Study Information

Research Title

Evaluating app-based treatments for chronic insomnia in adults: Health enSuite Insomnia Study

Research Team

Principal Investigator: Dr. Patrick McGrath, OC, PhD, FRSC, FCAHS
Centre for Research in Family Health, IWK Health Centre

Co-investigators: Dr. Cathy MacLean, MClSc, MD, CCFP, FCFP, MBA
Academic Family Medicine, University of Saskatchewan

Dr. Lori Wozney, PhD
Centre for Research in Family Health, IWK Health Centre

Dr. Fatemeh BaghbaniNaghsdehi, PhD

Jaisheen Kour Reen, MCS,B.Tech
Centre for Research in Family Health, IWK Health Centre

Research Consultants: Dr. David Gardner, PharmD
College of Pharmacy, Dalhousie University

Dr. Judith Davidson, PhD, C. Psych.
Department of Psychology, Queen's University

Funding

This project is funded by the Canadian Institutes of Health Research (CIHR).

How to contact the research team?

Email: TeamHealthEnSuite@iwk.nshealth.ca

Phone: (902) 470 7934 or call toll-free number: 1-877-341-8309 press 5

Health enSuite-Insomnia Application Consent Form (Trial I)
For Participants – Insomnia app without de-prescribing

Introduction
You are being invited to take part in the Health enSuite Insomnia Study.

Before you decide if you want to take part in this research study, it is important that you understand the purpose of the study, the risks and benefits, and what you will be asked to do.

You do not have to take part in this study. Taking part is entirely voluntary (your choice).

Informed consent starts with the initial contact about the study and continues until the end of the study.

You may contact study staff to answer any questions you have by calling toll-free (no charge) 1-877-341-8309 ext 5 or by clicking the [contact us] button.

You may decide not to take part, or you may withdraw from the study at any time. This will not affect the care you or your family members will receive from your health care provider.

This study is voluntary. I do not have to take part and can leave the study at any time.	**T**	**F**
TRUE: You do not have to take part in this study.		
	Continue	**No thanks, I am not interested**

Why are the researchers doing the study?

Many Canadians struggle to get to sleep and stay asleep at night. Our goal is to develop programs that can address this problem and help people sleep better. The Health enSuite Insomnia is a new application-based program that uses cognitive-behavioral therapy for insomnia to improve your sleep problems. The effectiveness of the two online treatments delivered by this program for adults with chronic insomnia is being compared and tested in this study.

The treatments delivered via Health enSuite Insomnia app are already proven to work. **T** **F**

FALSE: Health enSuite Insomnia is a new program. The content it delivers is based on existing cognitive behavioural treatments that have been found to improve sleep. The purpose of this study is to determine if these treatments can be delivered effectively through an app.

Continue **No thanks, I am not interested**

How will the researchers do the study?

This study uses a randomized controlled design. This means that you will be randomly (similar to flipping a coin) assigned to one of two treatment groups. You cannot choose which treatment you would like to receive during the study. After the study is over, you will have the opportunity to access the other treatment if you would like.

Our goal is to recruit a sample of up to 415 adults with chronic insomnia from across Canada. About half of them will be assigned to one type of treatment and the others will be assigned to another type of treatment. We will test to see whether there are any improvements in insomnia symptoms and related sleep patterns over time. We are interested in whether people who received one treatment tend to do better over time than people who received the other treatment.

All aspects of this study will be completed online within the Health enSuite Insomnia app. This app was designed specifically for this study. The information collected will be kept confidential.

You can download this app to use on your smartphone or access it through a web browser. The content in both versions is the same, so you can use whichever format you prefer.

I can choose the treatment group I want.	**T**	**F**
FALSE: Your treatment group will be randomly assigned.		
	Continue	**No thanks, I am not interested**

What will I be asked to do?

If you agree to participate in the study, the first step is to complete the baseline assessment. You will be asked to complete a series of questionnaires about your background, insomnia symptoms, and general physical and mental health. For the next 14 days, we will ask you to complete a brief "sleep diary" each morning. This "diary" is completed within the Health enSuite app and asks about your sleep the night before. It should not take more than a few minutes to complete each sleep diary. The baseline assessment is important because it lets us know how you are doing before the treatment begins.

