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A digital Cognitive Behavioural Therapy and Emotion Regulation intervention in the workplace: Study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental wellbeing and help them stay engaged and productive in work

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Abstract (283 words)

Introduction: This trial tests the feasibility of implementing a digital cognitive behavioural therapy for Common Mental Disorders in the workplace. The study protocol follows on the CONSORT (Consolidated Standards of Reporting Trials) recommendations.

Methods and analysis: Feasibility of the implementation for a mixed methods evaluation with a two-arm randomised waitlist control design of an eight-week digital cognitive behavioural therapy (dCBT) intervention through self-guided online platform versus waitlist control (i.e. life as usual). This study examines the ease of third-party buy in from organisations from approach to agreement, 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 through a framework analysis. Assessments take place at baseline (T0), at 8 weeks post-treatment (T1), and at follow-up 16-weeks post-randomisation (T2). We will recruit from the 1st July to 31st December 2021 for employees and self-employed workers with depression and anxiety symptoms (sub-clinical 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 (Aug-2021). Publication of results in peer- reviewed journals will inform the scientific, clinical and business communities. We will disseminate results to through webinars, conferences, newsletter as well as a lay summary of results on the study website (mhpp.me).

Trial registration: ISRCTN, ID: ISRCTN31161020. Registered on 08/06/2021.

Keywords: Common Mental Disorders, Feasibility, Workplace, iCBT, Online, Emotion Regulation, Mental Health, Productivity

Article Summary

Strengths and limitations of this study

- Novel hybrid digital cognitive behavioural therapy for anxiety and depression to test feasibility in workers recruited from small, medium and large businesses in the Midlands region of the UK
- Evaluation of this feasibility trial will be used to inform future large-scale research for early intervention of worker with mild to severe symptoms of insomnia and emotion regulation difficulties will contribute to the understanding of benefits of early interventions in the workplace, its impact on mental health and productivity.
- Mixed-methods research to identify insights of the intervention and study design to improve for future use.
- This study will provide unique insights to generate designs for potential larger nationwide service delivery programme of mental health interventions in the workplace.

Introduction

In the United Kingdom (UK), poor mental health costs the economy an estimated £70 billion/year, equivalent to 4.5% of the UK's 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]. 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 therapy (e.g. cognitive behavioural therapy) has been shown to be 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]. Unfortunately, empirical research has shown that many individuals do not make us of services for access to psychological or psychopharmacological treatment, for example only 42.6% of individuals diagnosed with a mental health disorder in the last 12-months make use of services provided [10].

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 digital-based dCBT (dCBT) provides access to resources for self-learning or supervised treatment [11]. dCBT is effective in the prevention [11,12] and treatment of the most common CMD – depression and anxiety [8,13–15] 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 [16,17]. Meta-analyses of workplace interventions for CMDs show a significant standardized mean difference of 0.12, demonstrating small significant effects [18]. A large randomised controlled trial demonstrated that dCBT showed strong effects in treating employees with major depressive episodes [19], furthermore iCBT interventions have also been shown to promote work engagement amongst sub-clinical and healthy workers [20].

The majority of studies to date have focused on clinical levels of depression and less so on individuals with sub-clinical symptoms. It has been suggested that sub-threshold populations of CMDs are greater than their clinical counterparts [21]; furthermore, interventions for subclinical populations are deemed highly cost-effective [22]. Cases of CMDs have been further intensified over the COVID-19 pandemic with rates of generalised-anxiety disorder increasing from one in ten to one in four adults in the US populations [23,24]. 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 [20]. Given the relatively few studies that examine intervention on subclinical and clinical levels of CMDs in the workplace, this trial is the first to explore a fully online intervention for a UK sample in the workplace.

This study - Reducing stress in the workplace using a digital intervention designed to improve employee wellbeing and help them stay engaged and productive in work (REST), will examine the feasibility of an dCBT for mild to severe depression and anxiety for employees in the workplace. The REST study is one of three trials under the Mental Health Productivity Pilots (MHPP), funded by the Midlands Engine [25] with a focus to improve workforce mental health and productivity.

Research aims

The primary aim of this trial is to investigate the feasibility of a multi-centre waitlist RCT in the Midlands region of England that examines whether an 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 upon:

- 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 an 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 Patient Health Questionnaire-9 (PHQ-9) and the General Anxiety Disorder-7 (GAD-7) psychometrics as well as work productivity.

Methods

Trial Design

We implement a multi-centre, waitlist randomised controlled trial (wRCT) in which we explore the feasibility of delivering an 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 in receipt of professional care for a mental health condition. The iCBT will be delivered via a self-guided digital online platform over an eight-week period.

Participants will be screened for the presence of depressive and anxious symptoms. Upon 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).

All participants in the WLC group will be offered the dCBT intervention at week 8 (see Fig. 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 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 program. 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 workers self-employed and 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 (Midlands Engine, 2021).

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 (e.g. GP, private clinic, Improving Access to Psychological Therapies (IAPT) 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: $x > 5$ or Patient Health Questionnaire-9 score: $x > 5$	In shift work*
$\geq$ 18 years of age	

*We do not specify on working hours, or place of work

Components of the REST intervention

The REST intervention is an online self-guided programme structured into eight-weekly sessions with varying number of topics each week, lasting approximately 60 minutes each. The content incorporates techniques from Cognitive Behavioural Therapy (CBT) and Emotion Regulation [26] 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 can be shown below on Table 2.

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 (e.g. sleep, physical activity)**
Week 8	• **Programme summary** • **Relapse management** • **Self-compassion** • **Resilience**

Waitlist control

Participants initially allocated to the waitlist control group, will be asked to provide a baseline response to primary and secondary measures but will not receive any active treatment for the first eight weeks. After the eight-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 a further eight weeks.

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 five days of non-response. Every effort will be made to obtain outcome data from participants, even those who discontinue the intervention.

Primary outcomes

To examine the feasibility of our intervention under a multi-centre waitlist randomised controlled trial 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 waitlist control group)
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 both recruitment pathways.

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 firstly explore the appropriateness of the assessment measures themselves; this is conducted by exploring the completion rate of questionnaires, we will further explore the descriptive statistics (e.g. distribution of the outcome measures, skew, kurtosis, 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 Supplementary section and will be collected at baseline (T0) post-study (T1), and follow up (T2). 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. See the supplementary 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 eight months from June to December 2021. We will explore the recruitment rate over time across the employer and direct social media advertisement.

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 (e.g., Twitter, LinkedIn and Facebook) and print (e.g., 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 but not employed by one of the partner organisations.

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 ISI. We will also ask participants to confirm they are older than 18, whether they have a diagnosis of a mental health condition, are under the management of a mental health service.

If the scores on any of the three scales yield above the clinical threshold, we will recommend these individuals to contact their GP and signpost to contact Improving Access to Psychological Therapies 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

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 block between two and eight, to minimise the risk of uneven groups. The randomisation is conducted using '*blockrand*' package [27]. 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 waitlist RCT, 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 handle 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.

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

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).

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	%	%	%	%	%	%

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

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	%	%	%	%	%	%

We will also conduct a chi-squared 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.

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, we will also report the intra-cluster 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 Supplementary 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 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 a randomised-controlled trial.

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 videoconferencing 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 (i.e., what helped or prevented participants from implementing aspects of the programme). We map the qualitative codes to the COM-B model [28], 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 [29]. Themes will be generated using the to 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.

[Figure 1 here]

Assessment of safety

We anticipate a low risk of serious adverse events (such as death or hospitalisation.) occurring during this trial, given the low base rate of negative events in the literature for dCBT interventions [30]. We will record occurrences of serious adverse events (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 investigator. Adverse events are also a low risk during this trial, however expected adverse events: concentration difficulties and low mood.

To report an AE or SAE, forms will be sent to the trial management team (CB, 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.

Dissemination

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.

Discussion

In this intervention we test the feasibility of implementing a waitlist randomised-controlled trial of dCBT intervention in sub-threshold non-clinical and clinical populations in the workforce. The results from this feasibility trial will be used to inform a fully-powered waitlist randomised controlled trial, which will test the efficacy of an dCBT intervention on depression and anxiety in a workplace setting, the unique contribution will also be to show that such effects are associated with improvement in work related outcomes such as productivity.

Trial status
Recruitment commenced on 18 June 2021 and will be stopped on 31st December 2021.

Authors' contributions
CM is principal investigator. CM, NT, LW, CT, KP, and TM were involved in the design of the study. CT and KP led the treatment development. KP drafted the manuscript and all authors revised and approved the final manuscript.

Competing interests
Ethics approval and consent to participate
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 (ISRCTN31161020). 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.

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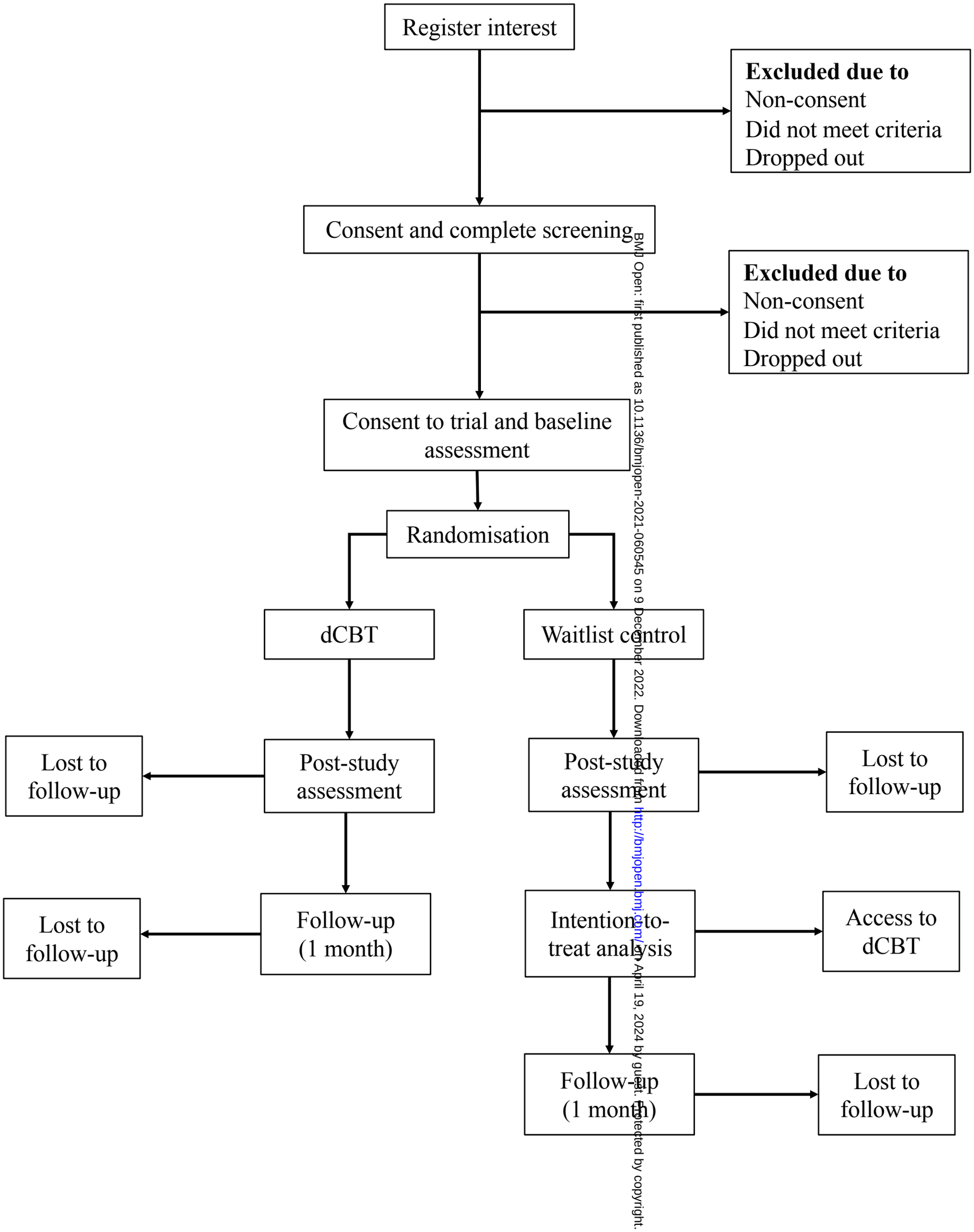

Supplementary Material

Secondary Measures

The following psychometric will be used to explore their utility as outcome measures for a future fully powered randomised-controlled trial.

The General Anxiety Disorder-7 (GAD-7) is commonly used in primary and secondary mental health settings to measure symptom severity for General Anxiety Disorder (Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is comprised on seven items each scored on a four-point Likert scale, a score of 10 has been shown to correctly diagnose cases of generalised anxiety disorder with 89% sensitivity and 82% specificity, with high test-retest reliability (ICC = 0.83). The GAD-7 also shows high concurrent validity with high scores being associated with disability and functional impairment (Ruiz et al., 2011; Spitzer et al., 2006).

The Patient Health Questionnaire-9 (PHQ-9) is commonly used, in primary care settings to assess the severity of depression across the nine DSM-IV criteria for major depressive disorder on a four-point Likert scale (Cameron, Crawford, Lawton, & Reid, 2008). The PHQ-9 has been shown to demonstrate high diagnostic accuracy in at risk populations (Haddad et al., 2013; Janneke et al., 2012), and in clinical populations. A criterion score of ≥10 has a 88% sensitivity and specificity for major depressive disorder (Kroenke, Spitzer, & Williams, 2001). Empirical research demonstrates high internal consistency (α = 0.91; Hansson, Chotai, Nordstöm, & Bodlund, 2009) and a valid latent structure even when administered in nonclinical samples (CFI = 0.914- 0.983; Ito, Takebayashi, Muramatsu, & Horikoshi, 2018).

The Insomnia Severity Index (ISI) is a seven-item psychometric which has been validated with reference to the diagnostic criteria for primary insomnia in the DSM-IV. The ISI uses a five point Likert scale response to each item (score range 0–28). A score of ≥15 identifies cases of clinical insomnia with 94% sensitivity and specificity (Bastien, Vallières, & Morin, 2001). A reduction of 8.4 has been shown to be associated with moderate improvement in clinical populations (Morin, Belleville, Bélanger, & Ivers, 2011), with responses being validated in non-clinical samples as demonstrating a high internal reliability (α = 0.81 - 0.91 (Morin et al., 2011; Yu, 2010).

Job productivity - measured through the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH; (Reilly, Zbrozek, & Dukes, 1993). The WPAI:GH is a six item psychometric which focuses on: 'Absenteeism', 'Presenteeism', 'Work productivity loss' and 'Activity Impairment'. The WPAI:GH has shown strong psychometric properties with good internal consistency (a = 0.74), with a high intraclass correlation coefficient (r = 0.79 – 0.90) in clinical populations (Zhang et al., 2010). The WPAI has been used in non-clinical samples and has shown good face validity (Duke & Montag, 2017).

Job satisfaction - measured using the Indiana Job Satisfaction Scale (IJSS; Resnick & Bond, 2001). The IJSS is a 32-item psychometric coded on a four-point Likert response of "Strongly disagree" to "Strongly agree", and is comprised of six subscales: 'General Satisfaction', 'Pay', 'Advancement and Security', 'Supervision', 'Coworkers' and 'How I feel about this job'. The IJSS yields strong psychometric properties with high internal consistence (a = 0.90) and test-retest reliability (*r* = .75) (Resnick & Bond, 2001).

