

A pilot randomized clinical trial of cognitive-behavioural therapy for insomnia in adolescents
with persistent post-concussion symptoms

Date: September 19, 2018

Supplement 1.
Trial Protocol.

Trial Design

This study involved a single-blind, parallel-group randomized control trial design comparing CBT-I and a treatment as usual (TAU) control group. Eligible participants were randomly assigned to either the active treatment (CBT-I) or the TAU control group using a gender blocked computer-based randomization tool (<https://www.randomizer.org/>). Participants who were randomized to the TAU condition were offered CBT-I after all follow-up measures were completed. Researchers administering the assessments were blinded to the randomization results. The trial followed and is reported according to CONSORT guidelines ¹. The outcome measures chosen were informed by recommendations for assessing outcome in insomnia trials, including assessment of potential secondary gains associated with treatment ². The study received was approved by the University of Calgary Conjoint Health Research Ethics Board (REB16-1166).

Participants and Procedures

Participants were recruited from the Alberta Children's Hospital (ACH) Brain Injury Clinic between October 2016 and August 2017. Adolescents were referred to the ACH Brain Injury Clinic based on persistent post-concussion symptoms. A total of 78 adolescents were approached, of whom 51 indicated interest in the study. Interested participants who could be contacted were screened for insomnia over the phone using the Insomnia Severity Index (ISI). If the potential participant received a score of ≥ 12 on the ISI, they were invited to attend a baseline session to determine eligibility. Of the participants who expressed interest in the study, 18 could not be reached for further screening and 9 did not meet the inclusion criteria. The final sample

consisted of 24 youth who were randomized to CBT-I (n=12) or TAU (n=12). Participant flow is presented in Figure 1.

Inclusion criteria included: (1) 12-18 years of age; (2) diagnosed with a concussion by a nurse practitioner or physician at the ACH Complex Concussion Clinic (i.e., concussion was defined as an traumatic injury to the head, at least one reported symptom [e.g., dizziness, headache, nausea] at the time of the injury, and a Glasgow Coma Scale rating of $\geq 13/15$ at 30 minutes after injury, or loss of consciousness < 30 minutes, or post-traumatic amnesia < 24 hours)³; (3) being at least 1 month but no more than 12 months post-injury to ensure symptoms were no longer acute, yet current and persistent; (4) reporting elevated symptoms of insomnia measured by an Insomnia Severity Index score of ≥ 12 ; and (5) ability to attend in-person treatment sessions. Exclusion criteria included: 1) moderate or severe TBI (i.e., Glasgow Coma scale rating of ≤ 12 , loss of consciousness exceeding 30 minutes, and/or post-traumatic amnesia exceeding 24 hours); and 2) visual, hearing, motor, and/or language deficits that would hinder the completion of questionnaires or engagement in CBT-I.

Assessments took approximately 45 minutes to complete and were conducted at baseline, post-treatment, and follow-up at four weeks after treatment. Assessments and treatment took place at the University of Calgary. In the first assessment at baseline, informed consent from the parent and informed assent from the adolescent were obtained in addition to baseline questionnaire data. If deemed eligible, participants were asked to fill out online sleep diaries for seven days. After the sleep diary was completed, participants were randomized to either CBT-I or TAU groups. If randomized to the CBT-I group, a study therapist contacted the participant and scheduled the first session. Seven weeks later, the post-treatment assessment was completed via online questionnaire and sleep diary. A third assessment was completed approximately four

weeks after treatment (follow-up) via online questionnaire and sleep diary. A research coordinator who was blinded to group membership collected all data. After the third assessment was completed, participants in the TAU group were invited to take part in the six-week CBT-I treatment (additional outcome measures were not collected if they did so). Identical measures were completed at each time point, with the exception of demographics, which were collected only at baseline. At every assessment, participants were given a fifteen-dollar gift card for completing the online questionnaires and an additional five dollars for every day that they completed the online sleep diary, for a potential total of fifty dollars.

Measures

Demographics. Demographic information included age, date of birth, ethnicity, sex, height, weight, and concussion history.

