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The open versus blind weight conundrum: A multisite randomized controlled trial across multiple levels of patient care for anorexia nervosa

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Abstract

Objective: Anorexia nervosa (AN) is a disorder characterized by a profound fear of weight gain, resulting in significant weight loss, as well as behavioral symptoms that interfere with weight normalization. In concert, weight gain remains a proximal goal of treatment, and patient weighing is a critical component of treatment. However, divergent approaches exist in how patient weighing is undertaken in clinical practice. The aim of this study is to investigate the impact of a brief course of open weighing (sharing weight data with patients) versus blind weighing (not sharing weight data with patients) on distress around being weighed and AN symptom severity.

Method: 216 patients with AN and atypical AN will be randomized to receive 4 weeks of open or blind weighing practices across residential, intensive outpatient, and outpatient treatment settings, within the context of manualized empirically supported treatment. Following 4 weeks of open or blind weighing, all patients will be enrolled into open weighing practices. Primary outcomes of interest will be patient-reported distress around being weighed at week 5 and eating disorder

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

symptom severity at week 5. Secondary outcomes will assess weight prediction error, intolerance of uncertainty, and the fear of food.

Discussion: No best practice guidelines exist in determining optimal practices around weighing patients with AN. This multisite randomized controlled trial will provide the first known data on the impact of open versus blind weighing practices upon weight-related distress and AN symptom severity.

Keywords

anorexia nervosa; blind weight; open weight; randomized controlled trial; registered report

1 | INTRODUCTION

The fear of weight gain has been documented since the first reported cases of AN (Gull, 1888) and has been featured in *every* iteration of the psychiatric diagnostic framework (American Psychiatric Association, 2013). Behaviorally, this fear manifests as an avoidance of eating particular quantities and types of food deemed likely to cause weight gain (Waller et al., 2007; Waller & Mountford, 2015), which in turn is *directly* associated with reduced food consumption in those with AN and is predictive of symptom severity in both laboratory and clinical settings (Kissileff, Brunstrom, Tesser, et al., 2015; Steinglass et al., 2010). Moreover, the fear of weight gain is centrally embedded in network models of AN psychopathology, both contemporaneously and temporally (Forrest, Jones, Ortiz, & Smith, 2018), and the fear-driven avoidance of calorie-dense foods accurately predicts relapse even after treatment discharge (Schebendach et al., 2008). Cumulatively, these data position the fear of weight gain as a key mechanism in the psychopathology of AN, such that reducing this fear may be crucial in optimizing treatment outcomes.

However, AN is unique among psychiatric disorders in that the primary symptomatic fear (i.e., weight gain) is uniformly adopted as the primary proximal treatment goal across *all* treatment modalities and platforms. That is, one cannot recover from AN while maintaining an underweight status, and central tenets in the treatment of AN posit that one must be restored to their developmentally appropriate weight and cannot continue to avoid specific foods for fear of weight gain (Waller & Mountford, 2015). As such, particular emphasis is afforded to patient weight throughout treatment, which often serves as a proxy for treatment progress, especially in the early stages. However, as patient weight increases throughout the early stages of treatment, and the avoidance of feared foods is therapeutically interrupted, the potential scope for *confirming* patient beliefs that feared food consumption causes immediate weight gain, have been noted (Murray et al., 2016; Murray, Loeb, & Le Grange, 2016). Thus, any therapeutic increase in weight, in the context of a profound fear of such weight gain, creates a conundrum around sharing weight-related data with patients, which has given rise to variable weighing practices in treatment (Forbush, Richardson, & Bohrer, 2014).