Well-being – we measure subjective well-being using the Warwick-Edinburgh Mental Health Well-being Scale (WEMWBS, Tennant et al., 2007). The WEMWBS consists of 14-items on a five-point likert scale ranging from "None of the time" to "All of the time". The scale has been shown to hold good psychometric properties, with strong internal consistency (α = 0.91) and was shown to hold high concurrent validity (Tennant et al., 2007). When applied to nonclinical samples the WEMWBS still shows similar psychometric properties with high internal consistency (α = 0.94; test-retest = 0.83; Dong et al., 2016).

Quality of life- measured using the EuroQOL EQ-5D-5L questionnaire (Herdman et al., 2011). The EQ-5D-5L consists of six items, five items measured through five-point likert-scale responses to mobility, self-care, usual activities, pain/discomfort and anxiety/depression, with a sixth item of a rating of health on a visual analogue scale ranging from 0-100. The EQ-5D-5L has shown high internal consistency in clinical samples (α = 0.86; (Bilbao et al., 2018) and in nonclinical populations (α = 0.84; Kim & Ko, 2018).

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3
	2b	Specific objectives or research questions for pilot trial	3
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
	4c	How participants were identified and consented	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6,7
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A

Sample size	7a	Rationale for numbers in the pilot trial	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8,9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9, 10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	N/A
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	N/A
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	N/A
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A

	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	13
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	13
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	13
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	14
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14
	26	Ethical approval or approval by research review committee, confirmed with reference number	14

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

A digital Cognitive Behavioural Therapy and Emotion Regulation intervention in the workplace: Study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental wellbeing and help them stay engaged and productive in work

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Keywords:	MENTAL HEALTH, Depression & mood disorders < PSYCHIATRY, Adult psychiatry < PSYCHIATRY

A digital Cognitive Behavioural Therapy and Emotion Regulation intervention in the workplace: Study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental wellbeing and help them stay engaged and productive in work

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Abstract (283 words)

Introduction: This trial tests the feasibility of implementing a digital cognitive behavioural therapy for Common Mental Disorders in the workplace. The study protocol follows on the CONSORT (Consolidated Standards of Reporting Trials) recommendations.

Methods and analysis: Feasibility of the implementation for a mixed methods evaluation with a two-arm randomised waitlist control design of an eight-week digital cognitive behavioural therapy (dCBT) intervention through self-guided online platform versus waitlist control (i.e. life as usual). This study examines the ease of third-party buy in from organisations from approach to agreement, 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 through a framework analysis. Assessments take place at baseline (T0), at 8 weeks post-treatment (T1), and at follow-up 16-weeks post-randomisation (T2). We will recruit from the 1st July to 31st December 2021 for employees and self-employed workers with depression and anxiety symptoms (sub-clinical 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 (Aug-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: ISRCTN, ID: ISRCTN31161020. Registered on 08/06/2021.

Keywords: Common Mental Disorders, Feasibility, Workplace, iCBT, Online, Emotion Regulation, Mental Health, Productivity

Article Summary

Strengths and limitations of this study

- We test the feasibility of running a novel hybrid digital cognitive behavioural therapy for anxiety and depression to workers recruited from small, medium and large businesses in the Midlands region of the UK
- This feasibility trial will be used to inform future large-scale research for early intervention of worker with mild to severe symptoms of insomnia and emotion regulation difficulties will contribute to the understanding of benefits of early interventions in the workplace, its impact on mental health and productivity.
- This trial incorporates mixed-methods research to identify barrers and facilitators to engagement of the platform and to inform study design in future use.
- This study will provide unique insights to generate designs for potential larger nationwide service delivery programme of mental health interventions in the workplace.

Introduction

In the United Kingdom (UK), poor mental health costs the economy an estimated £70 billion/year, equivalent to 4.5% of the UK's 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 therapy (e.g. cognitive behavioural therapy) has been shown to be 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]. Despite evidence showing that psychological therapies such as CBT are effective for depression and anxiety disorders [10], provision in primary care is low and in secondary care has been characterised by long waiting lists. To tackle this issue, Improving Access to Psychological Therapies (IAPT) was introduced to make psychological therapies for depression and anxiety available in a stepped approach within a collaborative model [11,12].

The World Health Organisation 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 [13]. Effective early interventions can prevent, delay or reduce the onset or progress of a mental health condition [14], and are more cost-effective than treatments through specialist services or primary care providers [15]. However, to be eligible for therapies through IAPT, individuals must have symptoms above the clinical cut-off (10 and above on the PHQ-9 for depression, or 8 and above on the GAD-7 for anxiety) [16]. 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 digital-based CBT (dCBT) provides access to resources for self-learning or supervised treatment [16]. dCBT is effective in the prevention [17,18] and treatment of the most common CMD – depression and anxiety [8,19–21] 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 [22,23]. Meta-analyses of workplace interventions for CMDs show a significant standardized mean difference of 0.12, demonstrating small significant effects [24]. A large randomised controlled trial demonstrated that dCBT showed strong effects in treating employees with major depressive episodes [25], furthermore dCBT interventions have also been shown to promote work engagement amongst sub-clinical and healthy workers [26].

The majority of studies to date have focused on clinical levels of depression and less so on individuals with sub-clinical symptoms. It has been suggested that sub-threshold populations of CMDs are greater than their clinical counterparts [27]. In addition, interventions for subclinical populations are deemed highly cost-effective [28]. Cases of CMDs have been further intensified over the COVID-19 pandemic with rates of generalised-anxiety disorder increasing from one in ten to one in four adults in the US populations [29, 30, 31]. 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 [26]. Given the relatively few studies that examine intervention on subclinical and clinical levels of CMDs in the workplace, this trial is the first to explore a fully online intervention for a UK sample in the workplace.

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 [25] with a focus to improve workforce mental health and productivity.

Research aims

The primary aim of this trial is to investigate the feasibility of a multi-centre waitlist RCT 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 upon:

- 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 Patient Health Questionnaire-9 (PHQ-9) and the General Anxiety Disorder-7 (GAD-7) psychometrics as well as work productivity.

Methods

Trial Design

We implement a multi-centre, waitlist randomised controlled trial (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 currently receiving professional care for a mental health condition. The dCBT will be delivered via a self-guided digital online platform over an eight-week period.

Participants will be screened for the presence of depressive and anxious symptoms. Upon 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). All participants in the WLC group will be offered the dCBT intervention at week 8 (see Fig. 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 program. 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 workers self-employed and 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 (Midlands Engine, 2021).

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 (e.g. GP, private clinic, Improving Access to Psychological Therapies (IAPT) 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 > 5 or Patient Health Questionnaire-9 score: x > 5	In shift work*
≥ 18 years of age	

*We do not specify on working hours, or place of work

** We use the Insomnia Severity Index to differentiate REST from other trials being conducted at the same time with the INWORK programme. This criterion is used to ensure that REST can be differentiated and that there is no population overlap between the INWORK trials.

Components of the REST intervention

The REST intervention is an online self-guided programme structured into eight-weekly sessions with varying number of topics each week, lasting approximately 60 minutes each. The content incorporates techniques from Cognitive Behavioural Therapy (CBT) and Emotion Regulation [32] 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 can be shown below on Table 2.

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 (e.g. sleep, physical activity)**
Week 8	• **Programme summary** • **Relapse management** • **Self-compassion** • **Resilience**

Waitlist control

Participants initially allocated to the waitlist control group, will be asked to provide a baseline response to primary and secondary measures but will not receive any active treatment for the first eight weeks. After the eight-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 a further eight weeks.

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 five days of non-response.

Primary outcomes

To examine the feasibility of our intervention under a multi-centre waitlist randomised controlled trial 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 waitlist control group)
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 firstly 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 (e.g. distribution of the outcome measures, skew, kurtosis, 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 Supplementary section and will be collected at baseline (T0) post-study (T1), and follow up (T2). 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 or if they are taking part in any other behavioural treatment of interventions. See the supplementary 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 eight 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 randomised controlled trial.

We anticipate a nominal sample size of 60 participants based on Lewis et al recommendations for feasibility trials [33].

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 (e.g., Twitter, LinkedIn and Facebook) and print (e.g., 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 ISI. We will also ask participants to confirm they are older than 18, whether they have a diagnosis of a mental health condition, 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 [34] or the PHQ-9 [35] or 15 of above on the ISI [36], we will recommend these individuals to contact their GP and signpost to contact Improving Access to Psychological Therapies 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

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 block between two and eight, to minimise the risk of uneven groups. The randomisation is conducted using '*blockrand*' package [37]. 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 waitlist RCT, 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 handle 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 be

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.

Analyses

We will record and report all participant flow through the trial in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 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).

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	%	%	%	%	%	%

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

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	%	%	%	%	%	%

We will also conduct a chi-squared 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, we will also report the intra-cluster 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 Supplementary 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 the 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 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 (IJSS, WPAI:GH and the WEMWBS) and potential additional treatment. In this model, we also include as a covariate, the baseline values of the ISI, GAD7 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 a randomised-controlled trial.

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 videoconferencing 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 (i.e., what helped or prevented participants from implementing aspects of the programme). We map the qualitative codes to the COM-B model [38], 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 [39]. Themes will be generated using the to 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.

[Figure 1 here]

Assessment of safety

We anticipate a low risk of serious adverse events (such as death or hospitalisation.) occurring during this trial, given the low base rate of negative events in the literature for dCBT interventions [40]. We will record occurrences of serious adverse events (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 investigator. Adverse events are also a low risk during this trial, however expected adverse events: concentration difficulties and low mood.

To report a AE or SAE, forms will be sent to the trial management team (CB, 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.

Dissemination

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.

Discussion

In this intervention we test the feasibility of implementing a waitlist randomised-controlled trial of dCBT intervention in sub-threshold non-clinical and clinical populations in the workforce. The results from this feasibility trial will be used to inform a fully-powered waitlist randomised controlled trial, which will test the efficacy of a dCBT intervention on depression and anxiety in a workplace setting, the unique contribution will also be to show that such effects are associated with improvement in work related outcomes such as productivity.

Trial status
Recruitment commenced on 18 June 2021 and will be stopped on 31st December 2021.

Authors' contributions
CM is principal investigator. CM, NT, LW, CT, KP, and TM were involved in the design of the study. CT and KP led the treatment development. KP drafted the manuscript and all authors revised and approved the final manuscript.

Competing interests
Ethics approval and consent to participate
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 (ISRCTN31161020). 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.

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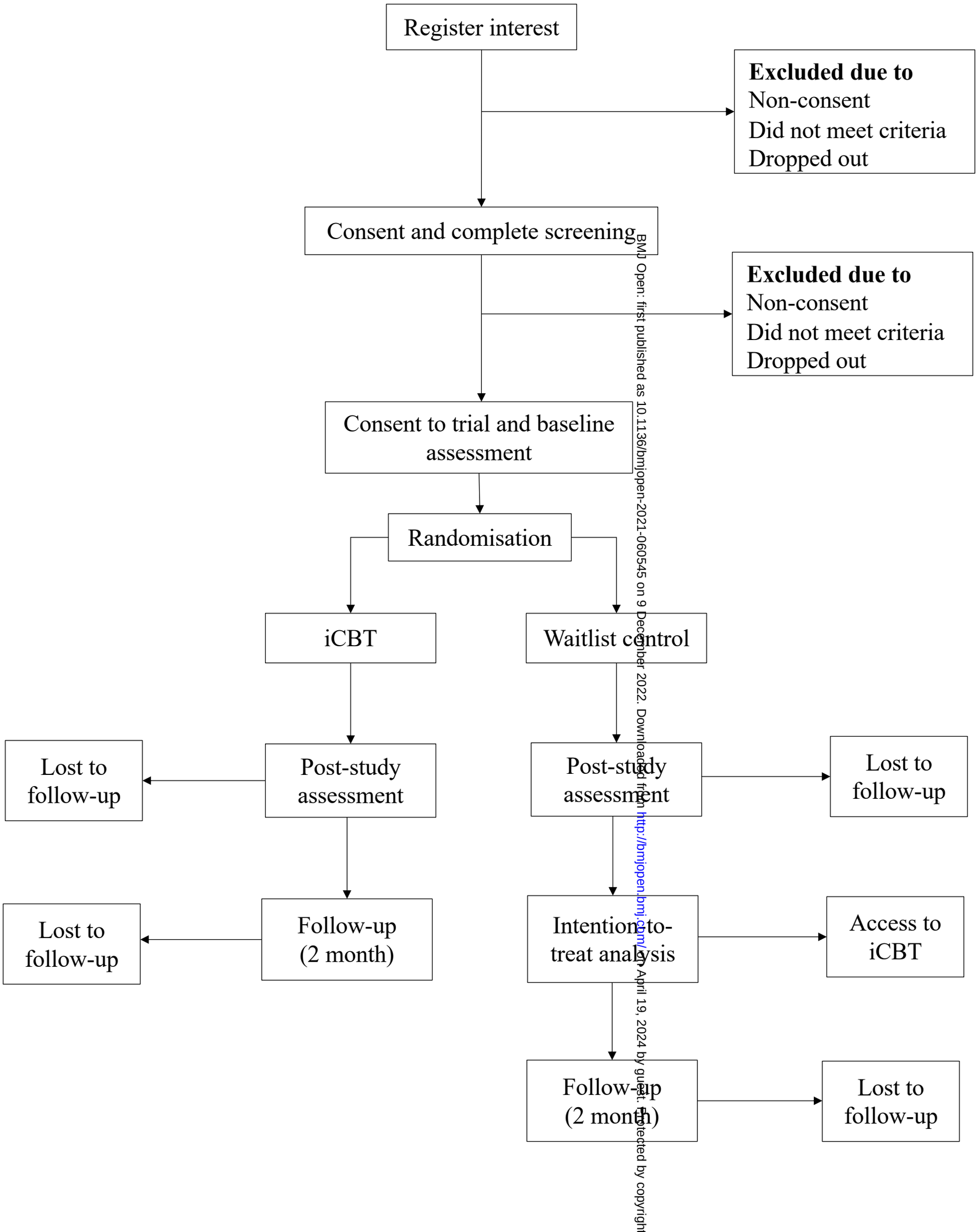
Figure 1. Participant flow in REST Trial design



Supplementary Material

Secondary Measures

The following psychometric will be used to explore their utility as outcome measures for a future fully powered randomised-controlled trial.

The General Anxiety Disorder-7 (GAD-7) is commonly used in primary and secondary mental health settings to measure symptom severity for General Anxiety Disorder (Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is comprised on seven items each scored on a four-point Likert scale, a score of 10 has been shown to correctly diagnose cases of generalised anxiety disorder with 89% sensitivity and 82% specificity, with high test-retest reliability (ICC = 0.83). The GAD-7 also shows high concurrent validity with high scores being associated with disability and functional impairment (Ruiz et al., 2011; Spitzer et al., 2006).