Insomnia Severity Index (ISI). The ISI is widely used to measure insomnia severity and treatment response in sleep research ⁴. The ISI is a seven-item self-report questionnaire that assesses sleep onset latency, sleep efficiency, and functional impact from sleep issues ⁴. The sleep latency and efficiency items are rated on a 5-point Likert scale from 0 (*none*) to 4 (*very severe*). The remaining four items measure dissatisfaction, how noticeable sleep problems are to others, distress from sleep problems, and interference with daily functioning (all rated on 5-point Likert scales). Total scores on the ISI range from 0-28. Although the ISI was originally designed for adults, it has been shown to be valid in adolescent populations ⁵⁻⁷. In a clinical sample, an ISI score ≥ 11 has been shown to have 97% specificity and 100% specificity to detect insomnia ⁴. The current study used a cut score of ≥ 12 for eligibility to maximize the likelihood that participants had clinically significant insomnia symptoms. The ISI total score was the primary outcome measure for treatment response.

Pittsburgh Sleep Quality Index (PSQI). The PSQI is a widely used brief self-report measure of sleep quality aimed at examining the facets of sleep disturbance ⁸. It is composed of 19 items that measure sleep disruptions in the month prior to questionnaire completion. The PSQI contains seven subscales: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction, which are combined into a total sleep quality score. The total PSQI raw score ranges from 0 to 21, with higher scores representing worse sleep disturbance; scores of greater than 5 indicate clinically significant sleep disruption ⁸. PSQI scores have adequate internal consistency ⁹. Additionally, the PSQI has shown validity for assessing sleep disturbances in adolescents following traumatic brain injury ⁹.

Online Sleep Diary. Participants completed an online sleep diary for the seven consecutive nights immediately following the completion of their questionnaire battery. Participants were asked to complete the sleep diary within an hour of waking up. The online sleep diary consisted of eight items assessing bedtime, duration of sleep initiation, night time waking, wake time, get-up time, nap time, and overall length and perceived quality of sleep. The perceived quality of sleep was collected by using a visual analog of a 5-point Likert scale ranging from 1 (*very poor*) to 5 (*very good*). Sleep diaries are a reliable estimate of sleep variables and considered a gold standard subjective sleep outcome ^{2,10}. Sleep diaries have been used in other CBT-I studies with adolescents and have been shown to provide accurate sleep information in adolescent populations ^{11,12}. Across each of the 7-day assessment periods, average total sleep time (TST), wake after sleep onset (WASO), sleep onset latency (SOL) and sleep efficiency (SE) were calculated.

The 24-Hour Sleep Patterns Interview (SPI) was used to ensure sleep diary compliance and consistency. The SPI is a telephone interview that asks participants questions about sleep patterns over the past 24 hours, including bedtime, night wakening (frequency and duration), and overall sleep quality. The 24-hour sleep patterns interview was developed to corroborate actigraphy data, but for the purposes of this study was used to ensure adherence and consistent reporting of sleep diary data. Participants received a phone call from a research assistant on day two and day five of the 7-day sleep diary period and were asked to verify their responses for the prior morning entry. This measure has been shown to be valid and feasible compared with a sleep diary ¹³.

Dysfunctional Beliefs and Attitudes about Sleep (DBAS-16). The DBAS was developed to identify unhelpful beliefs about sleep, and is composed of 16 items organized on an 11-point Likert scale that ranges from 0 (*strongly disagree*) to 10 (*strongly agree*). All item scores were summed to calculate a total raw score where higher scores indicate more negative beliefs and attitudes towards sleep. This scale identifies potential negative cognitions that can be held about sleep, such as the perceived consequences of insomnia, worry/helplessness about insomnia, general sleep expectations, and medications ^{14,15}.

Patient Reported Outcomes Measurement Information System (PROMIS®)

Anxiety. The pediatric PROMIS® Anxiety questionnaire was developed by the National Institutes of Health (NIH) to evaluate symptoms of anxiety, such as feelings of fear, anxious misery, and hyperarousal in pediatric populations ^{16,17}. The self-report version of the PROMIS® Anxiety questionnaire was included in this study. This 8-item measure queries anxiety symptom presentation based on the past seven days, with each item rated on a 5-point Likert scale ranging from 1 (*never*) to 5 (*almost always*). All item scores were summed to calculate a total raw score

where higher scores indicate more severe anxiety symptomology. The PROMIS® anxiety measure has been used in child, adolescent, and adult populations and has shown adequate or exceptional reliability ^{16,17}.

