

Study Title: HABIT (Health professional Administered Brief Insomnia Therapy) Study

HABIT Study

Patient Information Sheet



- We would like to invite you to take part in a research study.
- Insomnia refers to frequent problems with falling asleep or staying asleep during the night.
- This study compares two different ways of potentially helping people who experience insomnia.
- Before you decide if you would like to take part, we would like you to understand why the research is being done and what it would involve for you.
- Please take the time to read the information in this booklet and talk to others if you wish. If you have any questions please just ask.

You will receive up to
£50 gift vouchers as a
thank you for your
time!

Why have I been invited?

For this study we are inviting people (aged 18 years and over) who experience frequent difficulty with falling asleep and/or waking up during the night. Participants should have problems with sleep on at least 3 nights per week, which they have experienced for at least 3 months. The study will be carried out across different regions in England.

Do I have to take part?

No, taking part in the study is entirely voluntary. If you decide to take part, you will be asked to keep this information sheet and sign a consent form.

What will I have to do?

If you are interested in taking part in this study, we will first ask you to complete a questionnaire (either online, over the phone or in paper format, which will take no more than 5 minutes) to determine whether the study is suitable for you. The questionnaire will ask about your sleep as well as your physical and mental health. Please see the letter you received from your doctor to find out how you can access, complete and return the questionnaire. Alternatively, if you have not yet received a letter from your doctor please contact the study team (details below) to find out how you can complete the questionnaire.

Visit with our researcher

- If you decide to take part in this study, and are considered eligible after completing the questionnaire, you will be invited to meet with one of our researchers. This meeting will take place at your GP practice or other convenient location, where you will have the opportunity to ask any questions about the study.
- The researcher will ask you to complete a questionnaire about your health, daytime functioning and sleep pattern. This is expected to take no more than 20 minutes to complete.
- You will be provided with an actigraph watch, which you will be asked to wear on your wrist for 7 days. An actigraph watch measures movement allowing us to estimate your sleep-wake pattern.
- The researcher will also ask you to complete a daily sleep diary for 7 days.
- The researcher will give you instructions on how to use the actigraph watch and what you need to include in the sleep diary.

You will receive a £5 gift voucher for your time.

After your first visit with the researcher, you will be randomly put into one of two treatment groups that may help improve your sleep. This process is like tossing a coin and so you will have a 50/50 chance of being in either group.

Group 1 - will be given a booklet which describes tips on how to improve sleep

Group 2 - will be given a booklet which describes tips on how to improve sleep and will meet with their practice nurse over 4 weekly sessions, where they will be supported to follow a new tailored sleep schedule with the aim of improving sleep:

- **Week 1** – The first session will be face-to-face with a nurse at your GP practice. This session should take approximately 30 minutes. You will be asked to follow a new sleep schedule and complete a diary over the four weeks to help keep track of progress.
- **Week 2** – The second session will take place over the phone. This should last approximately 10 minutes.
- **Week 3** – For the third session you will be asked to attend your GP practice again to meet with the nurse for about 15 minutes.
- **Week 4** – The final session will take place over the phone and will last around 10 minutes.

Follow-up assessments

Your participation in the trial will last for 1 year and follow-up assessments will take place at 3, 6 and 12-months.

The research team will send you a pack at 3, 6 and 12-months after your first visit to ask you to:

- Complete a questionnaire – this can be done either electronically or on paper. This is expected to take no more than 20-25 minutes to complete.
- Wear the actigraph watch for 7 days (at 6 and 12 months only).
- Keep a sleep diary for 7 days (at 6 and 12 months only).
- Send back the actigraph watch and diary in a pre-paid envelope.

Please note: the research team may send you reminders by email, text or phone call to complete and return the questionnaire, actigraph watch and sleep diary.

Regardless of which group (1 or 2) you are assigned to, you will receive further gift vouchers for completing each of the assessments at 3 months (£10), 6 months (£15), and 12 months (£10).

Optional interview

You may also have the opportunity to share your experiences of taking part in the study by giving consent to be interviewed. This is an optional part of the study and selection depends on what group you are randomly assigned to. Therefore, not everyone will be interviewed; If you have agreed to take part in the interview a member of the research team will contact you via phone or email. Interviews will be conducted by a member of the research team either face to face at a convenient location or via Skype, and last approximately 30-60

minutes. Interviews will be audio recorded and anonymous quotes may be used in publications.

If you complete this interview you will receive a **further £10 gift voucher**.

What should I consider?

The treatments offered as part of this study can be completed alongside any medications you may be taking for your sleep or any other health condition. However, participants cannot take part in the study if pregnant or planning pregnancy in the next 6 months, have additional sleep disorders (e.g., sleep apnoea), are currently receiving cancer treatment or have a diagnosis of schizophrenia, dementia, bipolar disorder or epilepsy.

Confidentiality

All data will be kept securely according to relevant data protection legislation. Audio recordings and interview transcripts (write-up) will be stored and transferred securely via online system which will be password protected. All trial information collected will be made anonymous at the earliest practical opportunity. The information you provide at the first consultation and subsequent appointments, will be coded with a trial identification number so you cannot be identified from it by anyone other than the research team. 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 my data?

Information collected about you during the course of the study will be securely stored at the University of Oxford. In line with Good Clinical Practice guidelines and regulations at the University of Oxford, at the end of the study your data will be stored securely for at least 5 years. Arrangements for confidential destruction will then be made. If you withdraw consent for your data to be used, and ask that all records held for the study are destroyed, they will be confidentially destroyed.

Are there any benefits or risks to taking part?

You may benefit from improved sleep from taking part in this study. You will also contribute to research which may help develop better treatments for people experiencing insomnia. There are no known serious side effects from taking part in this study, however, any 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 and the decision to do so will not affect the treatment you receive from your GP or nurse. We would still like to use the data you have already provided, as this will be invaluable to our research. If you have any objection to this, please let us know.

What if there are any issues?

For queries about this trial, please contact the study team on <insert local team no> or email <insert local email id>

If you wish to complain about any aspect of the way in which you have been treated during the trial, you should contact the chief investigator, Dr Simon Kyle, or the Trial Manager (contact details below), or the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@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 trial. NHS indemnity operates in respect of the clinical treatment with which you are provided.

What will happen to the results?

The results of this research trial 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 and anonymous data may be shared with other researchers. We will send you a copy of the results via email. Anonymous quotes from digitally recorded interviews (optional part of the study) may be used in publications.

Who is organising the study?

This trial is being funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme.

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

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by Yorkshire and The Humber – Bradford Leeds.

Contact details

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

HABIT Trial Team

Chief Investigator: Dr Simon Kyle

Email: habit.study@phc.ox.ac.uk

Tel: 01865-289-591

Website:

To insert local coordinating centre details (if applicable)

Principle Investigator:

Local Contact: <insert name>

Email: <insert local contact>

Tel: <insert local contact>

Thank you for considering taking part in this trial.