The Patient Health Questionnaire-9 (PHQ-9) is commonly used, in primary care settings to assess the severity of depression across the nine DSM-IV criteria for major depressive disorder on a four-point Likert scale (Cameron, Crawford, Lawton, & Reid, 2008). The PHQ-9 has been shown to demonstrate high diagnostic accuracy in at risk populations (Haddad et al., 2013; Janneke et al., 2012), and in clinical populations. A criterion score of ≥10 has a 88% sensitivity and specificity for major depressive disorder (Kroenke, Spitzer, & Williams, 2001). Empirical research demonstrates high internal consistency (α = 0.91; Hansson, Chotai, Nordstöm, & Bodlund, 2009) and a valid latent structure even when administered in nonclinical samples (CFI = 0.914- 0.983; Ito, Takebayashi, Muramatsu, & Horikoshi, 2018).

The Insomnia Severity Index (ISI) is a seven-item psychometric which has been validated with reference to the diagnostic criteria for primary insomnia in the DSM-IV. The ISI uses a five point Likert scale response to each item (score range 0–28). A score of ≥15 identifies cases of clinical insomnia with 94% sensitivity and specificity (Bastien, Vallières, & Morin, 2001). A reduction of 8.4 has been shown to be associated with moderate improvement in clinical populations (Morin, Belleville, Bélanger, & Ivers, 2011), with responses being validated in non-clinical samples as demonstrating a high internal reliability (α = 0.81 - 0.91 (Morin et al., 2011; Yu, 2010).

Job productivity - measured through the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH; (Reilly, Zbrozek, & Dukes, 1993). The WPAI:GH is a six item psychometric which focuses on: 'Absenteeism', 'Presenteeism', 'Work productivity loss' and 'Activity Impairment'. The WPAI:GH has shown strong psychometric properties with good internal consistency (a = 0.74), with a high intraclass correlation coefficient (r = 0.79 – 0.90) in clinical populations (Zhang et al., 2010). The WPAI has been used in non-clinical samples and has shown good face validity (Duke & Montag, 2017).

Job satisfaction - measured using the Indiana Job Satisfaction Scale (IJSS; Resnick & Bond, 2001). The IJSS is a 32-item psychometric coded on a four-point Likert response of "Strongly disagree" to "Strongly agree", and is comprised of six subscales: 'General Satisfaction', 'Pay', 'Advancement and Security', 'Supervision', 'Coworkers' and 'How I feel about this job'. The IJSS yields strong psychometric properties with high internal consistence (a = 0.90) and test-retest reliability (*r* = .75) (Resnick & Bond, 2001).

Well-being – we measure subjective well-being using the Warwick-Edinburgh Mental Health Well-being Scale (WEMWBS, Tennant et al., 2007). The WEMWBS consists of 14-items on a five-point likert scale ranging from "None of the time" to "All of the time". The scale has been shown to hold good psychometric properties, with strong internal consistency (α = 0.91) and was shown to hold high concurrent validity (Tennant et al., 2007). When applied to nonclinical samples the WEMWBS still shows similar psychometric properties with high internal consistency (α = 0.94; test-retest = 0.83; Dong et al., 2016).

Quality of life- measured using the EuroQOL EQ-5D-5L questionnaire (Herdman et al., 2011). The EQ-5D-5L consists of six items, five items measured through five-point likert-scale responses to mobility, self-care, usual activities, pain/discomfort and anxiety/depression, with a sixth item of a rating of health on a visual analogue scale ranging from 0-100. The EQ-5D-5L has shown high internal consistency in clinical samples (α = 0.86; (Bilbao et al., 2018) and in nonclinical populations (α = 0.84; Kim & Ko, 2018).

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	2
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3
	2b	Specific objectives or research questions for pilot trial	3
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
	4c	How participants were identified and consented	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6,7
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A

Sample size	7a	Rationale for numbers in the pilot trial	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8,9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	9, 10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	N/A
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	N/A
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	N/A
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A

	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	13
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	13
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	13
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	13
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	14
Protocol	24	Where the pilot trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14
	26	Ethical approval or approval by research review committee, confirmed with reference number	14

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

A digital Cognitive Behavioural Therapy intervention in the workplace: Study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental wellbeing and help them stay engaged and productive in work.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-060545.R2
Article Type:	Protocol
Date Submitted by the Author:	01-Oct-2022
Complete List of Authors:	Patel, Krishane; University of Warwick Moukhtarian, Talar Rita; University of Warwick, WMG Walasek, Lukasz; University of Warwick, Psychology Daly, Guy; Coventry University Russell, Sean; Coventry University Tang, Nicole; University of Warwick, Psychology Toro, Carla; University of Warwick, Warwick Medical School Meyer, Caroline; University of Warwick, Warwick Medical School
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Occupational and environmental medicine
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Title: A digital Cognitive Behavioural Therapy intervention in the workplace: Study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental wellbeing and help them stay engaged and productive in work

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Abstract (283 words)

Introduction: This trial tests the feasibility of implementing a digital cognitive behavioural therapy for Common Mental Disorders in the workplace. The study protocol follows on the CONSORT (Consolidated Standards of Reporting Trials) recommendations.

Methods and analysis: Feasibility of the implementation using a mixed methods evaluation of a two-arm randomised waitlist control trial consisting of an eight-week digital cognitive behavioural therapy (dCBT) intervention for subthreshold to clinical depression and/or anxiety through self-guided online platform versus waitlist control (i.e. life as usual). This study examines the ease of third-party buy in from organisations from approach to agreement, 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 through a framework analysis. Assessments take place at baseline (T0), at 8 weeks post-treatment (T1), at short-term follow-up 16-weeks post-randomisation (T2) and long-term follow-ups (6 and 12 months post-randomisation). We will recruit from the 1st July to 31st December 2021 for employees and self-employed workers with depression and anxiety symptoms (sub-clinical 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 (Aug-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: ISRCTN, ID: ISRCTN31161020. Registered on 08/06/2021.

Keywords: Depression, Anxiety, Feasibility, Workplace, dCBT, Online, Mental Health, Productivity

Strengths and limitations of this study

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- Novel fully self-guided early intervention dCBT for employees in the workplace.
- Pilot RCT design within feasibility framework will inform full scale RCT in the future.
- Embedded qualitative study will inform challenges in delivering fully self-guided dCBT within the workplace.
- Intervention is light touch, accessible and low cost.
- Study will be underpowered to examine efficacy of intervention.

Introduction

In the United Kingdom (UK), poor mental health costs the economy an estimated £70 billion/year, equivalent to 4.5% of the UK's 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 therapy (e.g. cognitive behavioural therapy) has been shown to be 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]. Despite evidence showing that psychological therapies such as CBT are effective for depression and anxiety disorders [10], provision in primary care is low and in secondary care has been characterised by long waiting lists. In fact, 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 NHS 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 these groups prefer to manage their mental health themselves [13], which could be using self-guided dCBT for example. To tackle this issue, Improving Access to Psychological Therapies (IAPT) was introduced to make psychological therapies for depression and anxiety available in a stepped approach within a collaborative model [14,15].

The World Health Organisation 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 [16]. Effective early interventions can prevent, delay or reduce the onset or progress of a mental health condition [17], and are more cost-effective than treatments through specialist services or primary care providers [18]. However, to be eligible for therapies through IAPT, individuals must have symptoms above the clinical cut-off (10 and above on the PHQ-9 for depression, or 8 and above on the GAD-7 for anxiety) [19]. 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 digital-based CBT (dCBT) provides access to resources for self-learning or supervised treatment [20]. dCBT is effective in the prevention [20,21] and treatment of the most common CMDs – depression and anxiety [8,22-24], 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 [25,26]. Meta-

analyses of workplace interventions for CMDs show a significant standardized mean difference of 0.12, demonstrating small significant effects [27]. A large randomised controlled trial demonstrated that dCBT showed strong effects in treating employees with major depressive episodes [28], furthermore dCBT interventions have also been shown to promote work engagement amongst sub-clinical and healthy workers [29].

The majority of studies to date have focused on clinical levels of depression and less so on individuals with sub-clinical symptoms. It has been suggested that populations with sub-threshold CMDs are greater in number than their clinical counterparts [30]. In addition, interventions for subclinical populations are deemed highly cost-effective [31]. Cases of CMDs have been further intensified over the COVID-19 pandemic with rates of generalised-anxiety disorder increasing from one in ten to one in four adults in the US populations [32,33]. 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 [29]. 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 [34], 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 haven't pursued the traditional route of getting mental health support (e.g. approaching 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 [35] 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 multi-centre waitlist RCT 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 upon:

- 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 Patient Health Questionnaire-9 (PHQ-9) and the General Anxiety Disorder-7 (GAD-7) psychometrics as well as work productivity.

Methods and analysis

Study design

We implement a multi-centre, waitlist randomised controlled trial (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 eight-week period.

Participants will be screened for the presence of depressive and anxious symptoms. Upon 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 Fig. 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 program. 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 [36].

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 (e.g. GP, private clinic, Improving Access to Psychological Therapies (IAPT) 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 do not specify on working hours, or place of work
** We use the Insomnia Severity Index to differentiate REST from other trials being conducted at the same time with the INWORK programme. This criterion is used to ensure that REST can be differentiated and that there is no population overlap between the INWORK trials.

Components of the REST intervention

The REST intervention is an online self-guided programme structured into eight-weekly sessions with varying number of topics each week, lasting approximately 60 minutes each. The content incorporates techniques from Cognitive Behavioural Therapy (CBT) and Emotion Regulation [37] 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 can be shown below on Table 2.

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 (e.g. sleep, physical activity)**
Week 8	• **Programme summary** • **Relapse management** • **Self-compassion** • **Resilience**

Waitlist control

Participants initially allocated to the waitlist control group, will be asked to provide a baseline response to primary and secondary measures but will not receive any active treatment for the first eight weeks. After the eight-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 eight weeks. The waitlist control group serves two purposes. First, it provides an untreated comparison for the active dCBT group to determine if the treatment had an effect. Secondly 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 randomization) the impacts of exposure to the dCBT.

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 five days of non-response.

Primary outcomes

To examine the feasibility of our intervention under a multi-centre waitlist randomised controlled trial 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 waitlist control group)
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 firstly 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 (e.g. distribution of the outcome measures, skew, kurtosis, 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 Supplementary 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 supplementary 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 eight 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 randomised controlled trial.

We anticipate a nominal sample size of 60 participants based on Lewis et al recommendations for feasibility trials [38].

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 (e.g., Twitter, LinkedIn and Facebook) and print (e.g., 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 ISI. We will also ask participants to confirm they are older than 18, whether they have a diagnosis of a mental health condition, 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 [39] or the PHQ-9 [40] or 15 of above on the ISI [41], we will recommend these individuals to contact their GP and signpost to contact Improving Access to Psychological Therapies 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 block between two and eight, to minimise the risk of uneven groups. The randomisation is conducted using '*blockrand*' package [42]. 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 waitlist RCT, 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 handle 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 be 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 (CONSORT) 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).

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	%	%	%	%	%	%

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

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	%	%	%	%	%	%

We will also conduct a chi-squared 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, we will also report the intra-cluster 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 Supplementary 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 the 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 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 (IJSS, WPAI:GH and the WEMWBS) and potential additional treatment. In this model, we also include as a covariate, the baseline values of the ISI, GAD7 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 a randomised-controlled trial.

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 videoconferencing 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 (i.e., what helped or prevented participants from implementing aspects of the programme). We map the qualitative codes to the COM-B model [43], 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 [44]. Themes will be generated using the to 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.

[Figure 1 here]

Assessment of safety

We anticipate a low risk of serious adverse events (such as death or hospitalisation.) occurring during this trial, given the low base rate of negative events in the literature for dCBT interventions [45]. We will record occurrences of serious adverse events (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 investigator. Adverse events are also a low risk during this trial, however expected adverse events: concentration difficulties and low mood.

To report a AE or SAE, forms will be sent to the trial management team (CB, 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 (ISRCTN31161020). 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 31st December 2021.

Authors' contributions

KP, TM, CT, CM, LW, and NT were involved in design and interpretation of the work. CT and TM led the treatment development. KP drafted the first version of the manuscript. KP, TM, CT, LW, SR, NT, GD and CM all were involved in revising for critical intellectual content, and shared agreement for accountability in all aspects of the work.

Competing interests

The authors disclose no competing interests.

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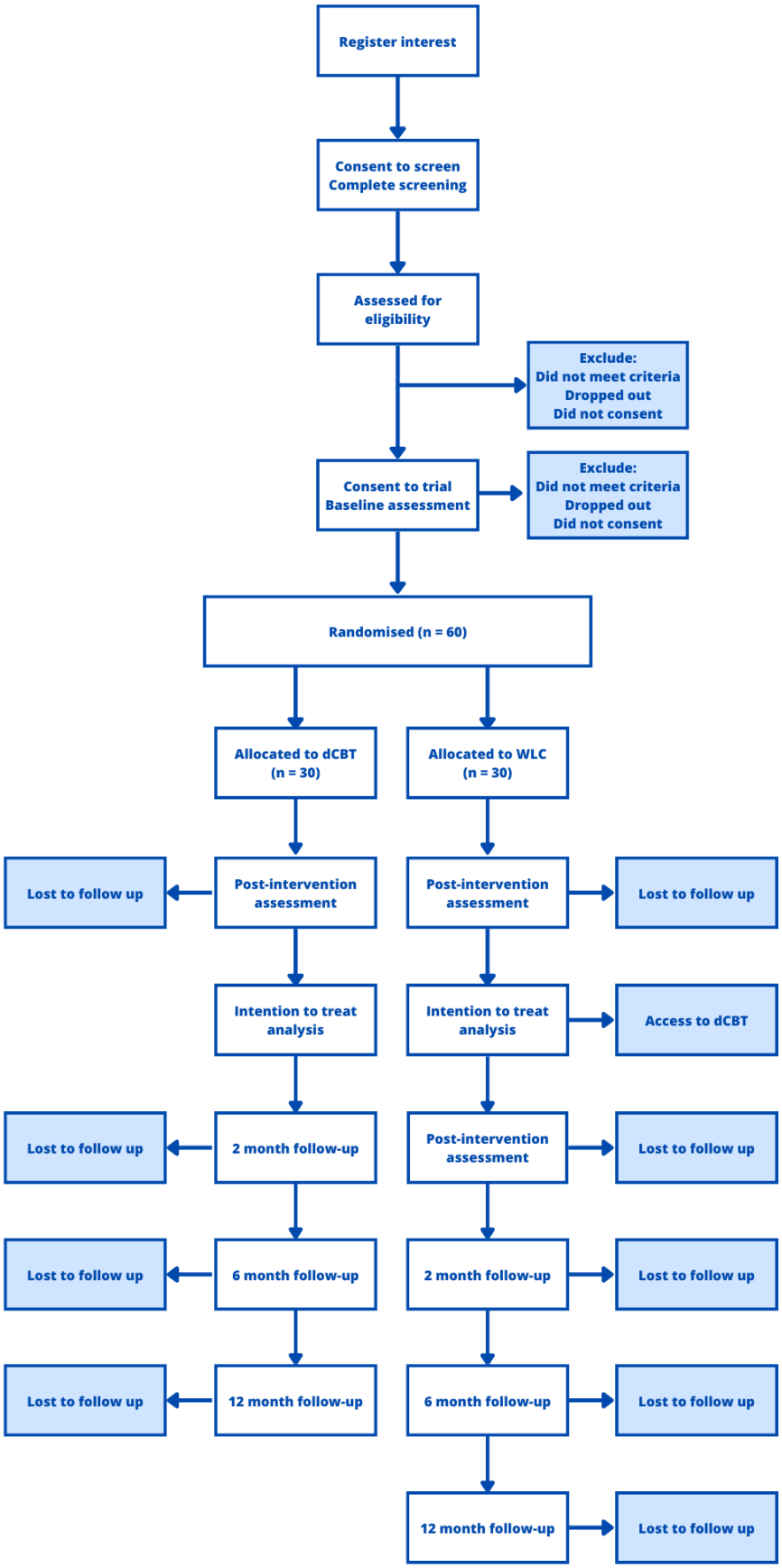
Figure 1. Flow chart diagram showing summary of the trial design for the REST study



Supplementary Material

Appendix A- Screening questionnaires

Q1.2 I confirm that I have read and understand the information sheet for the above study (INWORK PIL v1.7_IV- 24.08.21). If you have not already done so, please see the information sheet sent via the link in the screening invitation email. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- Yes (1)
- No (2)

Q1.3 I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my employment being affected.

