Research Ethics ID: REB24-0253

TITLE: Improving sleep to prevent adolescent depression

SPONSOR: University of Calgary, Mathison Centre/Hotchkiss Brain Institute

INVESTIGATORS: Dr. Daniel C. Kopala-Sibley (University of Calgary), Dr. Anna Mackinnon (University of Montreal), Dr. Lianne Tomfohr-Madsen (University of British Columbia), Dr. Norah Vincent (University of Manitoba)

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what you and your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

Approximately 75% of internalizing disorders (i.e., depression and anxiety) occur for the first time during adolescence. It is important to stop these disorders before they develop by addressing risk factors such as poor sleep quality. Previous studies have linked poor sleep and insomnia to the development of mental health disorders such as depression and anxiety in adolescents. Sleep interventions such as Cognitive Behavioral Therapy for Insomnia (CBT-I) have been shown to help treat existing depression and anxiety symptoms, however, little research has examined whether sleep interventions may be effective in preventing teenagers from developing these disorders altogether. The overarching aim of the proposed research is to conduct a pilot trial to evaluate whether a brief intervention for adolescent insomnia improves sleep, overall mood, and symptoms of depression and anxiety in teenagers who have not been diagnosed with any internalizing disorders. The results of this project would provide evidence that this sleep-based intervention may prevent first onsets of these disorders in teens.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to determine if sleep-focused interventions are effective at reducing symptoms of anxiety and depression in healthy teenagers aged 12-18 years.

WHAT WOULD I BE ASKED TO DO?

Interviews and Computer Questionnaires (~2 hours)

- All participants will be asked to complete an interview involving questions about your mood, feelings, and day-to-day behaviour at the beginning and end of the study. This interview will be conducted over the phone with a member of our research team. This interview will also be audio recorded with your permission. Only the researchers involved in this study will have access to these recordings, and they will not be used in any presentations. You will also be asked to complete questionnaires on a computer about your mood and feelings at the beginning and end of the study. No feedback will be given to you or your parent on your responses to these questionnaires. However, we will have to tell your parent if we feel that you are in danger of harming yourself or someone else. You will be asked to fill out a brief questionnaire each day about your sleep which will be completed online and should take approximately 5 minutes per entry.

In this study, you will be “randomized” into one of two study groups: Group A, or Group B. “Randomized” means that you will be put into a group by chance, like flipping a coin. Each group will complete separate tasks as follows:

Group A
Online Learning (~6 hours)

- We will ask you to complete six sessions of a treatment called Cognitive-Behavioural Therapy for Insomnia (CBT-I). These sessions will be delivered online, and you can complete them at your own pace. Each session will take about one hour. After each session, you will be asked to complete some exercises throughout the day, but they should only take about 5-10 minute each. To help you stay on track with the program, weekly reminders will be sent to encourage you to complete each week's session and accompanying exercises.

Group B
Sleep Information Reading (~10 minutes)

- You will be asked to read over a pamphlet with information about sleep quality and sleep hygiene.

WHAT ARE THE RISKS?
You might feel frustrated and/or tired while completing questionnaires or interviews. There are also questions that ask about sad mood, self-harm, thoughts of suicide, and substance use. You are free to not answer any question you do not want to and may stop at any time. All responses will be kept confidential and stored in a secure location.

ARE THERE ANY BENEFITS FOR ME?
By participating in this study, you may benefit from the clinical treatment and improve your quality of sleep.

This study will provide valuable information about the relationship between sleep and the development of internalizing disorders in adolescents. This information will ultimately lead to research providing better treatments for children with mental health problems.

DO I HAVE TO PARTICIPATE?
No. Participation in this study is voluntary and you may withdraw from the study at any time without jeopardizing your health care. If you decide to withdraw from the study, please notify Dr. Daniel Kopala-Sibley or the project coordinator, Hayley Schmidtler (hayley.schmidtler@ucalgary.ca; 403-210-6839). Researchers or research staff involved in this study can withdraw you from the study for any reason. If any new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?
To thank you for your time, you will be compensated with electronic gift cards. Due to the differing tasks, your compensation will be dependent on which group you are randomized into.

Group A
You will receive $200. Each completed online learning session is worth $25 and will be paid altogether after you complete all 6 online learning sessions. You will receive the remaining $50 after you complete a follow-up interview with us in 3 months.

Group B
You will receive $100 - $25 after completing the sleep information reading and initial surveys, $25 after completing the 6-week follow up interview, and $50 after completing the 3-month follow up interview.

WILL MY RECORDS BE KEPT PRIVATE?
Yes. Any information about you obtained from or for this research study will be kept confidential (private). All records pertaining to your involvement in this research study will be stored in a locked file cabinet and data will be both encrypted and password protected on secure U of C servers. A study identification (ID) number will be used on any research records (your name will not be on these records).

A master list connecting your name to your Study ID number will be kept in a separate, secure location. University policy requires that we keep your research records for a period of at least five years after final publication of the study results. Access to your identifying information will be limited to the researchers listed on the first page of this form. Research records may be released to other investigators for related research, and these records will not contain any personal identifiers. You will not be identified by name in any publication of the research results.

Since this study is about an online program, we will also collect user-data from website such as how many times you log in, how much time you spend on it, and what sections you complete.

If you participate, your reports related to this research will only be made available to the regulatory authorities including the University of Calgary Conjoint Health Research Ethics Board. This organization will treat such information with strict confidentially. This means that no records bearing your name will be provided to anyone with exception of the regulatory authorities, where necessary, and investigators involved in this study.

You may decide to withdraw from the study and discontinue your participation at any time. If you decide to withdraw from the study, you may also request that your data be withdrawn for up to 1 month following the end of your participation. To revoke your consent at any time, notify Dr. Daniel Kopala-Sibley or the project coordinator, Hayley Schmidtler.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the unlikely event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the researchers, the University of Calgary, or Alberta Health Services. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

* **SIGNATURE**

Your signature on this form indicates that you have understood the information regarding your participation in the research project and agree to participating as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time. If you have further questions concerning matters related to this research, please contact:

Dr. Daniel Kopala-Sibley or Hayley Schmidtler (403-210-6839; hayley.schmidtler@ucalgary.ca)

If you have any questions concerning your rights as a possible participant in this research, please contact The Chair, Conjoint Health Research Ethics Board, University of Calgary, at 403-220-7990.

Given the above information, do you give consent for your child to participate in this research study?

- ◯ Yes
- ◯ No

*** Your first and last name**

*** Today's date**

Date / Time

Date

MM/DD/YYYY

The investigator or a member of the research team will, as appropriate, explain to you the research and your involvement. They will seek your ongoing cooperation throughout the study.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study (REB24-0253)