (n = 8), states of altered consciousness (n = 6), insomnia (n = 2), personality and creativity (n = 6), smoking cessation (n = 6) or alcohol use (n = 1), for a total of 39 studies that were examined in detail. Only six studies investigated individuals diagnosed with a psychiatric disorder (e.g., anxiety, depression, or eating disorder), and of these, only one examined the effect of REST in anorexia nervosa (AN). In that single-group open label trial, floatation-REST was found to be safe and well tolerated by outpatients with AN and to acutely reduce body image disturbance and anxiety.

Added value of this study

The current study is the first randomised controlled trial examining the effects of floatation-REST in individuals with AN. We found that the AN inpatients randomised to floatation-REST experienced acute reductions in body image disturbance and anxiety compared to a care as usual group. Further, the longitudinal assessment of illness trajectories revealed group differences such that the floatation-REST group had significantly lower body image disturbance at six-months post intervention.

Implications of all the available evidence

Few studies have focused on the safety or clinical impacts of floatation-REST in individuals with psychiatric disorders. Our findings have implications for the clinical utilisation of floatation-REST in the treatment of eating disorders.

Introduction

Anorexia nervosa (AN) is a psychiatric disorder with standardised mortality rates estimated to be higher than many other severe psychiatric conditions including schizophrenia and bipolar disorder.[1] AN has a lifetime comorbidity of 50–60% with anxiety disorders,[2] and it is associated with a high personal and family burden that includes excessive healthcare costs, lost wages for patients and caregivers, and a substantially decreased quality of life.[3] Despite the intensive delivery of treatments for AN via inpatient settings the disorder has an extensive rate of relapse: as high as 50% within the first year of treatment,[4] with the greatest risk of relapse approximately 60 days after hospital discharge.[5] The considerable risk of relapse, in conjunction with the high mortality rate, substantial illness burden, and prolonged treatment duration highlights an urgent need for improved treatments for AN.

AN is characterised diagnostically by three core symptoms: 1) severe food restriction leading to weight loss; 2) intense fears of weight gain; and 3) body image disturbance in the form of an aversive overvaluation of one's own weight and shape. Body image is a multifaceted construct comprised of cognitive/affective (how one thinks and feels about their body) and perceptual (how one actually sees their body size/shape) components.[6] Body image disturbance is more resistant to change in women with AN than other eating disorders,[7] and it is involved in the maintenance and relapse of AN.[8] There is consistent evidence for perceptual overestimations of body size in AN[9–11] (but see[12,13]), although most current first-line treatments for AN primarily focus mainly on addressing the cognitive/affective component of body image disturbance. Perceptually-focused standalone body image treatments, such as mirror-exposure therapy and virtual reality manipulations can be successful for improving body image, but these studies have primarily been small or non-randomised, and some have been complicated by adverse events.[14] Other standalone interventions have targeted the affective/cognitive component using principles of cognitive behavioral therapy, but many of these studies may suffer from inflated effect size estimates due to small sample sizes or publication bias.[15] Additionally, a meta-analytic study found only a small effect (d = 0.38) for standalone treatments.[15] Thus, the present need for improved treatments for AN is compounded by a shortage of safe and empirically validated interventions targeting body image disturbance.

Traditional treatments for body image disturbance in eating disorders tend to apply a top-down approach (i.e., manipulating cognitions to affect perceptions of the body). However, more recent suppositions argue that body image perception may occur via the nervous

system's processing of multisensory inputs, affecting perception and ultimately cognition via the integration of afferent visual stimuli (i.e., what images are relayed by the retina to the brain), prior cognitive schemas (i.e., how one thinks and feels about their body), and incoming or anticipated interoceptive signals (i.e., how one senses their body's current physiological state).[16,17] This theoretical perspective suggests that the diminished perception of interoceptive body signals (i.e., an inability to accurately sense what is happening in the body) causes an increased reliance and sensitivity to exteroceptive body signals (especially visual), leading one to view their body as an object from the third-person perspective and negatively self-objectify it. As a consequence, AN individuals may have difficulty adaptively integrating external and internal signals, which could lead to an inaccurate mental representation of one's own body. Abnormal interoception is currently a non-diagnostic component of AN but it is increasingly recognised as playing a role in clinical expression of the disorder,[18–20] and functional neuroimaging studies have identified disruptions of signaling across areas of the brain that facilitate interoceptive and visuospatial representation in AN.[21,22] Diminished interoception has in turn been associated with self-objectification[23] and a susceptibility to altered self-focused visual attention.[24] Together, these findings suggest a mechanistic relationship between interoception and perceptual body image disturbance and implies that a bottom-up approach to treating disturbed body image may have therapeutic benefit.

Reduced Environmental Stimulation Therapy via floatation (floatation-REST) is a non-pharmacological intervention under increasing investigation for potential anxiolytic properties in clinically anxious and stressed populations. Floatation-REST involves immersion in a shallow pool of water saturated with Epsom salt, which, along with additional engineering calibrations, results in an environment that reduces nervous system input from exteroceptive sensory signals (e.g., light and sound proofing reduces visual and auditory stimulation). Proprioceptive signals are reduced by the high specific gravity of the water which facilitates effortless floating without requiring skeletal muscle movements, and thermosensory signals are equalised via heating the air and water to match the skin's temperature. As a result, floatation-REST simultaneously attenuates exteroceptive and proprioceptive sensory input and increases awareness of interoceptive sensations.[25] Studies in clinical populations have begun documenting the safety, tolerability, and efficacy of this intervention,[25–27] but only one to date has examined floatation-REST in AN. In a single-group open-label safety study, we found floatation-REST to be safe and well-tolerated in partially weight-restored outpatients with AN, with no evidence of orthostatic hypotension induced by the float environment (primary outcome).[28] During the secondary analysis of outcomes we found that floatation-REST produced moderate improvements in body dissatisfaction indexed via the Photographic Figure Rating Scale (PFRS), a measure of the perceptual component of body image disturbance. We also saw large acute reductions in state anxiety indexed via the State Trait Anxiety Inventory (STAI), as well as positively valenced increases in cardiorespiratory interoceptive sensations. These open-label findings suggested that further investigation of the clinical impact of floatation-REST in AN was warranted.

