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Digital cognitive behavioural therapy intervention in the workplace: study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental well-being, engagement and productivity

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ABSTRACT

Introduction One in six workers experience some form of mental health problems at work costing the UK economy an estimated £70 billion/year. Digital interventions provide low cost and easily scalable delivery methods to implement psychological interventions in the workplace. This trial tests the feasibility of implementing a self-guided 8-week digital cognitive behavioural therapy intervention for subthreshold to clinical depression and/or anxiety versus waitlist control (ie, life as usual) in the workplace.

Methods and analysis Feasibility of implementation will be tested using a mixed-methods evaluation of the two-arm randomised waitlist-control trial. Evaluation will include examination of organisational buy-in, and the engagement of employees through the trial indicated by the completion of outcome measures. In addition, we also explore how participants use the platform, the appropriateness of the analysis both with reference to the outcome measures and linear modelling. Finally, we examine the acceptability of the intervention based on participants experiences using qualitative interviews. Assessments take place at baseline (T0), at 8 weeks post-treatment (T1), at short-term follow-up 4 weeks post-treatment (T2) and long-term follow-ups (6 and 12 months after-end of treatment). We will recruit from 1 July 2021 to 31 December 2021 for employees and self-employed workers with depression and anxiety symptoms (subclinical and clinical levels) who are not seeking or engaged in treatment at the time of the trial.

Ethics and dissemination Full approval was given by the University of Warwick Biomedical and Research Ethics Committee (BSREC 45/20–21). The current protocol version is 2.8 (August 2021). Publication of results in peer-reviewed journals will inform the scientific, clinical and business communities. We will disseminate results through webinars, conferences, newsletter as well as a lay summary of results on the study website (mhpp.me).

Trial registration number ISRCTN31161020.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ REST is a novel self-guided, light touch, accessible and low-cost intervention of digital cognitive behavioural therapy for employees in the workplace.
⇒ A detailed mixed-methods evaluation will provide multiple insights to feasibility and acceptability of the intervention.
⇒ To enhance rigour, the design of this feasibility study incorporates single-blinding and randomisation.
⇒ The study will be underpowered to examine efficacy of the intervention, but may still inform a future full-scale randomised controlled trial.

INTRODUCTION

In the UK, poor mental health costs the economy an estimated £70 billion/year, equivalent to 4.5% of the UK's Gross Domestic Product (GDP).[1] Common mental disorders (CMD) comprising of depressive and anxiety-related disorders are a major contributor to these costs. Within the workplace, one in six workers experience some form of mental health problems[2] which may or may not be as a result of their workplace environment. Furthermore, workers who experience CMDs are significantly less likely to remain in employment than their healthy counterparts.[3 4] The prevalence of mental illness in the workplace is problematic because of (a) absenteeism where the loss in workforce as a result of sickness, with an estimated 11.6% of sickness absence caused by CMD,[5] totalling almost 16 million days across the UK labour market; (b) mental health can diminish productivity in the workplace, a concept called presenteeism[6] which can have

significant impact on employee productivity across the labour market.

Psychological therapies are effective in treating depression and anxiety.[7] One common form of psychological treatment is cognitive behavioural therapy (CBT) which uses cognitive and behavioural principles to treat underlying cognitions and behaviour of psychiatric conditions. CBT has been shown to significantly reduce symptoms of anxiety,[8] and depression.[9] In the UK, CBT is available for depression and anxiety disorders via primary care 'Improving Access to Psychological Therapies' (IAPT), however, issues around eligibility, access to care and low adherence means that not all those who could benefit manage to improve.[10] Furthermore, a high proportion (reported as 70–75%) of people with diagnosable mental illness receive no treatment at all.[11 12] These could be due to several reasons; for example, due to stigma associated with seeking support through traditional National Health Service routes or services not being accessible particularly to some groups such as those who are socially disadvantaged, or those with lower education level.[13] It has been shown that many individuals prefer to manage their mental health themselves and could benefit from self-guided digital cognitive behavioural therapy (dCBT), for example.[13 14]

