**The Postpartum Sleep Study for Mothers (The POSSUM Project)**

**Information for Participants**

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**1. Introduction**

The POSSUM Project was developed to improve the sleep and wellbeing of first-time mothers from 4-12 months postpartum. The project will evaluate the effectiveness of three wellbeing programs, which are aimed at reducing sleep problems and the associated daytime effects of sleep disturbances, such as fatigue. The wellbeing programs themselves run for **6 weeks**, with a follow-up assessment delivered at **Week 10**.

This page explains what is involved, so you can decide if you would like to participate. Please read this information carefully and ask any questions you may have. Before deciding whether or not to take part, feel free to discuss it with a relative, friend, or health professional.

**2. What is the purpose of this research project?**

The postpartum period is associated with significant challenges to sleep. Although baby sleep patterns start to stabilise around approximately 3-4 months, many mothers continue to face problems with their own sleep well after this. These sleep problems represent big challenges for first-time mothers and have a range of effects on their own wellbeing, as well as the wellbeing of their babies.

There are effective non-drug strategies for improving sleep and wellbeing, but they are not readily available to most new parents in the community and are not well integrated into routine postnatal care. The purpose of The POSSUM Project is to evaluate whether evidence-based programs for sleep will improve sleep disturbances and the overall wellbeing of first-time mothers from 4-12 months postpartum.

 **3. What does participation in The POSSUM Project involve?**

Once you consent to participate, you will receive an email with a personalised link to complete a questionnaire online (25-30 minutes). This questionnaire will ask you about your health, sleep, mood and a range of other factors. This questionnaire will also help us determine whether the POSSUM Project will be suitable for you.

If suitable, a researcher will then contact you for an introductory telephone call to ask about your health, sleep and life experiences which will take approximately 15-20 minutes. If still suitable, we will provide you with an orientation to the project via telephone which will take a maximum of 90 minutes.

If the project is not the best fit for you and if you require other support, we will provide you with information on more suitable services.

Participants who proceed with the POSSUM Project will be allocated to **1 of 4** groups:

**Group 1** – You will receive evidence-based information and strategies to improve your sleep and associated daytime effects. These materials will be send to you via brief, easy-to-read emails for 6 weeks (3-5 emails each week, 21 emails in total).

**Group 2** – You will receive the same materials as Group 1 delivered to you at Week 10, after you complete the final questionnaire. You may choose to receive these materials on a weekly basis or all at once.

**Group 3** – You will receive Light Therapy glasses with instructions on how to use them. You will be asked to wear the glasses when you wake up in the morning for the duration of the project (i.e. until Week 10). We ask that each time you use the glasses for 20 - 30 minutes each time and avoid wearing them while driving. Although there is no maximum duration of glasses usage per day, we recommend against using the glasses for more than 30 minutes *each time* that you use them, as exceeding this time does not necessarily lead to greater benefits. You will also receive strategies for daytime/night-time light exposure and will be provided with a night light. An email will be sent to you each week for the first 6 weeks to encourage your use of Light Therapy.

**Group 4** – You will receive both the written strategies in Group 1 **as well as** the Light Therapy glasses in Group 3. Like Group 3, you will wear the glasses for 20 minutes in the morning and will make use of strategies relating to daytime/night-time light exposure, as well as receiving a night light and a Light Therapy email each week for the first 6 weeks.

If you are allocated to Groups 1, 3 or 4, the orientation phone call will include information on how to make the most out of the project and will be individualised to your needs.

Regardless of your Group, you will also receive a telephone call mid-way through the project to touch base (5-15 minutes). All participants will receive a phone call from a researcher at Week 6 to assess sleep and health, taking a maximum of 10 minutes.

**Can I choose my program?** You will be randomly allocated to one of the four groups described above, which means that you will be unable to select what specific group you are allocated.

**Evaluating the POSSUM Project.** To evaluate whether the materials provided to you are helpful, we will ask you to complete questionnaires. You will complete a total of 4 online questionnaires (about 25-30 minutes each). These will be: when you sign up and at Weeks 3, 6 and 10 of the project.

**Compensation**. To compensate for your time, we will send you a $50 Coles Group & Myer Gift Card upon your completion of the final questionnaire at Week 10.