We conducted a randomised clinical efficacy trial of floatation-REST in AN with the primary objective to examine the acute impact of eight sessions of floatation-REST on body dissatisfaction in women and girls with AN receiving intensive treatment in an inpatient setting. We hypothesised that individuals receiving floatation-REST, in addition to care as usual, would exhibit significant reductions in body dissatisfaction from pre- to post-floatation-REST relative to a group receiving care as usual. Our secondary objectives were to evaluate the longitudinal impact of floatation-REST on body dissatisfaction (i.e., intervention effects from baseline to post-intervention and follow-ups) as well as the acute and longitudinal impacts of floatation-REST on anxiety, eating disorder symptom severity, functional ability, and other perceptual and attitudinal measures of body image. We hypothesised that the floatation-REST group would also exhibit lower body dissatisfaction at post-intervention and at six-week and six-month follow-up times compared to the usual care group.

Methods

Study design

The study was a parallel group randomised control trial performed at a single site. Ethical approval for the trial was granted by the WIRB-Copernicus Group (WCG) IRB on January 5, 2018, under study number 1182807. The trial was prospectively registered with the National Institute of Health clinicaltrials.gov (NCT03610451) at the start of the study on March 16, 2018, and the protocol is provided in the Appendix (pages 1–41). This protocol was developed via a pragmatic clinical trial framework. The Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheels for the intervention and care as usual groups are presented in the Appendix (page 40).

Participants

Inpatients with AN were recruited from the Laureate Eating Disorders Program (LEDP), a treatment program for women and girls located within the Laureate Psychiatric Clinic and Hospital in Tulsa, Oklahoma, USA. All individuals presenting to LEDP who met criteria for AN were considered for the trial. Participants were recruited via recommendations from facility staff and

posted fliers. They were included in the study if they met the following criteria: female, primary clinical diagnosis of AN, age 13–64 years, receiving inpatient treatment at the LEDP, body mass index (BMI) ≥16 (to reduce the likelihood participants were in a severe acute starvation state), independently ambulatory, and ability to comfortably lie in a supine position. Exclusion criteria were active suicidal ideation, active cutting or skin lacerating behaviors, current orthostatic hypotension, comorbid schizophrenia spectrum, bipolar, or other psychotic disorder, seizure within the previous 12 months, no smartphone/computer access, systolic blood pressure >160 mmHg, diastolic blood pressure >100 mmHg, and resting heart rate <40 beats per minute. More detailed inclusion and exclusion criteria are provided in the Appendix (pages 17–18). Written informed consent was obtained for participants 18–64 years of age. Parental consent and assent were obtained for participants 13–17 years of age.

Randomisation and masking

Participants were assigned randomly at a 2:1 ratio to floatation-REST or care as usual. The unequal randomisation was utilised to allow for greater ability to detect a small effect expected from floatation-REST in comparison to a care as usual comparator. The randomisation sequence was generated at the start of the study via online computer randomisation by an in-house statistical consultant who was uninvolved with the study. Randomisation occurred at the individual level only after verification that the inclusion criteria were met and upon completion of the baseline visit assessments, such that the research coordinator revealed the assignment to the individual and scheduled their subsequent assessments. Following the randomisation, the participants and study team were not masked to the participant's assigned condition in this behavioral clinical trial.

Procedures

All participants were receiving residential eating disorder care which involves individualised, intensive therapeutic intervention from multidisciplinary teams comprised of physicians, nursing staff, behavioral therapists, registered dieticians, chefs, yoga instructors, and school coordinators (if indicated). Treatment also includes medical stabilization, psychopharmacology (if indicated), nutritional assessments and interventions, as well as intensive psychotherapy via group, individual, and/or family therapy formats, totaling more than 40 h per week of clinical programming. All participants received the same level of care within LEDP regardless of randomisation status. Every participant was compensated for their involvement, with compensation provided by the Laureate Institute for Brain Research (LIBR).

Participants randomised to floatation-REST received care as usual and completed eight float sessions at a rate of approximately two sessions per week. Participants randomised to floatation-REST reported to the LIBR Float Clinic and Research Centre, a facility which was pre-existing and operated by LIBR, and located three floors below the residential eating disorder treatment program in the same building. Participants in the study did not incur personal cost or additional health insurance charges associated with the utilisation of floatation-REST. During the floatation-REST intervention participants floated in one of two shallow circular fiberglass pools. Each pool was 8 feet in diameter and contained 11 inches of reverse osmosis water saturated with ~1800 pounds of USP grade Epsom salt (magnesium sulfate), creating a dense saltwater solution maintained at a specific gravity of ~1.26. When laying supine, the density of this solution allowed participants to float effortlessly on their back. The temperature of the water and the air were calibrated to ~95.0 °F or skin temperature, helping to minimise the need for thermoregulation while reducing the thermal boundary between air, body, and water. Clothing was usually not worn during the float session per the usual application of this intervention, though participants were allowed to float in a bathing suit if they preferred. They had the option to float in total darkness or with soft ambient illumination provided via a blue light emitting diode. Participants were asked to shower before and after floating. Mirrors in the adjacent bathrooms were covered by a curtain to reduce potential effects of visual exposure to their own body image before and after floating. Each float lasted 60 min unless terminated early by the participant. Participants completed questionnaires before and after each float session via an electronic tablet containing the primary and secondary outcome measures. Participants randomised to the care as usual group completed the identical evaluation measures at approximately the same timepoints as the floatation-REST group. These time points took place during a scheduled programming break and snack time for both the usual care and floatation-REST group, thus avoiding potential interference with clinical outcomes assessment for care as usual participants and ensuring floatation-REST participants did not miss any scheduled therapeutic sessions given as part of usual care. This scheduled snack time was prescribed as part of the inpatient meal plan and adherence to this snack was monitored by the study staff.

