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Reducing stress in the workplace using a digital intervention designed to improve employee wellbeing and help them stay engaged and productive in work

Submission date
13/05/2021

Recruitment status
No longer recruiting

Registration date
08/06/2021

Overall study status
Completed

Last Edited
26/05/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Mental health problems affect one in six workers each year and are the leading cause of sickness absence, where stress, anxiety and depression are responsible for approximately half of the working days lost. The estimated annual cost of poor mental health has increased 16% since 2017, and is now up to £45 billion. It is estimated that approximately 41.8% of the UK population are at high risk of mental health problems due to their economic vulnerability and exposure to a negative economic shock as a result of the COVID-19 outbreak.
This project, funded by the Midlands Engine, comprises the initial pilot study of an intervention to improve workforce mental health and productivity as part of the Mental Health and Productivity Pilot program (https://mhpp.me/). REST is a digital intervention informed by cognitive behavioural therapy that aims to improve stress, depression and anxiety symptoms and productivity across the Midlands.

The aim of this study is to investigate how practical and feasible a multisite waitlist randomised trial would be in the Midlands to examines whether an iCBT treatment for mild to clinical levels of depression and anxiety reduces symptom severity for employees in the workplace. The study also aims to explore the feasibility of the methodological approach, focusing particularly upon:
1. The willingness of organisations to participate in a trial
2. The willingness of employees to participate in a trial
3. The adherence of participants to the treatment as measured through platform user data
4. Appropriateness of the analytical approach
5. Acceptability of the intervention based on participants experiences

The results of this study will be used to inform a future, fully powered RCT which will be undertaken to understand whether an iCBT treatment can help to reduce symptom severity and improve mental health for employees in the workplace. This trial therefore has a twofold contribution to the literature: it serves as an early indication of the potential benefits of iCBT in the workplace, and it provides evidence of the feasibility of this type of in-business trial in the

Midlands and nationally for mental health and productivity. Such trials can inform improvements in employer mental health policies and practices, benefitting both the organisations and their employees.

Who can participate?
Adults over 18 years, currently in employment, who suffer from insomnia and anxiety but are not currently receiving treatment.

What does the study involve?
REST will last for 8 weeks using a randomised waitlist-controlled trial design, where the control group will receive the intervention after eight weeks.
Those in the REST intervention will be offered an 8-week self-guided, digital intervention. The intervention will consist of an hour weekly commitment. Those in the waitlist control group will be asked to continue life as usual for 8-week (i.e. they will not receive the 8-week digital intervention or provided with any other treatment). Subsequently, participants will be offered the 8-week digital intervention. Participants will then be contacted after two months to complete the follow-up questionnaires.
Overall, the REST trial will last for 4 months, if participants are initially placed in the intervention group (8 weeks in intervention arm + follow up after 2 months). If a participant is initially placed in the waitlist control group, they will be offered the intervention after an 8-week delay, and be in the study for 6 months (8 weeks in waitlist control arm + 8 weeks in intervention arm + follow up after 2 months)
Upon completion of the 8-week study period, a qualitative evaluation will be conducted of the 8-week intervention programme using semi-structured interviews, aiming to explore effectiveness, acceptability, barriers, and facilitators of the intervention. This will be completed with a randomly selected 25 participants, who have completed the intervention, and consented to be contacted again for the qualitative part of the study.

What are the possible benefits and risks of participating?
We do not anticipate any major disadvantages, side effects or risks in taking part in this study. The PHQ-9 questionnaire of the study asks about self-harming and suicidal behaviour (item 9), which would require participants to disclose sensitive information. In addition, scores between 15-28 on the ISI, and scores between 15-27 on the PHQ-9 and GAD-7 questionnaires may indicate clinically significant conditions. This could highlight an undiagnosed severe mental-health condition for which the participant is not receiving care.