After you have completed the baseline assessment, you will be randomly assigned (similar to flipping a coin) to one of the groups to receive either intervention at the beginning of the study or after 6 months of enrollment. Both groups will receive information about the causes of insomnia and cognitive behavioural strategies to relieve insomnia symptoms and improve sleep. In one group all of the information you will receive is available from the beginning. Once you have access to the information, you will be able to revisit this content within the Health enSuite app as often as you like over the next 8 weeks. In the other group, the content is organized in a series of modules or levels. Only the content for Level 1 will be available in the first week. To advance to Level 2 you will need to complete specific tasks within the program. There are a total of 6 levels each with new content and features designed to help improve sleep. If you are assigned to this group, you will receive notifications prompting you to complete different tasks within the app (e.g., completing sleep diaries).

You can expect to be involved in the study for a total of 14 weeks: 2 weeks of baseline assessment, 8 weeks of intervention, and 2 weeks assessment at 3 months and again at 6

months follow up. Each assessments include completing sleep diaries in addition to a set of questionnaires about your physical and mental health for 14 consecutive days. It is important that you complete the follow-up assessment so that we know how well the treatment you received worked for you. At the end of the trials, you will no longer have access to Health enSuite Insomnia.

Question: I will be asked to answer questions about my sleep only once. T F

FALSE: You will be asked to answer questions about your sleep multiple times over the course of several months.

Continue No thanks, I am not interested

What are the burdens, harms, and potential harms?

Some aspects of the treatments we are testing may initially worsen your insomnia symptoms. You may be asked to temporarily reduce the amount of time you spend in bed trying to sleep. This may result in less sleep and greater fatigue during the day. You may also experience worse mood or increased irritability. These potential discomforts should be temporary.

Health enSuite Insomnia in no way replaces decisions made by or the treatment plan given to you by your primary healthcare provider. The Health enSuite Insomnia App will only be used to assist your healthcare provider to refer you to cognitive behavioural therapy. If you experience severe discomfort or distress associated with restricted sleep, please contact your health care provider. You may also let us know by emailing our study coordinator at TeamHealthEnSuite@iwk.nshealth.ca or calling : 902-470-7934 or toll-free number: 1-877-341-8309 press 5). You may also use the Contact Us button on the Health enSuite Insomnia to report any problems.

We will be responsible for protecting your personal health information. However, there is a rare possibility that your personal health information release inadvertently.

I may experience some discomfort if I participate in this study. **T** **F**

TRUE: If you experience discomfort, it should only be temporary.

Continue **No thanks, I am not interested**

What are the possible benefits?

If you choose to participate in this study, there may or may not be direct benefits to you. It is possible that you will experience some benefits from participating in this study like improvements in your insomnia symptoms and daytime functioning. It is possible that these improvements will persist long after treatment. You may learn more about your insomnia and how your lifestyle, habits and beliefs impact your ability to get adequate sleep.

Your participation in this study may also benefit others. The outcomes of this study could help other people to gain access to effective treatment that was previously unavailable. However, it is also possible that the study intervention may provide no benefits to some participants.

This study is guaranteed to cure my insomnia. **T** **F**

FALSE: It is possible that you will experience improvements in your sleep, but this is not guaranteed.

Continue **No thanks, I am not interested**

Can I withdraw from the study?

Your participation in this study is voluntary. You may withdraw from the study at any time. Withdrawing from the study at any time will not affect the care you or your family will receive from your health care provider.

To withdraw from the study you can use the "Withdraw from Research Study" tab within Health enSuite Insomnia, or you can contact us by email (TeamHealthEnSuite@iwk.nshealth.ca) or phone ((902) 470 7934 or toll-free number: 1-877-341-8309 press 5).

You will be sent an email confirming that you have withdrawn from the study.
Your identifiable information will be completely erased from the study database. Information from any assessments you have completed (e.g., questionnaires, sleep diaries) will be retained. This information will be identified with a unique system-generated code.

I may decide NOT to take part in the study – even after I sign the Consent Form.	**T**	**F**
TRUE: You may stop taking part in the study at any time and may ask that your personal information (name and contact information) be removed from the study.		
Continue	**No thanks, I am not interested**	

Will the study cost me anything?

It does not cost anything to participate in the study. To be eligible for the study however, you will need to have regular access to an internet connected device (smartphone, tablet, or computer). We do not provide you with a smartphone, tablet, computer, or internet access.

If you have limited internet access you should **check with your service provider** to make sure that you will not go over your allowed access per month, which may result in extra costs on your monthly bill.

The study staff will cover the cost of my internet service. **T** **F**

FALSE: We do not provide internet service. Using this online program is similar to reading other text on the Internet or watching short YouTube videos. However, you should always be aware of your Internet usage so that you do not go over your limit (if you have one).

