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VALUE OF A SLEEP QUALITY PROGRAM IN PEOPLE WITH CHRONIC LOW BACK PAIN

PARTICIPANT INFORMATION STATEMENT

(1) The Study

You are invited to take part in a research study investigating the value of a sleep quality program in people with low back pain. This study will help us to understand the effects of a 6-week online sleep program in people suffering with low back pain.

This study is being carried out at the University of Sydney by Mr Kevin Ho as the basis for a PhD under the supervision of Dr Paulo Henrique Ferreira.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about. You will be given a copy of this Participant Information Statement to keep.

(2) Your Participation

Firstly, we would like to invite you to answer a screening questionnaire to check if you are eligible to be included in our study. Your twin will also be invited to answer this screening questionnaire that will take 10-15 minutes to complete. If you are considered to be eligible based on the responses of this questionnaire, you will be invited to participate in an intervention study. All procedures involved in this study will be conducted online or by phone. You will each receive different web-based programs for sleep during 6 weeks. We will randomly allocate you to one of the program groups.

Before starting the program, we will ask you to answer a questionnaire to collect baseline information about your low back pain and sleep pattern. The completion of this questionnaire will take approximately 20-30 min.

The program will be conducted online and you will be asked to do weekly activities that will take an average of 30-60 minutes/week. You will be able to choose the best day and time to do the activities.

When you have finished the program and 6 weeks after the end of the program, we will ask you to answer a questionnaire on low back pain and sleep quality which will take about 20-30 minutes to complete. One week after finishing the program, you will be asked to answer another questionnaire which will take about 5 minutes and you will also be contacted by phone to provide feedback on your experience with the study. This phone interview will be recorded. You will have the option to receive the alternative sleep program after the last questionnaire is answered. There will not be any costs associated with this study.

(3) Who can take part in the study?

You are eligible to participate in this study if:

- You are aged between 18 and 65 years.
- You have had low back pain for more than 6 weeks.
- You have access to the internet with a device that has a speaker, such as a computer or tablet, and an active email account. All information for this study will be collected from you electronically.
- You do NOT have known or suspected serious spinal pathology (fracture, metastatic, inflammatory or infective diseases, widespread neurological disorder).
- You did NOT have spinal surgery in past 12 months.
- You are not receiving care regularly and frequently (at least once per week) for low back pain.
- You are NOT current using medication or receiving any other treatment for insomnia or for depression.
- You are NOT pregnant or lactating.
- You are NOT a shift worker.

Please note that this study is recruiting twins as well as non-twins to compare data.

(4) Participation is voluntary

You are under no obligation to be part of the study, and should you decide to participate, you are free to withdraw from the study at any time.

(5) Are there any risks or costs associated with being in the study?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

(6) Are there any benefits associated with being in the study?

We cannot guarantee that you will receive any direct benefits from being in the study. At the end of the study you will have the option to receive a report with your individual results. You will receive the program, believed to support people with sleep problems, free of charge. Also, you will be assisting greatly with important research in this field by helping us to identify treatments for low back pain and insomnia. Furthermore, one of the questionnaires is a screening tool to identify the possibility of a sleep disorder (specifically: narcolepsy, sleep breathing disorder, periodic limb movements in sleep, restless leg syndrome, circadian rhythm sleep disorder, and parasomnia). In response to the screening tool you may receive a letter from the researchers informing you of the

possibility of a sleep disorder diagnosis, and recommended to see a sleep specialist for further assessment.

(7) Use of your information

By providing your consent, you are agreeing for us to collect personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise. Any recording will be used for analysis only. Study findings may be published, but you will not be individually identifiable in these publications.

The information you provide for this project will be a valuable resource for both current and future research. We will keep the information we collect for this study for use in future ethically approved research. Your data will be stored securely and separately from any personal information that may identify you and your privacy will be protected within the limits of the law.

(8) Further Information

If you would like to know more about the study at any stage, please feel free to contact:

Mr Kevin Ho: (02) 9351 9010, kevin.ho@sydney.edu.au

Dr Paulo Henrique Ferreira: (02) 9351 9397, Email: paulo.ferreira@sydney.edu.au

(9) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study – along with personalised feedback concerning your individual results. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form or by contacting a member of the research team at any time. You will receive this feedback at the end of the study.

(10) What if I have a complaint or any concerns about the study?

Research in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [2015/386].

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Director of Research Integrity and Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 0200
- **Email:** research.integrity@sydney.edu.au

This information sheet is for you to keep