

Participant Information Leaflet

Study Title: REST: REducing STress in the workplace

Investigator(s): Krishane Patel (University of Warwick), Talar Moukhtarian (University of Warwick), Carla Toro (University of Warwick), Laura Chandler (University of Warwick), Nicole Tang (University of Warwick), Feroz Jadhakhan (University of Birmingham), Arianna Prudenzi (University of Birmingham), Steven Marwaha (University of Birmingham), Lukasz Walasek (University of Warwick), Caroline Meyer (University of Warwick)

Introduction

You are invited to take part in a research study. Before you decide if you want to take part, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information (wmg-mhpp@warwick.ac.uk). Take the time to decide whether or not you wish to take part.

Who is organising and funding the study?

This project is funded by the Midlands Engine partnership which brings together public sector partners and businesses to generate added value for the whole of the Midlands, its communities and the wider UK. The design, implementation and management of this study is being conducted by the University of Warwick and the University of Birmingham. This study is sponsored by the University of Warwick.

What is the study about?

The REST study aims to test the efficacy of a digital intervention designed to improve employee wellbeing to say engaged and productive in work. 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 (Deloitte, 2020). This study will assess the efficacy of a digital intervention, that is based on cognitive behavioural therapy (CBT) and emotion regulation skills to improve problems with stress. CBT is a type of talking treatment, that combines cognitive therapy (examining the things you think) and behaviour therapy (examining the things you do) and focuses on how your thoughts, beliefs and attitudes affect your feelings and behaviour, and teaches you skills for dealing with different problems. For further information on CBT, you can refer to the NHS¹ and MIND² websites.

Why have I been chosen for this trial?

You registered your interest to take part in one of the pilot trials and completed screening questionnaires to check your eligibility against the study inclusion criteria. Based the responses you provided, we are inviting you to take part in the REST intervention of the Mental Health and Productivity Pilot (<https://mhpp.me/>).

What would taking part involve?

Participation in this study is voluntary and you can withdraw your involvement at any time. If you agree to take part in the REST trial, please follow the link provided at the end of this form to consent to take part in the trial and complete the baseline measures of the study, which consists of a set of questionnaires on well-being, workplace productivity, job satisfaction, and health-related quality of life. In addition, you will be asked to provide some demographic information (i.e. workplace address, gender identity, age, ethnicity, working hours, income band, education level, relationship status, number in household, number of absent days from work, what medications- prescription and over-the-counter you use) to understand the characteristics of our target sample and use that information to guide future larger-scale studies. At 8 weeks, you will be asked to complete the same questionnaire measures again. All questionnaire measures will be self-completed on an online platform called Qualtrics accessed through links sent to you by email.

You will then be randomly placed into either the REST intervention group or a waitlist control group.

During the REST intervention you will be asked to be complete approximately one hour per week of online activity on the REST platform. This may involve training, reading through educational materials as well as completing exercises. The content of the intervention is entirely new and has not been tested

¹ <https://www.nhs.uk/conditions/cognitive-behavioural-therapy-cbt/>

² <https://www.mind.org.uk/information-support/drugs-and-treatments/cognitive-behavioural-therapy-cbt/about-cbt/>