Continue **No thanks, I am not interested**

As a gesture of appreciation for your involvement in this research study, you will receive online gift cards which will be provided at two timepoints during the study: one upon completion of post-intervention assessment and an additional one on completion of the follow -up assessment. It is important to note that these compensations are solely intended to acknowledge your valuable time and contribution to the study, without exerting any influence on your decision to participate. You will be provided with the option to accept or decline the offered gift cards. If you choose to accept the gift card, you will receive two separate emails upon the completion of post-intervention and the follow -up assessments. Each email will contain a unique code for redeeming the incentive. If you decline the gift card, you will not receive any correspondence related to this incentive.

As part of the study, you will be offered a gift card as a token of appreciation. You have the choice to accept or decline.

T F

TRUE: You can choose below either Option 1 if you wish to accept the gift card or Option 2 if you prefer to decline it

Please indicate your choice regarding the gift card: Accept Decline

Continue No thanks, I am not interested

Are there any conflicts of interest? What about possible profit from commercialization?

You should know that Dr. McGrath owns the Health enSuite apps. He intends to form a not-for-profit company to distribute Health enSuite in Canada.

He may form a for-profit company for distribution in other countries and may profit if any of the Health enSuite apps are commercialized in the future. If the program is commercialized and makes a profit, study participants will not receive any of these profits.

Continue **No thanks, I am not interested**

How will I be informed of the study results?

At the end of this form, you will be asked if you would like to receive an email summarizing the study results. You may receive results after about six months following participation in this study as we will need time to analyze the data and interpret the findings.

Continue **No thanks, I am not interested**

How will my privacy be protected?

Information you give us throughout the study will be kept confidential. Your personal, identifying information (e.g., name, date of birth) will only be seen by people directly involved in the study (researchers and study staff). When the study results are shared with someone outside the research team, your personal, identifying information will not be included.

None of the information you enter on Health enSuite Insomnia will be accessible or visible to other participants in the study. Only members of the research team, The IWK Research Ethics Board (IWK REB), the Nova Scotia Health Research Ethics Board (NSH REB), and the University of Saskatchewan Research Ethics Board (USASK REB) will have access to data collected in Health enSuite Insomnia. The NSH REB and IWK REB, or people working for NSH REB or IWK REB may need to look at your personal information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines.

E-messaging (email and texting) can be used by a member or members of the research team to communicate with you while you are in this study. All communication done with you will be done only through a NSH Webmail account, or text by a phone issued to a research member through Nova Scotia Health (NSH). All efforts are made to keep information sent or received private, but it is possible other people may be able to see, read, and change messages sent to or from NSH.

When the study is published, people will know I was a part of the study. T F
FALSE: All information gathered about you during the study is private and confidential. Identifying information will not be included in any presentation or publication of the results of the study.

Continue **No thanks, I am not interested**

Audits of this study could be done by the funding sources (CIHR) or the IWK Health Centre's Research Ethics Board. In the case of an audit your file could be reviewed. Anyone performing an audit would also keep your identity confidential.

Health care providers/NS Health may help us to recruit participants for the study. We may share information with them about their patients who are using Health enSuite Insomnia. The

appropriate act governing the health information protection as noted through legislation in each province will be adhered to in the conduct of this study.

I would like to share my information with health care provider. **□Yes** **□No** **(If you check Yes, then your sleep related progress report(s) that would be generated by you using the appropriate app feature will be shared with your permission with your primary care provider, and not with the institution.)** **Continue** **No thanks, I am not interested**

How will my information be stored?

All the information you give us during the study will be stored on a password-protected and encrypted database server residing within our secured cloud-based Amazon Web Services environment.

Your answers to the questionnaires may be stored on your smartphone or tablet if you complete them while the device is offline. The next time your device is online, your answers will be uploaded to the secure online database.

Any paper records related to your participation will be stored in a locked filing cabinet at the IWK Health Centre.

At the end of the study, the data collected as part of this study will be archived for a minimum of 5 years. The study information that will be archived will be de-identified and will not include any of your personal information (name, contact information). The archived de-identified information will be stored in a secure location within the IWK Health Centre or outside of the IWK Health Centre.

De-identified (no names or contact information) study information will be stored for years after the study results have been published. **□T □ F**

TRUE: De-identified study data will be stored securely for a minimum of five years after study results have been published. This allows the study results to be verified, if needed, and is recommended by the Research Ethics Board.