“Blind weighing” refers to the practice of weighing patients and *not sharing* weight data with patients. Treatment providers adopting blind weighing procedures typically report that they aim to minimize potential harm and distress that may accompany weight gain

or to reduce patient preoccupation with weight data (Forbush et al., 2014). Additionally, treatment providers may report preempting a rupture in therapeutic alliance if information about weight gain is provided (Kosmerly, Waller, & Robinson, 2015). Alternatively, "open weighing" refers to the practice of weighing patients and transparently *sharing* weight data with patients in real-time during treatment. Treatment providers adopting open weighing practices typically aim to provide exposure to weight data to avoid collusion with the notion that weight data are inherently *dangerous and/or intolerable*, and report that fear and anxiety relating to weight may gradually abate with exposure (Waller et al., 2007). In clinical practice, approximately 46% of eating disorder clinicians report generally adopting open weighing practices, whereas approximately 54% report typically adopting blind weighing practices (Forbush et al., 2014). In particular, clinicians appear more likely to withhold weight-related information during the early stages of treatment, exactly when patient weight gain may be more likely (Forbush et al., 2014).

Further clouding best practice guidelines around varied approaches to weighing practices, theoretical arguments may support both approaches. For instance, it is well known that weight checking practices may serve as compensatory mechanisms in the psychopathology of AN (Waller et al., 2007; Waller & Mountford, 2015), and empirical evidence, even in nonclinical populations, suggests that more frequent self-weighing is associated with greater body image dissatisfaction (Klos, Esser, & Kessler, 2012). As such, *not* sharing patient weight (i.e., blind weighing) may aim to reduce preoccupation with, and interrupt safety-seeking behaviors around, weight. Moreover, as neuroimaging research reveals more of the neurobiological basis of AN (Kaye, Fudge, & Paulus, 2009) and the specific constellation of temperament traits that cluster in those with AN, some have advocated working *with*, rather than against, these traits (Kaye et al., 2014), since these traits are not expected to change throughout treatment. For instance, with high trait anxiety reliably preceding and proceeding treatment (Kaye, Bulik, Thornton, Barbarich, & Masters, 2004; Klump, Bulik, Pollice, et al., 2000), some have contested that the avoidance of cues that promote additional anxiety during treatment (i.e., exposure to weight data) may maximize treatment compliance and adherence toward key treatment goals (Kaye et al., 2014).

At the same time, however, broader evidence relating to the treatment of pathological and irrational fear in anxiety disorders suggests that inhibitory learning is the central mechanism through which fear is inhibited throughout treatment (Craske et al., 2008; Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014). This theory posits that exposure to feared cues and contexts is essential in treatment, and moreover, that it is the discrepancy between predicted versus actual outcomes of exposure to feared cues that is the mechanism through which fear is abated. This violation of fear-based expectancies is thought to help generate new, nonfear associations to previously feared cues, which in turn, serves to inhibit fear and anxiety in future exposures to previously feared cues (Craske et al., 2008, 2014). In the context of AN, this would mean that exposure to weight data, alongside all other feared cues, is *essential*. For instance, the fear of weight gain may never be inhibited if patients do not *know* that they are gaining weight and learn that they can cope. Similarly, a fear of exponential weight gain may never be disconfirmed and inhibited if patients do not know their weight data.

In the context of AN, where (a) a specific focus on remediating the cognitive symptoms of AN is needed (Murray, Quintana, Loeb, Griffiths, & Le Grange, 2019), (b) the routine collection of weight data is a central component of the majority of treatment modalities, and (c) varied approaches exist in clinical practice relating to the sharing or nonsharing of patient weight data (Forbush et al., 2014), the systematic assessment of whether blind or open weighing practices differentially impact treatment outcome is an important endeavor. Therefore, the aim of the present investigation is to briefly manipulate weighing practices within the confines of empirically supported treatment for AN. The primary outcomes will be patient-reported distress around being weighed *and* AN symptom severity after 4 weeks of either blind or open weighing practices. In addition, we will explore whether baseline patient characteristics (i.e., sex, diagnosis, trait anxiety, intolerance of uncertainty, behavioral inhibition, fear of food, eating disorder symptom severity) will potentially moderate the impact of blind and open weighing practices, respectively. We hypothesize that those exposed to 4 weeks of open weighing practices will report less distress around being weighed at week 5, relative to those exposed to 4 weeks of blind weighing. Additionally, we hypothesize that those receiving 4 weeks of open weighing will report a reduced AN symptom severity at week 5, relative to those receiving blind weighing.