Additional self-reported outcomes data were collected at baseline (prior to intervention), at post intervention (immediately after completing the full eight-session intervention), at six-weeks, and at six-months post intervention, via electronic devices that included tablets, computers, and smartphones. These endpoints are detailed in the protocol (Appendix pages 16–17). Follow-up assessments were conducted remotely at six-week and six-month intervals post intervention.

Outcomes

The primary outcome was self-reported body dissatisfaction as measured by the Photographic Figure Rating Scale (PFRS),[29] assessed before and after each session. Participants are asked to select the image that most closely approximates their current and ideal body. The PFRS body dissatisfaction score is calculated as the absolute difference between the current and ideal bodies selected by the participant. Secondary outcome measures included the PFRS measured at baseline, immediately post intervention, at six-week, and six-month follow-ups. Secondary outcomes assessed at pre- and post-session timepoints included the State Trait Anxiety Inventory (STAI) state form,[30] Body Image States Scale (BISS), and interoceptive sensation ratings rated on a visual analog scale. Secondary outcome measures assessed at baseline, immediately post intervention, six weeks, and six months post intervention included: anxiety, eating disorder symptom severity, functional ability, and other perceptual and attitudinal measures of body image including the Body Appreciation Scale-2 (BAS). A detailed schedule of events is listed in the Appendix (page 24).

Monitoring of adverse events and safety outcomes including serious adverse events, as defined by the trial protocol (Appendix page 26), were recorded and reviewed regularly by the senior investigator to determine their relationship to the study. Adverse events were defined as death, a life-threatening adverse event, inpatient hospitalisation, or prolongation of existing hospitalisation, or a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions. There was no data monitoring committee for the study.

Choice of primary measure

We selected body dissatisfaction on the PFRS as our primary outcome because of the centrality of body image disturbance to the diagnosis of AN, the recalcitrance of this construct to treatment, and based on empirical observations from our safety study in AN[28] which identified reductions in body dissatisfaction on the PFRS during the secondary outcomes analysis.

Statistical analysis

We required a sample size of 54 participants, allocated in a 2:1 ratio, to detect a medium effect size of floatation-REST on PFRS body dissatisfaction. Our sample size estimate was made based on several assumptions: (1) the proposed float intervention (two float sessions per week for four weeks) would have similar effects as the three float sessions in the original safety study in AN,[28] (2) the care as usual group would show no average change in body dissatisfaction, (3) the care as usual and floatation groups would exhibit similar variance-covariance structures, and (4) a 10% dropout would be observed across the intervention for each group. Based on these assumptions, the sample size was calculated for 80% power based on a linear mixed-effects model with Group as the fixed-effect, and (a) a random intercept only (equivalent to exchangeable correlation structure) or (b) a random time/float slope (to capture temporal correlation), at the 0.05 significance level for various effect sizes by 10,000-run simulation for each scenario. Simulations were performed in R (version 3.3.2) using packages mvtnorm (version 1.0-6) to simulate multivariate normal data, lme4 version 1.1-14) for mixed-model inference.

We conducted all analyses using the intention-to-treat (ITT) principle such that all randomised participants with a recorded primary or secondary outcome were included, according to their group assignment. Frequency distributions, means, and standard deviations (SD) were calculated for each outcome measure at all measurement points. Distributions were examined for extreme outliers and for significant deviations from normality. Outliers were assessed using the generalised extreme studentised deviant test. Distributions were tested for normality using visual inspection of Q–Q plots and the Shapiro–Wilk normality test. Both outcome measures were assessed for covariance with several demographic metrics, including age, admission BMI, years of education, age of illness onset, and psychiatric medication status. Covariates significantly related to the outcome of interest were controlled for in the final models.

Linear mixed models (LMMs) were used to evaluate changes of each self-report metric in response to time and treatment. These models captured the acute and long-term effects of treatment (i.e., primary and secondary outcomes). All tests were 2-tailed, with significance set at $p < 0.05$. Analyses were conducted in R (version 3.6.1). LMMs were constructed using the lme4 package. Our initial intention, specified in the Protocol, was to impute missing values. However, that was not done as linear mixed models can handle missing values and can include partial data for a participant whose observations are incomplete. In presenting results from these models, interactions between treatment groups and time were examined to determine if changes over time differ by treatment group. This was followed, if appropriate, by post hoc comparisons of estimated marginal means (Δm) within each treatment group to determine what led to the significant interaction. This testing was conducting using the emmeans package in R.

Model 1 examined the acute effects of time (pre- and post-session), treatment condition (floatation-REST vs. care as usual) and their interaction in predicting primary (PFRS) and secondary outcome measures (STAI). The acute LMM modeled before and after floatation-REST effects, while controlling for inter-session variability by modeling the effects of session number (i.e., session 1–8) on the intercept. The model also accounted for overall effect from pre- to post-floatation by collapsing the effects of all eight sessions together. Additionally, random effects of each participant were modeled on the intercept and on the effect of time (pre,

post) to control for potential individual difference variations present in the multiple measurements taken from each participant. Models predicting the PFRS included age, age of onset, education, and admission BMI as covariates. Models predicting the STAI included age, age of onset, education, and psychotropic medication as covariates.

Model 2 examined the longitudinal effect of the intervention (i.e., cumulative effect of the eight floatation sessions) on PFRS body dissatisfaction. Time was modeled using a dummy code system with baseline as the comparator condition. Interactions were explored between time and treatment. Random effects of each participant were modeled on the intercept. Outcome measures at the conclusion of the intervention were modeled by comparing baseline values with values obtained immediately post-intervention, at six weeks post-intervention, and at six months post-intervention.

Role of the funding source

The funder of this study, The William K Warren foundation had no role in study design, data collection, data analysis, interpretation, or writing of the report. All authors had full access to all the data in the study and accept responsibility for the decision to submit for publication.