Continue **No thanks, I am not interested**

Are there things I can do to protect my privacy?

When you login to Health enSuite Insomnia, you will be asked to provide a username and password. By not sharing your username and password you can help to protect your privacy. We suggest NOT saving your login information on your web browser. If you are using a public computer, or are in a public area (e.g., library, internet café, etc.) make sure to log off and close any open browser windows so others cannot access your account after you leave.

When we email you about the study, we will only use your first name or nickname (if you provide one). We will not put your personal, identifying information in any email (e.g., phone number, date of birth). We cannot guarantee the security of using email. Please do not send confidential or sensitive (private) information by email.

Continue **No thanks, I am not interested**

What if I have study questions or problems?

You may contact us by phone or email with questions or problems. Our contact information is below:

Email: TeamHealthEnSuite@iwk.nshealth.ca

Phone: (902) 470 7934 or call toll-free number: 1-877-341-8309 press 5

Rekha Dhonde, our research coordinator, will be available to answer your call Monday to Friday from 10:00 am – 4:00 pm Atlantic Time. You may leave a message if our Research Coordinator is unable to take your call or you need to call outside of our working hours.

Continue **No thanks, I am not interested**

What are my research rights?

Completing this online consent form indicates that you have agreed to take part in this research and for your responses to be used. In no way does this waive your legal rights nor release the investigators or the IWK Health Centre from their legal and professional responsibilities. If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-8520, Monday to Friday between 9a.m. and 5p.m

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate in the study. In no way does this waive your legal rights nor release the principal investigator, the research team, the study sponsor or involved institutions from their legal and professional responsibilities.

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the research team.

If you would like to speak to a member of the Research Team about this Consent Form or ask questions about the study before you decide to take part, please click the Contact Us button or call toll-free: [1-877-341-8309 ext 5].

I would like to participate.	**I am not interested in participating.**

Participant Consent:

Please click beside each statement if you AGREE.

- ☐ I have read this Information and Consent Form.
- ☐ I have had the chance to ask questions which have been answered to my satisfaction before agreeing to take part.
- ☐ I was given sufficient time to think about participating.
- ☐ I acknowledge that I have been informed about the potential compensation, offered as a token of appreciation in this study.
- ☐ I understand the nature of the study that this study may not provide any benefits to me, and I also understand the potential risks.
- ☐ I understand that I have the right to withdraw from the study at any time without affecting my care.
- ☐ I understand that I will receive a copy of this Consent Form via email at the address that I provide.
- ☐ I give permission for the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.
- ☐ I give my permission to be contacted by a member or members of the research team from an NSH Webmail account or an NSH cell phone by research staff to communicate during this study.
- ☐ I give permission for the access of my identifiable personal health information for the research purposes described in this form.
- ☐ I agree to inform and update the research team if my phone number and/or my email address changes.

Submit

☐ I would like a summary of the study results emailed to me.

□ I would like to be contacted for future studies by this research team.

□ I understand that by signing this document I do not waive any of my legal rights.

Submit

You have the option of allowing your study data to be re-used by **approved researchers**. Any of your personal information (i.e., your name, address, telephone number) that can identify you will be removed before files are shared with other researchers. Researchers that wish to use study data must 1) have their new study approved by an **ethics board**; 2) sign an agreement ensuring your **confidentiality** and **restricting use** to only the approved study.

I agree for my study data to be used for future research. I understand that my study data may be made available to other researchers, but **my identity will be protected** and my **confidentiality will be preserved**.

□YES □NO

Submit

<<This text will be displayed to the participant on the screen for the Sign and Approve Consent tab on the application. When the participant has checked on all the checkboxes then the Email signature will be enabled for them to enter an email address to be able to digitally sign the Consent. >>

Electronic Signature

By providing your email address you freely agree to take part in the study according to the terms outlined in this Consent Form.

Full name:

Email address:

Verify email address:

Telephone number:

Name or Nickname used for communications from study staff:

No, Thanks	I Agree

<<After clicking I Agree the following message will appear >>

Thank you for your time. An email will be sent to you within 2 business days confirming your consent with the study information attached.