PROMIS® Depression. The pediatric PROMIS® Depression questionnaire was developed by the NIH to evaluate symptoms of depression, such as feelings of hopelessness, helplessness, and worthlessness in pediatric populations ^{16,17}. The self-report version of the PROMIS® Depression questionnaire was included in this study. This 8-item measure queries depression symptom presentation based on the past seven days, with each item rated on a 5-point Likert scale ranging from 1 (*never*) to 5 (*almost always*). All items were summed to calculate a total raw score where higher scores indicate more severe depressive mood symptomology. The PROMIS® depression measure has been used in child, adolescent, and adult populations and has shown adequate or exceptional reliability ^{16,17}.

Health and Behavior Inventory (HBI). The Health and Behavior Inventory (HBI) ¹⁸ was used to measure the presence and severity of post-concussive symptoms based on adolescent self-report. The HBI measures the frequency of common somatic and cognitive post-concussive complaints and does not include any sleep-related items. The HBI is a 20-item questionnaire where symptoms are rated on a 4-point Likert scale ranging from 1 (*never*) to 4 (*often*) based on frequency over the past week. All items were summed to calculate a total raw score where higher scores indicate more severe post-concussive symptoms. The HBI was developed as a measure for both child and parent-proxy reports of post-concussive symptoms in children ¹⁸. The HBI has strong internal reliability ¹⁹ and is identified as a core common data element for pediatric brain injury research by the National Institute of Neurological Disorders and Stroke (NINDS) ²⁰.

Treatment

Participants in the treatment group received six weekly sessions of CBT-I. The protocol included psychoeducation about insomnia, relaxation strategies, instruction on sleep consolidation, stimulus control/sleep hygiene, cognitive restructuring, and problem solving/relapse prevention and mindfulness techniques. Sessions two through six began with a review of sleep diaries, calculation of sleep efficiency (SE), and troubleshooting of any problems encountered in home practice. This was followed by the introduction of new treatment components and a personal project for the next week. The protocol was based on CBT-I for adults²¹ and was adapted for use with adolescents with concussion by the research team, which included an experienced CBT-I therapist (LTM). The initial adaptation was piloted in a group form, but based on feedback CBT-I was delivered individually in this trial.

Manualized treatment was delivered by PhD students in clinical psychology, all of whom underwent a two-day training in delivery of CBT-I by the first author and were supervised weekly by a licensed PhD level clinical psychologist with experience in delivery of CBT-I and group supervision (JWM). A detailed description of the treatment by week is presented in Table 1. Average number of sessions attended was 4.9 (SD = 2.2), with nine of twelve (75%) participants attending all six sessions.

Insert Table 1 About Here

Statistical Analysis

All analyses were conducted using SPSS 25.0²². Baseline demographic and medical variables for the two conditions were compared using one-way ANOVAs and χ^2 tests. Intent-to-treat (ITT) analyses were conducted in line with CONSORT guidelines (i.e., all participants who

started the intervention were included) ¹. ITT analyses were completed using maximum likelihood linear mixed model analyses. Between-group differences on primary and secondary outcome variables were also analyzed using linear mixed models. Linear mixed models are considered robust with respect to inclusion of participants with missing data in repeated measures research and are considered superior to traditional repeated measures ANOVA for longitudinal designs ^{23,24}. Treatment group (CBT-I or TAU) was specified as the between-subjects factor, and time of measurement was the within-subjects factor. The effect of interest was the treatment group by time interaction coefficient. Models were tested to include a linear and quadratic time coefficient; in final models the quadratic time coefficient was removed for all analyses in which it was not significant. Multiple structures were tested for sigma, and the identity structure was chosen because it provided the best Schwarz's Bayesian Information Criterion (BIC) for each model. The treatment group variable was introduced as a dummy-coded variable with TAU as reference group. An α of 0.05 was used to determine statistical significance. Effect sizes of 0.20, 0.50, and 0.80 were interpreted as indicating small, medium, and large effects, respectively. Standardized effect sizes for linear mixed models were derived by calculating standard deviation (SD)_{pooled} = $\sqrt{\frac{((\text{standard error } [se]_1 \cdot \sqrt{n_1})^2 \cdot (n_1 - 1) + (se_2 \cdot \sqrt{n_2})^2 \cdot (n_2 - 1))}{(n_1 + n_2 - 2)}}$ based on existing recommendations ²⁵⁻²⁷.

