Participant Information Leaflet

Study Title:	**INWORK:** INterventions to improve mental health in the WORKplace: A pilot study
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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. Talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information. 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, 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.

What is the study about?
The **INWORK** study assesses the efficacy of **three** different types of interventions based on employee needs and eligibility to improve wellbeing and to maintain and improve the productivity of employees across the Midlands.

1. **SLEEP**: Supporting empLoyEes with insomnia and Emotion regulation Problems

The **SLEEP** trial aims to test the efficacy of a hybrid digital intervention designed to improve employee wellbeing, targeting sleep problems and stress. The 8-week intervention starts with a 1-week sleep tracking, facilitated by a sleep tracker provided by us, followed by a 6-week digital intervention consisting of an hour weekly commitment, in addition to four 45 minutes online sessions with trained specialists, and finished with a 1-week sleep tracking. Participants in the **SLEEP** trial will be followed-up after 1 month.

2. **REST**: REducing STress in the workplace

The **REST** trial aims to test the efficacy of a self-guided 8-week digital intervention, consisting of an hour's weekly commitment, designed to reduce problems with stress. Participants in the **REST** trial will be followed-up after 2 months.

3. **MENTOR**: Supporting employers and employees receiving treatment for Mental hEalth problems to remain eNgaged and producTive wORk

The **MENTOR** trial aims to evaluate the efficacy of a Mental Health Employment Liaison Worker (MHELW) in supporting the mental health and productivity of employees with diagnosed mental health problems. MHELWs will act as an independent source of support for you, your line manager and your mental health practitioner. The intervention will last for 3 months and involve 7 x 1-hour meetings with your MHELW, with a follow-up at 3 months.

What would taking part involve?
If you would like to register your interest in the study, please follow the link provided at the end of this page. The research team will contact you shortly after that, with a link to consent for an online eligibility screener. The online screener consists of three questionnaires for insomnia, depression and anxiety, in addition to specific questions to identify whether you fit with our eligibility criteria for either one of the interventions available. Responses and scores from these questions will be used to determine your eligibility for the study.

To be eligible for either one of the trials, you must meet ALL the inclusion criteria below:

- English-speaking.
- ≥ 18 years of age.
- Not retiring in the next 10 months.
- Able to give written informed consent.
- In employment

Each intervention has in addition to the above, specific inclusion and exclusion criteria:

MENTOR	SLEEP	REST
• Currently receiving treatment (psychological or medication) from NHS services	• Score on the insomnia scale, and on either the depression or anxiety scales above "Mild" *	• Score on either the depression or anxiety scales above "Mild" *
Have a clinical mental health diagnosis	• Currently not receiving treatment (psychological or medication) from mental health services (e.g. GP, private clinic, IAPT, specialist and community mental health services)	• Currently not receiving treatment (psychological or medication) from mental health services (e.g. GP, private clinic, IAPT, specialist and community mental health services)
• **Not** receiving input from an Individual Placement and Support Worker (https://ipsworks.org/)	• **Not** taking part in other psychological intervention trials	• **Not** taking part in other psychological intervention trials
• **Not** on extended sick leave (i.e. > 4 weeks)	• **Not** Pregnant[1]	
• **Not** in acute mental health crisis as defined by their clinical team •	• **Not** in shift work[2]	
	• **No** current substance abuse/misuse problems, epilepsy, neurological diseases (e.g. Parkinson's or Alzheimer's), psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (e.g. sleep apnoea, periodic limb movement syndrome/restless leg syndrome, circadian rhythm disorders)[3]	
	• **No** current substance abuse/misuse problems, epilepsy, neurological diseases (e.g. Parkinson's or Alzheimer's), psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (e.g. sleep apnoea, periodic limb movement	

[1] Sleep undergoes considerable changes during pregnancy, as the intervention uses sleep restriction this can be stressful for yourself and foetus. Therefore, we are unable to include pregnant women in this study.
[2] Individuals in shift work will find that the sleep restriction in the intervention can become stressful and damaging. As such we are unable to include you in our study for your own safety and wellbeing.
[3] If you are suffering from any additional psychological conditions such as addiction, or neurological conditions, then this intervention may affect you negatively. As such we are unable to include you in our study for your own safety and wellbeing.

	syndrome/restless leg syndrome, circadian rhythm disorders)[4]	

After completing the screening questionnaires, we will be able to identify which of the trials you may be eligible for and contact you with more information about that trial. Participants who are not eligible for any of the trials will be sent links to self-help materials if wanted (such as NHS's Every Mind Matters) for future reference.

For those who are eligible, you will be asked to read the trial specific participant information leaflet and sign its corresponding consent form. All three trials are designed as randomised waitlist-controlled trials. This means that half of the participants will be given the intervention immediately, while the other half are put on a waiting list and be offered the intervention with a short delay.

Participation in the trials will, in addition consists of completing questionnaires before the intervention, at the end-of-intervention and at follow-up to evaluate the efficacy of the intervention. All questionnaire measures will be self-completed on an online platform called Qualtrics accessed through links sent to you by email. At the end of the interventions, you may be invited to take part in feedback (process evaluation) interviews (we will only contact those who have given prior consent), which will be take around 1 hour and conducted through a telephone or online through Microsoft Teams, and be audio recorded using a University of Warwick managed digital recorder.

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 one of the research team members at wmg-mhpp@warwick.ac.uk.

[4] If you are suffering from any additional psychological conditions such as addiction, or neurological conditions, then this intervention may affect you negatively. As such we are unable to include you in our study for your own safety and wellbeing.