2 | METHOD

The trial protocol is openly available at https://osf.io/a4cyr/. Moreover, this RCT will be prospectively registered with Clinicaltrials.gov prior to the randomization of any patients and collection of any data.

3 | DESIGN

This multisite randomized controlled trial is designed to index the impact of blind versus open weighing practices upon (a) self-reported distress around being weighed, (b) symptom severity, and (c) treatment outcome in those with AN, across three levels of patient care at three respective treatment sites. Patients with a DSM-5 diagnosis of AN and atypical AN will be randomized to receive 4 weeks of either open or blind weighing to commence treatment, before reverting to open weighing procedures at week 5 of treatment—which is the standard clinical practice at each site, respectively. Randomization will be performed independently of the researchers via an electronic random sequence generator. Randomization will be stratified by diagnostic status (i.e., AN and atypical AN). Specifically, a randomization sequence will be prospectively generated for each site and will be linked to prospective participant identification numbers. Upon the determination of patient eligibility, consecutive patients meeting criteria will be allocated a study identification number, and their randomization will proceed according to the randomized sequence. Due to the nature of this RCT, clinicians administering treatment will not be blinded to study conditions.

Prior to randomization, all prospective participants will undergo a formal diagnostic assessment with a licensed mental health provider with eating disorders expertise (i.e., psychiatrist, clinical psychologist, or masters-level supervised clinical psychologist) to determine study eligibility. Baseline data will be collected during this diagnostic assessment,

and all patients will receive information regarding their current weight at the time of study enrollment—per standard clinical protocol at each site. Open or blind weighing practices will be implemented during treatment sessions 1–4, and all participants will revert back to open weighing practices at treatment session 5 and for the remainder of their treatment. All participants in both conditions will be explicitly instructed not to weigh themselves outside of treatment settings.

4 | TREATMENT SETTINGS

All participants will receive manualized enhanced cognitive behavior therapy (Fairburn, 2008) as their primary treatment modality, across all treatment sites. Treatment approaches will be consistent within sites. The program director at each site (SBM at the University of Southern California; NRF at Rogers Behavioral Health; CAL at the Louisville Center for Eating Disorders) will oversee clinical treatment and ensure fidelity to manualized CBT (Fairburn, 2008), and treatment supervision meetings will be implemented on a weekly basis for the duration of the study at each site, respectively. Data collection will take place at each instance of being weighed within the context of standard clinical care at each site. In all settings, and in both open and blind weighing conditions, all patients will be routinely weighed, and these data will continue to inform treatment decisions.

The transparent sharing of patient weight is an integral component of CBT for eating disorders (Fairburn, 2008; Waller et al., 2007). However, with mounting evidence illustrating the prevalence of therapists “drifting” from evidence-based treatment throughout treatment (Waller, 2009), and with evidence illustrating much variability in weighing practices in real-world clinical settings (Forbush et al., 2014), the need to systematically examine the implications of open versus blind weighing is warranted. For the purposes of the present study, therefore, minor modifications to manualized treatment will be necessary in allowing for the experimental manipulation of weighing practices. These modifications will be standardized across sites, such that the only difference in patient’s treatment experience will be blind or open weighing. In executing blind weighing procedures in manualized CBT, patients will be weighed by clinicians at the beginning of each session, while stepping backward onto the school and looking forward. Clinicians will not openly disclose patient weight, or the directionality of weight change, and will focus on therapeutically challenging any patient distress around not knowing their weight, in addition to standardized CBT skills not relating specifically to weight and psychoeducation as to normative weight fluctuation (Figure 1).

5 | PARTICIPANTS

Participants ($N = 216$) will be recruited at three sites: (a) University of Southern California Eating Disorders Program, an outpatient setting; (b) Louisville Center for Eating Disorders Program, an intensive outpatient setting; and (c) Rogers Behavioral Health, a residential treatment setting. All three sites provide treatment for adolescents and adults. All patients presenting to these respective programs will be screened for eligibility during a formal diagnostic assessment. Those meeting criteria will be given site-specific participant information and consent forms. Written informed consent will be obtained prior to study

participation, and in adolescent presentations (<18 years), assent and parental consent will be required.