Other sleep data outcomes included change in PSQI, DBAS, and sleep diary measures. Most participants provided at least some sleep diary data. On average, participants provided data for 5.6 / 7 days at each assessment. Specifically, sleep diaries were completed by all 24 participants at baseline (mean days of completion = 6.0), by 19 participants at post-treatment (mean days of completion = 5.0), and by 20 participants at the four-week follow-up (mean days of completion = 5.7). All available sleep diary data were included in analyses.

Clinically significant change in ISI scores—the primary outcome variable—was also assessed in two ways. First, a variable indicating whether the ISI changed eight points or more was tested—a change of this magnitude is accepted as a meaningful change in CBT-I trials ²⁸. Additionally, we calculated and analyzed the proportion of participants in each condition that reached a score below a cut-off of 8 (i.e., 0-7) on the ISI at each time point, indicative of “absence of insomnia” ²⁹. To compare the proportion of participants who exhibited clinically significant change or reached a score below the cut-off, Fisher’s exact tests were used.

Supplement Table 1. Structure of Cognitive-Behavioural Therapy for Insomnia (CBT-I)

Session 1: Introduction

1. Psychoeducation about insomnia and the CBT-I treatment including basic principles for coping with sleep problems
2. Setting realistic sleep goals for treatment
3. Discuss the importance of self-monitoring
4. Practice using the Daily Sleep Diary

Session 2: Relaxation Training

1. Discuss the relationship between relaxation and sleep
2. Review common relaxation practices
3. Practice relaxation exercises in session

Session 3: Stimulus, Sleep Consolidation and Medication Use

1. Psychoeducation about stimulus control
2. Review progress using sleep consolidation procedures and help adjust the sleep window
3. Learn stimulus control procedures as a means of re-establishing a positive association between bed and sleeping
4. Talk about steps to take control of sleep problems
5. Review common sleep medications, uses and side effects

Session 4: Cognitive Therapy

1. Discuss the relationship between thoughts, feelings, and sleep behaviours.
2. Review biased ways of thinking about sleep, signs that self-talk may be negative and self-defeating and the categories of negative self-talk
3. Examine attitudes and beliefs about sleep
4. Identify and challenge participants' negative self-talk about their sleep
5. Discuss how worry may interfere with sleep and planning specific worry time

Session 5: Sleep Hygiene

1. Review the definition of sleep hygiene
2. Discuss how diet/liquids, environment, exercise temperature and sleep-wake schedule can contribute to sleep

Session 6: Mindfulness and Relapse Prevention

1. Discuss mindfulness techniques as a way to improve insomnia
2. Review common mindfulness practices in session
3. Practice mindfulness exercises in session
4. Emphasize the importance of maintaining treatment gains and continuing to work towards better sleep
5. Discuss effective ways to cope with relapse

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ASSENT FORM FOR YOUNGER PARTICIPANTS (12-14 years)

PROJECT TITLE: Treating sleep disturbance in adolescents who have protracted recovery from a mild traumatic brain injury: A pilot randomized controlled trial using CBT-Insomnia

PRINCIPAL INVESTIGATOR: Dr. Brian Brooks

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about the best way to help kids who have had a concussion and are having trouble sleeping. We think that Cognitive-Behavioural Therapy for Insomnia might be a good way to help sleep problems.

If you agree to join this study, you will be asked to answer questions about your sleep and your feelings, to participate in Cognitive-Behavioural Therapy for Insomnia for six weeks (one time per week), and then to answer the same questions again when the therapy is done and again one month later.

Risks

Some questions are tough and you may get frustrated when we give you hard questions. We will also ask you about your feelings and if you get sad you can talk to someone about them.

