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REGISTERED REPORT STAGE 1



A feasibility study of the delivery of online brief cognitive-behavioral therapy (CBT-T) for eating disorder pathology in the workplace

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Abstract

Objective: CBT-T is a brief (10 sessions) version of cognitive behavioral therapy for non-underweight eating disorders. This report describes the protocol for a single center, single group, feasibility trial of online CBT-T in the workplace as an alternative to the health-service setting. By offering mental health services for eating disorders in the workplace, greater accessibility and increased help-seeking behaviors could be achieved.

Method: Treatment will be delivered online over 10 weeks and offered to employees based on self-referral rather than meeting diagnostic criteria, making treatment available to employees with sub-threshold eating disorder symptoms.

Results: Assessments will be conducted at baseline, mid-treatment (week 4), post-treatment (week 10) and at follow-up (1 month and 3 months posttreatment). For the primary outcome, measures will include recruitment, attrition and attendance data using pre-set benchmarks to determine high, medium or low feasibility and acceptability. Qualitative participant experiences data will be analyzed using thematic analysis. Impact on work engagement and effect sizes will be determined from secondary outcome measures; the latter enabling sample size calculations for future study.

Discussion: These pilot data will provide insights to recruitment, acceptability, effectiveness and viability of a future fully powered clinical trial of online CBT-T in the workplace.

Public Significance Statement: This study will present feasibility data from an eating disorders intervention (online CBT-T) using the workplace as an alternative to the healthcare setting to recruit and treat workers. Recruitment will be based on self-reported eating and weight concerns rather than diagnosis potentially enabling

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treatment to employees who have not previously sought help. The data will also provide insights to recruitment, acceptability, effectiveness, and future viability of CBT-T in the workplace.

KEYWORDS

binge-eating disorder, bulimia nervosa, cognitive behavioral therapy, eating disorder, mental disorders, workplace

1 | INTRODUCTION

Eating disorders have an estimated prevalence of 0.7%, with an estimated 55.5 million cases in 2019 globally (Santomauro et al., 2021). There are substantial economic costs; furthermore, the costs for reduction in wellbeing is over five times total economic costs (Streatfeild et al., 2021), highlighting the extensive benefits to society of treating eating disorders.

Outpatient cognitive behavioral therapy (CBT) for eating disorders (CBT-ED) has a strong evidence base for nonunderweight patients with conditions such as binge-eating disorder (BED) and bulimia nervosa (BN: National Institute of Health and Care Excellence, 2017). However, this intervention is expensive, at up to 20 sessions of specialist care time. CBT-T, a shorter 10-week version of CBT-E, was introduced for nonunderweight patients aiming to overcome the issues of costs, clinician time commitments, and waiting lists (Waller, Turner, Tatham, Mountford, & Wade, 2019), CBT-T's effectiveness and remission rates are comparable with longer versions of CBT-ED within health clinic settings (e.g., Fairburn, 2008), as shown by cohort studies and nonrandomized comparison studies (e.g., Pellizzer, Waller, & Wade, 2019; Tatham, Hewitt, & Waller, 2020; Waller et al., 2019), meaning that it has the potential to address the capacity issues that many services experience in managing caseloads.

There is a growing body of research supporting the effectiveness of CBT-based interventions for mental health disorders offered in the workplace setting (Tan et al., 2014). As help-seeking rates for workers with mental health conditions ranges between 13% and 46% (Dewa, Thompson, & Jacobs, 2011; Lim, Sanderson, & Andrews, 2000), the availability of mental health services in the workplace could provide the opportunity to enhance access for a broader set of workers. Furthermore, there may be economic benefits by helping to boost work productivity (Dewa et al., 2011) and attendance, improving perceived health support from employers (Chen et al., 2015) and overall mental health (Dewa et al., 2011).

Help-seeking behaviors are characteristically low for most mental health disorders. This is likely to be exacerbated by the ego-syntonic nature of some eating disorders, where help-seeking rates range from 13% to 35.6% (Ali et al., 2020). Strikingly, working-age young adults are less likely to seek treatment, and present to eating disorder services later than adolescents (Ali et al., 2020). Eating disorder help-seeking disparities have also

been found related to gender and socioeconomic background. (Sonneville & Lipson, 2018). Making treatment for eating disorders more accessible via the workplace and less intrusive in terms of time commitments (e.g., the 10 sessions of CBT-T) could therefore help to address overall and differential patterns of help-seeking behaviors.