The WHO predicted around 10 years ago that by 2030 depression will be second to HIV/AIDS in international burden of disease with calls to focus on early intervention and prevention of the condition.[15] Effective early interventions can prevent, delay or reduce the onset or progress of a mental health condition,[16] and are more cost-effective than treatments through specialist services or primary care providers.[17] However, to be eligible for therapies through IAPT, individuals must have symptoms above the clinical cut-off (10 and above on the Patient Health Questionnaire-9 (PHQ-9) for depression, or 8 and above on the General Anxiety Disorder-7 (GAD-7) for anxiety).[18] Currently, there are no evidence-based early intervention provisions for individuals with subthreshold symptoms.

Digital interventions provide low cost, easily scalable delivery methods to provide access at the population-level, and to individuals that usual care services may not reach. This form of dCBT provides access to resources for self-learning or supervised treatment.[19] The dCBT is effective in the prevention[17 18] and treatment of the most common CMDs—depression and anxiety,[8 14 20–22] which indicates potential opportunities to tackle large-scale mental health issues through innovative and cost-effective means.

Implementation of CBT and dCBT intervention in workplace settings have been shown to improve mental health and reduce incidence of the clinical levels of CMDs.[23 24] Meta-analyses of workplace interventions for CMDs show a significant standardised mean difference of 0.12, demonstrating small significant effects.[25] A large randomised controlled trial (RCT) demonstrated that dCBT showed strong effects in treating employees with major depressive episodes,[26] furthermore dCBT interventions have also been shown to promote work engagement among subclinical and healthy workers.[27]

The majority of studies to date have focused on clinical levels of depression and less so on individuals with subclinical symptoms. It has been suggested that populations with subthreshold CMDs are greater in number than their clinical counterparts.[28] In addition, interventions for subclinical populations are deemed highly cost-effective.[17] Cases of CMDs have been further intensified over the COVID-19 pandemic with rates of generalised-anxiety disorder increasing from 1 in 10 to 1 in 4 adults in the US populations.[29 30] Interventions to reduce mental health severity in the workplace can therefore have subsequent effects in workplace absenteeism and productivity, as well as increased job satisfaction.[27] Given the relatively few studies that examine intervention on subclinical and clinical levels of CMDs in the workplace, and given that these studies have only assessed the short-term impact of interventions,[31] this trial is the first to explore a fully online intervention for a UK sample in the workplace with long-term follow-ups, which could trigger help-seeking for some who have not pursued the traditional route of getting mental health support (eg, approaching General Practitioner (GP; as first contact).

This study will examine the feasibility of a dCBT for mild-to-severe depression and anxiety for employees in the workplace. The study is one of three trials under the Mental Health Productivity Pilots (MHPP), funded by the Midlands Engine[32] with a focus to improve workforce mental health and productivity.

Study aims

The primary aim of this trial is to investigate the feasibility of a multicentre waitlist randomised controlled trial (wRCT) in the Midlands region of England that examines whether a dCBT treatment for employees reporting mild to clinical levels of depression or anxiety reduces symptom severity for employees in the workplace. The trial will partner with participating employers to recruit participants from workplace settings through employers and through social media advertisement.

Nested within this primary aim is an exploration of the feasibility of the methodological approach, focusing particularly on:

- Willingness of organisations to participate in a trial (Objective 1);
- Willingness of employees to participate in a trial (Objective 2);
- Adherence of participants to the treatment as measured through platform user data (Objective 3);
- Appropriateness of the analytical approach (Objective 4);
- Acceptability of the intervention based on participants subjective experiences (Objective 5).

The results of this feasibility trial will be used to inform a future RCT to understand whether a dCBT can help to reduce symptom severity and improve mental health and

productivity for employees in the workplace. In addition, secondary aims are to assess the barriers and enablers of the intervention programme to identify key mechanisms of actions through a process evaluation. Tertiary aims explore the impact of the intervention by examining the reduction in symptom severity for depressive and general anxiety-related symptoms as measured through the PHQ-9 and the GAD-7 psychometrics as well as work productivity.