Results

Screening and recruitment took place between March 16, 2018 and February 25, 2021, with a pause in data collection between March 2020 and July 2020 due to the COVID-19 pandemic. Following this pause in recruitment, rapid Sars-Cov-2 antigen testing was utilised to allow study entry. A total of 133 participants were screened for eligibility, and 86 were consented. Eighteen were excluded after consent and one additional participant randomised to care as usual withdrew before their first appointment, for a final randomisation sample of $n = 67$ participants (45 floatation-REST; 22 care as usual; see Fig. 1). Recruitment ended when a sufficient number of participants had been randomised to each condition.

Baseline characteristics for each group are listed in Table 1. The sample was predominantly Non-Hispanic, White (92%; $n = 42$); 6% identified as White/American Indian ($n = 4$), one participant identified as Chinese, and one was missing race and ethnicity data. The floatation-REST and care as usual group did not differ with respect to mean body mass index at admission (17.3 vs. 16.9, respectively), mean age (20.0 vs. 18.9 years, respectively), or mean age of illness onset (14.7 vs. 14.9 years, respectively).[f] Baseline eating disorder symptom severity was similar in the floatation-REST group ($m = 4.20$, $SD = 1.07$) and in the care as usual group ($m = 4.36$, $SD = 0.92$). Baseline levels of anxiety and body dissatisfaction were also similar across groups (see Table 1). The percentage of participants taking psychotropic medication was higher in the floatation-REST group (86%) than the care as usual group (50%). Participants randomised to the floatation-REST condition completed an average of 7.7 floatation sessions, with an average float session duration of $m = 49.4$ min, $SD = 12.6$ min across the study. Participants randomised to the care as usual condition completed an average of 7.6 measurement sessions. Prior to analyses, data were assessed for normality and outliers. No extreme deviations from normality or outliers were identified.

For the primary outcome, there was a significant session by treatment interaction on the PFRS ($F_{(1,62.0)} = 15.00$, $p = 0.00026$). This arose from significant reductions in body dissatisfaction from pre-to post-session for the floatation-REST group ($\Delta m = -0.43$; 95% CI −0.56 to −0.30, $p < 0.0001$, Cohen's $d = 0.23$), whereas the care as usual group showed no significant change in body dissatisfaction ($\Delta m = 0.02$; 95% CI −0.17 to 0.20, $p = 0.87$). See Fig. 2A and B, and Supplementary Material for additional model comparisons.

With regard to secondary outcomes for body dissatisfaction, there was a significant time by treatment interaction between baseline and immediately post treatment ($F_{(1,158.8)} = 6.50$, $p = 0.012$). Post hoc testing revealed that there was a trending within group difference for the floatation-REST condition ($\Delta m = -0.41$, 95% CI −0.86 to 0.03, $p = 0.068$) and care as usual condition ($\Delta m = 0.61$; 95% CI −0.04 to 1.27, $p = 0.070$). See Fig. 3 and Supplementary Material. The time by treatment interaction was not significant at the six-week follow-up ($F_{(1,158.9)} = 2.48$, $p = 0.12$). However, there was a significant time by treatment interaction between baseline and the six-month post-intervention time point ($F_{(1,159.0)} = 9.99$, $p = 0.0019$; see Fig. 3). Relative to their baseline, the floatation-REST group showed significantly decreased body dissatisfaction at the six-month time point ($\Delta m = -0.91$; 95% CI −1.37 to −0.45, $p = 0.00020$, Cohen's $d = 0.53$) whereas the care as usual group showed no significant change in this measure ($\Delta m = 0.35$; 95% CI −0.28 to 0.98, $p = 0.28$). For the secondary outcomes of attitudinal body image (i.e., Body Image States Scale and Body Appreciation Scale) there were no significant session by treatment interactions (all p's > 0.05).

For the secondary outcome of anxiety, there was a significant session by treatment interaction ($F_{(1,59.9)} = 66.11$, $p < 0.0001$). See Fig. 2C and D and Supplementary Material. Post hoc testing showed that there was a significant reduction in STAI-state anxiety from pre- to post-session for the floatation-REST group ($\Delta m = -15.75$; 95% CI −17.95 to −13.56, $p < 0.0001$,

[f]Age was calculated from each participant's self-reported date of birth, and age of onset and illness duration were obtained independently from their medical record.