Benefits

Being in this study may not help you. But it can help other kids who hit their heads and are having trouble sleeping because we will know more about how to help treat their sleep problems.

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study or if you join the study and change your mind later and stop.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study please feel free to contact Dr. Brooks (403-955-2597).

Would you like to be in this research study?

_____ Yes, I will be in this research study.

_____ No, I don't want to do this.

We would like you to choose a fake name for yourself for us to use when contacting you. What fake name do you choose?

Fake first name: _____

Fake surname: _____

Child's name

Person obtaining assent

Signature

Date



CONSENT FORM

TITLE: Treating sleep disturbance in adolescents who have protracted recovery from a mild traumatic brain injury: A pilot randomized controlled trial using CBT-Insomnia

SPONSOR: Clinical Research Grant, Cumming School of Medicine

INVESTIGATORS:

Principal Investigator:

Dr. Brian L. Brooks, Pediatric Neuropsychologist; (403) 955-2597

Co-Investigators:

Dr. Lianne Tomfohr, Assistant Professor and Clinical Psychologist

Dr. Karen M. Barlow, Pediatric Neurologist & Director of the Calgary Childhood Traumatic Brain Injury Program

Dr. Keith Owen Yeates, Professor and Neuropsychologist

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

Each year, 35,000 Canadian children and adolescents sustain a mild traumatic brain injury (mTBI) (also called a concussion). Although research supports that the vast majority of youth will recover quickly and return to normal functioning, some adolescents continue to report problems long after the injury. Disturbed sleep, notably trouble with sleep onset and sleep maintenance, is a frequently reported problem in those with slow recovery from an mTBI. Despite the identification of sleep disturbance as a problem associated with slow recovery, there are very few treatment options. Cognitive-behavioural therapy for insomnia (CBT-I) has shown promise in children and adolescents as an effective treatment for sleep disturbance, although it has yet to be applied to the adolescent mTBI population who also present with sleep problems.

Ethics ID: REB16-1166

Study Title: Treating sleep disturbance in adolescents who have protracted recovery from a mild traumatic brain injury: A pilot randomized controlled trial using CBT-Insomnia

PI: Dr. Brian L. Brooks

Version number/date: November 8, 2016

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CHREB Template March 2015

Participant's Initials: _____

WHAT IS THE PURPOSE OF THE STUDY?

The objective of this study is to examine the treatment of sleep disturbance using cognitive-behavioural therapy for insomnia (CBT-I) in those adolescents who have a slow recovery from their mTBI. This represents a novel treatment option for this patient population and is anticipated to improve outcomes and quality of life.

WHAT WOULD WE HAVE TO DO?

If you choose to participate in this study, you will be asked to do the following:

Week 1: At the start of the study, you will be interviewed about your sleep problems, and if eligible for the study, will fill out questionnaires about your sleep, symptoms, any pain, mood, and worrying. Questionnaires will take 30 minutes and will be done electronically. You will also complete a sleep diary, which takes about 5 minutes per day, and will be done online. Your parent will also fill out questionnaires about your sleep, mood and worrying, as well as demographic information. Parent questionnaires will take about 10 minutes to complete and are also done electronically.

Weeks 2-7: In this study, you will be “randomized” into one of the two study groups described as follows. “Randomized” means that you will be put into a treatment group by chance, like flipping a coin. If you are selected for treatment, you will participate in six weekly sessions that involve the treatment strategy called cognitive-behavioural therapy for insomnia (CBT-I). These sessions will be delivered in-person at the University of Calgary. The therapy sessions will be led by a clinical psychology graduate student who has experience in providing this therapy. The therapy will be supervised by a registered psychologist (Dr. Tomfohr-Madsen). Each week, you will also complete the sleep diary as part of the therapy, which will take about 5 minutes each time. If you are selected for the waitlist, you will not receive treatment at this time.

Week 8: Seven weeks after the first assessment, you and your parent will fill out the same questionnaires electronically that were filled out at the start of the study. It will take about 30 minutes for your questionnaires, 5-10 minutes for the parent questionnaires, and 5 minutes for the sleep diary each day.

