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Participant Information Sheet and Consent Form

Full Project Title: The **Sleep**, **Ca**ncer and **Re**st (**SleepCare**) Trial: A Randomised, Controlled Trial of Four Treatments for Sleep during Chemotherapy

Coordinating Principal Investigator: Dr Joshua Wiley

Site Principal Investigator: *[Insert site principal investigator]*

Location: *[Location]*

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1 Introduction

You are invited to take part in a research project that aims to improve sleep and wellbeing for women with breast cancer receiving intravenous or oral chemotherapy. You are being invited because you are receiving intravenous or oral chemotherapy for breast cancer.
This Participant Information Sheet and Consent Form provides information on the research project. It explains the tests and treatments involved. 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 your doctor. Taking part in this research is voluntary. If you do not wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section or provide verbal consent. By providing written or verbal consent you are telling us that you:
- Understand the information that you have read or has been read to you
- Consent to take part in the research project
- Consent to have the tests and treatments that are described below.
- Consent to the use of your personal and health information as described below.

You will receive a copy of this Participant Information and Consent Form via email as a record.

2 What is the purpose of this research?

This research aims to evaluate several treatments for better sleep and fatigue during chemotherapy. Poor sleep is a common complaint during breast cancer, especially during chemotherapy. Many factors are responsible for poor sleep during breast cancer, these include: the stress of a cancer diagnosis, the direct impact of breast cancer treatment and side effects, symptoms and hospitalisations. Poor sleep during breast cancer can impact physical and psychological health and someone's overall quality of life.

Although most women experience significant sleep problems during breast cancer, sleep problems often go untreated. To address this, the current study is evaluating a 6-week program focusing on three treatments:

1. Cognitive behavioural therapy. Cognitive behavioural therapy is a short-term therapy technique that focuses on changing ways of thinking and behavioural patterns to improve sleep.
2. Light therapy. Light therapy manages someone's exposure to light, particularly in the morning and evening, to help support energy levels during the day and improve sleep overnight.
3. Sleep hygiene therapy. Sleep hygiene therapy refers to a set of strategies that support healthy sleep habits.

The study is led by a team of researchers and psychologists from *[Name of institution]* and Monash University and will include at least 200 women receiving chemotherapy treatment for breast cancer treatment.

The results of this research will be used for scientific publications, conferences and by the researcher Jordan Maccora, PhD student, to obtain a Doctor of Philosophy (Clinical Psychology) degree.

3 What does participation in this research involve?

To participate, you need to be:

- Diagnosed with breast cancer
- At least 18 years of age
- Female
- Receiving oral or intravenous chemotherapy with at least 6 weeks of treatment remaining
- Able to read and write in English
- Able to provide informed consent
- Have regular email and internet access

There is no cost to you to participate in this study.

If you meet these criteria and would like to participate, a researcher will have a discussion with you to answer any questions you have and assess your suitability for this study. During this discussion, you will be asked about your health and life experiences.

Afterwards, you will be informed whether or not this project is suitable for you. 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.

Participating in the project

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for a condition. To find out we need to compare different groups to see if one group has better results than the other. To try to make sure the groups are the same, each participant is put into a group by chance (randomly).

If suitable, you will be randomly allocated to one of **four** groups: "cognitive behaviour and light therapy group" **or** "cognitive behaviour only" **or** "light therapy only" **or** "sleep hygiene group". Your participation will differ based on which group you are in.

Participants in all groups will:

- Receive helpful information on how to improve sleep and wellbeing during chemotherapy and throughout your breast cancer experience.
- Be involved in the study for about six weeks.