METHODS AND ANALYSIS

Study design

We implement a multicentre, wRCT in which we explore the feasibility of delivering a CBT intervention against a waitlist-control group (WLC) with no active treatment. We target recruitment for participants with mild-to-severe depression or general anxiety symptoms who have not received a formal diagnosis or are not currently receiving professional care for a mental health condition. The dCBT will be delivered via a self-guided digital online platform over an 8-week period.

Participants will be screened for the presence of depressive and anxious symptoms. On verification that inclusion criteria are met, participants will provide informed consent, complete outcome measure assessments and complete the intervention through web-based platforms. Online assessment of the primary and secondary dependent variables will take place at week 0 baseline (pre-intervention), week 8 (post-treatment) and week 16 (follow-up). In addition, participants will be followed-up in the long-term, at 6 and 12 months post-randomisation. All participants in the WLC group will be offered the dCBT intervention at week 8 (see figure 1 for trial flowchart).

Ethical approval has been granted from the University of Warwick Biomedical and Research Ethics Committee (BSREC 45/20–21 AM01) and the trial is registered at ISRCTN (ISRCTN13596153).

Participants

The REST (Reducing Stress in the workplace) trial shares a common screening process with two additional trials and therefore a shared participant information leaflet (PIL) is used, under the umbrella of the INWORK programme. However, no access is provided between trials and all studies use mutually exclusive inclusion/exclusion criteria to ensure no overlapping participant sample populations or competition in recruitment.

We will recruit full-time and part-time employees and self-employed workers from organisations across the Midlands region of England who fulfil the inclusion/exclusion criteria (table 1). This is defined by the Midlands Engine as a population of approximately 11 million, with 4.5 million jobs.[33]

Components of the rest intervention

The REST intervention is an online self-guided programme structured into 8 weekly sessions with varying

