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Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Peter MacCallum Cancer Centre

Title	Light Enhanced Cognitive Behavioural Therapy (CBT+) for Sleep and Fatigue: A Randomized Controlled Trial during Chemotherapy for Breast Cancer
Short Title	CBT+ for Women with Breast Cancer
Principal Investigator	Ms Justine Diggens
Location	Peter MacCallum Cancer Centre

Part 1 What does my participation involve?

1 Introduction

You are being invited to take part in a research project that aims to improve sleep and wellbeing for women with breast cancer undergoing chemotherapy. You are being invited because you are either commencing or undergoing chemotherapy for breast cancer treatment. This Participant Information Sheet/Consent Form tells you about 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 local doctor. Participation in this research is voluntary. If you don't 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. By signing it you are telling us that you:
- Understand what you have read
- 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 be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This research aims to evaluate a cognitive behavioural and bright light therapy program for better sleep and wellbeing during chemotherapy. Sleep disturbance 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 cancer treatment and side effects, medical symptoms and hospitalisations. Having sleep difficulties during breast cancer has been linked with many physical and psychological consequences and reduced overall quality of life.

Although most women experience significant sleep problems during breast cancer, sleep problems often go untreated. To address this issue, this study is evaluating a 6-week program with the goal of improving sleep and reducing symptoms of depression, anxiety and day time fatigue.

The study is led by a team of researchers and psychologists from the Peter MacCallum Cancer Centre and Monash University and will include at least 80 women engaged in chemotherapy treatment for breast cancer at the Peter MacCallum Cancer Centre.

The results of this research will be used for scientific publications, conferences and by the researcher Helena Bean, Doctoral candidate, to obtain a Doctor of Psychology in Clinical Psychology degree.

3 What does participation in this research involve?

To participate, you need to be:

- diagnosed with any stage primary breast cancer,
- over 18 years of age
- female
- receiving or will receive during the study period any form of chemotherapy
- able to provide informed consent
- able to understand and speak English
- able to regularly access and receive emails

If you meet these criteria and would like to participate, a researcher will have a discussion with you where any questions you have will be answered, and your suitability for this study will be assessed. 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.

Participating in the project

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating 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 (random).

If suitable, you will be randomly allocated to **either** the "cognitive behaviour light therapy group" **or** the "relaxation audio group". Your participation will differ based on which group you are in.

Participants in <u>both</u> 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 approximately six weeks.

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

- Attend 1 face to face session at the start of the 6-week program. This will be conducted at the Peter MacCallum Cancer Centre in the chemotherapy day unit. This session will take approximately 75 minutes and you will be reimbursed for car parking costs. Face to face sessions will be scheduled around participants existing appointments where possible to reduce burden of travel.
- Have 1 telephone call lasting approximately 30 minutes during the fourth week of the program.
- Receive weekly email modules for six weeks (7 in total) that will each take approximately 20 minutes to read.
- Be loaned 1 pair of light therapy glasses during the face to face session and wear them for 20 minutes each morning for 6 weeks.

If you are in the "relaxation audio group" you will:

- Receive two emails during the six weeks that include web links to relaxation audio tracks. You will be encouraged to listen to these guided relaxations whenever you feel they might be useful for you.
- Receive the 'cognitive behaviour light therapy group' email modules at the end of the 6-week study period to read at your leisure.

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 get in touch with a researcher who will be able to answer your questions (see contact details below).

Can I choose my group? This study requires completely random grouping, so you are unable to choose which program you are allocated to. Both groups will still receive the sleep skills and strategies information, just at different times.

Evaluating the study:

To evaluate whether the cognitive behavioural and light therapy is helpful for your sleep and wellbeing during chemotherapy, we will ask participants in **<u>both</u>** groups to complete the following tasks:

- **Questionnaires:** You will be asked to complete of a set of sleep and mood questionnaires at the beginning of the program, at the fourth week of the program and after the final sixth week of the program. These questionnaires will take approximately 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 six weeks. This will record your sleep and day time activity. You will also be asked to fill in a sleep diary each morning, this will take approximately 1-2 minutes 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:** Face to face sessions and telephone calls will be audio recorded to ensure that the researcher provides the same information to each woman in the study.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.
There are no costs associated with participating in this research project, nor will you be paid.