If you are in the "cognitive behaviour and light therapy group" you will:

- Attend 1 initial consultation at the start of the 6-week program. This will be conducted at *[Name of institution]* in the *[Insert location]* or via telehealth (phone or virtual consultation). This session will take about 75 minutes. If the session is conducted in person, we make every effort to schedule this when you are already at *[Name of institution]* for an appointment. If we cannot fit it around one of your appointments, or if you prefer to come in specially for this session, we will reimburse your car parking costs.
- Have 1 telephone call or a visit in the *[Insert location]* when you are receiving chemotherapy, depending on your preference, lasting about 30 minutes during the fourth week of the program.
- Receive biweekly email modules for six weeks (12 in total) that will each take about 20 minutes to read.
- Be loaned 1 pair of light therapy glasses and wear them for 20 minutes each morning for 6 weeks.

If you are in the "cognitive behaviour only" you will:

- Attend 1 initial consultation at the start of the 6-week program. This will be conducted at the *[Name of institution]* in the *[Insert location]* or via telehealth (phone or virtual consultation). This session will take about 60 minutes. If the session is conducted in person, we make every effort to schedule this when you are already at *[Name of institution]* for an appointment. If we cannot fit it around one of your appointments, or if you prefer to come in specially for this session, we will reimburse your car parking costs.
- Have 1 telephone call or a visit in the *[Insert location]* when you are receiving chemotherapy, depending on your preference, lasting about 30 minutes during the fourth week of the program.
- Receive biweekly email modules for six weeks (12 in total) that will each take approximately 20 minutes to read.

If you are in the "light therapy group" you will:

- Attend 1 initial consultation at the start of the 6-week program. This will be conducted at the *[Name of institution]* in the *[Insert location]* or via telehealth (phone or virtual consultation). This session will take about 30 minutes. If the session is conducted in person, we make every effort to schedule this when you are already at *[Name of institution]* for an appointment. If we cannot fit it around one of your appointments, or if you prefer to come in specially for this session, we will reimburse your car parking costs.
- Have 1 telephone call or a visit in the *[Insert location]* when you are receiving chemotherapy, depending on your preference, lasting about 30 minutes during the fourth week of the program.
- Be loaned 1 pair of light therapy glasses and wear them for 20 minutes each morning for 6 weeks.

- Receive weekly email modules for six weeks (6 in total) that will each take approximately 20 minutes to read.

If you are in the "sleep hygiene group" you will:

- Attend 1 initial consultation at the start of the 6-week program. This will be conducted at the *[Name of institution]*in the *[Insert location]* or via telehealth (phone or virtual consultation). This session will take about 30 minutes. If the session is conducted in person, we make every effort to schedule this when you are already at *[Name of institution]* for an appointment. If we cannot fit it around one of your appointments, or if you prefer to come in specially for this session, we will reimburse your car parking costs.
- Have 1 telephone call lasting approximately 30 minutes during the fourth week of the program.
- Receive weekly email modules for six weeks (6 in total) that will each take approximately 20 minutes to read.

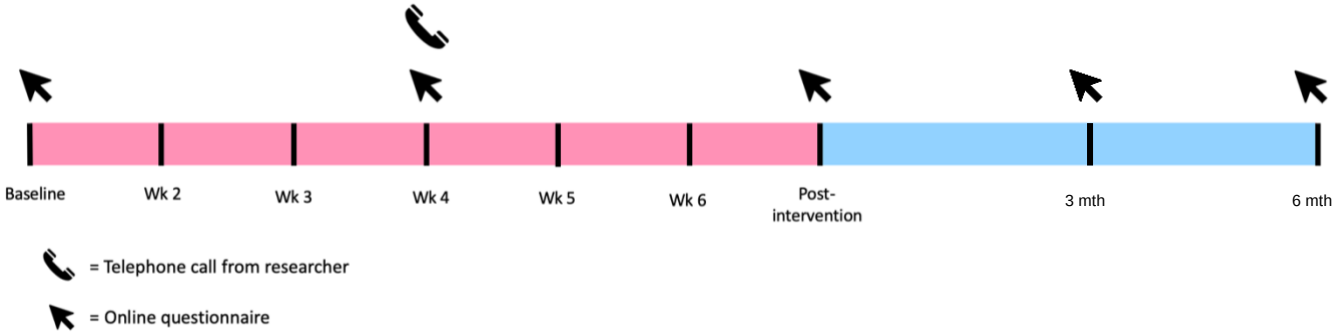
The email modules include fact sheets and strategies on *what to expec*t and *how to manage* sleep disturbances during breast cancer. If you have questions about the email materials, you can contact a researcher who will be able to answer your questions (see contact details below).

