

BITE: Is a study delivering cognitive behavioural therapy to treat eating disorders in the workplace possible?

Submission date 06/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/04/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Around 700,000 people in the UK struggle with an eating disorder, with extremely long waiting lists for treatment within healthcare settings. Common symptoms can include binge eating, restrictive eating, or compensatory behaviours to get “rid” of food (e.g. vomiting or laxatives). Symptoms such as these can significantly impact peoples’ lives, causing problems with mood, energy levels, social relationships and work. Mental health problems are the leading cause of sickness absence in workers and affect one in six workers each year. The aim of this study is to see if a brief therapy for eating disorders (cognitive-behavioural therapy [CBT-T]) is helpful for employees in the workplace (i.e a non-health setting). The researchers also hope to see how employees mood and productivity might be improved following its completion.

Who can participate?

Adults employed in the Midlands with a body mass index (BMI) of 18.5 kg/m² or over who might be avoiding food due to worries about losing control of eating or weight, who might be very worried or distressed about their body shape, weight and size, without a diagnosis of anorexia nervosa, who are not in their third trimester of pregnancy

What does the study involve?

CBT-T is a brief, ten-session therapy for symptoms of eating disorders in non-underweight individuals, based on Cognitive Behavioural Therapy. It is split into several phases which include:

1. Getting into a regular, healthy eating routine and tackling anxiety
2. Changing beliefs about food
3. Learning to tackle the emotions that drive eating problems
4. Normalising body image and strengthening body acceptance
5. Making sure that you stay well

The trial will offer employees access to up to 10 1-hour weekly therapy sessions with a specially trained therapist, together with two follow-up sessions 1 and 3 months later. All therapy sessions will be delivered remotely by video call.

What are the possible benefits and risks of participating?

CBT-T is much shorter (10 sessions) than the standard CBT for eating disorders (20+ sessions) and has been shown to be equally as effective in healthcare settings. It may also help to reduce any anxiety and other emotional concerns. Whilst the researchers cannot guarantee recovery, if participants engage fully with CBT-T then they have a stronger chance of a full recovery and being able to get on with their lives.

As with all therapy, participants may experience some discomfort when talking about their experiences. They may also experience a natural increase in anxiety when trying out new behaviour patterns. Participants will be fully supported by their therapist throughout the trial and can share any concerns with them.

Where is the study run from?

WMG, University of Warwick (UK)

When is the study starting and how long is it expected to run for?

June 2021 to August 2022

Who is funding the study?

Midlands Engine (UK)

Who is the main contact?

1. Charlotte Kershaw, Charlotte.Kershaw@warwick.ac.uk

2. Dr Carla Toro, Carla.Toro@warwick.ac.uk

Study website

https://warwick.ac.uk/fac/cross_fac/mentalhealth/get-involved/workplace-mental-health/bite/

Contact information

Type(s)

Scientific

Contact name

Prof Caroline Meyer

Contact details

University of Warwick

Coventry

United Kingdom

CV4 7AL

+44 (0)24 765 74463

c.meyer@warwick.ac.uk

Type(s)

Public

Contact name

Ms Charlotte Kershaw

Contact details

University of Warwick
Coventry
United Kingdom
CV4 7AL
+44 (0)24 76572566
charlotte.kershaw@warwick.ac.uk

Type(s)
Scientific

Contact name
Prof Carla Toro

Contact details
University of Warwick
Coventry
United Kingdom
CV4 7AL
+44 (0)24 76572566
carla.toro@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BSREC 152/20-21

Study information

Scientific Title
A feasibility study of the delivery of Brief Individual Treatment for Eating Disorders (BITE) in the workplace

Acronym
BITE

Study objectives
It is hypothesised that recruitment to and acceptability of cognitive-behavioural therapy (CBT-T) in the workplace will be comparable with the health setting. The preliminary effectiveness of the intervention within this setting will be tested using measures of eating pathology, anxiety and depression, and work engagement.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/09/2021, Biomedical and Scientific Research Ethics Committee (Kirby Corner Road, Coventry, CV4 8UW, UK; +44 24 765 73123; BSREC@warwick.ac.uk), ref: BSREC 152/20-21