Week 12: Approximately one month after the first follow-up assessment, you and your parent will fill out the same questionnaires electronically that were filled out at the start of the study. It will take about 30 minutes for your questionnaires, 5-10 minutes for the parent questionnaires, and 5 minutes for the sleep diary each day. If you were selected for the waitlist group and are still experiencing problems with sleep, at this time, you will be invited to participate in six weekly sessions of CBT-I.

WHAT ARE THE RISKS?

There are no identifiable risks associated with participation in this study. The treatment that you will receive has been previously used in helping people obtain better sleep. If you tell us that you are in danger of hurting someone, you are in danger of hurting yourself, or you are in danger of hurting others, we are required by law to ask you more questions to find out more about the situation, and see what steps need to be taken to keep you safe. If the situation is very serious that you are in danger of harming yourself, the safety steps might include making sure that you are taken to a hospital’s emergency department by ambulance.

The online questionnaires are being administered using a program called Qualtrics©, which is an American software company that is subject to U.S. laws (including the USA PATRIOT Act). Because the USA PATRIOT Act permits the government to look at data stored in their country, we will have you complete all questionnaires using a study ID number (not your name) and no identifiers will be included in the database or stored by Qualtrics (e.g., email addresses, IP addresses).

We will contact you by either email or text message (SMS) through the booking and scheduling service called “Jane”. Jane is based in Canada, so the USA PATRIOT Act does not apply to Jane. With Jane, we can send you convenient reminders about any appointments you have with our study, and we can send you convenient web-links to our Qualtrics questionnaires, so you do not have to worry about mailing them to us. As a precaution, we would like you to choose a fake name (pseudonym/alias/nick-name) that we would use to contact you through Jane.

The fake name (pseudonym/alias/nick-name) I choose for myself is:

Fake first name: _____ *Fake surname:* _____

I prefer to be sent reminders by: *Text message (SMS)* *Email*

ARE THERE ANY BENEFITS FOR ME?

If you agree to participate in this study, there may or may not be a direct benefit to you. We hope that you will have improved sleep as a result of this treatment program. However, we do not know this yet, which is why we need to study the program with adolescents just like you.

As far as we know, there are no medications or drugs that the government has said are safe for children and help them with their insomnia or sleeping problems in the long-term. Sometimes, doctors prescribe other hypnosis medications that were originally made for other problems. For children, it’s not recommended that these medications are used in the long-term, because researchers don’t know enough about how safe they are and how much they help.

DO WE HAVE TO PARTICIPATE?

NO. Participation is voluntary and you and your parent may withdraw at any time. If you choose to withdraw, simply call the principal investigator (Dr. Brooks). If any new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

WHAT ELSE DOES OUR PARTICIPATION INVOLVE?

Participation in this study involves engagement in a clinical treatment protocol to help with sleep. This means that you will participate in the treatment program and will have therapy-based tasks to complete each week. We will also ask parents to participate in the education session on week two of the treatment, as well as complete questionnaires (completed at start of treatment, end of treatment, and follow-up).

We ask for your permission to audio and video record the clinical treatment sessions during your therapy visits to our lab. The recordings will allow the therapy supervisor, who is a registered psychologist (Dr. Tomfohr-Madsen), to ensure that the therapists are providing the same therapy in a reliable and standard manner. The recordings are confidential, and they will be stored in a secure location, will not be used for any other purpose, and will be erased afterwards.

The recordings are completely voluntary, and you may decline to be video and/or audio recorded. Also, you can ask that the camera recorder be turned off at any time, and you can ask that the recording or any part of it be erased. Refusing to be video and/or audio recorded will not affect your participation in the study.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

As a token of appreciation for participation and commitment to our study, you will be reimbursed \$15 for each assessment questionnaire, and \$5 for each day the sleep diary is filled out during the baseline and follow-up visits. This amounts to up to \$50 per assessment (three assessments total). Any parking costs you or your parent incurs at the University of Calgary will be reimbursed. There is no cost for the in-person interventions.

WILL MY RECORDS BE KEPT PRIVATE?