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.

If you are randomised to the 'relaxation audio' group, you will need to complete the questionnaires at three time points across the six weeks, complete the sleep diary each morning and wear the actigraphy watch.

If you are randomised to the 'cognitive behaviour and light therapy' group, you will need to complete the questionnaires at three time points across the six weeks, complete the sleep diary each morning and wear the actigraphy watch. 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.

You will 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 Other relevant information about the research project

This project is only based at the Peter MacCallum Cancer Centre and will include a total of 80 women with breast cancer. The project is a collaboration between the Peter MacCallum Cancer Centre and Monash University.

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

Participation in any research project is voluntary. If you do not wish to take part, you do not have 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 take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy 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 the Peter MacCallum Cancer Centre.

7 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 Peter Mac Clinical Psychology Department. This service is cost free and clinical psychologists at Peter Mac are professionally trained in reducing any psychological distress associated with your breast cancer, 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.

8 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 breast 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. It will also be used to improve psychological health and wellbeing for women with breast cancer. You will make a significant contribution to advancing care for many other women in the future.

9 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 Helena Bean or Dr Josh Wiley during business hours 9am – 4pm on weekdays (contact information is detailed at the end of this form). Any counselling or psychological support provided by staff at the Peter MacCallum Cancer Centre 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.

10 Can I have other treatments during this research project?

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

11. What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team.

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.

12 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.

13 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 commencement. In addition, at the end of the study, we will host an information evening which you may attend to learn more about the findings of the study.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using personal and health information about you for this research project. The personal information that the research team collect and use is information from questionnaires, audio recordings of telephone calls, audio recordings of face to face sessions and actigraphy data. The research team will also collect information from your medical records held at this and other health organisations for the purpose of this research.
Any information you provide us will remain confidential and only the researchers will have access to your information.
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, including audio recordings, will be stored in password protected files.
You or any information that might identify you 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 you or any information that might identify you will not be released.
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.
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.

15 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.

16 Who is organising and funding the research?

This research project is being conducted by Justine Diggens, Dr Joshua Wiley, Helena Bean, Dr Bei Bei, Dr Lesley Stafford, Dr Maria Ftanou and Dr Marliese Alexander. The project is funded by Monash University and light therapy glasses are provided by Luminette. 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).

17 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 Peter MacCallum Cancer Centre.

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.

18 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 Project Coordinator, Ph: 03 9028 8540, email: psych.sleepwell@monash.edu
Please note, this phone will be answered by research team members (Helena Bean 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	Miss Helena Bean
Position	Doctoral candidate, provisional Clinical Psychologist
Telephone	03 9028 8540
Email	Psych.sleepwell@monash.edu

Name	Ms Justine Diggens
Position	Clinical Psychologist
Telephone	03 8559 5243

Email	Justine.diggens@petermac.org

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	Consumer Liaison
Telephone	(03) 8559 7517
email	consumerliaison@petermac.org

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:

HREC office contact:

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

Consent Form - *Adult providing own consent*

Title	Light Enhanced Cognitive Behavioural Therapy (CBT+) for Sleep and Fatigue: A Randomized Controlled Trial during Chemotherapy for Breast Cancer
Short Title	CBT+ for Women with Breast Cancer
Principal Investigator	Ms Justine Diggens
Location	Peter MacCallum Cancer Centre

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Peter MacCallum Cancer Centre concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 understand that all information about me will be treated with strict confidentiality.

☐ Yes ☐ No

I consent to the audio recording of the face to face session and telephone call components of the program. 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 study without affecting my future health care.
I understand that I will be given a signed copy of this document to keep.
I understand that I can contact the researchers if I have any queries about this research.

I understand that I will be allocated to either the "Cognitive behaviour and light therapy" or the "Relaxation audio" group, and that as part of the research protocol, I cannot choose which group I will be in. 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.

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.

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

Title	Light Enhanced Cognitive Behavioural Therapy (CBT+) for Sleep and Fatigue: A Randomized Controlled Trial during Chemotherapy for Breast Cancer
Short Title	CBT+ for Women with Breast Cancer
Protocol Number	
Principal Investigator	Ms Justine Diggens
Location	Peter MacCallum Cancer Centre

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 Peter MacCallum Cancer Centre.

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.