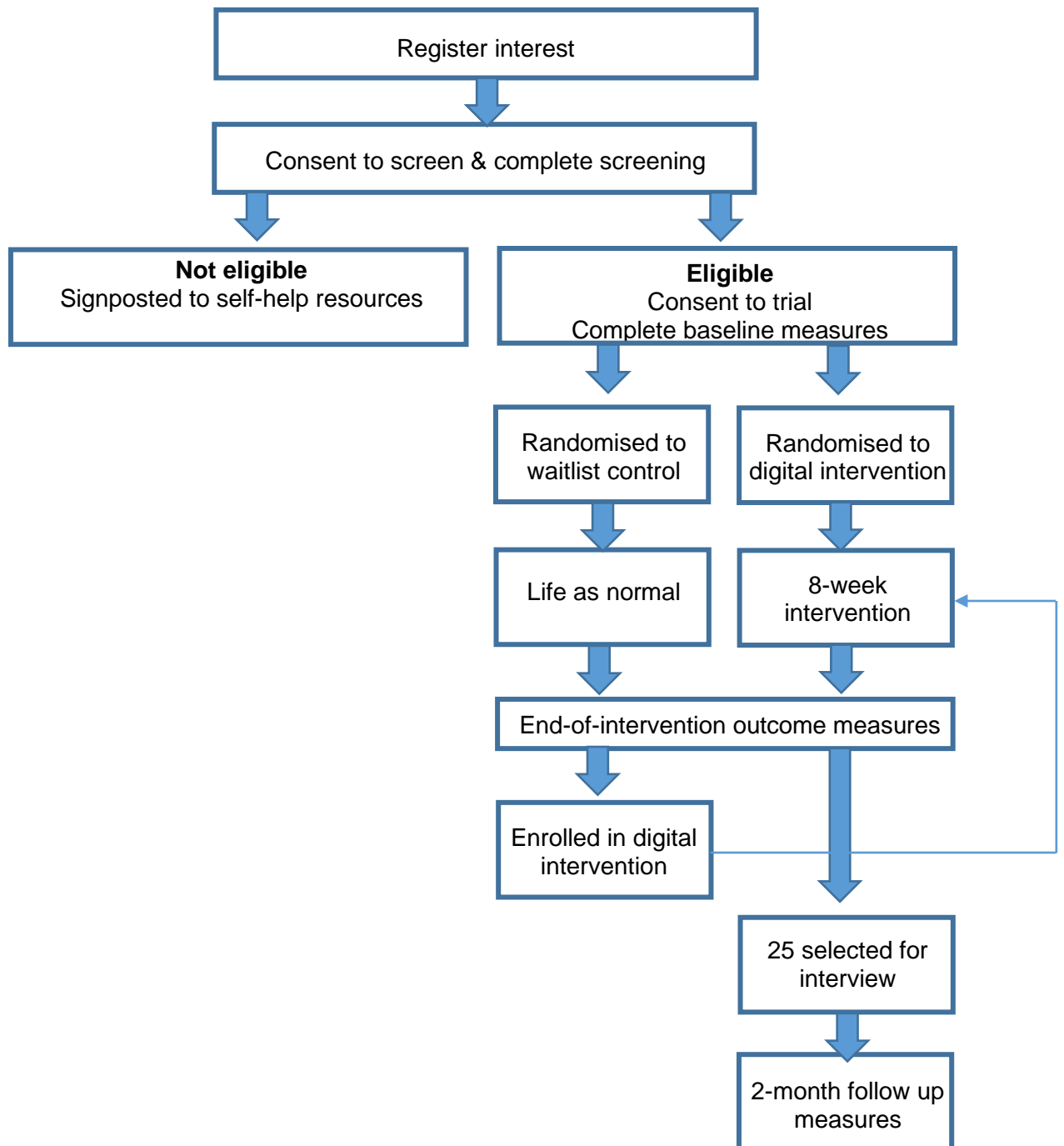
before. The content has been designed and generated based on empirical research.

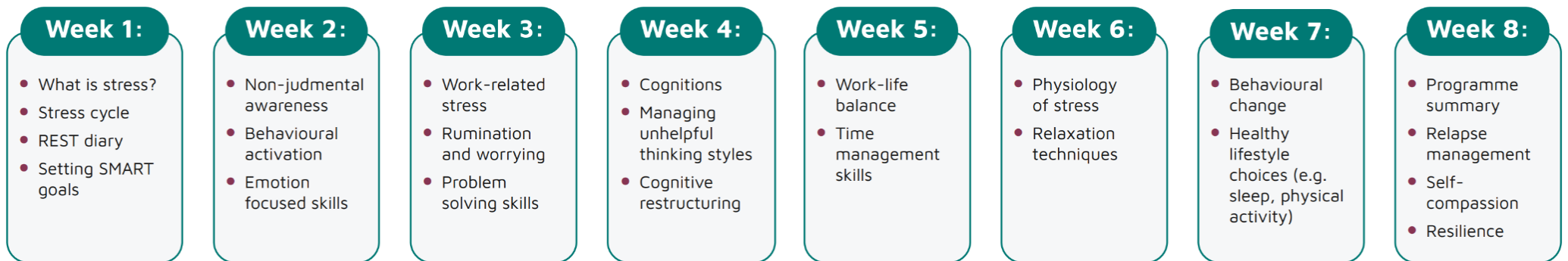
At the end of the digital intervention, we may ask you to take part in a qualitative feedback interview (if you consent to be interviewed) aiming to explore the effectiveness, acceptability, barriers, and facilitators of the intervention to inform future trials for subsequent evaluations. Interviews will be conducted online on Microsoft Teams or via telephone (participant's choice) by members of the research team, and audio-recorded using University of Warwick managed digital recording devices and then subsequently transcribed by a third-party University approved transcription company. A confidentiality agreement will be in place for the transcription process to ensure confidentiality and anonymity.

You will be contacted again after 2 months to complete the same questionnaire measures you completed at the start of the trial and at 8 weeks.

Overall, the study will last for 4 months, if you are initially placed in the intervention group (8-weeks in intervention arm + 2 months follow-up). If you are initially placed in the waitlist control group, you 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 + 2 months follow up). You will continue to have access to the digital platform until January 2022.

For more information please see the study flow chart on the next page.





Do I have to take part?

Participation in this study is completely voluntary. You can also choose to withdraw your participation at any time, without giving a reason by contacting the research team at wmg-mhpp@warwick.ac.uk. Further details about withdrawing from the study are provided at the end of this page.

What are the possible benefits of taking part in this study?

In this trial, we expect our digital intervention to reduce stress, and improve overall wellbeing to maintain and improve engagement and productivity at work. This will help businesses to get back on their feet in the current COVID-19 climate, helping businesses in the Midlands become more productive.