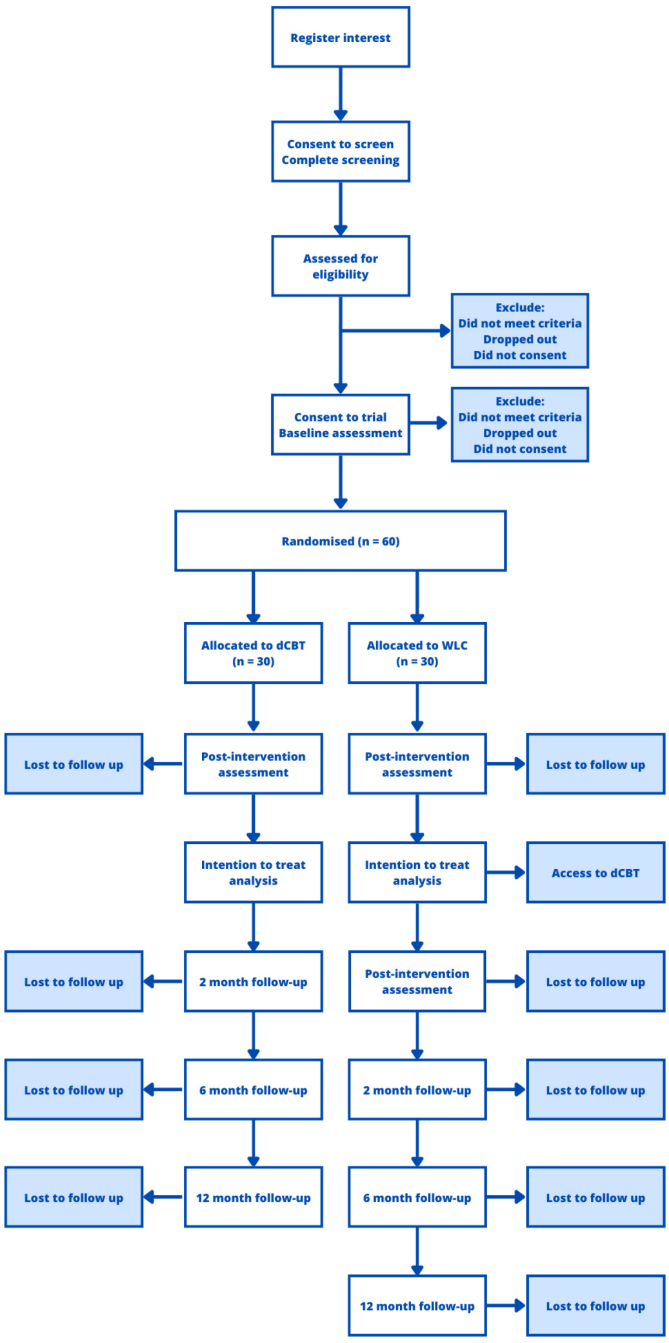

Figure 1 Flow chart diagram showing a summary of the trial design for the REST study. dCBT, digital cognitive behavioural therapy; WLC, waitlist-control group.

number of topics each week, lasting approximately 60 min each. The content incorporates techniques from CBT and emotion regulation[34] using workplace relevant examples. The goals of the intervention are to reduce symptoms of stress, depression and anxiety and provide participants with practical skills and techniques to help cope with stressful situations. The core components of the REST intervention are shown in table 2.

Waitlist control

Participants initially allocated to the WLC, will be asked to provide a baseline response to primary and secondary

Table 1 Inclusion/exclusion criteria for REST study

Inclusion criteria	Exclusion criteria
Able to give informed consent	Currently receiving treatment (psychological or pharmacological) from mental health services (eg, GP, private clinic, Improving Access to Psychological Therapies services, specialist and community mental health services)
English-speaking	Retiring in the next 10 months
In employment (including being on furlough)†	Currently taking part in other psychological intervention trials
Insomnia Severity Index score: x<8*	
General Anxiety Disorder-7 score: x>4 or Patient Health Questionnaire-9 score: x>4	
≥18 years of age	

*We use the Insomnia Severity Index to differentiate REST from other trials being conducted at the same time with the INWORK programme. This criterion of <8 is used to ensure that REST can be differentiated and that there is no population overlap with other INWORK trials.
†We do not specify on working hours, or place of work.
GP, General Practitioner.

measures but will not receive any active treatment for the first 8 weeks. After the 8-week period, waitlist-control participants will be asked to provide a post-control group measure for primary and secondary outcomes at which point they will be automatically enrolled into the intervention group for further 8 weeks. The WLC serves two purposes. First, it provides an untreated comparison for the active dCBT group to determine if the treatment had an effect. Second and for ethical reasons, it will provide an opportunity for all participants in the trial to receive the active intervention. It will allow us to assess the effect of the intervention against not receiving treatment during that same time period (since the groups are comparable), and any differences between the two groups should reflect (due to randomisation) the impacts of exposure to the dCBT.

Table 2 REST content across the intervention

Week 1	► What is stress? ► Stress cycle. ► REST diary. ► Setting SMART goals.
Week 2	► Non-judgmental awareness. ► Behavioural activation. ► Emotion focused skills.
Week 3	► Work-related stress. ► Rumination and worrying. ► Problem-solving skills.
Week 4	► Cognitions. ► Managing unhelpful thinking styles. ► Cognitive restructuring.
Week 5	► Work-life balance. ► Time management skills.
Week 6	► Physiology of stress. ► Relaxation techniques.
Week 7	► Behavioural change. ► Healthy lifestyle choices (eg, sleep, physical activity).
Week 8	► Programme summary. ► Relapse management. ► Self-compassion. ► Resilience.

Measures

Participants will be prompted by email to complete all outcome measures on a secure online survey platform (Qualtrics). The order of the assessments will be consistent across all participants and all time points. If participants do not complete measures within 5 days they will receive three further email reminders every 5 days of non-response.