Study Information

Research Title

Evaluating app-based treatments for chronic insomnia in adults: Health enSuite Insomnia Study

Research Team

Principal Investigator: Dr. Patrick McGrath, OC, PhD, FRSC, FCAHS
Centre for Research in Family Health, IWK Health Centre

Co-investigators: Dr. Cathy MacLean, MClSc, MD, CCFP, FCFP, MBA
Academic Family Medicine, University of Saskatchewan

Dr. Lori Wozney, PhD
Centre for Research in Family Health, IWK Health Centre

Dr. Fatemeh BaghbaniNaghsdehi, PhD

Jaisheen Kour Reen, MCS,B.Tech
Centre for Research in Family Health, IWK Health Centre

Research Consultants: Dr. David Gardner, PharmD
College of Pharmacy, Dalhousie University

Dr. Judith Davidson, PhD, C. Psych.
Department of Psychology, Queen's University

Funding

This project is funded by the Canadian Institutes of Health Research (CIHR).

How to contact the research team?

Email: TeamHealthEnSuite@iwk.nshealth.ca

Phone: (902) 470 7934 or call toll-free number: 1-877-341-8309 press 5

Health enSuite-Insomnia Application Consent Form (Trial II)
For Participants – Insomnia app with de-prescribing

Introduction
You are being invited to take part in the Health enSuite Insomnia Study.

Before you decide if you want to take part in this research study, it is important that you understand the purpose of the study, the risks and benefits, and what you will be asked to do.

You do not have to take part in this study. Taking part is entirely voluntary (your choice).

Informed consent starts with the initial contact about the study and continues until the end of the study.

You may contact study staff to answer any questions you have by calling toll-free (no charge) 1-877-341-8309 ext 5 or by clicking the [contact us] button.

You may decide not to take part, or you may withdraw from the study at any time. This will not affect the care you or your family members will receive from your health care provider.

This study is voluntary. I do not have to take part and can leave the study at any time. T F **TRUE: You do not have to take part in this study.** **Continue No thanks, I am not interested**

Why are the researchers doing the study?

Many Canadians struggle to get to sleep and stay asleep at night. Our goal is to develop programs that can address this problem and help people sleep better. The Health enSuite Insomnia is a new application-based program that uses a cognitive-behavioral program for insomnia (Health enSuite Insomnia) to improve your sleep problems. The effectiveness of the two online treatments delivered by this program for adults with chronic insomnia is being compared and tested in this study.

Some prescription medications can provide relief from insomnia symptoms. However, many of these medications have serious long-term side effects. Our goal is to develop a program that can help people with chronic insomnia systematically reduce their reliance on sleeping pills and help them learn new strategies to improve their sleep.

We are testing different ways of delivering information and advice to change thoughts and behaviours related to insomnia.

The treatments delivered via Health enSuite Insomnia app are already proven to work. **T** **F**

FALSE: Health enSuite Insomnia is a new program. The content it delivers is based on existing cognitive behavioural treatments that have been found to improve sleep. The purpose of this study is to determine if these treatments can be delivered effectively through an app.

Continue **No thanks, I am not interested**

How will the researchers do the study?

This study uses a randomized controlled design. This means that you will be randomly (similar to flipping a coin) assigned to one of two treatment groups. You cannot choose which treatment you would like to receive during the study. After the study is over, you will have the opportunity to access the other treatment if you would like.

Our goal is to recruit a sample of up to 415 adults with chronic insomnia who are taking sleep medications from across Canada. About half of them will be assigned to one type of treatment and the others will be assigned to another type of treatment. We will test to see whether there are any improvements in insomnia symptoms and related sleep patterns over time. We are interested in whether people who received one treatment tend to do better over time than people who received the other treatment.

All aspects of this study will be completed online within the Health enSuite Insomnia app. This app was designed specifically for this study. The information collected will be kept confidential. You can download this app to use on your smartphone or access it through a web browser. The content in both versions is the same, so you can use whichever format you prefer.

I can choose the treatment group I want. **T** **F**
FALSE: Your treatment group will be randomly assigned.
Continue **No thanks, I am not interested**

What will I be asked to do?

If you agree to participate in the study, the first step is to complete the baseline assessment. You will be asked to complete a series of questionnaires about your background, insomnia symptoms, and general physical and mental health. For the next 14 days, we will ask you to complete a brief "sleep diary" each morning. This "diary" is completed within Health enSuite Insomnia and asks about your sleep the night before. It should not take more than a few minutes to complete each sleep diary. The baseline assessment is important because it lets us know how you are doing before the treatment begins.