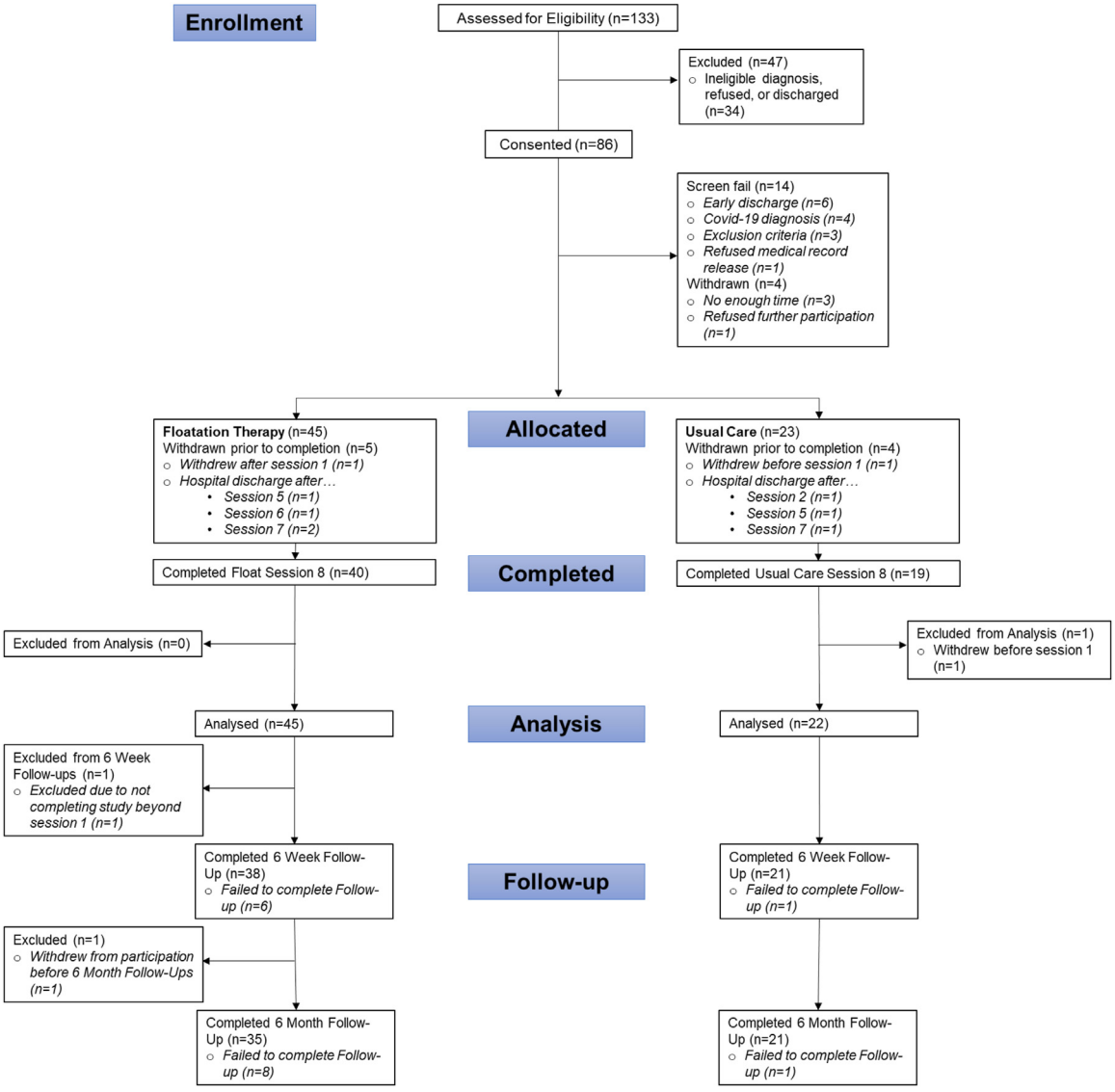

Fig. 1: **CONSORT flowchart of study enrollment, allocation, analysis, and follow-up.**

Cohen's d = 1.52), but not for the care as usual group (Δm = –0.01, 95% CI –3.10 to 3.13, p = 0.99). See Fig. 2C. For the secondary longitudinal outcome of trait anxiety (i.e., STAI-trait) there were no significant session by treatment interactions (all p's > 0.05). For all analyses, additional models were explored without the presence of covariates, with no change to the presented findings. There were no adverse events related to the trial during the study.

Discussion

This randomised clinical efficacy trial provided evidence that floatation-REST, when compared to care as usual, led to acute and longitudinal decreases in body dissatisfaction in women and girls with AN receiving inpatient treatment. Additionally, we found that the floatation-REST intervention was associated with large reductions in state anxiety. The magnitude of these findings is consistent with our previous nonrandomised safety study in AN outpatients[28] and with our hypotheses for the current study.

There was a signal suggesting that floatation-REST reduced body dissatisfaction more than usual care over time. The small size of this effect may partly reflect the well-known recalcitrance of body image disturbance to therapeutic modulation in AN.[7] It may also reflect the lack of targeting of body image using specific cognitive or behavioral strategies during the floatation-REST intervention. This finding is in line with other body

	Floatation-REST (*n* = 45)	Care as usual (*n* = 22)
Age in years, mean (SD)	20.0 (4.3)	18.9 (5.4)
Education, years, mean (SD)	13.2 (2.6)	12.0 (2.8)
Age of onset, years, mean (SD)	14.7 (3.8)	14.9 (2.6)
Illness duration, years, mean (SD)	6.0 (5.4)	3.5 (3.8)
Lowest BMI, mean (SD)	16.4 (2.4)	16.0 (2.6)
Admission BMI, mean (SD)	17.3 (1.8)	16.9 (1.6)
Psychiatric medication, mean (SD)	37 (86%)	11 (50%)
EDE-Q score at baseline, mean (SD)	4.20 (1.07)	4.36 (0.92)
STAI trait score at baseline, mean (SD)	60.7 (8.5)	61.0 (10.5)
PFRS score at baseline, mean (SD)	2.93 (1.70)	2.64 (1.62)
Ethnicity, *n* (%)		
White	42 (96%)[a]	20 (91%)
Asian	0 (0.0%)	1 (5%)
American Indian or Alaska Native	3 (7%)[a]	1 (5%)
Primary diagnosis, *n* (%)		
AN–restricting subtype	28 (64%)[a]	11 (50%)
AN–binge/purge subtype	7 (16%)[a]	2 (9%)
AN–unspecified	9 (21%)[a]	9 (41%)
Comorbid diagnosis, *n* (%)		
Major depressive disorder	23 (54%)[b]	9 (41%)
Generalised anxiety disorder	34 (79%)[b]	16 (73%)
Obsessive compulsive disorder	9 (21%)[b]	4 (18%)

AN, anorexia nervosa; BMI, body mass index; EDE-Q, Eating Disorder Examination Questionnaire; STAI, State Trait Anxiety Index; PFRS, Photographic Figure Rating Scale. [a]Percentage out of 44 participants due to missing demographic data. [b]Percentage is out of 43 participants due to missing diagnostic data. All percentages were rounded to nearest integer, thus may not add to 100%.

