

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 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 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 I HAVE TO DO?

In this study, you and your child 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 (~1 hour)

- We will ask you to complete one online parent information session to inform you of the treatment called Cognitive-Behavioural Therapy for Insomnia (CBT-I). This group session will be delivered online via Zoom. To help your child stay on track with the program, weekly reminders will be sent to you or your child (if they have an email) so it encourages them to complete each week's session and accompanying exercises.

Group B

- You will not be asked to complete any tasks if you and your child are randomized into Group B. However, your child will be given the chance to receive CBT-I after the study if they are still interested - in which case you will be invited to complete a parent information session.

WHAT ARE THE RISKS?

Online Information Session

- Other parents may see/hear you during the online information session. You are free to not participa

ARE THERE ANY BENEFITS FOR ME?

There are no direct benefits for you from participating in this research.

Indirectly, you may be able to better help your child sleep as a result of participating in this study. This study will also 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 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 earn the remaining \$50 after completing a follow-up interview 3 months later. Your \$25 compensation will be sent to you following your attendance at the online parent information session.

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 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.

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 confidentiality. 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.

Since this is an online program, we will also collect user-data from the website your child is going to use. 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.

*** 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 consent to participate in this research study?

☐ Yes

☐ No

*** Your first and last name**

*** Today's date**

Date / Time

Date