- Yes (1)
- No (2)

Q1.4 I understand that data collected during the study, may be looked at by individuals from the Universities of Warwick and Birmingham. I give permission for these individuals to have access to my data.

- Yes (1)
- No (2)

Q1.5 I understand that the screening phase of the above study is designed to assess my eligibility for the interventions being offered.

- Yes (1)
- No (2)

Q1.6 I understand that if I'm eligible for an intervention, I will be contacted again by the research team with further information on the specific intervention I may be eligible for and instructions on how to proceed.

- Yes (1)
- No (2)

Q1.7 Whether eligible or not for the INWORK study, would you like to be contacted by the research team with invitations for future studies?

- Yes (1)
- No (2)

Display This Question:
If Whether eligible or not for the INWORK study, would you like to be contacted by the research team... = Yes

Q1.8 I understand that my name and email address will be stored on the University of Warwick servers for 5 years.

- Yes (1)
- No (2)

End of Block: Consent

Start of Block: Description

Q2.1 Over the next series of questions we will assess your mood and sleep. Please answer the questions as accurately as possible and remember there are no correct answers.

You are free to withdraw at any time, should you wish to do so. If you have any issues completing the questionnaires, please contact the research team at

End of Block: Description

Start of Block: GAD-7

Q3.1 Over the last 2 weeks, how often have you been bothered by any of the following problems?

Q3.2 Feeling nervous, anxious or on edge?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.3 Not being able to stop or control worrying?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.4 Worrying too much about different things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.5 Trouble relaxing?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.6 Being so restless that it is hard to sit still?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.7 Becoming easily annoyed or irritable?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.8 Feeling afraid as if something awful might happen?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

End of Block: GAD-7

Start of Block: PHQ-9

Q4.1 Over the last two weeks, how often have you been bothered by any of the following problems?

Q4.2 Little interest or pleasure in doing things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.3 Feeling down, depressed, or hopeless?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.4 Trouble falling or staying asleep, or sleeping too much?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.5 Feeling tired or having little energy?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.6 Poor appetite or overeating?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.7 Feeling bad about yourself - or that you are a failure or have let yourself or your family down?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.8 Trouble concentrating on things, such as reading the newspaper or watching television?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.9 Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.10 Thoughts that you would be better off dead, or of hurting yourself in some way?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Display This Question:
If Thoughts that you would be better off dead, or of hurting yourself in some way? != Not at all

Q4.11 **Your safety:** We appreciate that you are willing to share your experiences and feelings with the research team. However, we cannot monitor in real time the information provided by you about your physical and mental health during this research. If you would like emotional support, or completing the survey has caused distress, we encourage you to reach out to someone you trust, or contact the research team on wmg-mhpp@warwick.ac.uk. Alternatively, if it is an emergency, and you need immediate help for yourself, call 999 straight away. For non-emergency physical and mental health support call 111 by or go to 111.nhs.uk.

End of Block: PHQ-9

Start of Block: ISI

Q5.1 For each question, please select the option that best describes your answer. Please rate the current (i.e. last 2 weeks) severity of your sleep problem(s).

Q5.2 Difficulty falling asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q5.3 Difficulty staying asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q5.4 Problems waking up too early

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q5.5 How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

- Very Satisfied (1)
- Satisfied (2)
- Moderately Satisfied (3)
- Dissatisfied (4)
- Very Dissatisfied (5)

Q5.6 How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

- Not at all Noticeable (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much (5)

Q5.7 How WORRIED/DISTRESSED are you about your current sleep problem?

- Not at all Worried (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Worried (5)

Q5.8 To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

- Not at all Interfering (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Interfering (5)

Q58
Copyright notice (C) *Morin, C.M. (1993 and 1996)*

End of Block: ISI

Start of Block: IAPT_GP

Q6.1
The responses you provided indicate that you might be having difficulties with your mental health.

This year has been really tough for many of us, especially when we are unable to do the usual things that bring us joy like seeing friends and family. Whilst you may still be eligible for the study, we strongly advise you to contact your GP or self-refer yourself to an NHS psychological therapies service (IAPT). To get in touch with IAPT please follow this link: https://www.nhs.uk/service-search/find-a-psychological-therapies-service/.

The intervention programme you may be offered in the study should not be used as an alternative for seeking diagnosis and treatment from a professional. You will subsequently be asked to consent to have read and take this advice into consideration. While you wait for an appointment, you can access expert advice and practical tips on the Every Mind Matters website. We have in addition put together resources below which you may find useful to look after your mental health. The Mind charity has

produced information on how to take care of your wellbeing during the pandemic including advice for coping in the winter which you might find helpful.

Mind Infoline: Call: 0300 123 3393
Email: info@mind.org.uk
Website: https://www.mind.org.uk/workplace/ Lines are open 9am to 6pm, Monday to Friday (except for bank holidays).

Samaritans
Call: 116 123
Email: jo@samaritans.org Website: https://www.samaritans.org/
For a listening ear or just someone to talk to the Samaritans are open 24 hours a day. If you need mental health information and the above helplines are closed then please visit Mind's Mental health A-Z resource or contact NHS 111.

NHS The NHS also has their own set of resources, this includes a website which provides access to other sources of information: https://www.england.nhs.uk/mental-health/resources/ If you have any questions or would like more information, please contact the research team at wmg-mhpp@warwick.ac.uk

Please confirm that you understand these requests. This does not impact your ability to take part in these studies in any way.

☐ I understand the request to contact my GP (4)

☐ I understand the request to contact IAPT (5)

End of Block: IAPT_GP

Start of Block: Block 7

Q60 Please confirm your employer and usual place of work.

If your employer is not shown, please select "My employer is not listed".
If you usual place is not shown, please select "My place of work is not listed".
Organisation (1)
Site (2)

End of Block: Block 7

Start of Block: Additional_requirements

Q7.1 Thank you for responding to the questionnaires about your mental wellbeing. We have only a few last questions to ask to help identify which study you may be eligible for out of REST, SLEEP or MENTOR

Q7.2 Are you over the age of 18?

- Yes (1)
- No (2)

Q7.3
Do you currently manage anyone?

- Yes (21)
- No (22)

Display This Question:
If Do you currently manage anyone? = Yes

Q7.4
Would you be happy to participate in the MENTOR trial if someone of your team was selected for MENTOR?

- Yes (21)
- No (22)

Q7.5 Do you have a current diagnosis of a mental health condition?

- Yes (1)
- No (2)

Display This Question:
If Do you have a current diagnosis of a mental health condition? = Yes

Q7.6 What is your mental health diagnosis?

_____

Q7.7 Are you currently under the care of a mental health care practitioner?

To clarify: are you currently receiving care through psychological treatment or through some form of medication?

This can include your GP as well as a consultant from NHS services.

- Yes (1)
- No (2)

Q7.8 Are you currently involved in any psychological intervention trials?

- Yes (1)
- No (2)

Display This Question:
If Do you have a current diagnosis of a mental health condition? = Yes

Q7.9 Are you currently receiving support from an Individual Placement and Support Worker?

- Yes (1)
- No (2)

Display This Question:
If Do you have a current diagnosis of a mental health condition? = Yes

Q7.10 Are you on extended sick leave (i.e. for more than 4 weeks) ?

- Yes (1)
- No (2)

Display This Question:
If Are you over the age of 18? = Yes
And Do you have a current diagnosis of a mental health condition? = Yes
And Are you currently under the care of a mental health care practitioner? To clarify: are you curren... = Yes

*

Q7.11 What is your line manager's email address?

_____

Display This Question:
If Are you over the age of 18? = Yes
And Do you have a current diagnosis of a mental health condition? = Yes
And Are you currently under the care of a mental health care practitioner? To clarify: are you curren... = Yes

Q7.12 Please confirm your line manager's email address

_____

REST_Questionnaire at each timepoint

Start of Block: Consent

Q1.2 I confirm that I have read and understand the information sheet (REST v1.7 7/07/21) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- Yes (1)
- No (2)

Q1.3 I confirm that I meet ALL the eligibility criteria of this study: English speaking; 18 years or above; Not retiring in the next 10 months; Currently not receiving treatment (psychological or medication) from mental health services; Currently not taking parting in other psychological intervention trials.

- Yes (1)
- No (2)

Q1.4 I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my employment being affected.

- Yes (1)
- No (2)

Q1.5 I understand that data collected during the study, may be looked at by individuals from University of Warwick. I give permission for these individuals to have access to my data.

- Yes (1)
- No (2)

Q1.6 Would you like to be contacted to participate in a qualitative interview to understand how we can improve the intervention further

- Yes (1)
- No (2)

Q1.7 I am happy for my anonymised data to be used in future research.

- Yes (1)
- No (2)

Q1.8 I agree to take part in the above study.

- Yes (1)
- No (2)

End of Block: Consent

Start of Block: Demographics

Q2.1 Thank you for consenting to take part in the REST trial. This study will last for 8 weeks during this time you will have access to an online e-learning platform. You will receive further information on how to access these in due course. For us to evaluate how well this intervention improves your sleep and wellbeing, we ask you next to complete a set of questionnaires. This will take approximately 45 minutes. Please read each question carefully before responding and feel free to take breaks where you need. If you do feel you need to take a break, please do not close the survey.
If you have any questions, please contact us at wmg-rest@warwick.ac.uk

Q2.2 How old are you?

	0 10 20 30 40 50 60 70 80 90 100
Age in years ()	

JS

Q2.3 What gender do you identify as?

- ○ Female (1)
- ○ Male (2)
- ○ Non-binary (3)
- ○ Other (please specify) (4) _____
- ○ Prefer not to specify (5)

Q2.4 What is your ethnicity? (1 of 2)

- ○ White... (1)
- ○ Mixed / Multiple ethnic groups... (2)
- ○ Asian or Asian British... (3)
- ○ Black or Black British... (4)
- ○ Mixed (5)
- ○ Hispanic/Latino (6)
- ○ Other (please specify) (7)

Display This Question:
If What is your ethnicity? (1 of 2) = White...

Q2.5 What is your ethnicity? (2 of 2)

- ○ English / Welsh / Scottish / Northern Irish / British (1)
- ○ Irish (2)
- ○ Gypsy or Irish Traveller (3)
- ○ Any other White background (please describe if you wish) (4)

_____

Display This Question:
If What is your ethnicity? (1 of 2) = Mixed

Q2.6 What is your ethnicity? (2 of 2)

- White and Black Caribbean (1)
- White and Black African (2)
- White and Asian (3)
- Any other Mixed / Multiple ethnic background (please describe if you wish) (4)

_____

Display This Question:
If What is your ethnicity? (1 of 2) = Asian or Asian British...

Q2.7 What is your ethnicity? (2 of 2)

- Indian (1)
- Pakistani (5)
- Bangladeshi (6)
- Chinese (7)
- Any other Asian background (please describe if you wish) (8)

_____

Display This Question:
If What is your ethnicity? (1 of 2) = Black or Black British...

Q2.8 What is your ethnicity? (2 of 2)

- African (1)
- Caribbean (4)
- Any other Black / African / Caribbean background (please describe if you wish) (5)

_____

Q2.9 How many hours do you work per week?

	0 5 10 15 20 25 30 35 40 45 50
Number of hours ()	

Q2.10 Information about income is very important to understand. Would you please give your best guess?Please indicate the answer that includes your entire household income in (previous year) before taxes.

- ○ £10,000 to £29,999 (1)
- ○ £30,000 to £49,999 (2)
- ○ £50,000 to £69,999 (3)
- ○ £70,000 to £89,999 (4)
- ○ £90,000 to £109,999 (5)
- ○ £110,000 to £149,999 (6)
- ○ £150,000 or more (7)

JS

Q2.11 How would you describe your current relationship status?

- ○ Single (1)
- ○ Cohabiting (2)
- ○ Married (3)
- ○ Separated (4)
- ○ Divorced (5)
- ○ Widowed (6)
- ○ Other (please specify) (7) _____

Q2.12 Who do you live with?

- I live by myself (1)
- I live with flatmates (2)
- I live with my partner (3)
- I live with my parents/carers (4)
- I live with other family members (6)

JS

Q2.13 What is your highest educational qualification?

- No formal qualification (1)
- Primary (2)
- Secondary (e.g., GCSE, O-levels, GNVQ) (3)
- Diploma (or professional qualification) (4)
- Bachelor's degree (5)
- Master's degree (6)
- Doctorate degree (7)
- Other (please specify) (8) _____

JS

Q2.14 In the last 8 weeks, to the best of your recollection, how much sick leave have you taken?

- I have taken (1) _____
- I have not taken any sick leave (2)
- I would prefer not to answer this question (3)

Q2.15 Are you currently using any self-help resources?

This includes but is not limited to self help books, apps and websites

- Yes (1)
- No (2)

Q2.16 Since completing the screening questionnaire of this study, did you start receiving treatment from mental health services?

- Yes (1)
- No (2)

End of Block: Demographics

Start of Block: Contact

Page Break

Q3.1 As part of this study we need to request some further personal information for us to contact you during this study.

JS

Q3.2 What is your phone number?

_____

End of Block: Contact

Start of Block: COVID_19

Q5.1 As part of our research, we are interested in your experiences with COVID-19 and how this has impacted your life. Please read each question carefully and select the most appropriate response for you.

Q5.2 How worried are you about contracting COVID-19?

- Not worried at all (1)
- Slightly worried (2)
- Moderately worried (3)
- Very worried (4)
- Extremely worried (5)

Q5.3 In which category are you considered to be in regard to COVID-19 according to the NHS and UK Government guidelines of England?

- Clinically extremely vulnerable (1)
- Clinically vulnerable (2)
- Low risk (3)

Q5.4 Since the start of the pandemic, have you tested positive for COVID-19?

- Yes (1)
- No (2)

Display This Question:
If Since the start of the pandemic, have you tested positive for COVID-19? = Yes

Q5.5 Have you required hospitalised treatment for COVID-19?

- Yes (1)
- No (2)

Display This Question:
If Since the start of the pandemic, have you tested positive for COVID-19? = No

Q5.6 Do you suspect that you may have had COVID-19 due to presenting with symptoms? (temperature/fever, new persistent cough, loss of smell & taste)

- Definitely (1)
- Probably (2)
- Unsure (3)
- No (4)

Display This Question:
If Since the start of the pandemic, have you tested positive for COVID-19? = Yes

Q5.7 For some people, coronavirus can cause symptoms that last weeks or months after the infection has gone. This is sometimes called post-COVID-19 syndrome or "long COVID". Have you

experienced any of the following long COVID symptoms 12 weeks after initial infection? (Check all that apply)

- ☐ No (I feel fully recovered) (1)
- ☐ Extreme tiredness (fatigue) (2)
- ☐ Shortness of breath (3)
- ☐ Chest pain or tightness (4)
- ☐ Problems with memory and concentration ("brain fog") (5)
- ☐ Difficulty sleeping (insomnia) (6)
- ☐ Heart palpitations (7)
- ☐ Dizziness (8)
- ☐ Pins and needles (9)
- ☐ Joint pain (10)
- ☐ Depression and anxiety (11)
- ☐ Tinnitus, earaches (12)
- ☐ Feeling sick, diarrhoea, stomach aches, loss of appetite (13)
- ☐ A high temperature, cough, headaches, sore throat, changes to sense of smell or taste (14)
- ☐ Rashes (15)

Q5.8 Since the start of the pandemic, have any people you know tested positive for COVID-19? (Choose all that apply)

- [ ] Immediate family members (1)
- [ ] Extended family members (2)
- [ ] Neighbours (3)
- [ ] Friends (4)
- [ ] Colleagues (5)
- [ ] No one I know has tested positive (6)

Q5.9 Since the start of the pandemic, have you been asked to stop working temporarily under the government "furlough" scheme?

- ○ No (1)
- ○ Yes, I am currently on furlough (2)
- ○ Yes, I will soon be on furlough (3)
- ○ Yes, but have since returned to work (full time or part time) (4)

Q5.10 As a result of colleagues being placed on furlough, do you think your workload will/has:

- ○ Increase (d) (1)
- ○ Decrease (d) (2)
- ○ Stay (ed) the same (3)
- ○ Can't say yet (4)
- ○ N/A, as no one I work with has been furloughed (5)
- ○ N/A, as I am currently been furloughed (6)

Page Break

Q5.11 In light of the COVID-19 pandemic, what changes had been made within your organisation that have impacted you? (Tick all that apply)

- ☐ Hours of work (1)
- ☐ Pay cut (2)
- ☐ Working remotely (3)
- ☐ Not applicable (4)

Display This Question:
If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

Q5.12 Have you experienced any ongoing challenges in working remotely? (Tick all that apply)

- ☐ Technical difficulties (e.g. with internet, computers, access to workplace data storage) (1)
- ☐ Practical difficulties (no separate/private area from which to work) (2)
- ☐ Balancing work with caregiving/parenting responsibilities (3)
- ☐ Motivational difficulties (4)
- ☐ Other (please specify) (5)
- ☐ No challenges experienced (6)

Display This Question:
If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

Q5.13 How comfortable do you feel returning back to work and having the appropriate support from your organisation? (e.g. Covid-19 risk assessment)?

- ○ Not comfortable at all (1)
- ○ Slightly comfortable (2)
- ○ Moderately comfortable (3)
- ○ Very comfortable (4)
- ○ Extremely comfortable (5)

Display This Question:
If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

Q5.14 How have these issues affected your ability to work?

- (Negative impact) -3 (1)
- -2 (2)
- -1 (3)
- 0 (4)
- 1 (5)
- 2 (6)
- (Positive Impact) 3 (7)

Q5.15 Have you experienced any of the following due to COVID-19? (Tick all that apply)
We understand this question may trigger distress and undesirable memories or thoughts. If so, please speak to a friend or family member or seek professional support (e.g. GP).

- ☐ Lost your job/unable to earn money (1)
- ☐ Another bill payer in your household lost their job or is/was unable to earn money (2)
- ☐ Unable to pay bills (3)
- ☐ Had difficulties accessing sufficient food (4)
- ☐ Evicted / lost accommodation (5)
- ☐ Had difficulties accessing required medication (6)
- ☐ Somebody close to you in hospital (7)
- ☐ Somebody close to you died (we are very sorry for your loss. We realise answering this question might make you uncomfortable or trigger unsettling feelings. If you feel you need to speak to someone or require support, please refer to this NHS resource) (8)
- ☐ Difficulties with family or social relationships (9)
- ☐ If you're a parent/carer, concerns about your child's/children's well-being and/or education (10)
- ☐ Having to change or delay major life plans or events (11)
- ☐ Not applicable (12)

Q5.16 How comfortable do you feel raising COVID-19 related issues with your organisation (e.g. line manager, human resources)?

- Not comfortable at all (1)
- Slightly comfortable (2)
- Moderately comfortable (3)
- Very comfortable (4)
- Extremely comfortable (5)

Q5.17 Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a research trial)

- Yes (1)
- No (2)

Display This Question:
If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Q5.19 Have you experienced any of the following symptoms as a result of having the vaccine? (Tick all that apply)

- [ ] Headaches (1)
- [ ] Feeling tired (2)
- [ ] Feeling achy (3)
- [ ] Soreness, redness and swelling at the site of the vaccination (4)
- [ ] Mild or high fever (5)
- [ ] Feeling or being sick (6)
- [ ] Allergic reaction (7)
- [ ] I did not have any symptoms (8)

Display This Question:
If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Q5.22 When did you receive your first dose? (please enter date as DD/MM/YYY)

_____

Display This Question:
If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Q5.23 Have you received a second dose of a COVID-19 vaccine?

- Yes (1)
- No (2)

Display This Question:
If Have you received a second dose of a COVID-19 vaccine? = Yes

Q5.24 When did you receive your second dose? (please enter date as DD/MM/YYY)

_____

Q5.25 What would you say is your one biggest concern or problem encountered, since the start of the pandemic?

_____
_____
_____
_____
_____

Page Break

Q5.26 Did you receive any help overcoming the concern/problem outlined above and if yes, what has been helpful or unhelpful? If no, what kind of help do you think you need right now?

_____
_____
_____
_____
_____

End of Block: COVID_19

Start of Block: WPAI_GH

Q6.1 The following questions ask about the effect of your health problems on your ability to work and perform regular activities. By health problems we mean any physical or emotional problem or symptom. Please fill in the blanks or indicate your response.

Q6.2 Are you currently employed (working for pay)?

- Yes (1)
- No (2)

Skip To: Q6.7 If Are you currently employed (working for pay)? = No

Q6.3 The next questions are about the **past seven days**, not including today.

Q6.4 During the past seven days, how many hours did you miss from work because of your health problems? Include hours you missed on sick days, times you went in late, left early, etc., because of your health problems. *Do not include time you missed to participate in this study.*

_____

Q6.5 During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

_____

Q6.6 During the past seven days, how many hours did you actually work?

_____

Q6.7 During the past seven days, how much did your health problems affect your productivity while you were working? *Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If health problems affected your work only a little, choose a low number. Choose a high number if health problems affected your work a great deal.* Consider only how much health problems affected productivity while you were working.

No effect on my work — Completely prevented me from working

0 1 2 3 4 5 6 7 8 9 10

1 ()	

Q6.8 During the past seven days, how much did your health problems affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal.

Consider only how much health problems affected your ability to do your regular daily activities, other than work at a job.

No effect on my daily activities — Completely prevented me from doing my daily activities

0 1 2 3 4 5 6 7 8 9 10

1 ()	

End of Block: WPAI_GH

Start of Block: IJSS

Q7.1 As part of our research, we are interested in the amount of job satisfaction with respect to your current role. This questionnaire is a valid and reliable measure of job satisfaction. Please read each statement carefully and tell us how much you agree with each statement.

There are no incorrect answers and none of the information you provide will be shared with your employer.

Q7.2 I feel good about this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.3 This job is worthwhile

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.4 The working conditions are good

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.5 I want to quit this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.6 This job is boring

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.7 I am happy with the amount this job pays

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.8 The vacation time and other benefits on this job are okay

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.9 I need more money than this job pays

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.10 This job does not provide the medical coverage I need

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)
- Not Applicable (5)

Q7.11 I have a fairly good chance for promotion in this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.12 This is a dead-end job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.13 I feel that there is a good chance of my losing this job in the future

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.14 My supervisor is fair

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.15 My supervisor is hard to please

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.16 My supervisor praises me when I do my job well

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.17 My supervisor is difficult to get along with

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.18 My supervisor recognizes my efforts

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.19 My coworkers are easy to get along with

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.20 My coworkers are lazy

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.21 My coworkers are unpleasant

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.22 My coworkers don't like me

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.23 My coworkers help me to like this job more

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.24 I have a coworker I can rely on

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.25 I have a coworker I consider a friend

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.26 I look forward to coming to work

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.27 I often feel tense on the job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.28 I don't know what's expected of me on this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.29 I feel physically worn out at the end of the day

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.30 Working makes me feel like I'm needed

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.31 My job keeps me busy

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.32 I get to do a lot of different things on my job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.33 I am satisfied with my schedule

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

End of Block: IJSS

Start of Block: WEMWBS

Page Break

Q8.1 Below are some statements about feelings and thoughts.
Please select the option that best describes your experience of each over the last 2 weeks

Q8.2 I've been feeling optimistic about the future

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.3 I've been feeling useful

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.4 I've been feeling relaxed

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.5 I've been feeling interested in other people

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.6 I've had energy to spare

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.7 I've been dealing with problems well

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.8 I've been thinking clearly

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.9 I've been feeling good about myself

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.10 I've been feeling close to other people

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.11 I've been feeling confident

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.12 I've been able to make up my own mind about things

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.13 I've been feeling loved

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.14 I've been interested in new things

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.15 I've been feeling cheerful

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

End of Block: WEMWBS

Start of Block: Medication_checklist

Q9.1 We would like to know what medication (prescriptions and/or over the counter) you use, what dose and for what condition. Medications are tablets or capsules, but could also be (eye) drops, sprays, creams, drinks, inhaler puffs, suppositories etc. Prescription medications are ones that a doctor prescribes. Over the counter medication are ones that you can purchase yourself without a prescription such as ibuprofen, vitamins, herbal remedies etc.

	Name of medication (1)	Dosage (mg/g/ml) (2)	How often do you take this medication (per day / week/ as needed) (3)	How much do you take per time (e.g. 2 tablets) (4)	What is this medication for? (5)	How long have you been using it for? (6)	Additional comments (7)
1. (1)							
2. (2)							
3 (6)							
4 (7)							
5 (8)							
6 (9)							
7 (10)							

End of Block: Medication_checklist

Start of Block: ISI

Page Break

Q12.1 For each question, please select the option that best describes your answer. Please rate the current (i.e. last 2 weeks) severity of your sleep problem(s).

Q12.2 Difficulty falling asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q12.3 Difficulty staying asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q12.4 Problems waking up too early

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q12.5 How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

- Very Satisfied (1)
- Satisfied (2)
- Moderately Satisfied (3)
- Dissatisfied (4)
- Very Dissatisfied (5)

Q12.6 How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

- Not at all Noticeable (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much (5)

Q12.7 How WORRIED/DISTRESSED are you about your current sleep problem?

- Not at all Worried (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Worried (5)

Q12.8 To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

- Not at all Interfering (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Interfering (5)

Q12.9
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For any information on the use of the Insomnia Severity Index, please contact Mapi Research Trust, Lyon, France. Internet: https://eprovide.mapi-trust.org

End of Block: ISI

Start of Block: GAD7

Page Break

Q10.1 Over the next series of questions we will assess your mood and sleep. Please answer the questions as accurately as possible and remember there are no correct answers.

Q10.2 Over the last 2 weeks, how often have you been bothered by any of the following problems?

Q10.3 Feeling nervous, anxious or on edge?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.4 Not being able to stop or control worrying?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.5 Worrying too much about different things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.6 Trouble relaxing?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.7 Being so restless that it is hard to sit still?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.8 Becoming easily annoyed or irritable?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.9 Feeling afraid as if something awful might happen?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

End of Block: GAD7

Start of Block: PHQ9

Page Break

Q11.1 Over the last two weeks, how often have you been bothered by any of the following problems?

Q11.2 Little interest or pleasure in doing things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.3 Feeling down, depressed, or hopeless?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.4 Trouble falling or staying asleep, or sleeping too much?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.5 Feeling tired or having little energy?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.6 Poor appetite or overeating?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.7 Feeling bad about yourself - or that you are a failure or have let yourself or your family down?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.8 Trouble concentrating on things, such as reading the newspaper or watching television?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.9 Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.10 Thoughts that you would be better off dead, or of hurting yourself in some way?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

End of Block: PHQ9

Start of Block: disclaimer

Q13.1 The responses you provided indicate that you might be having difficulties with your mental health. This year has been really tough for many of us, especially when we are unable to do the usual things that bring us joy like seeing friends and family. We strongly advise you to contact your GP or self-refer yourself to an NHS psychological therapies service (IAPT). To get in touch with IAPT please follow this link: https://www.nhs.uk/service-search/find-a-psychological-therapies-service/. The intervention programme should not be used as an alternative for seeking diagnosis and treatment from a professional. While you wait for an appointment, you can access expert advice and practical tips on the Every Mind Matters website. We have in addition put together resources below which you may find useful to look after your mental health. The Mind charity has produced information on how to take care of your wellbeing during the pandemic including advice for coping in the winter which you might find helpful. Mind Infoline: Call: 0300 123 3393
Email: info@mind.org.uk
Website: https://www.mind.org.uk/workplace/ Lines are open 9am to 6pm, Monday to Friday (except for bank holidays). Samaritans
Call: 116 123
Email: jo@samaritans.org Website: https://www.samaritans.org/
For a listening ear or just someone to talk to the Samaritans are open 24 hours a day. If you need mental health information and the above helplines are closed then please visit Mind's Mental health A-Z resource or contact NHS 111. NHS The NHS also has their own set of resources, this includes a website which provides access to other sources of information: https://www.england.nhs.uk/mental-health/resources/ If you have any questions or would like more information, please contact the research team at wmg-rest@warwick.ac.uk

Please confirm that you understand these requests. This does not impact your ability to take part in these studies in any way.

☐ I understand the request to contact my GP (4)

☐ I understand the request to contact IAPT (5)

End of Block: disclaimer

Appendix B- Outcome measures

The following psychometric will be used to explore their utility as outcome measures for a future fully powered randomised-controlled trial.

The General Anxiety Disorder-7 (GAD-7) is commonly used in primary and secondary mental health settings to measure symptom severity for General Anxiety Disorder (Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is comprised on seven items each scored on a four-point Likert scale, a score of 10 has been shown to correctly diagnose cases of generalised anxiety disorder with 89% sensitivity and 82% specificity, with high test-retest reliability (ICC = 0.83). The GAD-7 also shows high concurrent validity with high scores being associated with disability and functional impairment (Ruiz et al., 2011; Spitzer et al., 2006).