**4. What are the possible benefits?**

**For you as a participant.** By participating in The POSSUM Project, you will receive scientifically-based strategies for your sleep and fatigue, which are expected to have beneficial effects for your own health and wellbeing, as well as the wellbeing of your baby and family more broadly.

**For other women like you.** The information gathered from this study will be used to improve the sleep and wellbeing of other women like you. It will also build an awareness around the importance of maternal sleep in the community. By taking part in The POSSUM Project, you will make a significant contribution to advancing postnatal care for mothers in the community and across Australia.

**5. What are the possible risks?**

If you are allocated to Groups 3 or 4, you will undertake Light Therapy, which has been researched extensively and is a safe therapeutic device. However, some (yet minimal) side-effects have been identified including: infrequent states of elevated mood, irritability, eye strain, headaches and nausea. If you experience any side-effects, please discontinue use of the light glasses, contact us immediately (see below) so that we are best able to assist you and seek medical assistance if necessary. There are no significant foreseeable risks if you are allocated to Groups 1 or 2.

It is possible that when completing some questionnaires about your feelings, you might think about things that upset you. In the event of such discomfort, you can contact Dr Bei Bei (Clinical Psychologist – see below). If you prefer to speak to someone independent of this study about your distress during your participation, we strongly encourage you to speak to your doctor, who will be able to link you to appropriate support. If you are in crisis and would like to speak to a trained professional urgently, please call Lifeline at 13 11 14. Other counselling or support agencies include:

1. **Perinatal Anxiety & Depression Australia (PANDA)**

1300 726 306 (Mon - Fri, 9am - 7.30pm)

[www.panda.org.au](http://www.panda.org.au)

1. **beyondblue**

1300 224 636 (24 hours a day, 7 days a week)

Online forums: <https://www.beyondblue.org.au/get-support/online-forums>

1. **Parentline** **Victoria**

13 22 89 (8am – midnight, 7 days a week)

1. **Maternal and Child Health Line**

13 22 29 (24 hours a day, 7 days a week)

**6.  Do I have to take part in this research project?**

Participation in this study is voluntary. If you do not wish to take part, you are not obliged to. If you decide to take part and later change your mind, you may withdraw at a later stage by notifying a member of the research team. To help ensure the results of the study can be measured properly, the researchers would like to keep your information that has been collected. If you do not want them to do this, please tell them.

**7. How will I be informed of the final results of this research project?**

If you wish, a summary of the study findings can be sent to you at the completion of the study. It is anticipated that this summary will be available within 6 months of project completion.

**8. What will happen to information about me?**

Any information you provide us (i.e., via questionnaires and telephone) will remain strictly confidential. We will record all telephone interactions with you so that your responses can be cross-scored and checked. To maintain your privacy, information you provide will be held separately from your name and contact information, and you will be identified by code only. All information will be stored in locked cabinets (and in cases of digital files, in password protected files), in a secure office at Monash University.

Audio recordings of telephone interviews will be stored securely with password protection. Trained researchers will extract coded information from these recordings and store these codes securely with other information you have provided, for analysis.

Only the researchers named above will have access to your information. You or any information that might identify you (e.g., name, audio recording) will not be named in any reports or publications arising from this study.

Any publications or reports that arise from this study will include only combined results from all participants, so any information that might identify you (e.g., name, audio/video recording) will not be released. No information about you will be disclosed to any person or external organisation without your written permission. The information you provide will be held in a secure location for at least 7 years after publications, after which time any identifying information will be destroyed.

However, if we are concerned about your safety or the safety of others at any point throughout the project, we are legally and ethically obliged to disclose personal information. This also applies in the extremely rare circumstance in which we are subpoenaed by the legal system for whatever reason.

**9. Can I access research information kept about me?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

**10. Is this research project approved?**

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies. The Monash University Human Research Ethics Committee has approved the ethical aspects of this research project.

**11. Who can I contact?**

If you want any further information concerning this project or if you have any problems that may be related to your involvement in the project, you can contact the Project Coordinator via email: psych-possum@monash.edu

If you have questions related to the intervention materials you received, or have concerns about your own sleep, please contact Ms Sumedha Verma, email: sumedha.verma@monash.edu or Dr Bei Bei, Ph: (03) 9905 2464, email: bei.bei@monash.edu

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact: Executive Officer, Monash University Human Research Ethics (MUHREC), Ph: (03) 9905 2052, email: muhrec@monash.edu