After you have completed the baseline assessment, you will be randomly assigned (similar to flipping a coin) to one of the groups to receive either intervention at the beginning of the study or after 6 months of enrollment. Both groups will receive information about the causes of insomnia and cognitive behavioural strategies to relieve insomnia symptoms and improve sleep. In one group all of the information you will receive is available from the beginning. Once you have access to this information, you will be able to revisit this content within the Health enSuite app as often as you like over the next 8 weeks. In the other group, the content is organized in a series of modules or levels. Only the content for Level 1 will be available in the first week. To advance to level 2 you will need to complete specific tasks within the program. There are a total of 6 levels each with new content and features designed to help improve sleep. If you are assigned to this group, you will receive notifications prompting you to complete different tasks within the app (e.g., completing sleep diaries).

You can expect to be involved in the study for a total of 14 weeks: 2 weeks of baseline assessment, 8 weeks of intervention, and 2 weeks assessment at 3 months and again at 6 months follow up. Each assessment includes completing sleep diaries in addition to a set of questionnaires about your physical and mental health for 14 consecutive days. It is important that you complete the follow-up assessment so that we know how well the treatment you received worked for you. At the end of the trials, you will no longer have access to Health enSuite Insomnia.

Question: I will be asked to answer questions about my sleep only once. T F

FALSE: You will be asked to answer questions about your sleep multiple times over the course of 3 months.

Continue **No thanks, I am not interested**

What are the burdens, harms, and potential harms?

Some aspects of the treatments we are testing may initially worsen your insomnia symptoms. You may be asked to temporarily reduce the amount of time you spend in bed trying to sleep. This may result in less sleep and greater fatigue during the day. You may also experience worse mood or increased irritability. These potential discomforts should be temporary.

Health enSuite Insomnia in no way replaces decisions made by or the treatment plan given to you by your primary healthcare provider. The Health enSuite Insomnia App will only be used to assist your healthcare provider to support a deprescribing decision or to refer you to cognitive behavioural therapy. You may experience withdrawal symptoms associated with changes to your medications. In most cases these symptoms may subside within a few days. If you experience serious side effects associated with your medication schedule, or severe discomfort or distress associated with restricted sleep, please contact your health care provider. If you experience this, please contact your health care provider. You may also let us know by emailing our study coordinator at TeamHealthEnSuite@iwk.nshealth.ca or calling ((902) 470 7934 or toll-free number: 1-877-341-8309 press 5). You may also use the Contact Us on the Health enSuite Insomnia homepage to report any problems.
We will be responsible for protecting your personal health information. However, there is a rare possibility that your personal health information release inadvertently.

I may experience some discomfort if I participate in this study. **T** **F**

TRUE: If you experience discomfort, it should only be temporary.

Continue **No thanks, I am not interested**

What are the possible benefits?

If you choose to participate in this study, there may or may not be direct benefits to you. It is possible that you will experience some benefits from participating in this study. This could include improvements in your insomnia symptoms and daytime functioning. It is possible that these improvements will persist long after treatment. You may learn more about your insomnia and how your lifestyle, habits and beliefs impact your ability to get adequate sleep.

Your participation in this study may also benefit others. The outcomes of this study could help other people to gain access to effective treatment that was previously unavailable.

This study is guaranteed to cure my insomnia. **T** **F**

FALSE: It is possible that you will experience improvements in your sleep, but this is not guaranteed.

Continue **No thanks, I am not interested**

Can I withdraw from the study?

Your participation in this study is voluntary. You may withdraw from the study at any time. Withdrawing from the study at any time will not affect the care you or your family will receive from your health care provider.

To withdraw from the study you can use the "Withdraw from Research Study" tab within Health enSuite Insomnia, or you can contact us by email (TeamHealthEnSuite@iwk.nshealth.ca) or phone ((902) 470 7934 or toll-free number: 1-877-341-8309 press 5).

You will be sent an email confirming that you have withdrawn from the study. Your identifiable information will be completely erased from the study database. Information from any

assessments you have completed (e.g., questionnaires, sleep diaries) will be retained. This information will be identified with a unique system-generated code.

I may decide NOT to take part in the study – even after I sign the Consent Form.	**T**	**F**

TRUE: You may stop taking part in the study at any time and may ask that your personal information (name and contact information) be removed from the study.

Continue **No thanks, I am not interested**

Will the study cost me anything?

It does not cost anything to participate in the study. To be eligible for the study however, you will need to have regular access to an internet connected device (smartphone, tablet, or computer). We do not provide you with a smartphone, tablet, computer, or internet access.

If you have limited internet access you should **check with your service provider** to make sure that you will not go over your allowed access per month, which may result in extra costs on your monthly bill.