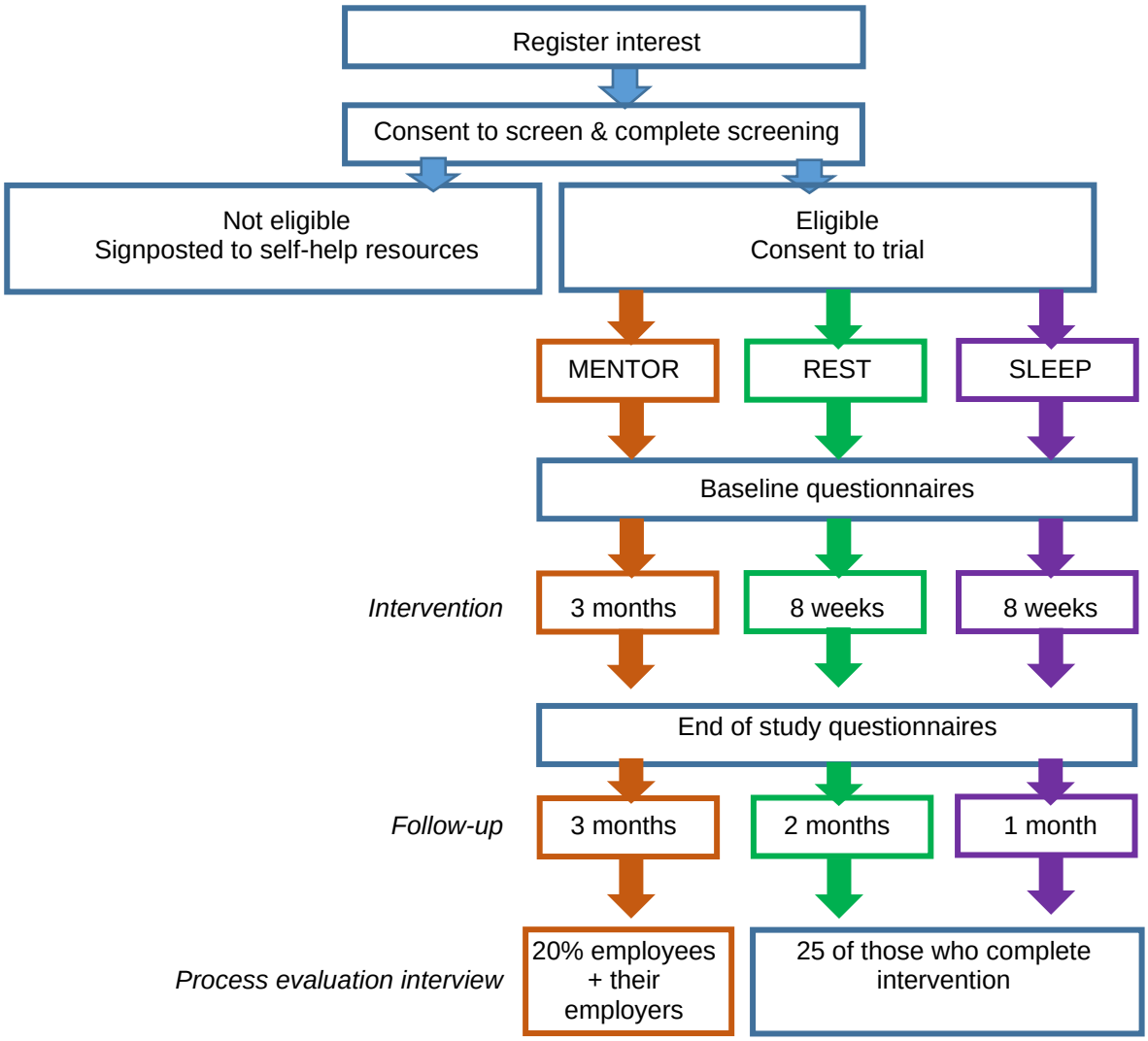

Figure 1 Study participation steps

What are the possible benefits of taking part in this study?
We expect our **INWORK** trials to improve overall wellbeing to maintain and improve engagement at work. This should have knock on effects on your employer, by increasing overall work productivity. This helps businesses to get back on their feet in current COVID-19 climate helping the Midlands and local areas 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. The **SLEEP** intervention targeting sleep problems could involve "sleep restriction therapy" and/or sleep re-scheduling therapy, which may be associated with minor side effects such as daytime sleepiness. You will be fully instructed as to the rationale and potential side effects of the treatment at the outset. In addition, you will be advised to not drive or operate machinery if experiencing excessive daytime sleepiness.

For all three trials, 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.

Expenses and payments
Participants in the **REST** intervention, will be entered into a prize draw with an opportunity to win a £100 Amazon voucher for each three waves of completed questionnaires (i.e. upon completion of baseline questionnaires, after intervention and at follow-up).

Participants in the **SLEEP** and **MENTOR** interventions, will be paid a £10 Amazon voucher, upon completion of each of the three-assessment wave.
Further, of those who have completed any of the interventions and have been selected and agreed to take part in the qualitative 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 collected at the screening stage will be de-identified as quickly as possible after data collection by assigning you a unique study ID number.

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 the trials.

Participating businesses will only receive a summary report which will not include any information that could identify 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.

Who has reviewed the study?
The **SLEEP** and **REST** studies have been reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC). Ref: BSREC 45/20-21. The **MENTOR** study has been reviewed and given favourable opinion by the University of Birmingham's Research Ethics Committee. Ref: ERN-20-1813.

Who should I contact if I want further information?
For more information contact the research team Dr Krishane Patel, Dr Feroz Jadhakhan 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.