The Patient Health Questionnaire-9 (PHQ-9) is commonly used, in primary care settings to assess the severity of depression across the nine DSM-IV criteria for major depressive disorder on a four-point Likert scale (Cameron, Crawford, Lawton, & Reid, 2008). The PHQ-9 has been shown to demonstrate high diagnostic accuracy in at risk populations (Haddad et al., 2013; Janneke et al., 2012), and in clinical populations. A criterion score of ≥10 has a 88% sensitivity and specificity for major depressive disorder (Kroenke, Spitzer, & Williams, 2001). Empirical research demonstrates high internal consistency (α = 0.91; Hansson, Chotai, Nordstöm, & Bodlund, 2009) and a valid latent

structure even when administered in nonclinical samples (CFI = 0.914- 0.983; Ito, Takebayashi, Muramatsu, & Horikoshi, 2018).

The Insomnia Severity Index (ISI) is a seven-item psychometric which has been validated with reference to the diagnostic criteria for primary insomnia in the DSM-IV. The ISI uses a five-point Likert scale response to each item (score range 0–28). A score of ≥15 identifies cases of clinical insomnia with 94% sensitivity and specificity (Bastien, Vallières, & Morin, 2001). A reduction of 8.4 has been shown to be associated with moderate improvement in clinical populations (Morin, Belleville, Bélanger, & Ivers, 2011), with responses being validated in non-clinical samples as demonstrating a high internal reliability (α = 0.81 - 0.91 (Morin et al., 2011; Yu, 2010).

Job productivity - measured through the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH; (Reilly, Zbrozek, & Dukes, 1993). The WPAI:GH is a six item psychometric which focuses on: 'Absenteeism', 'Presenteeism', 'Work productivity loss' and 'Activity Impairment'. The WPAI:GH has shown strong psychometric properties with good internal consistency (a = 0.74), with a high intraclass correlation coefficient (r = 0.79 – 0.90) in clinical populations (Zhang et al., 2010). The WPAI has been used in non-clinical samples and has shown good face validity (Duke & Montag, 2017).

Job satisfaction - measured using the Indiana Job Satisfaction Scale (IJSS; Resnick & Bond, 2001). The IJSS is a 32-item psychometric coded on a four-point Likert response of "Strongly disagree" to "Strongly agree", and is comprised of six subscales: 'General Satisfaction', 'Pay', 'Advancement and Security', 'Supervision', 'Coworkers' and 'How I feel about this job'. The IJSS yields strong psychometric properties with high internal consistence (a = 0.90) and test-retest reliability (*r* = .75) (Resnick & Bond, 2001).

Well-being – we measure subjective well-being using the Warwick-Edinburgh Mental Health Well-being Scale (WEMWBS, Tennant et al., 2007). The WEMWBS consists of 14-items on a five-point likert scale ranging from "None of the time" to "All of the time". The scale has been shown to hold good psychometric properties, with strong internal consistency (α = 0.91) and was shown to hold high concurrent validity (Tennant et al., 2007). When applied to nonclinical samples the WEMWBS still shows similar psychometric properties with high internal consistency (α = 0.94; test-retest = 0.83; Dong et al., 2016).

Quality of life- measured using the EuroQOL EQ-5D-5L questionnaire (Herdman et al., 2011). The EQ-5D-5L consists of six items, five items measured through five-point likert-scale responses to mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, with a sixth item of a rating of health on a visual analogue scale ranging from 0-100. The EQ-5D-5L has shown high internal consistency in clinical samples (α = 0.86; (Bilbao et al., 2018) and in nonclinical populations (α = 0.84; Kim & Ko, 2018).

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A digital Cognitive Behavioural Therapy intervention in the workplace: Study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental wellbeing, engagement and productivity.

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Title: A digital Cognitive Behavioural Therapy intervention in the workplace: Study protocol for a feasibility randomised waitlist-controlled trial to improve employee mental wellbeing, engagement and productivity.

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Abstract (283 words)

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 eight-week digital cognitive behavioural therapy (dCBT) intervention for subthreshold to clinical depression and/or anxiety versus waitlist control (i.e. 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 the 1st July to 31st December 2021 for employees and self-employed workers with depression and anxiety symptoms (sub-clinical 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 (Aug-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: ISRCTN, ID: ISRCTN31161020. Registered on 08/06/2021.

Keywords: Depression, Anxiety, Feasibility, Workplace, dCBT, Online, Mental Health, Productivity

Strengths and limitations of this study

- REST is a novel self-guided, light touch, accessible and low cost intervention of dCBT for employees in the workplace.
- .
- randomization 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 randomization.
- The study will be underpowered to examine efficacy of the intervention, but may still inform a future full-scale RCT.

Introduction

In the United Kingdom (UK), poor mental health costs the economy an estimated £70 billion/year, equivalent to 4.5% of the UK's 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 to 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 NHS 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 dCBT, for example [13,14].

The World Health Organisation 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 PHQ-9 for depression, or 8 and above on the 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 digital-based CBT (dCBT) provides access to resources for self-learning or supervised treatment [19]. 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 standardized mean

difference of 0.12, demonstrating small significant effects [25]. A large randomised controlled trial 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 amongst sub-clinical and healthy workers [27].

The majority of studies to date have focused on clinical levels of depression and less so on individuals with sub-clinical symptoms. It has been suggested that populations with sub-threshold CMDs are greater in number than their clinical counterparts [28]. In addition, interventions for subclinical populations are deemed highly cost-effective [29]. Cases of CMDs have been further intensified over the COVID-19 pandemic with rates of generalised-anxiety disorder increasing from one in ten to one in four adults in the US populations [30,31]. 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 [32], 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 haven't pursued the traditional route of getting mental health support (e.g. approaching 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 [33] 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 multi-centre waitlist RCT 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 upon:

- 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 Patient Health Questionnaire-9 (PHQ-9) and the General Anxiety Disorder-7 (GAD-7) psychometrics as well as work productivity.

Methods and analysis

Study design

We implement a multi-centre, waitlist randomised controlled trial (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 eight-week period.

Participants will be screened for the presence of depressive and anxious symptoms. Upon 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 Fig. 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 program. 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 [34].

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 (e.g. GP, private clinic, Improving Access to Psychological Therapies (IAPT) 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 do not specify on working hours, or place of work
** We use the Insomnia Severity Index to differentiate REST from other trials being conducted at the same time with the INWORK programme. This criterion is used to ensure that REST can be differentiated and that there is no population overlap between the INWORK trials.

Components of the REST intervention

The REST intervention is an online self-guided programme structured into eight-weekly sessions with varying number of topics each week, lasting approximately 60 minutes each. The content incorporates techniques from Cognitive Behavioural Therapy (CBT) and Emotion Regulation [35] 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 can be shown below on Table 2.

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 (e.g. sleep, physical activity)**
Week 8	• **Programme summary** • **Relapse management** • **Self-compassion** • **Resilience**

Waitlist control

Participants initially allocated to the waitlist control group, will be asked to provide a baseline response to primary and secondary measures but will not receive any active treatment for the first eight weeks. After the eight-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 eight weeks. The waitlist control group serves two purposes. First, it provides an untreated comparison for the active dCBT group to determine if the treatment had an effect. Secondly 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 randomization) the impacts of exposure to the dCBT.

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 five days of non-response.

Primary outcomes

To examine the feasibility of our intervention under a multi-centre waitlist randomised controlled trial 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 waitlist control group)
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 firstly 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 (e.g. distribution of the outcome measures, skew, kurtosis, 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 Supplementary 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 supplementary 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 eight 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 randomised controlled trial.

We anticipate a nominal sample size of 60 participants based on Lewis et al recommendations for feasibility trials [36].

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 (e.g., Twitter, LinkedIn and Facebook) and print (e.g., 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 ISI. We will also ask participants to confirm they are older than 18, whether they have a diagnosis of a mental health condition, 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 [37] or the PHQ-9 [38] or 15 of above on the ISI [39], we will recommend these individuals to contact their GP and signpost to contact Improving Access to Psychological Therapies 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 block between two and eight, to minimise the risk of uneven groups. The randomisation is conducted using '*blockrand*' package [40]. 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 waitlist RCT, 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 be 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 (CONSORT) 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).

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	%	%	%	%	%	%

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

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	%	%	%	%	%	%

We will also conduct a chi-squared 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, we will also report the intra-cluster 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 Supplementary 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 the 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 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 (IJSS, WPAI:GH and the WEMWBS) and potential additional treatment. In this model, we also include as a covariate, the baseline values of the ISI, GAD7 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 a randomised-controlled trial.

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 videoconferencing 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 (i.e., what helped or prevented participants from implementing aspects of the programme). We map the qualitative codes to the COM-B model [41], 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 [42]. Themes will be generated using the to 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.

[Figure 1 here]

Assessment of safety

We anticipate a low risk of serious adverse events (such as death or hospitalisation.) occurring during this trial, given the low base rate of negative events in the literature for dCBT interventions [43]. We will record occurrences of serious adverse events (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 investigator. Adverse events are also a low risk during this trial, however expected adverse events: concentration difficulties and low mood.

To report a AE or SAE, forms will be sent to the trial management team (CB, 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 (ISRCTN31161020). 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 31st December 2021.

Authors' contributions

KP, TM, CT, CM, LW, and NT were involved in design and interpretation of the work. CT and TM led the treatment development. KP drafted the first version of the manuscript. KP, TM, CT, LW, SR, NT, GD and CM all were involved in revising for critical intellectual content, and shared agreement for accountability in all aspects of the work.

Competing interests

The authors disclose no competing interests.

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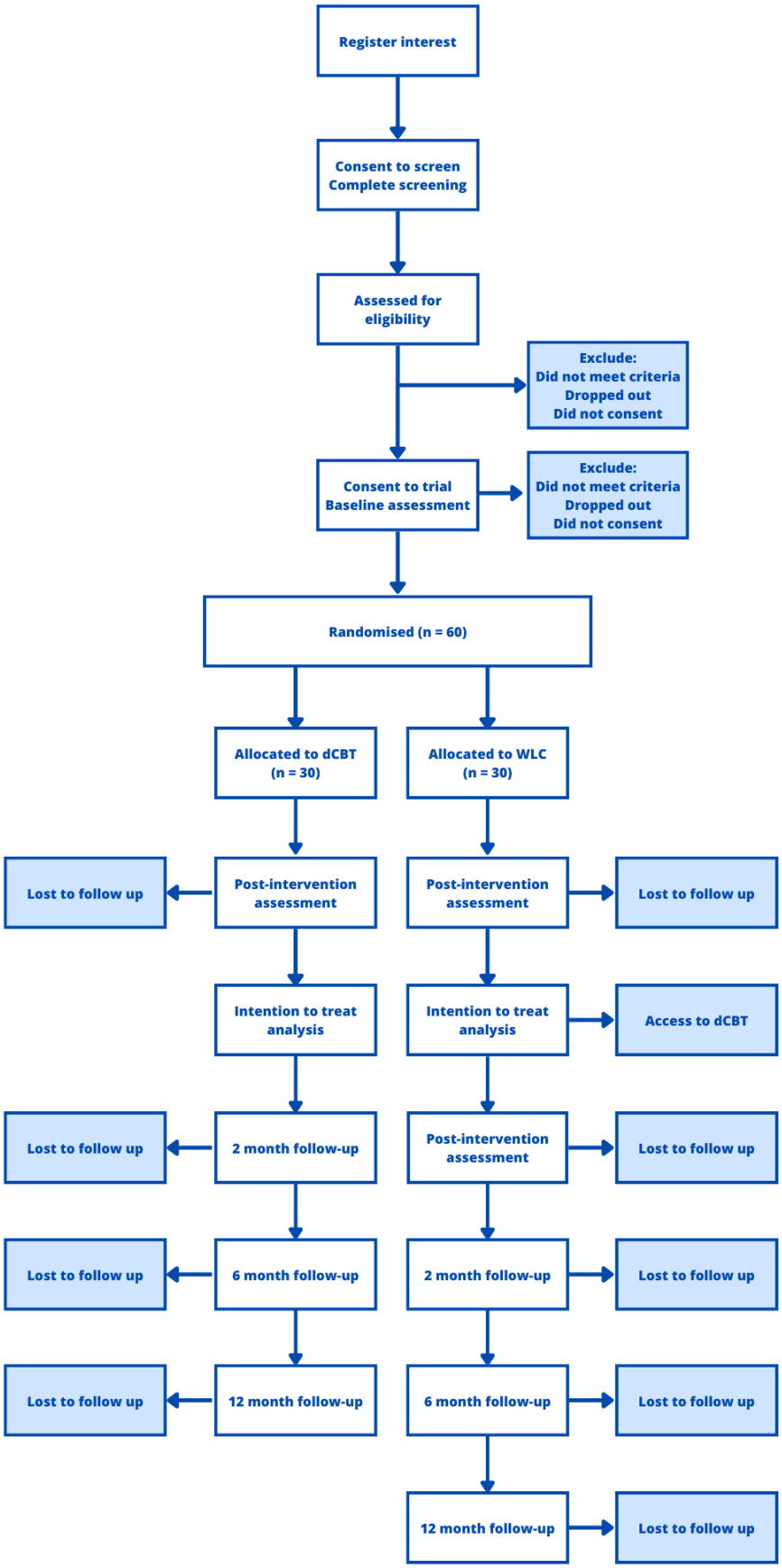
Figure Legends

Figure 1: Flow chart diagram showing a summary of the trial design for the REST study

Figure 1. Flow chart diagram showing summary of the trial design for the REST study



Supplementary Material

Appendix A- Screening questionnaires

Q1.2 I confirm that I have read and understand the information sheet for the above study (INWORK PIL v1.7_IV- 24.08.21). If you have not already done so, please see the information sheet sent via the link in the screening invitation email. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- Yes (1)
- No (2)

Q1.3 I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my employment being affected.

- Yes (1)
- No (2)

Q1.4 I understand that data collected during the study, may be looked at by individuals from the Universities of Warwick and Birmingham. I give permission for these individuals to have access to my data.

- Yes (1)
- No (2)

Q1.5 I understand that the screening phase of the above study is designed to assess my eligibility for the interventions being offered.

- Yes (1)
- No (2)

Q1.6 I understand that if I'm eligible for an intervention, I will be contacted again by the research team with further information on the specific intervention I may be eligible for and instructions on how to proceed.

- Yes (1)
- No (2)

Q1.7 Whether eligible or not for the INWORK study, would you like to be contacted by the research team with invitations for future studies?

- Yes (1)
- No (2)

Display This Question:
If Whether eligible or not for the INWORK study, would you like to be contacted by the research team... = Yes

Q1.8 I understand that my name and email address will be stored on the University of Warwick servers for 5 years.

- Yes (1)
- No (2)

End of Block: Consent

Start of Block: Description

Q2.1 Over the next series of questions we will assess your mood and sleep. Please answer the questions as accurately as possible and remember there are no correct answers.

You are free to withdraw at any time, should you wish to do so. If you have any issues completing the questionnaires, please contact the research team at

End of Block: Description

Start of Block: GAD-7

Q3.1 Over the last 2 weeks, how often have you been bothered by any of the following problems?

Q3.2 Feeling nervous, anxious or on edge?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.3 Not being able to stop or control worrying?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.4 Worrying too much about different things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.5 Trouble relaxing?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.6 Being so restless that it is hard to sit still?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.7 Becoming easily annoyed or irritable?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q3.8 Feeling afraid as if something awful might happen?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

End of Block: GAD-7

Start of Block: PHQ-9

Q4.1 Over the last two weeks, how often have you been bothered by any of the following problems?