Primary outcomes

To examine the feasibility of our intervention under a multicentre wRCT design, we explore five primary objectives. We examine Objective 1 by monitoring organisational traffic (defined as conversion rates and absolute counts) into the trial across four identified stages:

Stage 1: Contacted.
Stage 2: Teleconference.
Stage 3: Further engagement.
Stage 4: Verbal agreement and branch selection.

For each partnership with an organisation we document the number of centres as well as the number of employees.

We examine Objective 2 by exploring participant traffic across the trial flow (through social media and employer pathways). We define the trial flow for participants traffic as follows:

1. Expression of interest.
2. Screener completion.
3. Invitation to trial.
4. Consent to study and randomisation.
5. Post-study (which is defined as end of control and beginning of intervention for those initially placed in the WLC).

6. Follow-up measures or outcome measures from Qualtrics.

We will explore the conversion rates and absolute counts of employees from each stage of the trial flow, evaluating over recruitment pathways (please see section Recruitment procedures for more information on page 10).

We explore Objective 3 through the user data of platform access for the dCBT intervention. We will explore how much content was consumed by individuals on average, and the time to complete each block on average.

We explore Objective 4 through analysis of secondary measures listed below. We first explore the acceptability of the assessment measures themselves; this is conducted by exploring the completion rate of questionnaires, we will further explore the descriptive statistics (eg, distribution of the outcome measures, skew, kurtosis, Intraclass Correlation Coefficient (ICC), means and variances).

We will evaluate the fit of our statistical model comparing a fixed-effects regression model against a mixed-effects linear model (accounting for clusters in organisation level). Furthermore, we also evaluate the statistical cleaning procedures using a sensitivity analysis in which we compare multiple imputation methods against complete case analysis.

We also examine the feasibility of the trial implementation through semi-structured qualitative interviews as part of Objective 5, which will explore the feasibility and barriers of the intervention. We will use thematic analysis to identify the common themes mapped to a framework to provide a theoretical perspective on how to improve the intervention.

Secondary outcomes

Our secondary outcomes explore the impact of the intervention on prevalent mental health questionnaires to assess symptom severity in anxiety and depression. In addition, we also explore the impact of the intervention on job satisfaction, well-being, quality of life, work productivity and insomnia severity. The different measures are listed in the online supplemental section and will be collected at baseline (T0) post-study (T1), short-term (T2) and long-term (6 and 12 months) follow-ups. In addition, the GAD-7, PHQ-9 and the Insomnia Severity Index will be used as part of the screening questionnaire set to identify eligible participants for the study. We also ask participants to self-report use of self-help resources and if since completing the screening questionnaire whether they started receiving treatment from mental health services (psychological and pharmacological). These questions will be used as confounding variables in the analysis models. See the online supplemental file for a detailed list of the outcome measures being used, along with a summary of their psychometric properties.

Sample size

Given little a priori information, we will explore the feasibility of recruiting participants into the trial. We will recruit for 8 months from June to December 2021. We will explore the recruitment rate over time across the employer and direct social media advertisement. We will estimate the effect size obtained from the analysis of the trial detailed under Objective 4 in the Analyses section on page 11, for sample size estimation for a future full scale RCT.

We anticipate a nominal sample size of 60 participants based on Lewis *et al* recommendations for feasibility trials.[35]

Recruitment procedures

The REST study will recruit through multiple channels. The first pathway denotes employers registering interest as partners via the MHPP website (mhpp.me), who will act as gatekeepers to their employees. They will not recruit participants themselves but only signpost the information, employers will advertise the intervention within their organisations through newsletters and emails.

The second pathway is through direct recruitment by the research team via online social media (eg, Twitter, LinkedIn and Facebook) and print (eg, leaflets and flyers in public and retail settings) advertisements. Individuals who express interest through this pathway will be from the wider working community in the Midlands.

Initial interest will be taken through a survey form hosted by the Qualtrics servers. This will only take brief employment information (organisation name, location and email address) in order to determine whether this individual is listed under a partner or through direct recruitment strategies.