Only the research team named above will have access to information collected. You and your parent will be given a study number to help protect your identity. This study ID will be used for all electronic questionnaires. The database of results will contain only your study identification number to make the data de-identified. All data will be kept on password-protected computers for at least ten years, as required by the University, before being destroyed. All research documents and computers will be stored in a locked filing cabinet in a locked office. You will not be identified by name in any reports of the completed study and all publications will be based on group information. The University of Calgary Conjoint Health Research Ethics Board will have access to the research records.

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

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

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. 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 without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Brian Brooks, principal investigator: (403) 955-2597

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.

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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.

A signed copy of this consent form has been given to you to keep for your records and reference.

Ethics ID: REB16-1166

Study Title: Treating sleep disturbance in adolescents who have protracted recovery from a mild traumatic brain injury: A pilot randomized controlled trial using CBT-Insomnia

PI: Dr. Brian L. Brooks

Version number/date: November 8, 2016

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Participant’s Initials: _____



CONSENT FORM

TITLE: Treating sleep disturbance in adolescents who have protracted recovery from a mild traumatic brain injury: A pilot randomized controlled trial using CBT-Insomnia

SPONSOR: Clinical Research Grant, Cumming School of Medicine

INVESTIGATORS:

Principal Investigator:

Dr. Brian L. Brooks, Pediatric Neuropsychologist; (403) 955-2597

Co-Investigators:

Dr. Lianne Tomfohr, Assistant Professor and Clinical Psychologist

Dr. Karen M. Barlow, Pediatric Neurologist & Director of the Calgary Childhood Traumatic Brain Injury Program

Dr. Keith Owen Yeates, Professor and Neuropsychologist

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

Each year, 35,000 Canadian children and adolescents sustain a mild traumatic brain injury (mTBI) (also called a concussion). Although research supports that the vast majority of youth will recover quickly and return to normal functioning, some adolescents continue to report problems long after the injury. Disturbed sleep, notably trouble with sleep onset and sleep maintenance, is a frequently reported problem in those with slow recovery from an mTBI. Despite the identification of sleep disturbance as a problem associated with slow recovery, there are very few treatment options. Cognitive-behavioural therapy for insomnia (CBT-I) has shown promise in children and adolescents as an effective treatment for sleep disturbance, although it has yet to be applied to the adolescent mTBI population who also present with sleep problems.

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WHAT IS THE PURPOSE OF THE STUDY?

The objective of this study is to examine the treatment of sleep disturbance using cognitive-behavioural therapy for insomnia (CBT-I) in those adolescents who have a slow recovery from their mTBI. This represents a novel treatment option for this patient population and is anticipated to improve outcomes and quality of life.

WHAT WOULD WE HAVE TO DO?

If you and your child choose to participate in this study, you will be asked to do the following:

Week 1: At the start of the study, your child will be interviewed about their sleep problems, and if eligible for the study, will fill out questionnaires about their sleep, symptoms, any pain, mood, and worrying. Child questionnaires will take 30 minutes and will be done electronically. Your child will also complete a sleep diary, which takes about 5 minutes per day, and will be done online. We will also ask you to fill out questionnaires about your child's sleep, mood and worrying, as well as demographic information. Parent questionnaires will take about 10 minutes to complete and are also done electronically.

Weeks 2-7: In this study, your child will be "randomized" into one of the two study groups described as follows. "Randomized" means that they will be put into a treatment group by chance, like flipping a coin. Those selected for the treatment will participate in six weekly sessions that involve the treatment strategy called cognitive-behavioural therapy for insomnia (CBT-I). These sessions will be delivered in-person at the University of Calgary. The therapy sessions will be led by a clinical psychology graduate student who has experience in providing this therapy. The therapy will be supervised by a registered psychologist (Dr. Tomfohr-Madsen). Each week, your child will also complete the sleep diary as part of the therapy, which will take about 5 minutes each time. Those selected for the waitlist will not receive treatment at this time.

Week 8: Seven weeks after the first assessment, you and your child will fill out the same questionnaires electronically that were filled out at the start of the study. It will take about 30 minutes for child questionnaires, 5-10 minutes for the parent questionnaires, and 5 minutes for the sleep diary each day.