Table 1: **Participant demographics and selected baseline characteristics.**

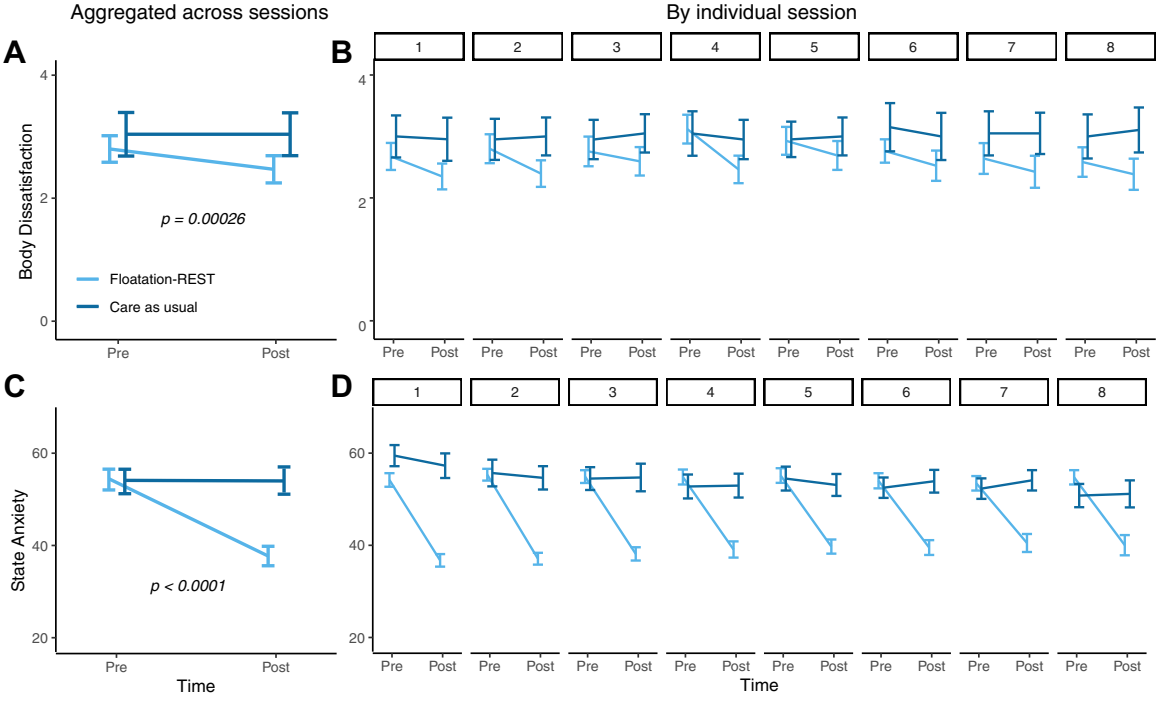

Fig. 2: **Acute effects of floatation-REST vs. care as usual.** A) Body dissatisfaction across eight sessions. *p* value indicates significant group by session interaction. B) Body dissatisfaction by individual session. C) Anxiety across eight sessions. *p* value indicates significant group by session interaction. D) Anxiety by individual session. Error bars reflect standard errors.

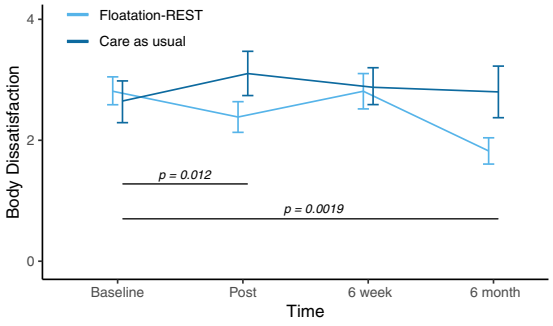

***Fig. 3*: Longitudinal effects of floatation-REST vs. care as usual on body dissatisfaction.** *p* values represent significant group by time interactions. Error bars reflect standard errors.

image disturbance therapies including mirror exposure,[14] acceptance-based approaches,[31] and cognitive restructuring,[32] which show evidence of small to medium effects.[14,15] Further, the current study did not find evidence that floatation-REST influenced cognitive/affective measures of body image disturbance. Additional investigation is necessary to determine whether cognitive or behavioral strategies focused on body image disturbance could be augmented with floatation-REST to exert larger and more comprehensive (i.e., cognitive, affective, and perceptual) therapeutic impacts. The present findings are well-poised for a pragmatic integration with current treatments for AN, particularly those focused on improving body image.

We also observed a robust impact of floatation-REST on acute anxiolysis in inpatients with AN. The magnitude of this effect ($d = 1.52$) was comparable with previous floatation-REST studies of clinically anxious outpatients[25,26] in addition to our study of outpatients with AN who reported lower levels of eating disorder symptoms.[28] This anxiolytic effect is noteworthy given the high comorbidity of anxiety disorders with AN and the challenges of finding effective short-acting interventions for anxiety that are non-sedating, particularly since previous work in AN has suggested a lack of anxiolytic response to the short-acting benzodiazepine alprazolam.[33] The magnitude of the anxiolytic effect of floatation-REST in AN is comparable to that of alprazolam for anxiety disorders ($d = 1.79$)[34] and larger than that of treatments for anxiety disorders involving a placebo ($d = 1.29$),[34] enhanced cognitive behavioral therapy for eating disorders ($d = 1.06$),[35] cognitive remediation therapy for eating disorders (no change),[36,37] and exposure therapy for meal related anxiety in AN ($d = 0.32$).[38] Thus, further investigation is necessary to determine whether traditional anxiolytic treatments for AN could be augmented with floatation-REST to exert larger therapeutic impacts, or whether it could be used to reduce the anxiety related to meals or weight restoration that is often observed during treatment.

This is the first randomised clinical efficacy study to examine the effects of floatation-REST on body image disturbance and anxiety in women and girls with AN. We employed a care as usual comparator group with robust sampling which provided a more reliable estimate than a wait-list control. Based on these initial results, additional trials employing other comparators appear warranted. For example, an active comparator intervention could be utilised to better control for potential nonspecific effects of therapeutic expectancy. However, since we view floatation-REST primarily as a tool for augmenting existing treatments rather than as a standalone treatment, such comparators would need to be designed carefully and might focus on matching the attentional characteristics of both interventions. Additional steps may determine whether floatation-REST has additive clinical utility when used to augment current cognitive affective treatments focused on body image disturbance. Investigations combining floatation-REST with perceptually focused body image treatments (e.g., mirror exposure) could be an alternative approach. Establishing the durability of such effects will be important.