Can I choose my group? This study requires completely random (chance) grouping, so you are unable to choose which program you are allocated to.

Evaluating the study:

To evaluate whether the cognitive behavioural therapy, light therapy or sleep hygiene therapy is helpful for your sleep and wellbeing during chemotherapy, we will ask participants in **all** groups to complete the following:

- **Questionnaires:** You will be asked to complete a set of sleep and mood questionnaires at the beginning of the program, at the fourth week of the program, after the final sixth week of the program and three months after the program's completion. At the start of the program you will also be asked some basic questions about yourself such as age, relationship status and financial income, which is important in helping us know who has participated in the study so we can better understand what type of women our findings apply to. We will also ask about your current and past mental health as well as some questions about your current breast cancer diagnosis and treatment. These questionnaires will take about 20 minutes to complete each time and are completed online from home unless you would prefer to complete them via telephone.
  Sleep measure: You will be asked to wear an actigraphy watch (similar to a wrist watch or Fitbit) for two, two-week periods occurring at the beginning of the program and during the final two weeks of the program. This will record your sleep and day time activity. You will also be asked to fill in a sleep diary each morning during this time, this will take approximately 1-2 minutes each day and will provide us with information on how you feel about your sleep.



- **Medical records access:** we will also ask your permission to collect some background information from your medical record (such as your health, cancer stage and cancer treatment)
- **Audio recording:** initial consultations and telehealth (phone or virtual consult) sessions will be audio recorded to ensure that the researcher provides the same information to each participant in the study.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

4 What do I have to do?

During your time participating in the study, all of your usual medical treatment will stay exactly the same. You will not need to change anything about your diet or lifestyle.

All groups will need to complete the questionnaires at three time points across the six weeks and once at approximately three months and six months after the program's completion. You will also complete a sleep diary each morning and wear an actigraphy watch for two two-week periods occurring at the beginning of the program and the during the final two weeks of the program.

If allocated to the "cognitive behaviour and light therapy group" **or** "light therapy only group" you will also need to wear your light glasses each morning when you wake up for 20 minutes. Whilst wearing the glasses, you are still able to move around, cook and eat breakfast, read and do most other household activities apart from showering. You must not drive whilst wearing the glasses.

If you are randomised to the "cognitive behaviour and light therapy group" **or** "cognitive behaviour only group" **or** "sleep hygiene group" you will also need to put some time aside each week to read your sleep and wellbeing strategies email and try to use these skills that you will read about to improve your sleep. For example, some of the strategies include: practicing waking up at the same time each morning and using simple relaxation and breathing exercises to help you sleep through pain and discomfort.

5 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 are free to withdraw from the project

at any stage. If you do decide to withdraw, please notify 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.

If you do decide to take part, you will be emailed a copy of this Participant Information and Consent Form to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, **WILL NOT** affect your routine treatment, your relationship with those treating you or your relationship with *[Name of institution]*. Before making your decision, you can discuss any questions you have about the research project with a member of the research team.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment for your sleep disturbance at this hospital. Other options are available; these include discussing your situation with a member of your treating team (e.g. doctors or nurses) or seeking a referral from a research team member or your medical team to the *[Name of institution]* Clinical Psychology Department. This service is cost free and clinical psychologists at *[Name of institution]* are professionally trained in reducing any psychological distress associated with your cancer diagnosis, including sleep problems. A study researcher will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your GP.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits include:
For you as a participant. By participating, you will learn skills for managing disruptions to your sleep and wellbeing that occur during chemotherapy and throughout your breast cancer experience. These skills are scientifically based and are likely to be helpful to you. You may also experience reduced fatigue and sleep disturbance, improved sleep quality, mood and wellbeing.

