Study Title: HABIT (**H**ealth professional **A**dministered **B**rief **I**nsomnia **T**herapy) Study

HABIT Study

Practice Staff Information Sheet

- We would like to invite you to take part in an interview as part of the Health professional Administered Brief Insomnia Therapy (HABIT) trial, which you or your practice are taking part in. The study compares two different ways of potentially helping people who have insomnia.
- The interview will be conducted via telephone, Skype or face-to-face, depending on your preference, and will explore your own experiences of the trial, or those of the practice.
- This interview is designed to examine how behavioural sleep treatments are currently (or could be) implemented in general practice, how these may benefit patients, and if there are other practice, patient, practitioner or wider factors that could affect this.
- 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.
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Why have I been invited?

We are inviting you because you or your practice are taking part in the Health professional Administered Brief Insomnia Therapy (HABIT) trial of people with insomnia.

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, please contact the research team with the contact details provided at the end of this leaflet.

Meeting with our researcher

- If you decide to take part in this study, you will be invited to speak with one of our researchers via telephone, Skype or face-to-face, depending on your preference.
- The researcher will ask you some questions about yourself and your role in the practice and then conduct an interview lasting around 30-60 minutes. The consent process and the interview will be digitally audio recorded.
- **Your practice will be reimbursed for your time being interviewed.**

Confidentiality

All data will be kept securely according to the relevant data protection regulations. 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 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, University of Manchester, University of Lincoln, [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 from 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?

There are no known risks to taking part in this study. By taking part, you will contribute to research which aims to understand how we can effectively incorporate behavioural treatment for insomnia into primary care.

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

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 572224 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.

What will happen to the results?

The results of this research trial will be published on the University website, and in scientific medical journals. Your individual results will not be identifiable nor would you be identified in any report or publication and may be shared with other researchers. Anonymised quotes from your interview may be published in journals and shared at scientific conferences.

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

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.