Primary care treatment of pain-related insomnia: A feasibility study of a hybrid cognitive-behavioural approach

INFORMATION SHEET FOR PARTICIPANTS

We would like to invite you to take part in our research, which aims to generate information for refining a new psychological treatment designed to improve sleep and reduce distress associated with chronic pain. Before you decide whether to sign up or not, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us any question you may have about the study.

1. *What is the purpose of the research?*

The current study is part of a research programme that seeks to develop better understanding and treatment of sleep disturbance associated with chronic pain. We have developed a brief and intensive form of talking therapy for insomnia linked to chronic pain. We are interested in finding out whether the new treatment would be found useful and acceptable by patients and whether it would be feasible to offer this new treatment in the NHS.

2. *Do I have to take part?*

You are invited to take part because your GP surgery is a research partner of this project. By taking part in this study, you will have a chance to receive the new treatment for pain-related insomnia, which is currently not available anywhere in the NHS. However, your participation in the study is entirely voluntary and you are at liberty to refuse to participate or to withdraw at any time without giving any reason for doing so. Should you decide not to take part in this study, this will not in any way affect your present or future treatments in the NHS. Similarly, your treatments in the NHS will not in any way be affected if you withdraw from the study.

3. *What do I have to do, if I agree to take part?*

If you agree to take part, you will first be asked to complete a screening questionnaire. If your answers match the inclusion criteria of the study, you will be invited to attend an assessment interview during which we will ask you further questions about your pain, sleep pattern and health in general.

The assessment interview will be approximately 2 hours long and will take place at your GP surgery. You will be informed of the assessment outcomes at the end of the interview. If you meet all inclusion criteria of the study, you will be randomly assigned to one of two groups:

If you are assigned to Group 1, you will be arranged to start a self-help treatment following a 2-week sleep and pain monitoring procedure. You will be mailed 4 reading booklets (1 each week for 4 weeks) containing information about these symptoms and coping strategies. You will have the flexibility to decide how much and at what pace you wish to try out the coping strategies introduced in the booklets. At the end of the 4-week period, you will be asked to repeat the sleep and pain monitoring procedure for 2 further weeks.

If you are assigned to Group 2, you will be arranged to start a hybrid cognitive-behavioural therapy following a 2-week sleep and pain monitoring procedure. You will be offered 4 weekly, face-to-face sessions with a Health Psychologist to work on your sleep and pain issues. Each session will be 2 hours long and will take place at your GP surgery. The general approach of this treatment is collaborative; you will work with your therapist to try out different coping strategies. With your consent, all sessions will be audio-recorded to ensure treatment quality and integrity. To enhance treatment quality, the audio tapes will be kept by the therapist for clinical supervision with a senior colleague. To establish treatment integrity, a small sample of these tapes will be independently reviewed by a member of the research team. At the end of the 4-week treatment period, you will be asked to repeat the sleep and pain monitoring procedure for 2 further weeks.

The sleep and pain monitoring procedure will involve you keeping a symptom diary and wearing a non-intrusive, wrist-watch like actigraph to monitor your day-to-day physical activity. These instruments are very user-friendly. We will provide training to show you how to complete the diary and how to operate the actigraph.

To help us evaluate the utility of the study, we will ask you to complete a questionnaire on five different occasions; (i) during or just before the assessment interview, (ii) before treatment, (iii) immediately after treatment (iv) 12 weeks after treatment, and (v) 24 weeks after treatment. We want to keep track of your progress at 12- and 24-week after treatment because it is important to know whether or not the treatment effect sustains in the medium term. Questionnaires to be completed at home will be posted to you with a pre-paid return envelope to make it as easy as possible for you.

4. What are the possible benefits of taking part?

Chronic pain patients often also have severe problems sleeping, which amplify pain and increase distress and disability. We know that chronic pain patients do request treatment for their insomnia, but such treatment is not always a main focus in specialist pain management programmes. In primary care, drugs remain first-line treatments for pain-related insomnia but are potentially of limited effect.