For other women with cancer. The information gathered from this study will be used to improve the way we support women living with breast cancer and going through chemotherapy. Study results will inform treatment development, with the potential to improve the sleep and wellbeing of other women like you. It will also build awareness around the importance of sleep health during breast cancer in the community and will contribute to advancing routine care for many other women in the future.

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

There are no significant foreseen risks in participating in this study. It is possible that when completing some questionnaires about your feelings, you might think about things that upset you. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in this research, or if the research team is concerned about your physical or psychological well-being, we will inform your treating team (this may include your oncologist, nurse, allied health

or psychosocial departments) who will be able to discuss your needs and assist in arranging appropriate support and follow-up. You can also contact Jordan Maccora or Dr Joshua Wiley on 03 9028 8540 during business hours 9am – 4pm on weekdays. Any counselling or psychological support provided by staff at the *[Name of institution]* will be provided free of charge. If you prefer to speak to someone independent of this study about your distress, we strongly encourage you to speak to your GP, 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**.

9 Can I have other treatments during this research project?

Participating in this research project will not impact your regular cancer treatment in anyway. You should continue to work with your treating team and undergo prescribed treatments and procedures as usual.

10 What if I withdraw from this research project?

If you do consent to participate, you may still withdraw your consent at any later point in time. If you decide to withdraw from the project, please notify a member of the research team. Following withdrawal, a research team member may contact you to complete a brief closing phone call. If you do withdraw your consent during the research project, the research team will not collect additional personal information from you. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

Your decision whether to take part or not to take part, or to take part and then withdraw, **WILL NOT** affect your routine treatment, your relationship with those treating you or your relationship with the *[Name of institution]*.

11 What happens when the research project ends?

The cognitive behaviour therapy component of the project is designed to be of use to you in the future, after the project ends. If you have found the strategies helpful for your sleep and wellbeing, we encourage you to keep using the materials as part of your own self-care routine. If you have found the light therapy to be helpful, you are able to purchase the light therapy glasses yourself. Please speak with a researcher if you would like further information about this.

12 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 18 months of study completion. In addition, at the end of the study, you may request more detailed findings by contacting us at 03 9028 8540.

13 What will happen to information about me?

Any information you provide us, including those via questionnaires, face-to-face or telehealth (phone or virtual consult) contact, audio recording and actigraphy data will remain confidential. To maintain your privacy, you will be assigned a numeric identification code. Any identifiable

information you provide such as your name and contact information will be stored in a program that meets stringent criteria for data security of health-related information. Outside of this program, you will only be identified by your numeric code. All hard copies of data collected will be kept in secure locked filing cabinets at Monash University and/or *[Name of institution]*.

Only members of the research team will have access to information that might identify you (e.g., name, audio recording). Any publications or reports that arise from this study will include only combined results from many participants, so you or any information that might identify you (e.g., name, audio recording) will not be released.

7 years after the final publication, we will de-identify the data by removing names, date of birth, addresses/contact details, and any information that may link the data to you personally. These personally identifying data will be completely erased and destroyed. The de-identified database will be made publicly available through Monash Bridges to maximize the potential benefit to the scientific and research community.

While information you provide as part of this research will remain confidential and only accessible by the research team, we may come across additional information about your physical or emotional well-being that we need to refer back to your treating team (including your medical team as well as allied health and psycho-social oncology services) for them to follow-up and address as part of usual care.

If a member of our research team believes that there is a potential risk or danger posed to you or someone else, your contact details may be provided to support services. These may include, but not limited to, *[Name of institution]* psycho-social oncology services, your local specialist mental health service, or emergency services.