While the results of the current trial are promising, there are several design characteristics to consider. The intervention was limited to a modest sample of participants recruited from a single inpatient treatment centre with a restricted ethnoracial background. The pragmatic design of this study entailed a limited mechanistic framework (i.e., no biomarker assessments). As this study focused on individuals with AN, a transdiagnostic approach including individuals with other eating disorders characterised by overvaluation of weight and shape would be useful in future investigations. As floatation-REST is presently considered a novel therapeutic tool, treatment expectancies may have played a role in the current results, and future studies should examine such expectancies and how they relate to symptom improvement. The current study did not account for additional treatment participants may have sought after leaving residential treatment and it is unknown if participants in the floatation-REST group continued with floatation-REST after discharge or if this group differed from the usual care group in post-hospitalisation treatment utilisation. Finally, while there were significant time by treatment interactions on the PFRS, suggesting a signal related to floatation-REST, the differences between groups at certain discrete time points were not significant. This may in part be due to insufficient power to detect group differences as the repeated measures study design was better powered to detect longitudinal within group differences. It will be important for future studies to consider the potential influence of these factors on observed outcomes. A pragmatic trial examining the practicalities and cost of augmenting eating disorder treatment with floatation-REST would be instructive as to the real-world feasibility of this intervention. Despite

these considerations, the current study exhibited multiple strengths in that it was prospectively designed using a rigorous and pragmatic framework, and used randomisation to evaluate the efficacy of floatation-REST in AN. Further, the design of the study drew upon phenomenological and participatory insights gathered from interviews conducted with AN participants during the prior safety trial.[28]

In conclusion, this study provides evidence that floatation-REST led to sustained reductions in body dissatisfaction and acute anxiolysis in inpatient women and girls with AN. Floatation-REST thus has potential as an efficacious tool for treatment of body image disturbance and anxiety in AN.

Contributors

SSK and JSF were responsible for the analytic design of the study. MCF, EMC and SSK were responsible for data analysis and verification of all data. EMC, MCF, and SSK wrote the first draft of the manuscript. All authors interpreted the results of the study and had input on the final manuscript. All authors had full access to all the data in the study and accept responsibility for the decision to submit for publication.

Data sharing statement

Deidentified participant data may be shared with the publication following requests submitted via email to the corresponding author. A signed data access agreement is a requirement.

Declaration of interests

Martin Paulus is an advisor to Spring Care, Inc., a behavioral health startup, he has previously received royalties for an article about methamphetamine in UpToDate, and consulting fees from Hoffmann-La Roche Ltd. Justin Feinstein is the president and director of the nonprofit Float Research Collective. Sahib Khalsa is an executive committee member of the International Society of Contemplative Research and a board member of the Float Research Collective, both of which are unpaid roles. All other authors declare no competing interests. Sahib Khalsa was supported by the National Institute of Mental Health (R01MH127225, K23MH112949). Martin Paulus, Justin Feinstein, and Sahib Khalsa were supported by the National Institute of General Medical Sciences (1P20GM121312). Emily Choquette and Michael Flux received support for travel and hotel to speak at the 2022 Float Conference. The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication.

Acknowledgements

We wish to thank Hung-Wen Yeh, Maria Puhl, and Emily Adamic who provided statistical consultation, and Jamie Feusner, Armen Arevian, and Rachel Lapidus who helped with data collection. Funding for this study was provided by The William K. Warren Foundation.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2023.102173.

