Participant Informed Consent Form

Full Title:	**A Randomized Controlled Trial of Online Cognitive Behavior Therapy for Insomnia (CBT-I) and Perceived Cognitive Impairment (PCI) in Cancer Survivors**
Short Title:	**Online CBT-I for PCI**
Clinical Trials Information	NCT04026048
Principal Investigator:	Sheila N. Garland, PhD[1,2]
Co-Investigators:	Joshua Rash, PhD[1] Melanie Seal, MD, FRCP[2] Josée Savard, PhD[3] Robin Urquhart, PhD[4] John Thoms, MD FRCPC[2] Kara Laing, MD, FRCP[2]
Patient Co-Investigator:	Sondria Browne
Affiliations:	[1] Department of Psychology, MUN Faculty of Science [2] Division of Oncology, MUN Faculty of Medicine [3] Département d'école de psychologie, Université Laval [4] Department of Community Health and Epidemiology, Faculty of Medicine, Dalhousie University
Sponsor:	Canadian Institutes of Health Research (CIHR)

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I am now going to read some important information about our study. Please feel free to stop me to ask questions at any time.

The title of our study is "A Randomized Controlled Trial of Online Cognitive Behaviour Therapy for Insomnia (CBT-I) and Perceived Cognitive Impairment (PCI) in Cancer Survivors".

The Principal Investigator, also known as the Study Doctor, is Dr. Sheila Garland, a Psychologist at in the departments of psychology and oncology at Memorial University.

Why am I being asked to participate?

You are being asked to participate in this study because you have completed cancer treatment at least 6 months ago and currently report problems with sleep and difficulties paying attention, concentrating, and/or remembering things. Please ask as many questions as you like before deciding to take part in this research study. You can discuss this with your family, friends, and your health-care team. If you do wish to have extra time deciding on your participation, please contact a member of the study team at 709-864-8035 or email sleeplab@mun.ca. Alternatively, you can contact the study doctor, Dr. Sheila Garland, at 709-864-4897, who can also help to answer your questions.

Why is this study being done?

For cancer survivors, two of the biggest barriers to resuming normal functioning are cognitive impairment and insomnia. Approximately 75% of cancer patients report a decline in a variety of cognitive domains during cancer treatment, and up to 35% continue to experience cognitive difficulties for months or years post-treatment. Sleep disturbances affect 30-50% of individuals who have been treated for cancer and can have a negative effect on cancer recovery and overall quality of life. To help address this issue, our study will investigate if online treatment for insomnia can improve memory, concentration, and attention in cancer survivors. We are hoping to enroll 124 participants across Atlantic Canada.

Do you have any questions or is there anything you would like me to clarify?

How is this study designed?

Our study is a two-group, randomized, controlled trial. This means that you are put into a group by chance (like flipping a coin). Neither you, nor the research team can choose the group you will be in. You will have an equal (50:50) chance of being assigned to either of the programs (group 1 is immediate treatment and group 2 will receive treatment after a waitlist period). The purpose of randomization is to ensure that those in each group are identical in every other respect. That way, we can be sure that any differences we observe between the two groups are due to the study intervention and nothing else.

If you are in group 1, you will receive immediate treatment with online CBT-I. You will complete 5 assessments over an 8-month period. If you are in group 2, you will receive treatment with online CBT-I after a waiting period of two months, during this period you will be monitored and still required to complete some assessments. You will complete 7 assessments over a 10-month period.

What is expected of me?

If you agree to take part in this study, you will participate in the following tests and procedures:

Screening for Eligibility:
At this point, you have been deemed to be eligible for the study.

Online Cognitive Behavior Therapy for Insomnia (CBT-I):
CBT-I is a multicomponent treatment designed to address behaviors and thoughts that are known to influence the development and maintenance of sleep difficulties. You will receive seven individual sessions of CBT-I delivered by via video-conferencing over the course of eight weeks. We want to make sure that everyone is getting the highest quality treatment and that treatment is being delivered consistently to everyone. In order to do this, we need to tape the sessions and have them reviewed by the principal investigator of the study. The tapings will be deleted immediately after review.

Sleep and Cognitive Assessments:
You will be required to complete some questionnaires and performance tasks before, during, after treatment.The questionnaires will assess your sleep, your ability to remember things, pay attention, concentrate, and your psychological wellbeing. We will also ask about the impact of your insomnia on your ability to work, your mood, and energy levels, and your ability to remember things, pay attention, and concentrate. The performance tasks will assess your ability to learn and remember things. This will involve recalling and repeating a series of words, numbers, and other similar tasks. Each performance task and questionnaire will take about 2-5 minutes to complete. The purpose of the performance tasks and questionnaires is to understand if CBT-I can be used to improve memory, concentration, and attention.

Participant Diaries:
You will be asked to keep a diary of your sleep history for one week after each assessment period. You will be required to return the diary by email or you will be provided with a stamped envelope to return by mail.

Screening for Adverse Events
Although adverse events related to CBT-I are unlikely we will ask you about your experience during your mid and post treatment assessments.

Do you have any questions or is there anything you would like me to clarify?

How long will I be involved in the study?

Your participation will last 8 months if in the immediate treatment group or 10 months if in the wait-list treatment group.

What are the potential risks or discomforts I may experience?

The potential risks to taking part in this study are minimal. With CBT-I, the most common side effects are short-term (less than 2 weeks) and include increases in daytime sleepiness and mood disturbance. Some of the questionnaires you will be completing may touch on sensitive areas. It is possible that you may feel upset by your performance on the tests or certain questions. You do not have to answer any questions you are uncomfortable with. Should you

become upset, Dr. Garland will evaluate your psychosocial well-being and refer you to the appropriate services. You are encouraged to discuss with a member of the study team any negative feelings or experiences you have as a result of participating in this research project.