14 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. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

15 Who is organising and funding the research?

This research project is being conducted by *[Insert site principal investigator]*, Dr Joshua Wiley, Jordan Maccora, Dr Bei Bei and *[Insert associate investigators]*. The project is funded by Monash University, the National Health and Medical Research Council and light therapy glasses are provided by Lucimed SA. All members of the research team have no financial interests in the outcome of this research and will not benefit financially from this research project.
You will not benefit financially from your involvement in this research project.
No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

16 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the *[Name of institution]*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

17 Further information and who to contact

The person you may need to contact will depend on the nature of your query. Please note the following

Further information:
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 Study Coordinator, Ph: 03 9028 8540, email: psych.sleepcare@monash.edu

Please note, this phone will be answered by research team members (Jordan Maccora or Joshua Wiley) between 9am and 4pm on weekdays. All messages, emails and voicemails will be responded to within one week.

If you have questions related to the intervention materials you received, or have concerns about your sleep, please contact:

Clinical contact person

Name	Mr Jordan Maccora
Position	PhD student, provisional psychologist
Telephone	03 9028 8540
Email	psych.sleepcare@monash.edu

Name	*[Insert site principal investigator]*
Position	*[Insert position]*
Telephone	*[Insert telephone number]*
Email	*[Insert email address]*

Complaints and compensation:
If you suffer any injuries or complications as a result of this research project, you should contact the study team (details above) as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Position	*[Insert consumer liaison contact]*
Telephone	*[Insert telephone number]*

Email	*[Insert email address]*

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 the HREC executive officer:

Reviewing HREC name	Peter MacCallum Cancer Centre Ethics Committee
HREC Executive Officer	Ethics Coordinator
Telephone	(03) 8559 7540
Email	ethics@petermac.org

HREC office contact:

Future studies on sleep during cancer and chemotherapy:
Our research team may conduct further studies on sleep and cancer in the future. Please indicate on the consent form if you would be agreeable to future contact for this purpose.

Insert Header with institution's name or institution's letterhead

Consent Form - *Adult providing own consent*

Full Project Title	The SleepCare Study
Coordinating Principal Investigator	Dr Joshua Wiley
Site Principal Investigator	*[Insert site principal investigator]*
Location	*[Location]*

Declaration by Participant

I have read the Participant Information Sheet and I understand the purposes, procedures, and risks of this research project as described in this document. I understand that I can contact the researchers if I have any queries about this research and that I will be given a copy of the Participant Information and Consent Form to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to my treating hospital concerning my disease and treatment for the purposes of this project.

I consent for relevant information including any comorbid medical conditions, medications used during the study period, cancer and tumour staging information, all treatment regimens and dates (surgery, type of surgery, when it occurred, chemotherapy, type of chemotherapy, when it commenced/ duration), height, weight, and age, to be extracted from my medical records and used in this research project. I also give consent for my telehealth and face-to-face contact with the research team to be recorded, as outlined in the Participant Information Sheet.

The researchers have agreed not to reveal my identity and personal details if information about this project is published or presented in any public form. I understand that all information collected about me will be treated with strict confidentiality unless there is a risk posed to myself or someone else, or when required by law, at which time my information may be disclosed.

I understand that I will be allocated to one of four (4) project groups and that as part of the research protocol, I cannot choose which group I will be in. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I would like to receive a summary of the project findings at the conclusion of the study. ☐

I agree to being contacted for future studies related to sleep and wellbeing and agree to my name, email and phone being added to a list for this future contact. ☐

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior 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 Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.

Insert Header with institution's name or institution's letterhead

Form for Withdrawal of Participation - *Adult providing own consent*

Full Project Title	The SleepCare Study
Coordinating Principal Investigator	Dr Joshua Wiley
Site Principal Investigator	*[Insert site principal investigator]*
Location	*[Location]*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the *[Name of institution]*.

Name of Participant (please print) _____

Signature _____ Date _____

If applicable - Description of verbally communicated participant decision to withdraw:

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.