Slow help-seeking can result in eating disorders lasting much longer than necessary (Austin et al., 2021), and eating disorder treatments that are provided earlier can both reduce waiting times and alleviate this risk (Brown et al., 2018). If work-based access to treatment of eating disorders is viable and effective, it could have similar benefit. Availability of treatment in the workplace could also be useful for individuals with sub-threshold eating disorder symptoms, which are associated with significant comorbidities, such as anxiety and depression (Smith et al., 2017). Furthermore, offering eating disorder services in the workplace could address the work stress that can itself contribute to the development of eating disorders, such as increases stress appraisal, which in turn predicts binge-eating behavior (Srivastava, Lampe, Michael, Manasse, & Juarascio, 2021). Similarly, in a study of work burnout among doctors, a fifth of them had apparent symptoms of BED (Medisauskaite & Kamau, 2019a). To our knowledge, only one previous study has assessed the impact of a workplace mental health intervention on eating disorder symptoms (Medisauskaite & Kamau, 2019b).

This is the first study that will explore the feasibility of offering online CBT-T treatment for eating disorders to employees at the workplace as an alternative to the healthcare setting. Determining feasibility will require assessing the commitment by employer organizations to support the mental health of their employees by facilitating recruitment of employees and by providing a confidential environment for delivery of mental health interventions during work hours.

The aim of the study is to evaluate whether the workplace is a viable setting for recruitment to and delivery of online CBT-T, which is effective in clinical settings but offers the possibility of being less disruptive of work commitments and patterns for workers. The treatment will be offered to employees who self-refer, broadening eligibility and offering treatment to employees with sub-threshold eating disorder symptoms. Feasibility will be assessed in terms of recruitment to and acceptability of online CBT-T in the workplace drawn from quantitative data during therapy and from both quantitative and qualitative

data after the study. Preliminary effectiveness will be tested using measures of eating pathology, anxiety and depression, and work engagement.

2 | METHODS

2.1 | Ethical approval and preregistration

This study was approved by the Biomedical and Scientific Research Ethics committee, University of Warwick, UK (reference 125/20-21). This feasibility trial has been registered with ISRCTN (reference number: ISRCTN45943700).

2.2 | Design

This study is a single center (University of Warwick), single group, feasibility study of online CBT-T delivery to employees in a non-healthcare setting (the workplace). We acknowledge a lack of comparison control group, randomization and blinding as limitations in the design. Nevertheless, the data will help determine whether the workplace setting could be a suitable location for recruiting to and conducting a fully powered RCT.

2.3 | Participants

Sample size power calculations need to take into consideration the absence of relevant recruitment data from the workplace setting and the expectation that a significant proportion of participants may have a subthreshold diagnosis. CBT-T results in strong and comparable effect sizes (Cohen's d > 1.0) for core eating pathology (global EDE-Q scores), in both clinical and subthreshold high-risk groups (AlShebali, Becker, Kellett, AlHadi, & Waller, 2021; Tatham et al., 2020). Sample size analysis (G*Power 3.1.9.2) shows that 19 participants is sufficient to identify reliable pre-post differences in a within-subject t test, assuming an alpha of .05, power of 95% and an effect size of d=0.8. A sample of 40 will be sought, to allow for attrition at 47%, as found by Tatham et al. (2020). Feasibility and attrition will be benchmarked around those figures.

2.4 | Procedure

The study has been advertised to employers across the Midlands region of England, as part of a large research program delivering several free of charge mental health interventions to workers in the workplace rather than healthcare setting (the Mental Health and Productivity Pilot; MHPP; mhpp.me). The Midlands region of the UK has a population of approximately 11 million, with 4.5 million jobs (Midlands Engine, 2021). A convenience sampling approach has been used whereby 24 organizations with previous involvement in other MHPP trials were sent information about the trial. Of these,

TABLE 1 Screening questions for eligibility

- 1. Are you 18 or over?
- 2. Are you currently employed?
- 3. Do you try to avoid food because you are worried that eating normally would mean that you lost control of your eating and weight?
- 4. Are you very worried or distressed about your body shape, weight and size?
- 5. Is your BMI 18.5 or over?
- 6. Do you have a diagnosis of Anorexia Nervosa?
- 7. Are you currently in your third trimester of pregnancy?

Note: For eligibility, answers to questions 1 to 5 need to be "YES" and answers to questions 6 and 7 need to be "NO."

11 employers (six large at >250 employees and five small to medium at <250 employees) have or will advertise the trial to their employees; approximately 9000 employees in total. Business sectors include education, information and communication, manufacturing, business support, public administration and defense. Employers advertise the service by a general announcement to workers via poster and/or newsletters and/or emails to all employees. Interested employees register their voluntary interest in the study by contacting the research team directly without needing to speak to their employer, to retain confidentiality. Participation and individual data collected from the study will not be shared with participants' employer. Nor will participants be under any obligation to report their involvement to their employer. Participating employers will receive a report following the trial that excludes individual data, in order to maintain confidentiality.

Recruitment of participants to the study will take place between October 12, 2021 and February 28, 2022. The study uses a two-stage consent process, with initial consent to the eligibility screening, after which eligible participants elect to enroll to the trial via informed consent. The advertising materials have a link to the study webpage on which there is an option to register interest. Potential participants are then sent a link via email to the screening consent and eligibility questionnaire (see Table 1). Participants who are not eligible for the study will be contacted and signposted to appropriate support, including information regarding UK mental health and eating disorder charities (e.g., Mind, Beat), local primary care services including family physicians, and NHS Improving Access to Psychological Therapies (IAPT) services and self-help resources. Participants who are eligible will be invited to attend a brief (20 min) online video call with a therapist to screen for suicide risk and to provide further information about online CBT-T and the trial. If no current suicidal ideation is present, the participant will be invited to participate in the full trial. During the video call participants are provided with information on the informed consent and trial processes and given the opportunity to ask questions prior to being given access via email to the electronic informed consent form. Following informed consent, individuals are invited to attend up to 10 weekly sessions of online CBT-T (with a formal review at session 4, where therapy may be discontinued if no significant changes have been made, as per the CBT-T protocol).

Sessions will be delivered by a therapist on the research team via online video call and will predominantly take place during office hours (9 a.m. to 5.30 p.m.). Some flexibility is available for early mornings/evening meetings if participants do not wish to share their participation with their employer and to request time off (though participating employers have been asked to commit to creating an allowing environment for participation). The therapy will be delivered remotely, via Microsoft Teams, by Masters-level Psychology-qualified "Psychological Wellbeing Practitioners" with experience in delivering CBTbased low intensity interventions in the healthcare settings. The therapists have been trained and will be clinically supervised in CBT-T by a member of the research team (GW) who co-developed the intervention and has extensive experience in training and delivering CBT-T. Their training includes self-guided study, clinical skills practice between therapists, role plays of skills, and addressing clinical issues via weekly supervision (with GW). Progress with each participant will be discussed during weekly supervision sessions to ensure fidelity and best practice.

Therapists will use a CBT-T Therapy Tracker (developed by Dr. Karina Allen & Dr. Vicki Mountford—see: http://cbt-t.group. shef.ac.uk/resources/) to record and store data from sessions with participants across the 10 weekly sessions and at the two follow-ups. The Tracker is used weekly by therapists as part of research or service provision, as it enables the creation of overview summaries and graphs (e.g., weight, ED-15 and EDE-Q scores; and frequency of eating related behaviors [vomit, objective binge, exercise, laxatives]) over the course of therapy for individual participants. The summaries are also used for discussion during clinical supervision.

Although we anticipate a low risk of such events, the occurrence of both serious adverse events and adverse events will be recorded within specified time periods and reported to the trial management team, PI and ethics committee as appropriate. In addition, the trial management team will record the total numbers of events per month to the Chair of an independent Trial Monitoring Committee in order to expedite a safety review if more serious adverse events are being seen than would be expected.

At 1-month follow-up, we will ask all participants to fill out a "participant experiences" questionnaire consisting of closed and openended questions which explore participant opinions on and experiences of the therapy and the workplace setting (see Data S1).

2.5 | Measures

All questionnaire measures will be administered online through the platform Qualtrics at timepoints specified in Table 2. These will be collected within the 24 h prior to the therapy session they relate to, to ensure up-to-date symptoms can be discussed in sessions.

2.5.1 | Eating disorder diagnostic scale

The eating disorder diagnostic scale (EDDS) is a 22-item diagnostic self-report measure based on DSM-IV criteria for AN, BN, and BED

(Stice et al., 2000). The measure has strong test-retest reliability, internal consistency and validity for full and subthreshold diagnoses (Krabbenborg et al., 2011). This measure is being collected at baseline to add to the validity of the study results in terms of providing diagnostic data. Diagnoses (or the lack thereof for sub-clinical participants), as outlined in Stice et al. (2000), will be assigned for the purpose of data analysis. The speed to complete this measure was a driver for its use in this feasibility study—we envision using a validated interview-based measure for eating disorder diagnosis in a future study to reduce the risk of over-diagnosis (Lee et al., 2007).

2.5.2 | ED-15

The ED-15 consists of a brief 15-item, session-by-session self-report measure to track and monitor eating cognitions and behaviors, including binges, use of laxatives and vomiting (Tatham et al., 2015). The measure is clinically meaningful, sensitive to change and includes two attitudinal subscales defined as "Weight and Shape Concerns" and "Eating Concerns" (Tatham et al., 2015).

2.5.3 | Eating disorders examination questionnaire, version 6.0

The eating disorders examination questionnaire (EDE-Q) is a self-report measure originally developed by Fairburn and Beglin (2008). The measure includes four attitudinal subscales (restraint, eating concern, shape concern, and weight concern) as well as a global score, with higher scores indicating more problematic eating attitudes and behaviors. The measure has been extensively reviewed and is shown to have good test-retest reliability (Berg, Peterson, Frazier, & Crow, 2011). A clinical cut-off score of 2.3 on the global scale will be used for analysis, as recommended by Mond, Hay, Rodgers, Owen, and Beumont (2004) for community samples.

The use of multiple eating disorder measures (EDDS, EDE-Q, and ED-15) may highlight any that are differentially effective in identifying outcomes with both clinical and subthreshold cases and help determine appropriate measures for future research.

2.5.4 | Patient health questionnaire-9

The patient health questionnaire-9 (PHQ-9) is a brief, 9-item, self-report questionnaire (Kroenke et al., 2001) designed to measure symptoms of depression, and will be useful to detect depression comorbidity. The measure is well-validated and sensitive to change (Kroenke, Spitzer, Williams, & Löwe, 2010). The suggested clinical cut-off score of ≥ 10 will be used in analysis (Kroenke et al., 2010). Question 9 (suicidality) will also be used at the screening video call to inform the risk assessment of suicidality, before full consent to the trial is sought. Individuals scoring ≥ 1 ("several days" or more) will be referred for immediate support from primary care services and will not be able to participate in the program.

 TABLE 2
 Data collection before, during, and after the intervention

	Description (and reference where relevant)	Background questionnaires (week 0)	Therapy sessions (week no.)										Follow-up	
Data			1 (baseline)	2	3	4	5	6	7	8	9	10	1 month	3 months
Demographic data	Age, gender, ethnicity, socioeconomic origin, generic information regarding employment	Х										X		
Work Productivity and Activity Impairment Questionnaire: General Health V2.0 (WPAI:GH)	Six questions on work satisfaction and engagement in relation to health condition/s (Reilly, Zbrozek, & Dukes, 1993)	X										X	X	X
Absenteeism question	Single question asking how many days sick leave taken over the past 8 weeks	Х										X	X	
Eating Disorder Diagnostic Scale (EDDS)	To be used as an objective diagnostic tool (questions are based on the past 3–6 months; Stice, Telch, & Rizvi, 2000)	X												
Height	To calculate BMI	Χ												
Weight	To calculate BMI	Χ	X ^a	Xa	Xa	X ^a	Xa	Xa	X^{a}	X^{a}	Xa	X ^a	X ^a	X ^a
Eating Attitudes questionnaire (ED-15)	To track and monitor weekly changes in eating cognitions and behaviors (including binges, use of laxatives, vomiting; Tatham et al., 2015)		X	X	X	X	X	X	X	X	X	X	X	X
Eating Disorders Examination- Questionnaire (EDE-Q)	To track and monitor more long- term changes in eating attitudes and behaviors (questions are based on the last 4 weeks; Fairburn, 2008)		X			X						X	X	X
General Anxiety Disorder questionnaire (GAD-7)	Anxiety symptom tracking (questions are based on the past 2 weeks; Spitzer, Kroenke, Williams, & Löwe, 2006)		Х			X						X	X	X
Patient Health Questionnaire- 9 (PHQ-9)	Depression symptom tracking (questions are based on the past 2 weeks; Kroenke, Spitzer, & Williams, 2001). Where question 9 only (Q9) is gathered, this is for risk screening purposes.	X (Q9) ^a	X			X						X	X	X

^aTo be gathered in session with therapist, or (for weight only) to be emailed to the therapist as soon as possible after if participant does not have access to scales (e.g., at work).

2.5.5 | Generalized anxiety disorder-7

The generalized anxiety disorder-7 (GAD-7) is a brief, 7-item self-report questionnaire (Spitzer et al., 2006), designed to measure symptoms of generalized anxiety. A systematic review by Kroenke et al. (2010) provides evidence for good validity and sensitivity to change. The suggested clinical cut-off score of ≥8 will be used in analysis (Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007).