Inclusion criteria will be broad to allow the most clinically representative sample. Participants must be aged between 12 and 60 years of age and have a primary DSM-5 diagnosis of AN or atypical AN (restrictive type Other Specified Feeding or Eating Disorder). The weight threshold for AN diagnoses will be less than 87% of expected body weight at the time of assessment, according to population norms and adjusted for age, sex, and height. Those with a diagnosis of atypical AN must meet all diagnostic criteria for AN but have a weight greater than 94% of expected body weight, according to population norms and adjusted for age, sex, and height. Participants must also have the ability to read and speak English fluently. Participants with psychotic symptoms will be excluded. In mitigating the risk of outcome data being impacted by within-trial transitions to more or less intensive doses of treatment, participants transitioning between levels of care (i.e., outpatient, intensive outpatient, inpatient) during the first 4 weeks of treatment will be excluded.

6 | OUTCOMES MEASURES

6.1 | Primary outcomes

6.1.1 | Subjective units of distress—Self-reported state anxiety will be measured via subjective units of distress (SUDS), which is a behavioral measure commonly used to index self-reported anxiety and distress during exposure treatment and behavioral assessments. SUDS ratings range from 0 (completely calm) to 100 (highest anxiety), and this scale has been shown to be a valid and reliable measure of state anxiety for both clinical and research outcomes (Kaplan, Smith, & Coons, 1995).

SUDS will be measured immediately before and immediately after each instance of being weighed.

6.1.2 | The ED-15—The ED-15 is a 10-item self-report measure of eating disorder symptomatology, designed to measure session-by-session fluctuation in symptom severity on a weekly basis (Tatham et al., 2015). The ED-15 comprises two subscales—the Weight & Shape Concerns subscale and the Eating Concerns subscale. This scale measures near-identical constructs to the Eating Disorder Examination–Questionnaire (Fairburn & Beglin, 2008), and demonstrates comparable sensitivity in discerning clinical from nonclinical symptomatology (Tatham et al., 2015), but crucially, allows for symptom recording over the previous 7 days, as opposed to the previous 28 days. The ED-15 demonstrates strong internal consistency and test–retest reliability (Tatham et al., 2015).

6.1.3 | Patient weight—Clinician-recorded patient bodyweight will be recorded at each session.

6.2 | Secondary outcomes

6.2.1 | Weight prediction error—In keeping with suggested guidelines around patient weighing (Waller & Mountford, 2015), immediately prior to being weighed, participants will

be asked to predict their weight, which will be recorded by clinicians on a weekly basis. Prediction error will be calculated as the discrepancy between predicted versus actual weight at each instance of being weighed.

6.2.2 | Fear of food measure—The fear of food measure (FOFM) is a three-factor, 23-item self-report measure which indexes (a) trait anxiety relating to eating, (b) food avoidance, and (c) feared concerns relating to eating (Levinson & Byrne, 2015). Items are scored on a seven-point Likert scale, with greater scores indicating greater fear of food. The FOFM has demonstrated good internal consistency in clinical populations (Cronbach's α = .74–.95) and may reliably predict food intake among those with eating disorders (Levinson & Byrne, 2015).

6.2.3 | Intolerance of uncertainty scale—Short form—The Intolerance of Uncertainty Scale—Short Form (IUS-12) is a 12-item version of the Intolerance of Uncertainty Scale (Freeston, Rheaume, Letarte, Dugas, & Ladouceur, 1994), and measures the tendency to fear or negatively interpret ambiguous situations (Carleton, Norton, & Asmundson, 2007). Items are rated on a five-point Likert scale between 1 and 5, with higher scores indicating greater intolerance of uncertainty. Strong correlations with the larger 27-item measure have been noted, alongside good internal consistency (Cronbach's α = .92; Carleton et al., 2007).

6.2.4 | Eating disorder examination-Questionnaire 6.0 (EDE-Q)—The EDE-Q is a widely used self-report measure of eating disorder symptomatology, which assesses the presence and severity of eating pathology during the past 28 days (Fairburn & Beglin, 2008). The measure provides a Global score representing the average of four subscale scores: dietary restraint, eating concern, shape concern, and weight concern. However, since no reliable or definitive factor structure has been identified, only the EDE-Q Global score will be used in the current study (Allen, Byrne, Lampard, Watson, & Fursland, 2011; Byrne et al., 2009). The EDE-Q Global score has demonstrated adequate internal consistency among clinical samples (Cronbach's α = .90; Peterson et al., 2007).

6.3 | Baseline measures

6.3.1 | Demographic questionnaire—We will develop a demographic questionnaire to record participant's age, height, weight, ethnicity, gender, diagnosis, illness duration, treatment history, psychiatric comorbidities, and medication regimes. Alongside this, clinicians will also complete basic demographic questions relating to their professional qualifications, years of clinical practice, and their expectations of how open versus blind weighing may impact treatment outcomes.

6.3.2 | State trait anxiety inventory—The State trait anxiety inventory (STAI) consists of two 20-item scales for measuring the intensity of anxiety as an affective state (state anxiety), and individual differences in anxiety proneness as a personality trait (trait anxiety), respectively (Spielberger, 1972). The STAI demonstrates adequate internal consistency (Spielberger, 1972) and has been widely used in eating disorder research.

6.3.3 | Behavioral inhibition system/behavioral activation system scale—

The Behavioral inhibition system/behavioral activation system scale (BIS/BAS) is a 20-item self-report measure of trait sensitivity levels of the behavioral inhibition system—thought to underlie anxiety and threat detection, and the behavioral activation system—thought to function as a reward-mediating response to appetitive stimuli (Carver & White, 1994). Items are scored on a four-point Likert scale, with the BIS scale consisting of seven items, and the BAS scale consisting of 13 items. This scale has demonstrated adequate internal consistency in clinical populations (Cronbach's α = .84; Meyer, Johnson, & Winters, 2001).

7 | FIDELITY CHECK

At each treatment session, in both open and blind weighing conditions, patients will complete a series of closed questionnaire items to disclose whether they have either weighed themselves since their previous treatment session, or whether they have been made aware of their weight (Table 1).

8 | DATA ANALYSIS

Sample size was calculated using the "pwr" package in R. For a power of 70%, a conservative moderate effect size of 0.6, and an α level of .05, a minimum sample of 36 was considered for each experimental condition (open vs. blind weighing). However, owing to the inherently differing levels of clinical severity and treatment dose at each level of care, we opted not to conflate groups. Thus, we will recruit 72 participants from each site, leaving a total sample size of 216 participants. This will afford adequate statistical power to examine each site independently, compare treatment responses across sites, and follow data-driven approaches as to whether data from sites can be aggregated into larger analyses.

Primary outcome analyses at week 5 will assess group differences in (a) self-reported distress immediately prior to being openly weighed, (b) self-reported distress immediately following being openly weighed, (c) patient body weight, and (d) ED-15 scores. After the intervention (at week 5), a series of two-way analysis of covariance analyses will be conducted to assess blind versus open weighing (factor 1), across treatment settings (factor 2), in SUDS immediately prior and immediately following being openly weighed, patient weight, and ED-15 scores, adjusted by baseline continuous measures (STAI, IUS-2, BIS/BAS, FOFM).

A series of exploratory analyses will be conducted to assess whether the magnitude of weight prediction error (the difference between predicted weight versus actual weight) (a) declines over time and (b) is predictive of or related to week-5's SUDS. In order to assess whether weight prediction error declines over time, within and between group comparison analyses will be conducted across time points. Also, a generalized regression model approach will assess the effect of weight prediction errors upon week-5's SUDS score. In addition, independent group comparison analyses will assess differences in weight prediction error at week 5 across open and blind weighing groups. Finally, at 3-month follow-up, a series of independent group comparison analyses will assess differences in EDE-Q, weight FOFM, and IOU across groups.

9 | CONCLUSION

AN is a chronic and often relapsing psychiatric illness, where treatment outcomes remain modest (Murray et al., 2019) and illness burden and mortality remain high (Arcelus, Mitchell, Wales, & Nielsen, 2011). The development of methods to optimize treatment outcomes is of critical importance. This RCT will provide evidence relating to the efficacy and impact of open versus blind weighing practices within evidence-based treatment for AN. In particular, this study will provide data as to whether one approach to patient weighing over another portends greater weight-related distress and AN psychopathology. The potential significance and impact of this study are noteworthy, since (a) patient weighing is an essential component of treatment for AN across all modalities, and (b) no best practice guidelines currently exist. Moreover, the identification of moderators may also inform the development of precision approaches to patient weighing.

DATA AVAILABILITY STATEMENT

All data generated from the trial will be publicly available at https://osf.io/a4cyr/. Once collected, data will be made available upon reasonable request.

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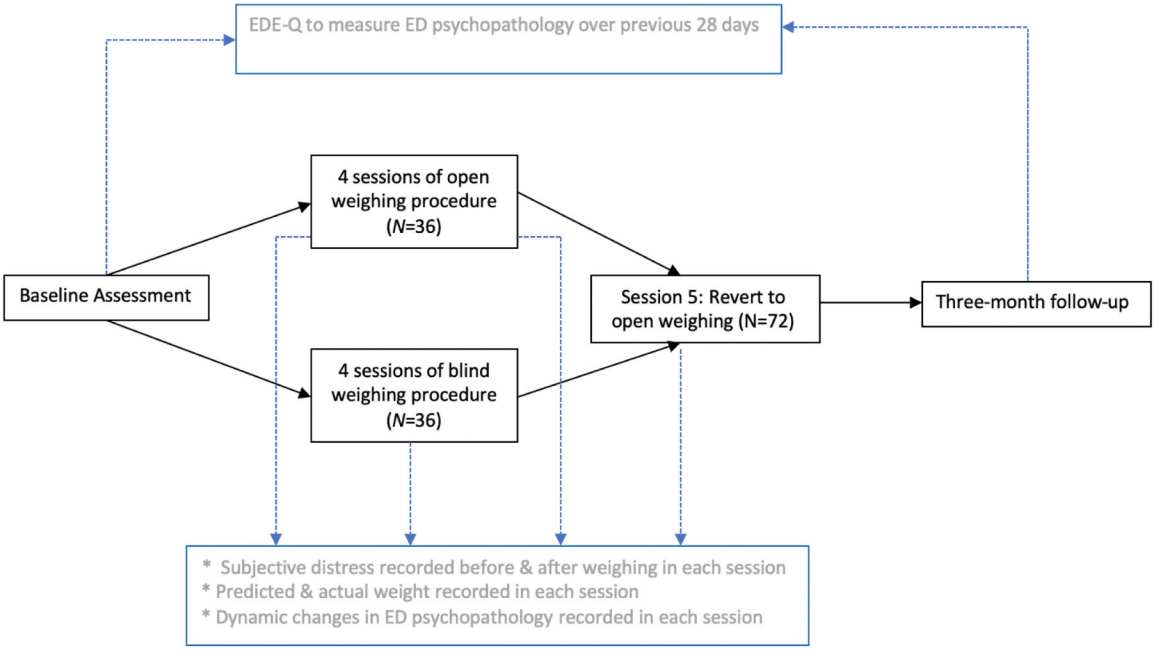

FIGURE 1.
Overview of study design to be implemented at each site

TABLE 1

Overview of study measures and data collection timepoints

Measure	Baseline	Weeks 1–4	Week 5	3-month follow-up
ED-15	X	X	X	X
EDE-Q	X		X	X
STAI	X			
IUS-12	X		X	X
BIS/BAS Scale	X			
FOFM	X			X
SUDS		X	X	X
Weight Prediction		X	X	X
Body Weight	X	X	X	X