What should I consider?

The treatment offered as part of this study can be completed alongside any other treatments you may be receiving for your sleep, depression, or any other health condition. The study should not be seen as an alternative to any current or future treatments administered by a healthcare professional. If you are concerned about your mental or physical health at any time during the study then we advise that you speak with your general practitioner. There are some reasons that you may not be able to take part in the study:

- if pregnant or planning pregnancy in the next 6 months, have additional sleep disorders (e.g., sleep apnoea, restless legs syndrome, or narcolepsy) or if the study team thinks that you might have one of these conditions.
- if you work night, evening, early morning, or rotating shift-work, or if you are currently receiving psychological treatment for insomnia from a health professional, or taking part in an online treatment programme for insomnia.
- if you are currently receiving cancer treatment or have a diagnosis of psychosis (schizophrenia or bipolar disorder), dementia or mild cognitive impairment, or epilepsy. You also cannot take part if you experience alcohol or recreational drug dependency.
- if you are currently experiencing suicidal thoughts and plan to act on these thoughts, or have recently attempted suicide.
- if another member of your household is already taking part in the study

Confidentiality

All data will be processed in accordance with relevant data protection legislation and all information about you will be handled in confidence. Audio recordings will be stored and transferred securely via online systems which will be password protected. All study information collected will be made de-identified at the earliest practical opportunity. The information you provide at the first consultation and subsequent appointments will be coded with a study identification number so you cannot be identified from it by anyone other than the research team. The people who analyse this information will not be able to identify you or find out your contact details. Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the Study to ensure that the research is complying with applicable regulations.

The NHS will collect information from you and your medical records for this clinical study in accordance with the study's requirements. The NHS will not pass on any information not required for this study to the University of Oxford.

What will happen to my data?

UK Data protection regulation requires that we state the legal basis for processing information about you. We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, based in the United Kingdom as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 5 years after the study has finished, *with the exception of your contact details, which will kept only for up to 12 months of the study ending*. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the University of Oxford for 5 years after the end of the study.

Your information may also be shared with third parties working with the University of Oxford for the purposes of the clinical study. We will be using a company called P1vital Products Ltd. ('P1vital') to collect, process and store some elements of data for the study (the computerised tasks). P1vital will be a data processor along with the Primary Care Clinical Trials Unit. Access to this system requires you to create a login on their data capture system, ePRO. To create this, we will require your email address. All information from these tasks is securely stored on their server and encrypted before being transferred to the research group for analysis. P1vital will use minimum personally identifiable information. P1vital will store this data until deletion is requested by us. This will take place after the study has terminated and all relevant data has been transferred to our research staff. Participants email addresses and any other personal information will be deleted from the system at the end of the study. P1vital has a contract with the University of Oxford which specifies that P1vital will not use your personal data for any reason other than this trial. P1vital reserve the right to use the anonymised computer task data and basic demographic data such as sex & age (unattached to names or identifiable information) for non-commercial, internal research purposes.

The local study team (based at your GP practice) will use your name, NHS number, home address, and contact details, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The consent form you complete for this study will be kept for 5 years after the study has finished.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.admin.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting the Chief Investigator (details at the end of this document).

Are there any benefits or risks to taking part?

We do not anticipate that there are any risks in taking part. However, involvement in the study will involve answering questions about sensitive and potentially upsetting topics. If you do not feel comfortable answering such questions, we would discourage you from participating in the study, or taking part in the online eligibility questionnaire.

You may benefit from improved sleep and mood from taking part in this study. You will also contribute to research, which may help develop better treatments for people experiencing depression and poor sleep. There are no known serious side effects from taking part in this study; however, change to your sleep pattern may be associated with a short-term increase in sleepiness. If you do feel sleepy during the study, we advise that you avoid activities that require a high degree of vigilance, such as driving or operating heavy machinery.

What if I don't want to take part anymore?

You can leave the study at any point by contacting the trial team or your GP practice and the decision to do so will not affect the treatment you receive from your GP or nurse. Information that we have already collected for the research will still be used in the Study.

What if there are any issues?

For queries about this study, please contact the study team on the details below. If you wish to complain about any aspect of the way in which you have been treated during the study, you should contact the Chief Investigator, Dr Simon Kyle, or the Study Manager (contact details below), or the University of Oxford Research Governance, Ethics & Assurance Team (RGEA)office on 01865 616480 or email RGEA.Complaints@admin.ox.ac.uk.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment with which you are provided.

How have patients and the public been involved in this study?

Patient and public Involvement (PPI) advisors with experience of both depression and insomnia have been involved in the design of the research and the reviewing of participant facing documentation. The following link provides general information about taking part in research.

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-Study/

What will happen to the results?

The results of this research study will be published on the University website, in scientific medical journals and promoted on social media. Your individual results will not be identifiable, nor would you be identified in any report or publication. After the end of the study an

anonymised dataset will be created and stored for as long as it is useful, and may be shared with other researchers upon request. We will send you a copy of the study results via your preferred contact method if you tell us we can on the consent form.

Who is organising and funding the study?

This study is being funded by the National Institute for Health Research (NIHR) Health Efficacy and Mechanism Evaluation.

The study is being conducted by the research team at the University of Oxford, and is being run across different regions within England, UK.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London – Surrey Research Ethics Committee.

Contact details

If you would like to take part in this study or require any further information, you can contact the research team:

RESTED Study Team
Chief Investigator: Dr Simon Kyle
Website: https://www.phctrials.ox.ac.uk/trials-portfolio

Contact telephone number: 01865-617828