What are the possible disadvantages, side effects or risks, of taking part in this study?

We do not anticipate any major disadvantages, side effects or risks in taking part. Some participants will be randomly placed on the waitlist control group, in which case, the intervention will still be provided to them, but after a delay. You will be offered different channels to communicate with our research team and will be encouraged to report any unwanted/unexpected effects (attributable or not to the treatment offered) to the research team as soon as they emerge.

The process evaluation interview at the end of the intervention, which aims to explore the effectiveness, acceptability, barriers, and facilitators of the intervention might cause distress to some individuals. Should that occur, we will offer to pause and/or stop the interview and offer you appropriate support. Due to the minimal direct contact the research team will have with participants, we advise and encourage you to report any event that you think may or may not be related to your being part of the study to the research team by email (wmg-mhpp@warwick.ac.uk).

Expenses and payments

For each of the three assessment waves (i.e. upon completion of baseline questionnaires, after intervention at 8 weeks, and at 2-months follow-up), you will be entered into a prize draw for a £100 Amazon voucher as a gesture of good-will for your time and commitment to the study. Of those who have completed the intervention and have agreed to take part in the qualitative interview, we will randomly select 25 participants- those who complete the interview will also receive an additional £10 Amazon voucher.

Will my taking part be kept confidential?

Your data will be kept confidential throughout the study. Research data will be de-identified as quickly as possible after data collection. Your study data will instead be associated with a unique participant ID number to complete all assessments and interventions. The key to identification will be stored separately and securely to the research data to safeguard your identity and access will be limited to the lead researcher (CT) and the project manager (CK), neither of whom will have any access to the study data. We are collecting your phone number to contact you during the course of the study. At the end of the intervention, you may be invited to take part in qualitative interviews (if you consent). The interviews will be audio recorded using University of Warwick managed digital recording devices for transcriptions, from which direct quotes may be included in the publication, however, these will not reveal any information that could identify enrolled employees (e.g. name). Personally identifiable data (e.g. name, email) collected in this study will be stored in password protected folders, kept separate from the study data; all of which will be stored securely on the University of Warwick servers.

Your participation and individual data collected from the study will not be shared with your employer, nor are you under obligation to report your participation to your employer. It will also not be possible to identify you or infer your employment within an organisation from publications stemming from this study. Your employer is under no obligation to support you in taking part in this trial. We would like you to note that any resource request may identify you and therefore renders your participation not to be fully anonymous.

Participating businesses will only receive a summary report which will not include any identifiable information about enrolled employees. Additionally, no identifiable information (e.g., name) will be used for analysis or in publications emerging from this study.

What will happen to the data collected about me?

We will be using information from you in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation.

We will examine individual usage of the digital intervention platform, this will include the number of log-ins, the frequency with which you use hyperlinks, how often you download any resources, submit assignments and any other additional requirements. The anonymous intervention adherence data will be downloaded from the platform and transferred to a password protected folder:/ on the University of Warwick servers.

The process evaluation interviews (conducted on a selected 25 participants only) will be done through a telephone or video interview through Microsoft Teams, and the interviews will be audio recorded using University of Warwick managed digital recorders. The audio data will be transcribed then immediately deleted. The transcriptions will be kept on the University of Warwick servers in a password protected folder, with all personal identifiable information removed and pseudonyms used to protect participants' identity.

Study and personal data: Questionnaire data will be deleted from the Qualtrics platform, five days after being transferred to the University of Warwick servers. We will also delete personal data from the University of Warwick servers immediately after the trial is completed (anticipated date: 12/2021), with the exception of consent forms, and contact details of any participants who consent to be contacted for future related research. The pseudo-anonymised study data will be deleted after 10 years from the University of Warwick servers.

Anonymised study data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

The anonymous data may be shared with the University of Birmingham for analysis purposes. Researchers from the University of Birmingham may conduct the process evaluations. For this process we will share your identifiable contact data, however, this will be minimised to ensure that only the data required to perform the process evaluations are shared and no additional data. Data sharing agreements and confidentiality clauses will be in place to ensure that you are treated with anonymity and confidentiality.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here: <https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice> or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

Participation is entirely voluntary; you have the right to withdraw at any time without giving a reason, but we will keep information about you that we already have. If you wish to withdraw you will need to email the research team wmg-mhpp@warwick.ac.uk stating your intention to withdraw.

What will happen to the results of the study?

The data collected will be analysed by researchers at the University of Warwick. The results are expected to be published in peer reviewed scientific journals and reported at national and international research meetings. Additionally, summary reports will be shared with all participating employers and our funders, the Midlands Engine. It will not be possible to identify you personally in these publications and reports.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC). Ref: BSREC 45/20-21

Who should I contact if I want further information?

For more information contact the research team's Dr Krishane Patel or Dr Talar Moukhtarian at wmg-mhpp@warwick.ac.uk.

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance

Research & Impact Services
University House

University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this participant information leaflet.