Where is the study run from?
University of Warwick (UK)

When is the study starting and how long is it expected to run for?
January 2021 to April 2022

Who is funding the study?
Midlands Engine (UK)

Who is the main contact?
Charlotte Kershaw, Charlotte.Kershaw@warwick.ac.uk
Dr Carla Toro, Carla.Toro@warwick.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Charlotte Kershaw

Contact details
University of Warwick
Coventry
United Kingdom
CV4 7AL
-
Charlotte.Kershaw@warwick.ac.uk

Type(s)
Scientific

Contact name
Dr Carla Toro

Contact details
University of Warwick
Coventry
United Kingdom
CV4 7AL
-
Carla.Toro@warwick.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BSREC 45/20-21

Study information

Scientific Title
REducing STress in the workplace

Acronym
REST

Study objectives
Current study hypothesis as of 29/10/2021:
A future, fully powered multisite waitlist-controlled RCT will enable us to assess the effect of

the REST intervention on anxiety and depression scores on the General Anxiety Disorder-7 (GAD-7) and Patient Health Questionnaire-9 (PHQ-9).

Previous study hypothesis:
The REST intervention will reduce anxiety and depression scores on the General Anxiety Disorder-7 (GAD-7) and Patient Health Questionnaire-9 (PHQ-9) respectively compared to those initially assigned to the waitlist control group at 8 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, Biomedical Sciences Research Ethics Committee (University of Warwick, Coventry, CV4 7AL, UK; +44 (0)24 765 73123; BSREC@warwick.ac.uk), ref: BSREC 45/20-21

Study design
Multicentre interventional waitlist randomized-controlled feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention and treatment of anxiety and depression in employees from across the Midlands region in the United Kingdom.

Interventions
Participants are randomly allocated through blocked randomised with stratification into the REST intervention or a waitlist control. We stratify across different employer sites in the Midlands to ensure weighting approximate to staff size and representative of the larger population.

Those in the REST intervention will be offered an 8-week self-guided, digital intervention. The intervention will consist of an hour weekly commitment. Content for the self-guided intervention will be digitised and presented via an online platform, with each component being tailored to maximise relevance of the treatment as a workplace intervention and generalisability of the treatment across industries.

The core components of the REST intervention will include:
1. Psychoeducation on stress, depression and anxiety
2. Emotion regulation skills training (non-judgmental awareness, acceptance and tolerance, effective self-support, analysis and modification)
3. Problem solving skills training and goal setting
4. Managing negative thoughts and cognitive restructuring
5. Mental health in times of COVID-19 (e.g. work life balance, psychological detachment from work when working from home)
6. Healthy lifestyle (e.g. physical activity, relaxation and mindfulness, eating habits and sleep)
7. Self-compassion and resiliency

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 28/10/2021:
1. Number of organisations contacted and participating in the trial measured using recruitment and participation data collected during the recruitment process and throughout the trial
2. Number of employees registering interest, screening for, and participating in the trial measured using recruitment and participation data collected during the recruitment process and throughout the trial
3. Number of topics covered by each participant on platform measured using usage data collected by the platform over the 8 week intervention period
4. Average duration to cover each topic by each participant measured using usage data collected by the platform over the 8 week intervention period

Previous primary outcome measure:
1. Anxiety is measured using the General Anxiety Disorder-7 at baseline, post-intervention (8-weeks) and follow-up (12-weeks)
2. Depression is measured using the Patient Health Questionnaire-9 at baseline, post-intervention (8-weeks) and follow-up (12-weeks)

Key secondary outcome(s))
Current secondary outcome measures as of 28/10/2021:
1. Anxiety is measured using the General Anxiety Disorder-7 at baseline, post-intervention (8-weeks) and follow-up (12-weeks)
2. Depression is measured using the Patient Health Questionnaire-9 at baseline, post-intervention (8-weeks) and follow-up (12-weeks)
3. Job productivity measured through Work Productivity and Activity Impairment: General Health v2.0 at baseline, post-intervention (8-weeks) and follow up (12-weeks)
4. Job satisfaction measured using the Indiana Job Satisfaction Scale at baseline, post-intervention (8-weeks) and follow up (12-weeks)
5. Well-being measured using the Warwick-Edinburgh Mental Health Well-being Scale at baseline, post-intervention (8-weeks) and follow up (12-weeks)
6. Quality of life measured using the EuroQOL EQ-5D-5L questionnaire at baseline, post-intervention (8-weeks) and follow up (12-weeks)