The research team will then contact interested employees by sending them the INWORK PIL. This trial uses a two-stage consent process, where after initial interest, participants will be asked to take part in an eligibility screening questionnaire set, after which those eligible will be invited to take part in the trial. The screening questionnaire set consists of the GAD-7, PHQ-9 and the Insomnia Severity Index (ISI). We will also ask participants to confirm they are older than 18, whether they have a diagnosis of a mental health condition or are under the management of a mental health service.

If the scores on any of the three scales yield above the clinical threshold (this is denoted with a score of at-l5 on the GAD-7[36] or the PHQ-9[37] or 15 of above on the ISI,[38] we will recommend these individuals to contact their GP and signpost to contact IAPT services. Symptom severity will not exclude them from taking part in the study. Participants will need to acknowledge reading the advice to continue with the screening questionnaire set. Individuals who pass the eligibility criteria as listed in table 1 above will be invited into the REST trial.

Patient and public involvement

We have formed a group of four individuals with lived experience of mental health problems who are currently in employment, and they will contribute during the trial by reviewing participant information sheets, consent

form, intervention materials and questionnaire measures. They will advise on recruitment procedures and methods to engage prospective participants/retain enrolled participants.

Randomisation

Participants are assigned to the dCBT or WLC arms through a simple randomisation with blocking using a 1:1 allocation ratio. We use random length blocks between two and eight, to minimise the risk of uneven groups. The randomisation is conducted using the 'blockrand' package.[39] We stratify the randomisation process across centres based on employee size within the partnered employer pathway.

Due to unknown organisation size considerations, individuals through direct recruitment will not be stratified over centres. Randomisation will be conducted by a researcher independent of allocating participants and will be blinded to the subsequent allocations. Members of the research team will be unable to influence randomisation and will be concealed from future assignments.

Allocation concealment mechanism

The trial statistician (KP) will provide a prescriptive randomisation allocation sequence file stored in a *.csv file. The file is provided to the trial coordination team, who enrols participants into the trial, doing so automatically allocates a condition to each participant. The allocation list is locked to prevent any tampering.

Implementation

The trial statistician (KP) generates the random allocation sequence, and the code to match each participant to their respective allocation sequence (through row wise matching of row numbers). The allocation is conducted as part of the trial coordination team enrolling participants into the trial Masterfile as part of parsing in logistical data. Participants are assigned to their respective allocation through an email sent by the trial coordination team.

Blinding

As this is a single-blind wRCT, participants after consent will be informed of the two allocation groups, will not be blinded to their randomisation outcome and will be explicitly informed of their allocation once randomised. The trial coordination team who handles the administrative and logistical requirements of the trial will be unblinded to the allocation of participants, however the researchers will be blinded to the trial allocation. Statistical analyses will be conducted by members of the research team who will only have access to all non-identifiable data.

Any instances of unblinding would be documented and retained in trial documentation. It is likely that the majority of instances of unblinding would usually involve a participant withdrawing for treatment or undergoing treatment cessation due to unforeseen circumstances and would therefore require no further action from the researcher. However, in cases of mistakes where participants have contacted the researcher, then any further contact with that participant will be handled by a separate researcher.

Data analyses

We will record and report all participant flow through the trial in accordance with the Consolidated Standards of Reporting Trials guidelines. We will report descriptive statistics for recruitment, dropout and completeness of interventions, in addition we will report a sample breakdown.

We assess the feasibility of the REST trial in accordance with the five research objectives:

- Willingness of organisations to participate in a trial (Objective 1);
- Willingness of employees to participate in a trial (Objective 2);
- Adherence of participants to the treatment as measured through platform user data (Objective 3);
- Appropriateness of the analytical approach (Objective 4);
- Acceptability of the intervention based on participants subjective experiences (Objective 5).

Objective 1 explores organisational traffic in partnering with third-party organisations to recruit employees in workplace settings. To analyse organisational traffic into the study we use descriptive statistics calculating frequency counts and percentage. Table 3 below demonstrates the template in which we will document and present the information across (Stage 1: Engagement; Stage 2: Teleconference; Stage 3: Further engagement; Stage 4: Verbal agreement and centre selection).