The study staff will cover the cost of my internet service. **T** **F**

FALSE: We do not provide internet service. Using this online program is similar to reading other text on the Internet or watching short YouTube videos. However, you should always be aware of your Internet usage so that you do not go over your limit (if you have one).

Continue **No thanks, I am not interested**

As a gesture of appreciation for your involvement in this research study, you will receive online gift cards which will be provided at two timepoints during the study: one upon completion of post-intervention assessment and an additional one on completion of the follow -up assessment. It is important to note that these compensations are solely intended to acknowledge your valuable time and contribution to the study, without exerting any influence on your decision to participate. You will be provided with the option to accept or decline the offered gift cards. If you choose to accept the gift card, you will receive two separate emails upon the completion of post-intervention and the follow -up assessments. Each email will contain a unique code for redeeming the incentive. If you decline the gift card, you will not receive any correspondence related to this incentive.

As part of the study, you will be offered a gift card as a token of appreciation. You have the choice to accept or decline.

T F

TRUE: You can choose below either Option 1 if you wish to accept the gift card or Option 2 if you prefer to decline it

Please indicate your choice regarding the gift card: Accept Decline

Continue **No thanks, I am not interested**

Are there any conflicts of interest? What about possible profit from commercialization?

You should know that Dr. McGrath owns the Health enSuite apps. He intends to form a not-for-profit company to distribute Health enSuite in Canada.

He may form a for-profit company for distribution in other countries and may profit if any of the Health enSuite apps are commercialized in the future. If the program is commercialized and makes a profit, study participants will not receive any of these profits.

Continue **No thanks, I am not interested**

How will I be informed of the study results?

At the end of this form, you will be asked if you would like to receive an email summarizing the study results. You may receive results after about six months following participation in this study as we will need time to analyze the data and interpret the findings.

Continue **No thanks, I am not interested**

How will my privacy be protected?

Information you give us throughout the study will be kept confidential. Your personal, identifying information (e.g., name, date of birth) will only be seen by people directly involved in the study (researchers and study staff). When the study results are shared with someone outside the research team, your personal, identifying information will not be included.

None of the information you enter on Health enSuite Insomnia will be accessible or visible to other participants in the study. Only members of the research team, The IWK Research Ethics Board (IWK REB), the Nova Scotia Health Research Ethics Board (NSH REB), and the University of Saskatchewan Research Ethics Board (USASK REB) will have access to data collected in Health enSuite Insomnia. The NSH REB and IWK REB, or people working for NSH REB or IWK REB may need to look at your personal information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines.

E-messaging (email and texting) can be used by a member or members of the research team to communicate with you while you are in this study. All communication done with you will be done only through a NSH Webmail account, or text by a phone issued to a research member through Nova Scotia Health (NSH). All efforts are made to keep information sent or received private, but it is possible other people may be able to see, read, and change messages sent to or from NSH.

When the study is published, people will know I was a part of the study. T F
FALSE: All information gathered about you during the study is private and confidential. Identifying information will not be included in any presentation or publication of the results of the study.

Continue **No thanks, I am not interested**

Audits of this study could be done by the funding sources (CIHR) or the IWK Health Centre's Research Ethics Board. In the case of an audit your file could be reviewed. Anyone performing an audit would also keep your identity confidential.

Health care providers/NS Health may help us to recruit participants for the study. We may share information with them about their patients who are using Health enSuite Insomnia. The appropriate act governing the health information protection as noted through legislation in each province will be adhered to in the conduct of this study.

I would like to share my information with health care provider. **□Yes** **□No**

If you check Yes, then your sleep related progress report(s) that would be generated by you using the appropriate app feature will be shared with your permission with your primary care provider, and not with the institution.

Continue **No thanks, I am not interested**

How will my information be stored?

All the information you give us during the study will be stored on a password-protected and encrypted database server residing within our secured cloud-based Amazon Web Services environment.

Your answers to the questionnaires may be stored on your smartphone or tablet if you complete them while the device is offline. The next time your device is online, your answers will be uploaded to the secure online database.

Any paper records related to your participation will be stored in a locked filing cabinet at the IWK Health Centre.

At the end of the study, the data collected as part of this study will be archived for a minimum of 5 years. The study information that will be archived will be de-identified and will not include any of your personal information (name, contact information). The archived de-identified information will be stored in a secure location within the IWK Health Centre or outside of the IWK Health Centre.