2.5.6 | Work productivity and activity impairment questionnaire: General health V2.0 (WPAI:GH)

Given the evidence that improvements to mental health increase productivity in the workplace (e.g., Dewa et al., 2011), we will measure productivity before and after therapy using the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH; Reilly et al., 1993). This is a six-item questionnaire

TABLE 3 Phases, content, and targets of CBT-T (taken from Waller et al., 2019)

Phase number and title	Weeks	Phase content	Phase targets
Learning and changing eating	Weeks 1 to 4	(a) Nutrition,(b) Psychoeducation,(c) Exposure with response prevention	Education; change in biology; reduction in anxiety; reduction in binge/purge behavior (formal review by week 4 to decide about continuing or ending therapy)
Challenging beliefs about eating, food and weight	Weeks 3 to 6	(a) Behavioral experiments, (b) Cognitive restructuring	Cognitive change
3. Addressing emotional triggers	Weeks 5 to 7	(a) Exposure,(b) Cognitive restructuring(c) Imagery rescripting	Reduction in emotionally driven bulimic behaviors
4. Body image work	Weeks 5 to 9	(a) Surveys,(b) Behavioral experiments,(c) Exposure,(d) Imagery re-scripting	Reduction in maintaining behaviors; enhanced body image acceptance
5. Relapse prevention & implementing therapy blueprint	Weeks 5 to 10	(a) Therapy blueprint (b) Internal attribution of change	Maintain changes; plan follow-up; cement patient's attributional shifts

that focuses on: "Absenteeism" (time off sick), "Presenteeism" (being at work while should be off sick), "Work productivity loss" and "Activity Impairment." The WPAI:GH has shown strong psychometric properties with good internal consistency (alpha = 0.74) and a high intraclass correlation coefficient (r = 0.79–0.90) in clinical and nonclinical populations (Duke & Montag, 2017; Zhang et al., 2010). An additional single-item absenteeism question is added at baseline and 3-month followup, focusing on the previous 8 weeks.

Demographic data (including age, gender, ethnicity, socioeconomic status [Cabinet Office, 2018], and height), and information regarding employment will be collected as part of the questionnaires during therapy (see Table 2). Weight (kg) will be measured live in each video call session using the participant's own scales. Participants who are unable to weigh themselves in-session will be requested to send a photograph of their scale weight.

2.6 | Intervention

The CBT-T manual (Waller et al., 2019) will be the guide for therapists, who will be trained in therapy delivery prior to the study and supervised weekly. CBT-T consists of 10 weekly sessions lasting 45 to 60 min, plus two follow-up sessions at 1- and 3-months post-intervention. The weekly sessions are structured around five sequential phases. See Table 3 for a summary of the intervention phases, content, and targets.

2.7 | Data analysis

We will use SPSS (version 26 or later) for statistical analysis.

2.7.1 | Primary outcomes

For the primary outcome, measures will include recruitment, attrition and attendance data. We will use the following benchmarks to determine high, medium or low feasibility and acceptability:

- (a) Recruitment success (measured at the point of consenting to the trial)—enrolment of ≥40 participants will be considered high, 20–39 medium, and ≤19 low;
- (b) Attrition—retention of ≥50% of patients through all assessments will be considered high, 35–49% medium, and ≤ 34% low;
- (c) Study retention: ≥80% attendance at all therapy sessions will be considered high, anything below this will be considered low.

Quantitative data from response rating scales in the Participant Experiences questionnaire (Data S1) will be summarized as means and SD, along with data from standardized measures. Qualitative data from open-ended questions will be analyzed using thematic analysis (Braun & Clarke, 2006), where the identification of themes and allocation of material by one researcher will be validated by a second researcher. The N for this analysis will be determined by saturation of themes (defined as no new themes over the most recent five participants).

2.7.2 | Secondary outcomes

Secondary outcome measures will include the EDDS, ED-15, EDE-Q, PHQ-9, GAD-7, and WPAI:GH. We will use both completer analyses and intention to treat analyses, using 20 multiple imputations and repeated-measures ANOVAs (or nonparametric equivalents, depending on sample size and data distribution) to assess changes in outcome measures. Effect sizes will be calculated and presented with confidence intervals, enabling sample size calculations for future study.

CONCLUSIONS

The current study will provide critical pilot data to determine the feasibility of providing CBT-T to employees at the workplace, and the basis for a future fully powered clinical trial.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Once collected, the data that support the findings of this study will be available from the corresponding author upon reasonable request.

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