Objective 2 investigates the feasibility of recruiting and maintaining participants in the REST trial. We explore

Table 3 Organisational traffic into the REST study

Employer ID	Number of employees	Number of potential centres	Stage 1	Stage 2	Stage 3	Stage 4
1	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no
2	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no
…	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no
n	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no	Yes or no
Total	N	N	N	N	N	N
Attrition	%	%	%	%	%	%

Table 4 Organisational traffic into the REST study

Recruitment pathway	Employer ID	Express interest	Screener	Invite to trial	Consent, randomise and baseline measure completion (T0)	Post-study outcome measure completion at 8 weeks (T1)	Follow-up measure completion at 16 weeks post randomisation (T2)
Employer pathway	1						
	2						
	…						
	n						
	Total	N	N	N	N	N	N
	Attrition	%	%	%	%	%	%
Direct social media advertisement pathway	1						
	2						
	…						
	n						
	Total	N	N	N	N	N	N
	Attrition	%	%	%	%	%	%

Objective 2 by examining participant traffic across the trial flow (see figure 1), through social media and employer recruitment pathways. To analyse organisational traffic into the study, we use descriptive statistics calculating frequency counts and percentage across the trial stages (see table 4).

We will also conduct a χ^2 test to compare overall attrition rates across the two recruitment pathways to determine if there is any practical utility in one form of recruitment over another.

Objective 3 investigates the adherence of participants to the treatment as measured through platform user data. Here we explore the user data from the platform through exploring the average amount of content consumed by individuals on average for the dCBT intervention. We will also explore the time taken to consume each block on average. The user data provided will include at the aggregate level information on which links were accessed and frequency count data of link usage. We will obtain aggregate data at the individual level such as the amount of content (at the weekly level) consumed by each participant, but not how long was spent on each page.

Objective 4 explores the appropriateness of the analysis, which consists of exploratory analyses of the secondary measures (which will be used to measure the trial in future case), as well as understanding the most appropriate model to fit to the data. To examine the appropriateness of the assessment measures themselves, we will explore the distribution of the different outcome measures by assessing the skew, kurtosis, means and variances, and we will also report the intracluster correlation coefficient.

To explore the most appropriate model, we will compare three linear regression models; a simplified fixed-effect model, a full fixed-effects model (which includes covariates beyond the control vectors (please see online supplemental file for list of such measures)) and a mixed-effects regression (includes a random effect to account for clusters in organisation level) and finally a complete case analysis using mixed-effects model (to conduct a sensitivity analysis of multiple imputation).

We will try to fit a model as complex as it fits the following decision rule: 20 participants per variable. We adopt a decision rule to ensure that the models can converge and that the results are interpretable. We will only fit models that conform to the above decision rule using the GAD-7 and PHQ-9 as dependent variables. We account for family-wise error using a Bonferroni correction and divide our alpha-level across our two dependent variables.

We aim to fit three models, each growing in further complexity. The first model uses a simple mixed-effects specification which includes a dummy variable for treatment effects with an additional factor for cohort, and an interaction term for both treatment and cohort, we also include a random effect for each participant.

The second model includes the terms specified in the above nested model, in addition, we also include a vector of control variables to account for demographic factors, as well as employer, in addition to potential covariates from the secondary measures (Indiana Job Satisfaction Scale (IJSS); Work Productivity and Activity Impairment; General Health questionnaire (WPAI:GH) and the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS)) and potential additional treatment. In this model, we also include as a covariate, the baseline values of the ISI, GAD-7 and PHQ-9 in this full fixed-effects model.

If the sample size is appropriate, we also implement a third more complex model which is the same as the previous model, but we include an additional random-effects term of employer in the mixed-effects model to account for clustering effects.

We will use an intention-to-treat analysis to ensure robustness of the results. We will compare the simplified, full and mixed-model fits to identify the most appropriate analysis for an RCT.

