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 child's 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 efficacious at reducing symptoms of anxiety and depression in healthy teenagers aged 12-18 years who have a parent with a history of mood difficulties.

WHAT WOULD MY CHILD HAVE TO DO?

Interviews and Computer Questionnaires (~2 hours)

- All youth participants will be asked to complete an interview involving questions about their 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 child's permission. Only the researchers involved in this study will have access to these recordings, and no identifiable information will be used in any presentations or reports. Your child will also be asked to complete questionnaires on a computer about their mood and feelings at the beginning and end of the study. No feedback will be given to you or your child on the responses given during these questionnaires. However, we will inform you if we feel that your child is at risk of harming themselves or others.

In this study, your child will be "randomized" into one of two study groups: Group A, or Group B. "Randomized" means that they 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 your child to complete six sessions of a treatment called Cognitive-Behavioural Therapy for Insomnia (CBT-I). These sessions will be delivered online, and they are able to complete them at their own pace. Each session will take about one hour. After each session, they will be asked to complete some exercises throughout the week, but they should only take about 5-10 minutes each day. To help your child stay on track with the program, weekly reminders will be sent to encourage them to complete each week's session and accompanying exercises.

Group B
Sleep Information Reading (~10 minutes)

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

WHAT ARE THE RISKS?
Your child 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. All participants will be made aware that they are not required to answer any questions they do not want to and may stop their participation at any time. All responses will be kept confidential and stored in a secure location.

ARE THERE ANY BENEFITS FOR MY CHILD?
Children in this study may benefit from the clinical treatment and improve their 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.

DOES MY CHILD HAVE TO PARTICIPATE?
No. Participation in this study is voluntary and you may withdraw your child from the study at any time without jeopardizing their health care. If you decide to withdraw from the study, please notify Dr. Daniel Kopala-Sibley. Researchers or research staff involved in this study can withdraw your child from the study for any reason. If any new information becomes available that might affect your willingness to participate in the study, you and your child will be informed as soon as possible.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?
To thank you and your child for your participation and valued contribution to this research, your family will receive compensation through the form of electronic gift cards. Due to the differing tasks, your compensation will be dependent on which group you are randomized into.

Group A
Your family will receive $225 total: $200 for your child, and $25 for you. Each completed online learning session is worth $25 for your child, and will be paid in a lump sum after completing the 6 online learning sessions ($150 total). Your child will then earn the remaining $50 after completing a follow up interview 3 months later.

Group B
Your child 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 CHILD'S RECORDS BE KEPT PRIVATE?

Yes. Any information about your child obtained from or for this research study will be kept confidential (private). All records pertaining to your child's 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 child's name will not be on these records).

A master list connecting your child's name to their Study ID number will be kept in a separate, secure location. University policy requires that we keep your child's research records for a period of at least five years after final publication of the study results. Access to your child's 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. Your child will not be identified by name in any publication of the research results. Any future use of this research data is required to undergo review by a Research Ethics Board.

If you participate, your child's 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 child's name will be provided to anyone with exception of the regulatory authorities, where necessary, and investigators involved in this study.

Since this is an online program, we will also collect user-data from the website your child is going to us. This includes whether or not they logged in, how much time they spent on it, and what modules they completed.

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, notify Dr. Daniel Kopala-Sibley or the project coordinator, Hayley Schmidtler.

IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

In the unlikely event that your child suffers 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**

*** Your child's 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 your child the research and his or her involvement. They will seek your child’s ongoing cooperation throughout the study.

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