De-identified (no names or contact information) study information will be stored for years after the study results have been published. **□T □ F**

TRUE: De-identified study data will be stored securely for a minimum of five years after study results have been published. This allows the study results to be verified, if needed, and is recommended by the Research Ethics Board.

Continue **No thanks, I am not interested**

Are there things I can do to protect my privacy?

When you login to Health enSuite Insomnia, you will be asked to provide a username and password. By not sharing your username and password you can help to protect your privacy. We suggest NOT saving your login information on your web browser. If you are using a public computer, or are in a public area (e.g., library, internet café, etc.) make sure to log off and close any open browser windows so others cannot access your account after you leave.

When we email you about the study, we will only use your first name or nickname (if you provide one). We will not put your personal, identifying information in any email (e.g., phone number, date of birth). We cannot guarantee the security of using email. Please do not send confidential or sensitive (private) information by email.

Continue **No thanks, I am not interested**

What if I have study questions or problems?

You may contact us by phone or email with questions or problems. Our contact information is below:

Email: TeamHealthEnSuite@iwk.nshealth.ca

Phone: (902) 470 7934 or call toll-free number: 1-877-341-8309 press 5

Rekha Dhonde, our research coordinator, will be available to answer your call Monday to Friday from 10:00 am – 4:00 pm Atlantic Time. You may leave a message if our Research Coordinator is unable to take your call or you need to call outside of our working hours.

Continue	**No thanks, I am not interested**

What are my research rights?

Completing this online consent form indicates that you have agreed to take part in this research and for your responses to be used. In no way does this waive your legal rights nor release the investigators or the IWK Health Centre from their legal and professional responsibilities. If you have any questions at any time during or after the study about research in general you may contact the Research Office of the IWK Health Centre at (902) 470-8520, Monday to Friday between 9a.m. and 5p.m

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate in the study. In no way does this waive your legal rights nor release the principal investigator, the research team, the study sponsor or involved institutions from their legal and professional responsibilities.

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the research team.

If you would like to speak to a member of the Research Team about this Consent Form or ask questions about the study before you decide to take part, please click the Contact Us button or call toll-free: [1-877-341-8309 ext 5].

I would like to participate.	**I am not interested in participating.**

Participant Consent:

Please click beside each statement if you AGREE.

- ☐ I have read this Information and Consent Form.
- ☐ I have had the chance to ask questions which have been answered to my satisfaction before agreeing to take part.
- ☐ I was given sufficient time to think about participating.
- ☐ I acknowledge that I have been informed about the potential compensation, offered as a token of appreciation in this study.
- ☐ I understand the nature of the study that this study may not provide any benefits to me, and I also understand the potential risks.
- ☐ I understand that I have the right to withdraw from the study at any time without affecting my care.
- ☐ I understand that I will receive a copy of this Consent Form via email at the address that I provide.
- ☐ I give permission for the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.
- ☐ I give my permission to be contacted by a member or members of the research team from an NSH Webmail account or an NSH cell phone by research staff to communicate during this study.
- ☐ I give permission for the access of my identifiable personal health information for the research purposes described in this form.
- ☐ I agree to inform and update the research team if my phone number and/or my email address changes.

Submit

□ I would like a summary of the study results emailed to me.

□ I would like to be contacted for future studies by this research team.

□ I understand that by signing this document I do not waive any of my legal rights.

Submit

You have the option of allowing your study data to be re-used by **approved researchers**. Any of your personal information (i.e., your name, address, telephone number) that can identify you will be removed before files are shared with other researchers. Researchers that wish to use study data must 1) have their new study approved by an **ethics board**; 2) sign an agreement ensuring your **confidentiality** and **restricting use** to only the approved study.

I agree for my study data to be used for future research. I understand that my study data may be made available to other researchers, but **my identity will be protected** and my **confidentiality will be preserved**.

○YES ○NO

Submit

<<This text will be displayed to the participant on the screen for the Sign and Approve Consent tab on the application. When the participant has checked on all the checkboxes then the Email signature will be enabled for them to enter an email address to be able to digitally sign the Consent. >>

Electronic Signature

By providing your email address you freely agree to take part in the study according to the terms outlined in this Consent Form.

Full name:

Email address:

Verify email address:

Telephone number:

Name or Nickname used for communications from study staff:

No, Thanks	I Agree

<<After clicking I Agree the following message will appear. >>

Thank you for your time. An email will be sent to you within 2 business days confirming your consent with the study information attached.