Study design

Single-centre single-group pilot study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Eating disorders

Interventions

All participants who consent to this trial will be offered the CBT-T intervention facilitated by a therapist via video call. CBT-T consists of 10 weekly sessions lasting 45 to 60 minutes, plus two follow-up sessions at 1 and 3 months post-intervention. The weekly sessions are structured around five sequential phases:

Phase 1 - education, nutrition and exposure with response prevention

Phase 2 - behavioural experiments and cognitive restructuring relating to food

Phase 3 - exposure and cognitive restructuring relating to emotions

Phase 4 - approaches to body image

Phase 5 - relapse prevention

Intervention Type

Behavioural

Primary outcome measure

1. Recruitment success is measured by number of participants who have consented to the full trial within 3 months of recruitment opening
2. Attrition is measured via % retention of participants through all assessments over the 10 weekly sessions and 2 follow up sessions
3. Study retention is measured through the percentage of participant attendance of all therapy sessions

Secondary outcome measures

1. Eating disorder symptoms measured using:
 - 1.1. ED-15 at sessions 1-10 and post-intervention at 1 and 3 months
 - 1.2. Eating Disorder Diagnostic Scale (EDDS) at baseline
 - 1.3. Eating Disorder Examination Questionnaire at sessions 1, 4, 10 and post-intervention at 1 and 3 months
2. Mood disorder symptoms measured using the Patient Health Questionnaire-9 and Generalised Anxiety Disorder-7 at sessions 1, 4, 10 and post-intervention at 1 and 3 months
3. Work productivity measured through the Work Productivity and Activity Impairment: General Health v2.0 at baseline, session 10 and post-intervention at 1 and 3 months

Overall study start date

01/06/2021

Completion date

12/08/2022

Eligibility

Key inclusion criteria

1. Able to give informed consent
2. English speaking
3. ≥ 18 years of age
4. In employment
5. Food avoidance due to concern about losing control of eating and weight
6. Concern or distress about body weight, shape or size

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Total final enrolment

47

Key exclusion criteria

1. Diagnosis of anorexia nervosa
2. Body mass index $< 18.5 \text{ kg/m}^2$
3. In the third trimester of pregnancy
4. Current suicidal ideation

Date of first enrolment

05/10/2021

Date of final enrolment

04/01/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

WMG, University of Warwick

International Digital Laboratory

Coventry

United Kingdom

CV4 7AL

Sponsor information

Organisation

University of Warwick

Sponsor details

Kirby Corner Road

Coventry

England

United Kingdom

CV4 8UW

+44 (0)24 765 73123

BSREC@warwick.ac.uk

Sponsor type

University/education

Website

<http://www2.warwick.ac.uk/>

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Other

Funder Name

Midlands Engine

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 08/09/2022:

Planned publication in the International Journal of Eating Disorders (IJED). Protocol already published by IJED as a Registered Report 1 (<https://pubmed.ncbi.nlm.nih.gov/35289953/>). Results from the trial will be submitted as a Registered Report 2 in October 2022.

Previous publication and dissemination plan:

Planned publication in high-impact peer-reviewed journals e.g. International Journal of Eating Disorders. Protocol already submitted to the International Journal of Eating Disorders as a Registered Report 1 and corrections made after an initial round of peer-review. Results from the trial will be submitted as a Registered Report 2 in October 2022.

Intention to publish date

31/01/2023

Individual participant data (IPD) sharing plan

Participant-level (raw) data will be available upon request. Requests for data should go to the corresponding author for the published protocol, Dr Carla Toro (carla.toro@warwick.ac.uk). Raw scores from measures listed in the protocol, and objective data collected during clinical contacts will be available following the publication of the final report for a period of 10 years. The data will be shared with anyone by email upon reasonable request (e.g. for related research purposes). Participants have consented to the use of their anonymised data for future research. Shared data will be fully anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	01/10/2021	20/12/2021	No	Yes
Protocol article		15/03/2022	08/09/2022	Yes	No
Results article		19/04/2023	20/04/2023	Yes	No