Do you have any questions or is there anything you would like me to clarify?

Can I expect to benefit from participating in this research study?

Participants who receive online CBT-I may experience an improvement in their insomnia or their ability to remember things, pay attention, and concentrate. Improving insomnia and other problematic symptoms often leads to an improvement in overall physical and emotional well-being. We hope that the information learned from this study can be used in the future to benefit other cancer survivors with insomnia by helping us understand the effectiveness of CBT-I for improving your ability to remember things, pay attention, and concentrate.

Are there other choices?

Your alternative is not to participate. If you do not enroll in this study, you may contact your personal physician to discuss other treatments for insomnia, which may include other behavioral strategies or medications.

If I agree now, can I change my mind and withdraw later?

You are free to withdraw from the study at any time without providing the investigator with a reason. If you decide to withdraw, you may also request that any data associated with you up to that point in the study be deleted. Your participation in the study may be stopped for any of the following reasons:

- The principal investigator feels it is in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You are unable to complete all required study procedures.
- You need treatment not allowed in the study.
- The study is stopped by the Health Research Ethics Board (HREB) or your study doctor.

Do you have any questions or is there anything you would like me to clarify?

Will I be paid for my participation or will there be any additional costs to me?

There will be no costs to you associated with the study. You will be compensated as a token of our appreciation. You will be given $100 in total (if in the immediate treatment group) or $140 in total (if in the delayed treatment group) for your participation in this study ($20 per assessment). This will be given in the form of an online gift card to a store of your choice (Tim Hortons, Esso, Home Hardware, or Amazon). A number of participants have peers that may be eligible for the study and we will also compensate participants for their referrals. You will receive an additional $10 to your gift card for each eligible person you refer to the study and you can receive up to $20 (2 referrals).

How is my personal information being protected?

- All personal health information such as your cancer stage and cancer treatment and your personal identifying information (PII), such as your name, address, date of birth, etc. will be kept confidential.
- Release of your personal information will only be allowed if it is legally required.
- As a participant, you will be assigned a coded study number that will be used throughout the study on all your study records. A Master List provides the link between your identifying information and the coded study number. This list will only be available to Dr. Sheila Garland and the study team and will not leave this site.
- The use of Zoom and Qualtrics is secured by industry standard, and the protective technology will ensure that information sent to and from this site is protected. The taping of treatment sessions is important to ensure you are given consistent and high quality treatment and tapings will be deleted immediately after review.
- You will not be identified in any publications or presentations resulting from this study.
- Study information collected during the study will kept at this site and stored in a secure, locked place that only the study staff will be able to access. After the study closes, study information will kept as long as required by law, which could be 25 years or more. This information will be stored in a locked office in the Department of Psychology at Memorial University. Dr. Sheila Garland is the person responsible for keeping it secure.
- A description of this clinical trial is available on clinicaltrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time by visiting: https://clinicaltrials.gov/ and entering NCT04026048 under find studies -> other terms.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

For Atlantic Path participants only:

- Because you were recruited through Atlantic Path we are required to share your data from the current study with Atlantic Path. At the conclusion of the ACTION study your responses to the questionnaires and performance tasks will be sent to Atlantic Path. None of your personal information will be shared with Atlantic Path. Information shared with Atlantic Path will be stored securely at Dalhousie University in Halifax, NS, Canada. Mr. Jason Hicks is the person responsible for keeping data shared with Atlantic Path secure.

Do you have any questions or is there anything you would like me to clarify?

What are my responsibilities as a study participant?

It is important to remember the following things during this study:

- Ask the study coordinator or the principal investigator if you have any questions or concerns.
- Tell the study coordinator or the principal investigator if anything about your health has changed including new medications or medications you plan on taking.
- Tell the study team if you have any problems you think might be related to taking part in the study.
- Return any unused study equipment if applicable.
- Tell a member of the study team if you are thinking of participating in another study.

Who do I contact if I have any further questions?

If you have any questions about this study, please contact the Principal Investigator, Dr. Sheila Garland, at 709-864-4897, or you can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person is the research ethics office and can be reached by telephone at 709-777-6974 or by email at info@hrea.ca.

Verbal Consent to Participate in Research

Ok, that's all the information about our study, did you have any questions for me? Would you still like to participate?

No - No problem, thank you so much for taking the time to speak with me today, take care and have a great day!

Yes – Great! Then I have some specific questions for you

Checklist

- Do you understand that you are being asked to participate in a research study which seeks to evaluate the effectiveness of an online treatment for insomnia to improve attention, concentration, and/or memory? □ Yes □ No

- Do you understand treatment sessions will be taped but deleted immediately following review? □ Yes □ No

- ***Atlantic Path Participants Only:*** Do you understand that your responses to questionnaires and performance tasks will be de-identified an shared with the Atlantic Path study? □ Yes □ No

- I have had each page of this Consent Form read to me. □ Yes □ No

- If I decide later that I would like to withdraw my participation and/or consent from the study, I know that I can do so at any time. □ Yes □ No

- All of my questions have been answered to my satisfaction. □ Yes □ No

- I voluntarily agree to participate in this study. □ Yes □ No

Participation in Future Research Studies

We would like your permission to contact you in the future to see if you would be interested in participating in other research studies.

- Are you willing to be contacted about other research studies? □ Yes □ No

To be completed by Research Assistant

- Date (*dd/mm/yy)* _____
- Participant Name _____expressed a desire to participate in the study.
- Study procedures and consent form were reviewed with the participant by _____.
- The participant was given the opportunity to ask any questions ___.
- The consent procedure took ____ minutes.
- Consent was obtained prior to any study-specific procedures ____.

Research delegate name: _____

Research delegate signature: _____