Previous secondary outcome measures:
1. Job productivity measured through Work Productivity and Activity Impairment: General Health v2.0 at baseline, post-intervention (8-weeks) and follow up (12-weeks)
2. Job satisfaction measured using the Indiana Job Satisfaction Scale at baseline, post-intervention (8-weeks) and follow up (12-weeks)
3. Well-being measured using the Warwick-Edinburgh Mental Health Well-being Scale at baseline, post-intervention (8-weeks) and follow up (12-weeks)
4. Quality of life measured using the EuroQOL EQ-5D-5L questionnaire at baseline, post-intervention (8-weeks) and follow up (12-weeks)
5. User Experience behaviour of platform usage measured using the number of “log-in”-s and “counts” of activities completed on the platform over the 8 weeks intervention period

Completion date
01/04/2022

Eligibility

Key inclusion criteria
1. Able to give informed consent
2. English-speaking
3. In employment (including being on furlough)
4. Insomnia Severity Index score <8
5. General Anxiety Disorder-7 score >5 or Patient Health Questionnaire-9 score >5
6. ≥18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
53

Key exclusion criteria
1. 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)
2. Retiring in the next 10 months
3. Currently taking part in other psychological intervention trials

Date of first enrolment
11/06/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
New Cross Hospital
Royal Wolverhampton NHS Trust
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
ICFC
King stadium
Filbert way
Leicester
United Kingdom
LE2 7FL

Study participating centre
Conference Care
Hinckley
Leicestershire
United Kingdom
LE10 3EY

Study participating centre
Pathfinder schools
Havelock Infant School
Desborough
Northamptonshire
United Kingdom
NN14 2LU

Study participating centre
Birmingham City council
Birmingham
United Kingdom
B1 1BB

Study participating centre
Noble Events
Leicestershire
United Kingdom
LE7 4UZ

Study participating centre
The University of Warwick
University Road
Coventry
United Kingdom
CV4 7AL

Study participating centre
JLR
Banbury Road
Abbey road
Whitley
Coventry
United Kingdom
CV4 7AL

Study participating centre
CCM Group
Nunn Brook road
Huthwaite
United Kingdom
NG17 2HU

Study participating centre
Mice and Dice
Newcastle-under-Lyme
Newcastle
United Kingdom
ST5 2RP

Study participating centre
NTT
Darwin House
Lichfield South
Birmingham Road
Lichfield
United Kingdom
WS14 0QP

Study participating centre
H&W Chamber of commerce
Severn House
Prescott Drive
Worcester
United Kingdom
WR4 9NE

Study participating centre
Micronclean
Skegness Roman Bank
Skegness
United Kingdom
PE25 1SQ

Study participating centre
WJ
North 7
Brock way
Newcastle under Lyme
United Kingdom
ST5 6AZ

Study participating centre
Colas Rail
Plant Depot
Mill Road
Rugby
United Kingdom
CV21 1BE

Study participating centre
Perfect Home
Eagle Court 2
Hatchford Way
Sheldon
Birmingham
United Kingdom
B26 3RZ

Study participating centre
Streets Heaver
Lincoln
United Kingdom
LN6 3QN

Study participating centre
Capgemini UK
Stafford Park 11
Telford
United Kingdom
TF3 3AY

Study participating centre
D2N2 Ltd
8 Experian Way
ng2 Business Park
Nottingham
United Kingdom
NG2 1EP

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Midlands Engine

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository, the Open Science Framework (OSF) (https://osf.io/v8c5j/).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/12/2022	06/01/2023	Yes	No
Basic results			26/05/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		14/10/2022	03/11/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes