Government of South Australia | Health Central Adelaide Local Health Network

THE UNIVERSITY of ADELAIDE

PARTICIPANT INFORMATION SHEET

Project title: Does light treatment improve sleep and pain?

Protocol Number: 13930

Principal Investigator: Dr Tiffany Gill

Introduction

This Participant Information Sheet and Consent Form (PICF) tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section at your first visit. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described

You will be given a copy of this PICF and your signed consent to keep.

What is the project about?

Healthy sleep is important to all aspects of human health. This is particularly relevant for patients living with chronic illness, as poor sleep can alter the experience of pain, affect tissue growth and repair, and negatively influence cognition and memory. Poor sleep has been reported in patients with chronic pain, including people living with fibromyalgia and lower back pain. However, the root cause of poor sleep is poorly understood. Poor sleep health can be a consequence of:

- clinical sleep disorders (including insomnia, obstructive sleep apnoea, and circadian rhythm disruption),
- environmental factors (e.g. the sleep environment), and
- behaviours which negatively influence sleep (e.g. night exposure to light and food, use of social media/technology, and other habits known to influence sleep).

Management of sleep health as a result depends on identifying the key cause(s). This has not been explored in patients with fibromyalgia or lower back pain to date. Identifying and providing pathways to management is crucial in a time when we now have new, non-invasive, non-pharmaceutical interventions which can address sleep problems. Thus, this project aims to accurately characterise habitual sleep patterns in people with fibromyalgia and back pain in order to identify appropriate, targeted, sleep interventions and determine whether exposure to light therapy improves sleep and pain sensitivity.

Who is undertaking the project?

This project is being conducted by Dr Tiffany Gill and a team of researchers from the University of Adelaide, The Queen Elizabeth Hospital, and Flinders University.

Who is funding the research?

The Hospital Research Foundation has provided funds for this study.

What will I be asked to do?

This study has two separate phases plus an optional sub-study. In phase 1, you will be asked to attend an assessment visit at The Queen Elizabeth Hospital, Rheumatology Department where the study will be discussed in detail before you are asked to sign your consent form for this phase. Demographic information, a brief medical history, body measurements and medication use will be recorded and a venous blood sample will be taken before you will be asked to complete several questionnaires about your pain, health and sleep. We will provide you with the following to take home for two weeks:

- A sleep diary to record when and how you sleep

- A sleep mat for you to plug in and place under your mattress. While you sleep the mat will measure your sleep cycles and stages, heart rate and movements. We will ask you to install an App on your smart phone to capture the data. We will later use this information to examine your sleep patterns.
- A watch-like device to wear on your wrist to measure your activity

People diagnosed with fibromyalgia will have the opportunity to participate in an optional sub-study which involves the ingestion of a small, single-use capsule which continuously monitors your central body temperature while insitu. You will need to carry a portable reader (the size of a mobile phone) with you to capture the data. The capsule is comparable in size to a vitamin capsule and travels through the gastrointestinal tract without affecting bodily functions. Once eliminated by the body it simply flushes away. You will be asked to wear a medical information bracelet from the period of ingestion to elimination of the capsule as you are not able to have a Magnetic Resonance Imaging (MRI) procedure whilst the capsule is within your body. All participants in the sub-study will receive an information sheet and be provided with the after-hours contact details for the Clinical Trials Manager. There are a few situations which may prevent you from participating in the sub-study. The Clinical Trials Coordinator will discuss those contraindications with you and complete a checklist to ascertain whether you are able to participate in the sub-study.

Depending on your sleep pattern in phase 1, we may invite you to participate in phase 2 of the study. This phase is six weeks long and you will be asked to attend the Queen Elizabeth Hospital every two weeks for four assessment visits. You will continue to wear your activity watch, use the sleep mat and complete sleep diaries and questionnaires as you did in phase 1. You will be provided with sleep counselling material and may be asked to wear special glasses every morning for one hour for the first two weeks.

How much time will the project take?

Phase 1 has one visit only and should take about 1.5 hours. Phase 2 has an additional four visits with each visit being around one hour. If you are unwell and cannot attend one of your visits,

we may be able to conduct that visit on-line. This can be discussed with the study coordinators at the time.

Costs and reimbursement

Participants are not paid to be involved in the study, however you will be reimbursed on the day for parking costs incurred from your clinic visits to The Queen Elizabeth Hospital when parking in the multi-storey carpark on-site.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to participate, your medical care will not be affected in any way. If you do decide to take part, you will be required to sign this Participant Information and Consent Form at your first visit and you will be given a copy to keep.