Q4.2 Little interest or pleasure in doing things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.3 Feeling down, depressed, or hopeless?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.4 Trouble falling or staying asleep, or sleeping too much?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.5 Feeling tired or having little energy?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.6 Poor appetite or overeating?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.7 Feeling bad about yourself - or that you are a failure or have let yourself or your family down?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.8 Trouble concentrating on things, such as reading the newspaper or watching television?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.9 Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q4.10 Thoughts that you would be better off dead, or of hurting yourself in some way?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Display This Question:
If Thoughts that you would be better off dead, or of hurting yourself in some way? != Not at all

Q4.11 **Your safety:** We appreciate that you are willing to share your experiences and feelings with the research team. However, we cannot monitor in real time the information provided by you about your physical and mental health during this research. If you would like emotional support, or completing the survey has caused distress, we encourage you to reach out to someone you trust, or contact the research team on wmg-mhpp@warwick.ac.uk. Alternatively, if it is an emergency, and you need immediate help for yourself, call 999 straight away. For non-emergency physical and mental health support call 111 by or go to 111.nhs.uk.

End of Block: PHQ-9

Start of Block: ISI

Q5.1 For each question, please select the option that best describes your answer. Please rate the current (i.e. last 2 weeks) severity of your sleep problem(s).

Q5.2 Difficulty falling asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q5.3 Difficulty staying asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q5.4 Problems waking up too early

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q5.5 How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

- Very Satisfied (1)
- Satisfied (2)
- Moderately Satisfied (3)
- Dissatisfied (4)
- Very Dissatisfied (5)

Q5.6 How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

- Not at all Noticeable (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much (5)

Q5.7 How WORRIED/DISTRESSED are you about your current sleep problem?

- Not at all Worried (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Worried (5)

Q5.8 To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

- Not at all Interfering (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Interfering (5)

Q58
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End of Block: ISI

Start of Block: IAPT_GP

Q6.1
The responses you provided indicate that you might be having difficulties with your mental health.

This year has been really tough for many of us, especially when we are unable to do the usual things that bring us joy like seeing friends and family. Whilst you may still be eligible for the study, we strongly advise you to contact your GP or self-refer yourself to an NHS psychological therapies service (IAPT). To get in touch with IAPT please follow this link: https://www.nhs.uk/service-search/find-a-psychological-therapies-service/.

The intervention programme you may be offered in the study should not be used as an alternative for seeking diagnosis and treatment from a professional. You will subsequently be asked to consent to have read and take this advice into consideration. While you wait for an appointment, you can access expert advice and practical tips on the Every Mind Matters website. We have in addition put together resources below which you may find useful to look after your mental health. The Mind charity has

produced information on how to take care of your wellbeing during the pandemic including advice for coping in the winter which you might find helpful.

Mind Infoline: Call: 0300 123 3393
Email: info@mind.org.uk
Website: https://www.mind.org.uk/workplace/ Lines are open 9am to 6pm, Monday to Friday (except for bank holidays).

Samaritans
Call: 116 123
Email: jo@samaritans.org Website: https://www.samaritans.org/
For a listening ear or just someone to talk to the Samaritans are open 24 hours a day. If you need mental health information and the above helplines are closed then please visit Mind's Mental health A-Z resource or contact NHS 111.

NHS The NHS also has their own set of resources, this includes a website which provides access to other sources of information: https://www.england.nhs.uk/mental-health/resources/ If you have any questions or would like more information, please contact the research team at wmg-mhpp@warwick.ac.uk

Please confirm that you understand these requests. This does not impact your ability to take part in these studies in any way.

☐ I understand the request to contact my GP (4)

☐ I understand the request to contact IAPT (5)

End of Block: IAPT_GP

Start of Block: Block 7

Q60 Please confirm your employer and usual place of work.

If your employer is not shown, please select "My employer is not listed".
If you usual place is not shown, please select "My place of work is not listed".
Organisation (1)
Site (2)

End of Block: Block 7

Start of Block: Additional_requirements

Q7.1 Thank you for responding to the questionnaires about your mental wellbeing. We have only a few last questions to ask to help identify which study you may be eligible for out of REST, SLEEP or MENTOR

Q7.2 Are you over the age of 18?

- Yes (1)
- No (2)

Q7.3
Do you currently manage anyone?

- Yes (21)
- No (22)

Display This Question:
If Do you currently manage anyone? = Yes

Q7.4
Would you be happy to participate in the MENTOR trial if someone of your team was selected for MENTOR?

- Yes (21)
- No (22)

Q7.5 Do you have a current diagnosis of a mental health condition?

- Yes (1)
- No (2)

Display This Question:
If Do you have a current diagnosis of a mental health condition? = Yes

Q7.6 What is your mental health diagnosis?

_____

Q7.7 Are you currently under the care of a mental health care practitioner?

To clarify: are you currently receiving care through psychological treatment or through some form of medication?

This can include your GP as well as a consultant from NHS services.

- Yes (1)
- No (2)

Q7.8 Are you currently involved in any psychological intervention trials?

- Yes (1)
- No (2)

Display This Question:
If Do you have a current diagnosis of a mental health condition? = Yes

Q7.9 Are you currently receiving support from an Individual Placement and Support Worker?

- Yes (1)
- No (2)

Display This Question:
If Do you have a current diagnosis of a mental health condition? = Yes

Q7.10 Are you on extended sick leave (i.e. for more than 4 weeks) ?

- Yes (1)
- No (2)

Display This Question:
If Are you over the age of 18? = Yes
And Do you have a current diagnosis of a mental health condition? = Yes
And Are you currently under the care of a mental health care practitioner? To clarify: are you curren... = Yes

*

Q7.11 What is your line manager's email address?

_____

Display This Question:
If Are you over the age of 18? = Yes
And Do you have a current diagnosis of a mental health condition? = Yes
And Are you currently under the care of a mental health care practitioner? To clarify: are you curren... = Yes

Q7.12 Please confirm your line manager's email address

_____

REST_Questionnaire at each timepoint

Start of Block: Consent

Q1.2 I confirm that I have read and understand the information sheet (REST v1.7 7/07/21) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- Yes (1)
- No (2)

Q1.3 I confirm that I meet ALL the eligibility criteria of this study: English speaking; 18 years or above; Not retiring in the next 10 months; Currently not receiving treatment (psychological or medication) from mental health services; Currently not taking parting in other psychological intervention trials.

- Yes (1)
- No (2)

Q1.4 I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my employment being affected.

- Yes (1)
- No (2)

Q1.5 I understand that data collected during the study, may be looked at by individuals from University of Warwick. I give permission for these individuals to have access to my data.

- Yes (1)
- No (2)

Q1.6 Would you like to be contacted to participate in a qualitative interview to understand how we can improve the intervention further

- Yes (1)
- No (2)

Q1.7 I am happy for my anonymised data to be used in future research.

- Yes (1)
- No (2)

Q1.8 I agree to take part in the above study.

- Yes (1)
- No (2)

End of Block: Consent

Start of Block: Demographics

Q2.1 Thank you for consenting to take part in the REST trial. This study will last for 8 weeks during this time you will have access to an online e-learning platform. You will receive further information on how to access these in due course. For us to evaluate how well this intervention improves your sleep and wellbeing, we ask you next to complete a set of questionnaires. This will take approximately 45 minutes. Please read each question carefully before responding and feel free to take breaks where you need. If you do feel you need to take a break, please do not close the survey.
If you have any questions, please contact us at wmg-rest@warwick.ac.uk

Q2.2 How old are you?

	0 10 20 30 40 50 60 70 80 90 100
Age in years ()	

JS

Q2.3 What gender do you identify as?

- ○ Female (1)
- ○ Male (2)
- ○ Non-binary (3)
- ○ Other (please specify) (4) _____
- ○ Prefer not to specify (5)

Q2.4 What is your ethnicity? (1 of 2)

- ○ White... (1)
- ○ Mixed / Multiple ethnic groups... (2)
- ○ Asian or Asian British... (3)
- ○ Black or Black British... (4)
- ○ Mixed (5)
- ○ Hispanic/Latino (6)
- ○ Other (please specify) (7)

Display This Question:
If What is your ethnicity? (1 of 2) = White...

Q2.5 What is your ethnicity? (2 of 2)

- ○ English / Welsh / Scottish / Northern Irish / British (1)
- ○ Irish (2)
- ○ Gypsy or Irish Traveller (3)
- ○ Any other White background (please describe if you wish) (4)

_____

Display This Question:
If What is your ethnicity? (1 of 2) = Mixed

Q2.6 What is your ethnicity? (2 of 2)

- White and Black Caribbean (1)
- White and Black African (2)
- White and Asian (3)
- Any other Mixed / Multiple ethnic background (please describe if you wish) (4)

_____

Display This Question:
If What is your ethnicity? (1 of 2) = Asian or Asian British...

Q2.7 What is your ethnicity? (2 of 2)

- Indian (1)
- Pakistani (5)
- Bangladeshi (6)
- Chinese (7)
- Any other Asian background (please describe if you wish) (8)

_____

Display This Question:
If What is your ethnicity? (1 of 2) = Black or Black British...

Q2.8 What is your ethnicity? (2 of 2)

- African (1)
- Caribbean (4)
- Any other Black / African / Caribbean background (please describe if you wish) (5)

_____

Q2.9 How many hours do you work per week?

	0 5 10 15 20 25 30 35 40 45 50
Number of hours ()	

Q2.10 Information about income is very important to understand. Would you please give your best guess?Please indicate the answer that includes your entire household income in (previous year) before taxes.

- ○ £10,000 to £29,999 (1)
- ○ £30,000 to £49,999 (2)
- ○ £50,000 to £69,999 (3)
- ○ £70,000 to £89,999 (4)
- ○ £90,000 to £109,999 (5)
- ○ £110,000 to £149,999 (6)
- ○ £150,000 or more (7)

JS

Q2.11 How would you describe your current relationship status?

- ○ Single (1)
- ○ Cohabiting (2)
- ○ Married (3)
- ○ Separated (4)
- ○ Divorced (5)
- ○ Widowed (6)
- ○ Other (please specify) (7) _____

Q2.12 Who do you live with?

- I live by myself (1)
- I live with flatmates (2)
- I live with my partner (3)
- I live with my parents/carers (4)
- I live with other family members (6)

JS

Q2.13 What is your highest educational qualification?

- No formal qualification (1)
- Primary (2)
- Secondary (e.g., GCSE, O-levels, GNVQ) (3)
- Diploma (or professional qualification) (4)
- Bachelor's degree (5)
- Master's degree (6)
- Doctorate degree (7)
- Other (please specify) (8) _____

JS

Q2.14 In the last 8 weeks, to the best of your recollection, how much sick leave have you taken?

- I have taken (1) _____
- I have not taken any sick leave (2)
- I would prefer not to answer this question (3)

Q2.15 Are you currently using any self-help resources?

This includes but is not limited to self help books, apps and websites

- Yes (1)
- No (2)

Q2.16 Since completing the screening questionnaire of this study, did you start receiving treatment from mental health services?

- Yes (1)
- No (2)

End of Block: Demographics

Start of Block: Contact

Page Break

Q3.1 As part of this study we need to request some further personal information for us to contact you during this study.

JS

Q3.2 What is your phone number?

_____

End of Block: Contact

Start of Block: COVID_19

Q5.1 As part of our research, we are interested in your experiences with COVID-19 and how this has impacted your life. Please read each question carefully and select the most appropriate response for you.

Q5.2 How worried are you about contracting COVID-19?

- Not worried at all (1)
- Slightly worried (2)
- Moderately worried (3)
- Very worried (4)
- Extremely worried (5)

Q5.3 In which category are you considered to be in regard to COVID-19 according to the NHS and UK Government guidelines of England?

- Clinically extremely vulnerable (1)
- Clinically vulnerable (2)
- Low risk (3)

Q5.4 Since the start of the pandemic, have you tested positive for COVID-19?

- Yes (1)
- No (2)

Display This Question:
If Since the start of the pandemic, have you tested positive for COVID-19? = Yes

Q5.5 Have you required hospitalised treatment for COVID-19?

- Yes (1)
- No (2)

Display This Question:
If Since the start of the pandemic, have you tested positive for COVID-19? = No

Q5.6 Do you suspect that you may have had COVID-19 due to presenting with symptoms? (temperature/fever, new persistent cough, loss of smell & taste)

- Definitely (1)
- Probably (2)
- Unsure (3)
- No (4)

Display This Question:
If Since the start of the pandemic, have you tested positive for COVID-19? = Yes

Q5.7 For some people, coronavirus can cause symptoms that last weeks or months after the infection has gone. This is sometimes called post-COVID-19 syndrome or "long COVID". Have you

experienced any of the following long COVID symptoms 12 weeks after initial infection? (Check all that apply)

- ☐ No (I feel fully recovered) (1)
- ☐ Extreme tiredness (fatigue) (2)
- ☐ Shortness of breath (3)
- ☐ Chest pain or tightness (4)
- ☐ Problems with memory and concentration ("brain fog") (5)
- ☐ Difficulty sleeping (insomnia) (6)
- ☐ Heart palpitations (7)
- ☐ Dizziness (8)
- ☐ Pins and needles (9)
- ☐ Joint pain (10)
- ☐ Depression and anxiety (11)
- ☐ Tinnitus, earaches (12)
- ☐ Feeling sick, diarrhoea, stomach aches, loss of appetite (13)
- ☐ A high temperature, cough, headaches, sore throat, changes to sense of smell or taste (14)
- ☐ Rashes (15)

Q5.8 Since the start of the pandemic, have any people you know tested positive for COVID-19? (Choose all that apply)

- [ ] Immediate family members (1)
- [ ] Extended family members (2)
- [ ] Neighbours (3)
- [ ] Friends (4)
- [ ] Colleagues (5)
- [ ] No one I know has tested positive (6)

Q5.9 Since the start of the pandemic, have you been asked to stop working temporarily under the government "furlough" scheme?

- ○ No (1)
- ○ Yes, I am currently on furlough (2)
- ○ Yes, I will soon be on furlough (3)
- ○ Yes, but have since returned to work (full time or part time) (4)

Q5.10 As a result of colleagues being placed on furlough, do you think your workload will/has:

- ○ Increase (d) (1)
- ○ Decrease (d) (2)
- ○ Stay (ed) the same (3)
- ○ Can't say yet (4)
- ○ N/A, as no one I work with has been furloughed (5)
- ○ N/A, as I am currently been furloughed (6)

Page Break

Q5.11 In light of the COVID-19 pandemic, what changes had been made within your organisation that have impacted you? (Tick all that apply)

- ☐ Hours of work (1)
- ☐ Pay cut (2)
- ☐ Working remotely (3)
- ☐ Not applicable (4)

Display This Question:
If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

Q5.12 Have you experienced any ongoing challenges in working remotely? (Tick all that apply)

- ☐ Technical difficulties (e.g. with internet, computers, access to workplace data storage) (1)
- ☐ Practical difficulties (no separate/private area from which to work) (2)
- ☐ Balancing work with caregiving/parenting responsibilities (3)
- ☐ Motivational difficulties (4)
- ☐ Other (please specify) (5)
- ☐ No challenges experienced (6)

Display This Question:
If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

Q5.13 How comfortable do you feel returning back to work and having the appropriate support from your organisation? (e.g. Covid-19 risk assessment)?