References

1 Hoang U, Goldacre M, James A. Mortality following hospital discharge with a diagnosis of eating disorder: national record linkage study, England, 2001-2009. *Int J Eat Disord*. 2014;47(5):507–515.
2 Rojo-Moreno L, Arribas P, Plumed J, et al. Prevalence and comorbidity of eating disorders among a community sample of adolescents: 2-year follow-up. *Psychiatry Res*. 2015;227(1):52–57.
3 van Hoeken D, Hoek HW. Review of the burden of eating disorders: mortality, disability, costs, quality of life, and family burden. *Curr Opin Psychiatr*. 2020;33(6):521–527.
4 Khalsa SS, Portnoff LC, McCurdy-McKinnon D, Feusner JD. What happens after treatment? A systematic review of relapse, remission, and recovery in anorexia nervosa. *J Eat Disord*. 2017;5:20.
5 Walsh BT, Xu T, Wang Y, Attia E, Kaplan AS. Time course of relapse following acute treatment for anorexia nervosa. *Am J Psychiatry*. 2021;178(9):848–853.
6 Cash TF, Green GK. Body weight and body image among college women: perception, cognition, and affect. *J Pers Assess*. 1986;50(2):290–301.
7 Chapa DAN, Hagan KE, Forbush KT, Clark KE, Tregarten JP, Argue S. Longitudinal trajectories of behavior change in a national sample of patients seeking eating-disorder treatment. *Int J Eat Disord*. 2020;53(6):917–925.
8 Glashouwer KA, van der Veer RML, Adipatria F, de Jong PJ, Vocks S. The role of body image disturbance in the onset, maintenance, and relapse of anorexia nervosa: a systematic review. *Clin Psychol Rev*. 2019;74:101771.
9 Gardner RM, Brown DL. Body size estimation in anorexia nervosa: a brief review of findings from 2003 through 2013. *Psychiatry Res*. 2014;219(3):407–410.
10 Molbert SC, Klein L, Thaler A, et al. Depictive and metric body size estimation in anorexia nervosa and bulimia nervosa: a systematic review and meta-analysis. *Clin Psychol Rev*. 2017;57:21–31.
11 Cash TF, Deagle EA 3rd. The nature and extent of body-image disturbances in anorexia nervosa and bulimia nervosa: a meta-analysis. *Int J Eat Disord*. 1997;22(2):107–125.
12 Mölbert SC, Thaler A, Mohler BJ, et al. Assessing body image in anorexia nervosa using biometric self-avatars in virtual reality: attitudinal components rather than visual body size estimation are distorted. *Psychol Med*. 2018;48(4):642–653.
13 Cornelissen KK, Cornelissen PL, Hancock PJ, Tovée MJ. Fixation patterns, not clinical diagnosis, predict body size over-estimation in eating disordered women and healthy controls. *Int J Eat Disord*. 2016;49(5):507–518.
14 Griffen TC, Naumann E, Hildebrandt T. Mirror exposure therapy for body image disturbances and eating disorders: a review. *Clin Psychol Rev*. 2018;65:163–174.
15 Alleva JM, Sheeran P, Webb TL, Martijn C, Miles E. A meta-analytic review of stand-alone interventions to improve body image. *PLoS One*. 2015;10(9):e0139177.
16 Stanghellini G, Ballerini M, Mancini M. The optical-coenaesthetic disproportion hypothesis of feeding and eating disorders in the light of neuroscience. *Front Psychiatry*. 2019;10:630.
17 Gadsby S. Distorted body representations in anorexia nervosa. *Conscious Cogn*. 2017;51:17–33.
18 Jenkinson PM, Taylor L, Laws KR. Self-reported interoceptive deficits in eating disorders: a meta-analysis of studies using the eating disorder inventory. *J Psychosom Res*. 2018;110:38–45.
19 Khalsa SS, Berner LA, Anderson LM. Gastrointestinal interoception in eating disorders: charting a new path. *Curr Psychiatry Rep*. 2022;24(1):47–60.
20 Jacquemot A, Park R. The role of interoception in the pathogenesis and treatment of anorexia nervosa: a narrative review. *Front Psychiatry*. 2020;11:281.
21 De la Cruz F, Teed AR, Lapidus RC, et al. Central autonomic network alterations in anorexia nervosa following peripheral adrenergic stimulation. *Biol Psychiatry Cogn Neurosci Neuroimaging*. 2022;8(7):720–730.
22 Favaro A, Santonastaso P, Manara R, et al. Disruption of visuospatial and somatosensory functional connectivity in anorexia nervosa. *Biol Psychiatry*. 2012;72(10):864–870.
23 Ainley V, Tsakiris M. Body conscious? Interoceptive awareness, measured by heartbeat perception, is negatively correlated with self-objectification. *PLoS One*. 2013;8(2):e55568.
24 Pollatos O, Herbert BM, Berberich G, Zaudig M, Krauseneck T, Tsakiris M. Atypical self-focus effect on interoceptive accuracy in anorexia nervosa. *Front Hum Neurosci*. 2016;10:484.
25 Feinstein JS, Khalsa SS, Yeh H, et al. The elicitation of relaxation and interoceptive awareness using floatation therapy in individuals with high anxiety sensitivity. *Biol Psychiatry Cogn Neurosci Neuroimaging*. 2018;3(6):555–562.
26 Feinstein JS, Khalsa SS, Yeh HW, et al. Examining the short-term anxiolytic and antidepressant effect of floatation-REST. *PLoS One*. 2018;13(2):e0190292.

27 Jonsson K, Kjellgren A. Promising effects of treatment with flotation-REST (restricted environmental stimulation technique) as an intervention for generalized anxiety disorder (GAD): a randomized controlled pilot trial. *BMC Complement Altern Med*. 2016;16:108.
28 Khalsa SS, Moseman SE, Yeh H-W, et al. Reduced environmental stimulation in anorexia nervosa: an early-phase clinical trial. *Front Psychol*. 2020;11:567499.
29 Swami V, Salem N, Furnham A, Tovée MJ. Initial examination of the validity and reliability of the female photographic figure rating scale for body image assessment. *Pers Indiv Differ*. 2008;44(8):1752–1761.
30 Spielberger C, Gorsuch R, Lushene R, Vagg PR, Jacobs G. *Manual for the state-trait anxiety inventory (Form Y1 – Y2)*. 1983.
31 Fogelkvist M, Gustafsson SA, Kjellin L, Parling T. Acceptance and commitment therapy to reduce eating disorder symptoms and body image problems in patients with residual eating disorder symptoms: a randomized controlled trial. *Body Image*. 2020;32:155–166.
32 Fairburn CG. *Cognitive behavior therapy and eating disorders*. Guilford Press; 2008.
33 Steinglass JE, Kaplan SC, Liu Y, Wang Y, Walsh BT. The (lack of) effect of alprazolam on eating behavior in anorexia nervosa: a preliminary report. *Int J Eat Disord*. 2014;47(8):901–904.
34 Bandelow B, Reitt M, Röver C, Michaelis S, Görlich Y, Wedekind D. Efficacy of treatments for anxiety disorders: a meta-analysis. *Int Clin Psychopharmacol*. 2015;30(4):183–192.
35 Byrne SM, Fursland A, Allen KL, Watson H. The effectiveness of enhanced cognitive behavioural therapy for eating disorders: an open trial. *Behav Res Ther*. 2011;49(4):219–226.
36 Lock J, Fitzpatrick KK, Agras WS, Weinbach N, Jo B. Feasibility study combining art therapy or cognitive remediation therapy with family-based treatment for adolescent anorexia nervosa. *Eur Eat Disord Rev*. 2018;26(1):62–68.
37 Herbrich L, van Noort B, Pfeiffer E, Lehmkuhl U, Winter S, Kappel V. Follow-up assessment of cognitive remediation therapy in adolescent anorexia nervosa: a pilot study. *Eur Eat Disord Rev*. 2017;25(2):104–113.
38 Steinglass JE, Albano AM, Simpson HB, et al. Confronting fear using exposure and response prevention for anorexia nervosa: a randomized controlled pilot study. *Int J Eat Disord*. 2014;47(2):174–180.