Week 12: Approximately one month after the first follow-up assessment, you and your child will fill out the same questionnaires electronically that were filled out at the start of the study. It will take about 30 minutes for child questionnaires, 5-10 minutes for the parent questionnaires, and 5 minutes for the sleep diary each day. If your child was selected for the waitlist group and is still experiencing problems with sleep, at this time, they will be invited to participate in six weekly sessions of CBT-I.

WHAT ARE THE RISKS?

There are no identifiable risks associated with participation in this study. The treatment that your child will receive has been previously used in helping people obtain better sleep. If you tell us that you are in danger of getting hurt by someone, you are in danger of hurting yourself, or you are in danger of hurting others, we are required by law to ask you more questions to find out more about the situation, and see what steps need to be taken to keep you or your child safe. If the situation is very serious that you or your child are in danger of harming yourselves, the safety steps might include making sure that you are taken to a hospital’s emergency department by ambulance.

The online questionnaires are being administered using a program called Qualtrics©, which is an American software company that is subject to U.S. laws (including the USA PATRIOT Act). Because the USA PATRIOT Act permits the government to look at data stored in their country, we will have you complete all questionnaires using a study ID number (not your name) and no identifiers will be included in the database or stored by Qualtrics (e.g., email addresses, IP addresses).

We will contact you by either email or text message (SMS) through the booking and scheduling service called “Jane”. Jane is based in Canada, so the USA PATRIOT Act does not apply to Jane. With Jane, we can send you convenient reminders about any appointments you have with our study, and we can send you convenient web-links to our Qualtrics questionnaires, so you do not have to worry about mailing them to us. As a precaution, we would like you to choose a fake name (pseudonym/alias/nick-name) that we would use to contact you through Jane.

The fake name (pseudonym/alias/nick-name) I choose for myself is:

Fake first name: _____ *Fake surname:* _____

I prefer to be sent reminders by: *Text message (SMS)* *Email*

ARE THERE ANY BENEFITS FOR MY CHILD?

If you and your child agree to participate in this study, there may or may not be a direct benefit to you. We hope that your child will have improved sleep as a result of this treatment program. However, we do not know this yet, which is why we need to study the program with adolescents just like your child.

To the best of our knowledge, there appears to be no Food and Drug Administration (FDA) - approved medications/pharmacotherapy that is effective in the long-term, efficacious and safe for use with children. Despite this, medications/pharmacotherapy, such as hypnotic medications, have been prescribed off-label to children to treat sleep disruption in the short-term; long-term use is not recommended as little evidence exists regarding efficacy and safety.

DO WE HAVE TO PARTICIPATE?

NO. Participation is voluntary and you and your child may withdraw at any time. If you choose to withdraw, simply call the principal investigator (Dr. Brooks). If any new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

WHAT ELSE DOES OUR PARTICIPATION INVOLVE?

Participation in this study involves engagement in a clinical treatment protocol to help with sleep. This means that your child will participate in the treatment program and will have therapy-based tasks to complete each week. We will also ask parents to participate in the education session on week two of the treatment, as well as complete questionnaires (completed at start of treatment, end of treatment, and follow-up).

We ask for your permission to audio and video record the clinical treatment sessions during your therapy visits to our lab. The recordings will allow the therapy supervisor, who is a registered psychologist (Dr. Tomfohr-Madsen), to ensure that the therapists are providing the same therapy in a reliable and standard manner. The recordings are confidential, and they will be stored in a secure location, will not be used for any other purpose, and will be erased afterwards.

The recordings are completely voluntary, and you may decline to be video and/or audio recorded. Also, you can ask that the camera recorder be turned off at any time, and you can ask that the recording or any part of it be erased. Declining to be video and/or audio recorded will not affect your participation in the study.

WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

As a token of appreciation for participation and commitment to our study, your child will be reimbursed \$15 for each assessment questionnaire, and \$5 for each day the sleep diary is filled out during the baseline and follow-up visits. This amounts to up to \$50 per assessment (three assessments total). Any parking costs you incur at the University of Calgary will be reimbursed. There is no cost for the in-person interventions.

WILL MY RECORDS BE KEPT PRIVATE?

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