Psychological interventions, particularly cognitive-behavioural therapy (CBT), offer a promising treatment alternative. However, these treatments are often not available for chronic pain patients because of a shortage of skilled therapists and an absence of infrastructure to deliver CBT for insomnia/pain in medical primary care settings.

By participating in this trial, you will receive a novel psychological treatment for pain and insomnia that normally would not be offered by your GP or provided as a service in hospital pain clinics. The treatment protocol developed for this study is based on previous work on primary insomnia treatment and our recent research on chronic pain. It is expected that over half of the completers of this study would experience improvements in their sleep and/or a reduction in pain interference.

5. Fees

Both treatments in this study will be offered for free.

6. *Will my taking part in this study be kept confidential?*

We will not disclose your participation to anyone (including your family members and GP) unless you indicate your wish otherwise. The information you provide throughout the course of the study will be kept strictly confidential and will only be used, with your consent, for the purpose of this research and other relevant studies conducted by our research team. All materials will be given a unique code that will be used in subsequent data analyses. Nothing will be reported that might identify individuals. If you wish to receive a summary of the findings when this becomes available, please indicate in the consent form. Please also indicate in the consent form whether you would be happy for us to inform your GP that you are taking part in this study.

7. *Who has reviewed the study?*

This project has been reviewed by the Solihull NHS Research Ethics Committee West Midlands. The ethics approval reference number is: 14/WM/1053.

8. *What are the possible disadvantages and risks of taking part?*

If you are assigned to Group 2, completing the study will involve you visiting your GP surgery to attend the assessment and treatment sessions. We realise that it is a significant time commitment on your part and will try to arrange the appointments to times that are most convenient for you.

Throughout the course of the treatment, you will be asked to complete several questionnaires as part of the evaluation process. Sometimes, people find themselves thinking a lot more about their pain and other health issues after completing these questionnaires. If this distresses you, you are encouraged to discuss these with your therapist during the session.

As we work with you altering your sleep/wake schedule, it is expected that you will have to go through a temporary phase of mild sleep loss before you experience any improvement in your sleep quantity and quality. There is a chance that you may experience daytime sleepiness during the initial phase of the treatment. For your safety, we advise that you do not drive or operate machines during the initial phase of the treatment if the daytime drowsiness is prominent.

9. Who is organizing and funding the study

Dr. Nicole Tang is the chief investigator of this study, which is funded by a grant awarded by the National Institute of Health Research (NIHR) Research for Patient Benefit Programme. The study is sponsored by the University of Warwick and will be managed by the research team at the Department of Psychology and the Clinical Trials Unit at the University of Warwick.

10. Where can I get more information about the study?

For more information about the study, please do not hesitate to contact:

Corran Moore
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Phone: 02476 150039
Email: Corran.Moore@warwick.ac.uk

For independent advice about taking part in research trials, please visit the NHS choices website: www.nhs.uk/conditions/clinical-trials/

If you have any concerns or complaints about the Research, Staff, and Conduct, please contact:

Ms. Jo Horsburgh, Deputy Registrar
University of Warwick, Research Support Services, University House, Kirby Corner Road, Coventry, CV4 8UW
Phone: 02476522785
Email: n.lynch@warwick.ac.uk

For general confidential advice, support, and information on health-related matters, you may contact the Patient Advice and Liaison Service, PALS, in your local hospital. The following link will help you search for a PALS closest to you:

http://www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363

Alternatively, the contact details of the PALS at University Hospital (Coventry) are as follows:

Clifford Bridge Road
Coventry, CV2 2DX
Phone: 0800 028 4203

Thanks again for your interest in this research. We look forward to hearing from you!

The Warwick Pain and Insomnia study team.

Please keep this information sheet for your records.
If you agree to enter the study, please sign the enclosed consent form and we will return a copy to you.