What are the benefits of the research project?

We cannot guarantee or promise that you will receive any benefits from this research. However, the study may provide a way of improving your sleep which is turn may increase activity levels, reduce pain and improve quality of life without the use of other medications.

Are there any risks associated with participating in this project?

- Blood draws may cause discomfort or pain, bleeding, and/or bruising. There is also a risk of infection with redness and irritation of the vein at the puncture site where blood is collected. If you have felt faint or passed out previously when having blood taken, please inform the study staff.
- There is a negligible risk of minor discomfort, or inconvenience from wearing the glasses.

Can I withdraw from the project?

If you agree to participate, you can withdraw from the study at any time or only participate in some aspects of this study. If you decide to leave the study, information already collected up to the time you withdraw will be retained and form part of the study results. If you do not want your data to be included, please advise us when you withdraw from the study.

What will happen to my information?

The data and information collected from this study including from questionnaires that you complete and from the activity watch and sleep mat will be de-identified, meaning that any results will not be able to be traced back to you as an individual. Your information is stored electronically on secure password protected computers, accessible by relevant research staff only. Paper based records will be stored in a locked cupboard, again, accessible only by relevant research staff for a minimum of 15 years. These data will all be stored at the University of Adelaide.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any scientific journal publication, conference presentation, or report to the funding body (The Hospital Research Foundation) information will be provided in such a way that you cannot be identified. There is potential that the data may be used in the future by any researchers in any field, who will apply to access the deidentified data through the relevant research team.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored and be disclosed only with your permission, or as required by law.

What happens if I am injured from taking part in the study?

In the unlikely event of you being injured in the study, a public hospital, including The Royal Adelaide Hospital, The Queen Elizabeth, Lyell McEwin or Modbury Hospitals will provide

medical treatment. Your participation in the study will not affect any other right to compensation you may have under common law.

Who do I contact if I have questions about the project?

If you wish to speak to the study investigators please contact the study coordinator Dr Nerylee Watson, on (08) 8222 7369, or email nerylee.watson@sa.gov.au

What if I have a complaint or any concerns?

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates.

This statement has been developed to protect the interests of people who agree to participate in human research studies.

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC, reference number 13930). If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the HREC Support Officer, Research Ethics Committee, on (08) 7117 2229 or email: Health.CALHNResearchEthics@sa.gov.au Any complaints should also be directed to the HREC Support Officer, CALHN HREC, Telephone: (08) 7117 2229; Email: Health.CALHNResearchEthics@sa.gov.au All complaints will be treated in confidence and fully investigated. You will be informed of the outcome.

If I want to participate, what do I do?

If you are interested, please contact the study co-ordinator who will organise an appointment for you to attend The Queen Elizabeth Hospital Rheumatology Department for the first assessment.

Phase 1 Consent Form Study ID:

Project Title: Does light treatment improve sleep and pain?

Protocol Number: 13930

Principal Investigator: Dr Tiffany Gill

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)	
Signature	Date

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print)	
Signature	Date

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Phase 2 Consent Form Study ID:

Project Title: Does light treatment improve sleep and pain?

Protocol Number: 13930

Principal Investigator: Dr Tiffany Gill

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)	_____
Signature _____	Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print)	
Signature _____	Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Optional Sub-Study Consent Form Study ID:

Project Title: Does light treatment improve sleep and pain?

This consent form covers the optional sub-study involving the ingestion of a small capsule which records the participant's central body temperature.

Principal Investigator: Dr Tiffany Gill

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the optional study.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)	
Signature	Date

Declaration by Researcher†

I have given a verbal explanation of the optional sub-study research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print)	
Signature	Date

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

PARTICIPANT WITHDRAWAL OF CONSENT FORM Study ID: _____

Project Title: Does light treatment improve sleep and pain?

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I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Adelaide Institute for Sleep Health or Flinders University.

Name of Participant (please print) _____

Signature_____Date_____

We would be very grateful if you could provide some feedback on your experience in this trial by responding to a few questions, however, you are under no obligation to answer these questions.

You did not complete the full study, could you briefly explain why?

_____

_____

_____

How many times on average per week have you accessed your sleep data via Withings app?

_____

_____

_____

Do you think having access to the Withings app has changed your attitude about your sleep?

_____

_____

_____

Is there any other feedback you would like to leave for the researchers?

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