Missing data will be reported (alongside reasons for missingness where available), and the missing data pattern will be explored. To explore the impact of missing data, we will run a sensitivity analysis comparing the complete case analysis against multiple imputation to see any observed differences in effects.

Objective 5 will be examined through semi-structured qualitative interviews to explore the feasibility of the intervention, facilitators and barriers that impact engagement with the intervention and subsequent behavioural changes. In these interviews, we aim to understand the mechanisms of behaviour change, as facilitated by the intervention, and explore implementation processes to identify the contextual factors that act as barriers and facilitators to engagement. To do this, we ask about user perceptions and experiences of the intervention. We will explore the perceived benefits from the participants perspective, as well as any negative effects and fidelity constraints. We will randomly select 25 participants who have completed the intervention (from both treatment and control arms) and have consented to be contacted about follow-up interviews. These individuals will be invited to take part in an online video conferencing interview over Microsoft Teams with researchers from the University of Warwick who are independent from the treatment delivery team of the individual. Interviews will be audio recorded using OBS studio and then subsequently transcribed by a third-party university approved vendor. Qualitative interviews will be conducted using a semi-structured interview schedule, consisting of open-ended questions and suggested prompts. Interview recordings will be analysed using thematic and framework analysis to identify the barriers and facilitators to change (ie, what helped or prevented participants from implementing aspects of the programme). We map the qualitative codes to the Capability Opportunity and Motivation Model of Behaviour (COM-B),[40] using a framework consisting of the three core behavioural determinants within this model: capability, opportunity and motivation. Capability refers to physical and psychological capability (such as disability and memory or knowledge respectfully). Opportunity refers to the physical and social connections and affords the behaviours (such as geography and word of mouth referrals). Motivation denotes the activation of approach and avoidance drives.[41] Themes will be generated using the COM-B framework as a guide, where barriers and facilitators relating to each behavioural determinant will be identified, and a thematic map will present a conceptualisation of which barriers and facilitators were particularly important in impacting change. Any other insights relevant to intervention feasibility, that cannot be mapped to the COM-B framework, will also be considered when generating themes.

Assessment of safety

We anticipate a low risk of serious adverse events (SAEs) (such as death or hospitalisation) occurring during this trial, given the low base rate of negative events in the literature for dCBT interventions.[42] We will record occurrences of SAEs in this trial as resulting; in death, hospitalisation, life threatening, in persistent or significant disability or incapacity, of a congenital abnormality or birth defect or is otherwise considered medically significant by the investigator. Adverse events (AEs) are also a low risk during this trial, however expected AEs are concentration difficulties and low mood.

To report an AE or SAE, forms will be sent to the trial management team (CB and CK), who will log them in a central database for trial monitoring. All forms will be logged in a central database and reviewed by the trial management team on a monthly basis, with a cumulative review of all safety information by an independent Trial Monitoring Committee (TMC). In addition, the trial management team will monitor and send the total numbers of SAEs per month to the TMC Chair—in order to expedite a safety review if more SAEs are being seen than would be expected.

Given the online nature of the intervention and little contact with participants, it is unlikely that the research team will be aware of SAE or AE unless reported by participants through contact channels such as emails.

ETHICS AND DISSEMINATION

In accordance with Good Clinical Practice, all participants are provided with an information sheet and are required to provide informed consent for the screener and the trial, in order to participate. This included consent for their anonymised data to be published. Ethical approval for the study was granted by the University of Warwick's Biomedical Science and Research Ethics Committee (BSREC 45/20–21 AM01) and the trial is registered at ISRCTN. Protocol modifications will be submitted for approval to the BSREC committees prior to implementation, with the protocol amendments being disseminated across the research team and updated to the trial registry.

We will publish the results of this study in peer-reviewed journals. Findings will also be presented at both national and international scientific meetings. The anonymised data will be made accessible online wherever possible, if permitted by journal policies.

Trial status

Recruitment commenced on 18 June 2021 and was completed on 31 December 2021.

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