Oxford Health NHS
NHS Foundation Trust

UNIVERSITY OF OXFORD

Sleep Well

Participant Information Sheet – 16-25 years
Study Title: The SleepWell Trial

We would like to invite you to take part in our research study.

Before you decide, we would like you to understand why the research is being done and what it would involve for you.

One of our team will go through this information sheet with you and answer any questions you have.

Talk to others, including your family, about the study if you wish.

Please ask us if you would like further information.

Key facts:

- The SleepWell trial is for people aged 14-25 years who have difficulties with sleep. This includes problems getting to sleep or staying asleep, sleeping for too long, or sleeping at the wrong times of day.
- The purpose of this study is to find out whether a type of psychological treatment called 'cognitive therapy' can help people to sleep better.
- To carry out this trial, half the people who take part will receive the sleep therapy (in addition to their usual care) and half will simply continue with their usual care. Whether a person has the therapy is decided by chance (this is called random selection). We then compare how people who have had the therapy are getting on compared to people who have not had the therapy.
- This type of cognitive therapy is designed specifically to improve sleep. The therapy involves 6-8 meetings with a therapist focused on sleep.
- Everybody will also meet a research assessor at the beginning and then after 3 months and 9 months. These assessments will allow us to see if there have been any changes in your sleep.
- At the end of the study you may be invited to give feedback on the project and the therapy (if you had it). This is because we want to hear your views and opinions about the study.
- It is entirely your choice whether to take part in the research or not. Your usual treatment will not be affected in any way by your decision. Even if you decide to take part, you will be free to leave at any time, without giving a reason.

Why is the research being done?
We have a new brief psychological therapy to help people sleep better. It is called cognitive therapy for sleep difficulties, and is provided in up to eight meetings with a clinical psychologist. The purpose of this research is to test whether it works. We want to see whether this new therapy improves sleep, and to see whether it reduces anxiety, distress, or other experiences such as hearing voices. If it is shown to work then we hope to introduce this therapy into NHS services and help more young people improve their sleep.

Who can take part in the research?
The research is for people aged 14-25 years who have difficulties sleeping and other difficulties such as worries about other people or hearing voices. We will first check with you whether the research study is suitable for you. Our aim is for 40 people to take part in the research; however, you won't meet with the other participants as part of this study.

Do I have to take part?
No. If you are eligible, it is up to you to decide whether to take part. If you agree to take part, we will then give you a consent form to sign. You are free to withdraw at any time, without giving a reason. Your usual treatment will not be affected if you withdraw from this study.

What will happen if I take part?
You will be part of the study for nine months. We will first check that the research is suitable for you, by asking you about your sleep and any worries or distressing experiences. This will include completing a questionnaire about your sleep. This meeting usually takes around 30 minutes. We will also ask your permission to check your clinical notes.

Everyone who takes part will be asked to meet with a research assessor three different times for an assessment: at the beginning of the study, then after three months and finally after nine months.

At each assessment you will be asked to complete questionnaires about sleep, how you've been feeling, and any other concerns that you may have. This may include wearing an actigraphy watch (like a fitness tracker) so that we can measure how many hours of sleep you are getting. You do not have to wear the watch; it is up to you.

We expect the first assessment to take 1-1.5 hours and the later assessments around an hour each. You can very much go at your own pace so the exact length of the assessment will be under your control. The assessment can be broken down into shorter chunks if you would like. We will also try to do the assessments at times that are most convenient to you and will not interfere with school, college or work.

After the first assessment, whether you have the sleep therapy or not will be randomly decided by a computer (rather like flipping a coin). This is called

"randomisation". Randomisation means that you may - or may not - receive the sleep therapy.

If you have the sleep therapy, you will have up to eight meetings with a clinical psychologist (therapist) to work on improving your sleep. The exact number of sessions depends on what you and the therapist think will be best (with a maximum of eight). Your therapist will offer extra support (e.g. phone calls, text messages) between sessions to help you try out new strategies to improve your sleep. The therapy will take place over about 12 weeks. The focus of the therapy will be on ways to improve sleep, using psychological techniques. You will be given information about sleep difficulties and will work out with your therapist the best new techniques for you to sleep much better. These meetings can be held at your local team base or at your home, whichever you prefer. The therapy sessions and extra support are all optional.

In some therapy meetings you may be asked whether you are happy for the meeting to be audio-taped, in order that we can check the quality of the work carried out by the therapist. If you do not want us to make any audio-recordings then that is perfectly okay. Your permission would always be needed for this to occur.

The sleep therapy will be in addition to any routine appointments and assessments (your usual care). Nothing will change in the usual treatments you are already receiving. Your clinical team will know you are taking part in the research. The research worker and therapist will look at your clinical notes to see how long you have had difficulties, what treatments have been provided, and how you are during the next nine months.

If you do not have the sleep therapy you will continue with your usual care and complete the assessments at 3 and 9 months. After the last assessment at 9 months, you will be offered a one-off session with a therapist to talk about ideas to improve your sleep. This will be at the end of the study.