- ○ Not comfortable at all (1)
- ○ Slightly comfortable (2)
- ○ Moderately comfortable (3)
- ○ Very comfortable (4)
- ○ Extremely comfortable (5)

Display This Question:
If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

Q5.14 How have these issues affected your ability to work?

- (Negative impact) -3 (1)
- -2 (2)
- -1 (3)
- 0 (4)
- 1 (5)
- 2 (6)
- (Positive Impact) 3 (7)

Q5.15 Have you experienced any of the following due to COVID-19? (Tick all that apply)
We understand this question may trigger distress and undesirable memories or thoughts. If so, please speak to a friend or family member or seek professional support (e.g. GP).

- ☐ Lost your job/unable to earn money (1)
- ☐ Another bill payer in your household lost their job or is/was unable to earn money (2)
- ☐ Unable to pay bills (3)
- ☐ Had difficulties accessing sufficient food (4)
- ☐ Evicted / lost accommodation (5)
- ☐ Had difficulties accessing required medication (6)
- ☐ Somebody close to you in hospital (7)
- ☐ Somebody close to you died (we are very sorry for your loss. We realise answering this question might make you uncomfortable or trigger unsettling feelings. If you feel you need to speak to someone or require support, please refer to this NHS resource) (8)
- ☐ Difficulties with family or social relationships (9)
- ☐ If you're a parent/carer, concerns about your child's/children's well-being and/or education (10)
- ☐ Having to change or delay major life plans or events (11)
- ☐ Not applicable (12)

Q5.16 How comfortable do you feel raising COVID-19 related issues with your organisation (e.g. line manager, human resources)?

- Not comfortable at all (1)
- Slightly comfortable (2)
- Moderately comfortable (3)
- Very comfortable (4)
- Extremely comfortable (5)

Q5.17 Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a research trial)

- Yes (1)
- No (2)

Display This Question:
If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Q5.19 Have you experienced any of the following symptoms as a result of having the vaccine? (Tick all that apply)

- [ ] Headaches (1)
- [ ] Feeling tired (2)
- [ ] Feeling achy (3)
- [ ] Soreness, redness and swelling at the site of the vaccination (4)
- [ ] Mild or high fever (5)
- [ ] Feeling or being sick (6)
- [ ] Allergic reaction (7)
- [ ] I did not have any symptoms (8)

Display This Question:
If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Q5.22 When did you receive your first dose? (please enter date as DD/MM/YYY)

_____

Display This Question:
If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Q5.23 Have you received a second dose of a COVID-19 vaccine?

- Yes (1)
- No (2)

Display This Question:
If Have you received a second dose of a COVID-19 vaccine? = Yes

Q5.24 When did you receive your second dose? (please enter date as DD/MM/YYY)

_____

Q5.25 What would you say is your one biggest concern or problem encountered, since the start of the pandemic?

_____
_____
_____
_____
_____

Page Break

Q5.26 Did you receive any help overcoming the concern/problem outlined above and if yes, what has been helpful or unhelpful? If no, what kind of help do you think you need right now?

_____
_____
_____
_____
_____

End of Block: COVID_19

Start of Block: WPAI_GH

Q6.1 The following questions ask about the effect of your health problems on your ability to work and perform regular activities. By health problems we mean any physical or emotional problem or symptom. Please fill in the blanks or indicate your response.

Q6.2 Are you currently employed (working for pay)?

- Yes (1)
- No (2)

Skip To: Q6.7 If Are you currently employed (working for pay)? = No

Q6.3 The next questions are about the **past seven days**, not including today.

Q6.4 During the past seven days, how many hours did you miss from work because of your health problems? Include hours you missed on sick days, times you went in late, left early, etc., because of your health problems. *Do not include time you missed to participate in this study.*

_____

Q6.5 During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

_____

Q6.6 During the past seven days, how many hours did you actually work?

_____

Q6.7 During the past seven days, how much did your health problems affect your productivity while you were working? *Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If health problems affected your work only a little, choose a low number. Choose a high number if health problems affected your work a great deal.* Consider only how much health problems affected productivity while you were working.

No effect on my work — Completely prevented me from working

0 1 2 3 4 5 6 7 8 9 10

1 ()	

Q6.8 During the past seven days, how much did your health problems affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal.

Consider only how much health problems affected your ability to do your regular daily activities, other than work at a job.

No effect on my daily activities — Completely prevented me from doing my daily activities

0 1 2 3 4 5 6 7 8 9 10

1 ()	

End of Block: WPAI_GH

Start of Block: IJSS

Q7.1 As part of our research, we are interested in the amount of job satisfaction with respect to your current role. This questionnaire is a valid and reliable measure of job satisfaction. Please read each statement carefully and tell us how much you agree with each statement.

There are no incorrect answers and none of the information you provide will be shared with your employer.

Q7.2 I feel good about this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.3 This job is worthwhile

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.4 The working conditions are good

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.5 I want to quit this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.6 This job is boring

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.7 I am happy with the amount this job pays

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.8 The vacation time and other benefits on this job are okay

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.9 I need more money than this job pays

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.10 This job does not provide the medical coverage I need

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)
- Not Applicable (5)

Q7.11 I have a fairly good chance for promotion in this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.12 This is a dead-end job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.13 I feel that there is a good chance of my losing this job in the future

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.14 My supervisor is fair

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.15 My supervisor is hard to please

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.16 My supervisor praises me when I do my job well

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.17 My supervisor is difficult to get along with

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.18 My supervisor recognizes my efforts

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.19 My coworkers are easy to get along with

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.20 My coworkers are lazy

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.21 My coworkers are unpleasant

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.22 My coworkers don't like me

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.23 My coworkers help me to like this job more

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.24 I have a coworker I can rely on

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.25 I have a coworker I consider a friend

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.26 I look forward to coming to work

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.27 I often feel tense on the job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.28 I don't know what's expected of me on this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.29 I feel physically worn out at the end of the day

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.30 Working makes me feel like I'm needed

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.31 My job keeps me busy

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.32 I get to do a lot of different things on my job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Q7.33 I am satisfied with my schedule

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

End of Block: IJSS

Start of Block: WEMWBS

Page Break

Q8.1 Below are some statements about feelings and thoughts.
Please select the option that best describes your experience of each over the last 2 weeks

Q8.2 I've been feeling optimistic about the future

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.3 I've been feeling useful

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.4 I've been feeling relaxed

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.5 I've been feeling interested in other people

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.6 I've had energy to spare

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.7 I've been dealing with problems well

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.8 I've been thinking clearly

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.9 I've been feeling good about myself

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.10 I've been feeling close to other people

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.11 I've been feeling confident

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.12 I've been able to make up my own mind about things

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.13 I've been feeling loved

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.14 I've been interested in new things

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

Q8.15 I've been feeling cheerful

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

End of Block: WEMWBS

Start of Block: Medication_checklist

Q9.1 We would like to know what medication (prescriptions and/or over the counter) you use, what dose and for what condition. Medications are tablets or capsules, but could also be (eye) drops, sprays, creams, drinks, inhaler puffs, suppositories etc. Prescription medications are ones that a doctor prescribes. Over the counter medication are ones that you can purchase yourself without a prescription such as ibuprofen, vitamins, herbal remedies etc.

	Name of medication (1)	Dosage (mg/g/ml) (2)	How often do you take this medication (per day / week/ as needed) (3)	How much do you take per time (e.g. 2 tablets) (4)	What is this medication for? (5)	How long have you been using it for? (6)	Additional comments (7)
1. (1)							
2. (2)							
3 (6)							
4 (7)							
5 (8)							
6 (9)							
7 (10)							

End of Block: Medication_checklist

Start of Block: ISI

Page Break

Q12.1 For each question, please select the option that best describes your answer. Please rate the current (i.e. last 2 weeks) severity of your sleep problem(s).

Q12.2 Difficulty falling asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q12.3 Difficulty staying asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q12.4 Problems waking up too early

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Q12.5 How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

- Very Satisfied (1)
- Satisfied (2)
- Moderately Satisfied (3)
- Dissatisfied (4)
- Very Dissatisfied (5)

Q12.6 How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

- Not at all Noticeable (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much (5)

Q12.7 How WORRIED/DISTRESSED are you about your current sleep problem?

- Not at all Worried (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Worried (5)

Q12.8 To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

- Not at all Interfering (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much Interfering (5)

Q12.9
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End of Block: ISI

Start of Block: GAD7

Page Break

Q10.1 Over the next series of questions we will assess your mood and sleep. Please answer the questions as accurately as possible and remember there are no correct answers.

Q10.2 Over the last 2 weeks, how often have you been bothered by any of the following problems?

Q10.3 Feeling nervous, anxious or on edge?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.4 Not being able to stop or control worrying?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.5 Worrying too much about different things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.6 Trouble relaxing?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.7 Being so restless that it is hard to sit still?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.8 Becoming easily annoyed or irritable?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q10.9 Feeling afraid as if something awful might happen?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

End of Block: GAD7

Start of Block: PHQ9

Page Break

Q11.1 Over the last two weeks, how often have you been bothered by any of the following problems?

Q11.2 Little interest or pleasure in doing things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.3 Feeling down, depressed, or hopeless?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.4 Trouble falling or staying asleep, or sleeping too much?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.5 Feeling tired or having little energy?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.6 Poor appetite or overeating?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.7 Feeling bad about yourself - or that you are a failure or have let yourself or your family down?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.8 Trouble concentrating on things, such as reading the newspaper or watching television?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.9 Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Q11.10 Thoughts that you would be better off dead, or of hurting yourself in some way?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

End of Block: PHQ9

Start of Block: disclaimer

Q13.1 The responses you provided indicate that you might be having difficulties with your mental health. This year has been really tough for many of us, especially when we are unable to do the usual things that bring us joy like seeing friends and family. We strongly advise you to contact your GP or self-refer yourself to an NHS psychological therapies service (IAPT). To get in touch with IAPT please follow this link: https://www.nhs.uk/service-search/find-a-psychological-therapies-service/. The intervention programme should not be used as an alternative for seeking diagnosis and treatment from a professional. While you wait for an appointment, you can access expert advice and practical tips on the Every Mind Matters website. We have in addition put together resources below which you may find useful to look after your mental health. The Mind charity has produced information on how to take care of your wellbeing during the pandemic including advice for coping in the winter which you might find helpful. Mind Infoline: Call: 0300 123 3393
Email: info@mind.org.uk
Website: https://www.mind.org.uk/workplace/ Lines are open 9am to 6pm, Monday to Friday (except for bank holidays). Samaritans
Call: 116 123
Email: jo@samaritans.org Website: https://www.samaritans.org/
For a listening ear or just someone to talk to the Samaritans are open 24 hours a day. If you need mental health information and the above helplines are closed then please visit Mind's Mental health A-Z resource or contact NHS 111. NHS The NHS also has their own set of resources, this includes a website which provides access to other sources of information: https://www.england.nhs.uk/mental-health/resources/ If you have any questions or would like more information, please contact the research team at wmg-rest@warwick.ac.uk

Please confirm that you understand these requests. This does not impact your ability to take part in these studies in any way.

☐ I understand the request to contact my GP (4)

☐ I understand the request to contact IAPT (5)

End of Block: disclaimer

Appendix B- Outcome measures

The following psychometric will be used to explore their utility as outcome measures for a future fully powered randomised-controlled trial.

The General Anxiety Disorder-7 (GAD-7) is commonly used in primary and secondary mental health settings to measure symptom severity for General Anxiety Disorder (Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is comprised on seven items each scored on a four-point Likert scale, a score of 10 has been shown to correctly diagnose cases of generalised anxiety disorder with 89% sensitivity and 82% specificity, with high test-retest reliability (ICC = 0.83). The GAD-7 also shows high concurrent validity with high scores being associated with disability and functional impairment (Ruiz et al., 2011; Spitzer et al., 2006).

The Patient Health Questionnaire-9 (PHQ-9) is commonly used, in primary care settings to assess the severity of depression across the nine DSM-IV criteria for major depressive disorder on a four-point Likert scale (Cameron, Crawford, Lawton, & Reid, 2008). The PHQ-9 has been shown to demonstrate high diagnostic accuracy in at risk populations (Haddad et al., 2013; Janneke et al., 2012), and in clinical populations. A criterion score of ≥10 has a 88% sensitivity and specificity for major depressive disorder (Kroenke, Spitzer, & Williams, 2001). Empirical research demonstrates high internal consistency (α = 0.91; Hansson, Chotai, Nordstöm, & Bodlund, 2009) and a valid latent

structure even when administered in nonclinical samples (CFI = 0.914- 0.983; Ito, Takebayashi, Muramatsu, & Horikoshi, 2018).

The Insomnia Severity Index (ISI) is a seven-item psychometric which has been validated with reference to the diagnostic criteria for primary insomnia in the DSM-IV. The ISI uses a five-point Likert scale response to each item (score range 0–28). A score of ≥15 identifies cases of clinical insomnia with 94% sensitivity and specificity (Bastien, Vallières, & Morin, 2001). A reduction of 8.4 has been shown to be associated with moderate improvement in clinical populations (Morin, Belleville, Bélanger, & Ivers, 2011), with responses being validated in non-clinical samples as demonstrating a high internal reliability (α = 0.81 - 0.91 (Morin et al., 2011; Yu, 2010).

Job productivity - measured through the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH; (Reilly, Zbrozek, & Dukes, 1993). The WPAI:GH is a six item psychometric which focuses on: 'Absenteeism', 'Presenteeism', 'Work productivity loss' and 'Activity Impairment'. The WPAI:GH has shown strong psychometric properties with good internal consistency (a = 0.74), with a high intraclass correlation coefficient (r = 0.79 – 0.90) in clinical populations (Zhang et al., 2010). The WPAI has been used in non-clinical samples and has shown good face validity (Duke & Montag, 2017).

Job satisfaction - measured using the Indiana Job Satisfaction Scale (IJSS; Resnick & Bond, 2001). The IJSS is a 32-item psychometric coded on a four-point Likert response of "Strongly disagree" to "Strongly agree", and is comprised of six subscales: 'General Satisfaction', 'Pay', 'Advancement and Security', 'Supervision', 'Coworkers' and 'How I feel about this job'. The IJSS yields strong psychometric properties with high internal consistence (a = 0.90) and test-retest reliability (*r* = .75) (Resnick & Bond, 2001).

Well-being – we measure subjective well-being using the Warwick-Edinburgh Mental Health Well-being Scale (WEMWBS, Tennant et al., 2007). The WEMWBS consists of 14-items on a five-point likert scale ranging from "None of the time" to "All of the time". The scale has been shown to hold good psychometric properties, with strong internal consistency (α = 0.91) and was shown to hold high concurrent validity (Tennant et al., 2007). When applied to nonclinical samples the WEMWBS still shows similar psychometric properties with high internal consistency (α = 0.94; test-retest = 0.83; Dong et al., 2016).

Quality of life- measured using the EuroQOL EQ-5D-5L questionnaire (Herdman et al., 2011). The EQ-5D-5L consists of six items, five items measured through five-point likert-scale responses to mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, with a sixth item of a rating of health on a visual analogue scale ranging from 0-100. The EQ-5D-5L has shown high internal consistency in clinical samples (α = 0.86; (Bilbao et al., 2018) and in nonclinical populations (α = 0.84; Kim & Ko, 2018).