At the end of the study, you may be invited to take part in an additional meeting. This will be an interview with a research worker to talk about your experiences of the study. We want to hear from participants with a range of views and experiences of the study. We will ask participants who received the sleep therapy as well as those who didn't. The interview will be 'semi-structured', which means it'll cover certain topics but will also be flexible, and the interviewer will respond to what you say. The interview will take place at your home or in a room at your local NHS base. The interview usually takes about 45 minutes. The interview

will be audio recorded and transcribed (written up word for word) but all transcripts will be de-identified. We will ask if we can use quotes under a different name when writing about the study in research journals or teaching and presentation materials. This is optional. You do not have to give us feedback on the study.

What if I want to stop?
You are free to withdraw at any time, without giving a reason. Your current and future care will not be affected if you withdraw from the study. If you don't want to carry on in the study, then we will use the information from the assessments that you have already completed unless you ask us not to.

Will I get paid?
You will be paid £15 for each assessment session (£45 in total) and a further £15 for the feedback interview. We will also pay travel expenses, including for the sleep therapy sessions with the psychologist.

What are the potential benefits of taking part?
Half the people taking part will get the new sleep therapy. We hope that the therapy will help people sleep better. We also expect it to increase people's activity levels and improve mood. Those participants who do not get the sleep therapy will be offered a one-off session to talk about ideas to improve sleep. We cannot guarantee that all participants will benefit as expected. This trial aims to find out more about the potential benefits of sleep therapy.

What are the potential risks or disadvantages of taking part?
We do not anticipate that there will be any risks in taking part.

The questionnaires ask about sleep and mental health, which may be considered sensitive topics. Our team of psychologists are trained to help people with their mental health. All the questions are optional, you do not have to answer if you do not want to.

Only half the participants will receive the sleep therapy. Those who do not receive the sleep therapy will be offered a one-off session to talk about ideas to improve sleep at the end of the study.

The feedback interview asks about your experiences of taking part in the study. You do not have to talk about anything that you don't want to, and if you feel that you don't want to carry on with the interview at any point, then we can stop it immediately without giving a reason.

Will other people be told that I am taking part?
Your clinical team, including your GP, will be told you are taking part in the study. All other information will be kept confidential from everyone, including your parents. The exceptions are where there are significant safeguarding concerns about you or other people.

If you wanted, we would let your team know the results of the assessment and how you found therapy. But we would only do this with your permission.

The assessment forms you complete will have a participant ID on them instead of your name, and will be kept in a locked cabinet in a locked room.

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.

What will happen to the results of this study?
The results of the study are written up, looking at the total effects of the treatment for all patients, and no individual is identified. Direct quotes from your interview may be used in written reports, but these will be de-identified with no identifiable information. The results will be presented in a scientific paper and in conferences. We will make a summary of the results of the study available to you.

What will happen to my data?
Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your medical records in order to carry out this study.

Information that can be used to identify you (e.g. your name or NHS number) helps the research team to keep in contact with you about the research study, make sure that relevant information about the study is recorded for your care, and ensures the quality of the study. During the research, the research team will need to use this type of information, but we will try to keep this to a minimum. We will not share this information with anyone outside the research team. We will keep information that might identify you for 3-6 months after the study has finished.

Your data will be stored securely with our research team at the University of Oxford. Any data that you provide on hard copies (i.e. pen and paper) will be kept in a locked filing cabinet at the University of Oxford. Any electronic data that is collected (e.g. emails, questionnaire scores) will be kept on a computer at the University of Oxford and will be protected with a password. Only members of the research team will know the password or have access to the filing cabinet.

At the end of the study, all of the research data and any research documents with personal information, such as consent forms, will be stored at the University of Oxford for 10 years.

Your NHS Trust will use your name, NHS number, home address, and contact details to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study in keeping with local policy for medical notes retention.

If you agree to take part in an interview and have this audio recorded, the recording will be sent in a secure manner to a transcription service contracted by the University. The transcription service type a written copy of the interview word-for-word. Transcriptions will be de-identified, and transcribers will delete the audio files on completion. The interview recording will be password protected and also stored on a secure university server. Once analysis is complete, this copy of the audio-recording will be deleted.

If you agree to wearing an activity watch, de-identified actigraphy data will be collected at assessment sessions and stored on a secure university server. Only summary totals (for example, number of steps taken each day) will be collected and stored.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your wishes with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting the research team, using the contact details given at the end of this document.

Who is organising and funding the study?
The study is funded by the NHS National Institute of Health Research (NIHR) and sponsored by the University of Oxford. The NIHR fund health and care research and translate discoveries into practical products, treatments, devices and procedures, involving patients and the public in all their work.

What if there is a problem?
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.

If you wish to complain about any aspect of the study, you should contact Dr Felicity Waite (contact details below) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) by telephone 01865 616480 or email ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

Who has reviewed the study?
The study has been reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and

dignity. This group includes both NHS staff and members of the public. This study has been reviewed and given favourable opinion by the South Central – Oxford A Research Ethics Committee (20/SC/0281).

** Please do not hesitate to ask us if you have any questions. It can also be helpful to talk to someone else about whether you'd like to take part **

CONTACT DETAILS

If you have any questions about the study please contact us:

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A diagram summarising the research