DALHOUSIE UNIVERSITY

CONSENT FORM
PARTICIPANT COPY

Project title: Your Answers When Needing Sleep in New Brunswick Study (YAWNS in NB study)

This study is being led by:
Lead researchers: Drs. David Gardner and Andrea Murphy, Dalhousie University, Halifax

Other researchers are:
Dr. Margaret Rajda, Dalhousie University, Halifax
Dr. Justin Turner, University of Montreal, Montreal
Dr. Sandra Magalhaes, University of New Brunswick, Fredericton

Funding provided by: Government of New Brunswick, Healthy Seniors Pilot Project Funding

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Contents

1. Participant Copy

This version of the consent form is for study participants. It can be read in advance of conducting the telephone consent.

2. Telephone consent

All consents will be completed verbally by telephone. After completing the screening process, you will be offered to go through the consent process to determine if you interested in participating in the study. The content of this consent document matches that of the verbal consent document.

3. Study Explanation

The researcher will be reading from a script to make sure that they do not miss anything and to keep information given to all potential participants the same. However, you can interrupt the researcher at any time with questions. You will also notice that the researcher will pause after reviewing information to check in with you to see if you have questions or require additional information.

Before reviewing the details, the researcher would like to make sure you know how to reach them in case there is any reason that our call is interrupted today.

The researcher can be reached at 1-844-929-6762.

You can also give the researcher your phone number and they can call you back if the consent interview is interrupted.

Your phone number:

Introduction

You are invited to take part in a research study being conducted by Drs. David Gardner and Andrea Murphy of Dalhousie University, in conjunction with other researchers based in Halifax, Fredericton and Montreal. It is your choice about whether you want to participate. There will be no impact on your health services or any other services if you decide to participate or not.

Purpose and Outline of the Research Study

This study will test the effect of receiving a written information package by mail on sleep and sleeping pill use. Different groups of participants will receive different information packages. You will receive a package shortly after enrolling in the study or 6 months later.
Information will be gathered in this study two different ways; by telephone interviews and from health care records. These records will be used to gather data about medication use and health care visits during the study. Our aim is to recruit 1025 participants.

What You Will Be Asked to Do

You can participate in this study from your home.

An initial telephone appointment will be conducted with a researcher to collect information which we refer to as “baseline”.

The remaining activities for this study can all be done by telephone by speaking with a member of the research team. Or, if you use a computer with internet connection, you may choose to complete some parts of this study online. If you choose to do this, we will send you an email with a link to a secure website where you can directly respond to the research questions. If you choose this option, we can give you support if needed for completing the study questions online.

4. Options for Participating

There are three different ways to participate in this study.

Option A *(*Full participation): If you choose the full participation option:

1. You agree to be contacted twice by a member of the research team.
2. *The first contact will be shortly after consenting to enroll in the study and you will be asked to respond to a series of questions. This will take 30-60 minutes.*
3. The second contact will be 6 months later and you will be asked to respond to a series of questions. This will also take between 30-60 minutes.
4. Information will be gathered over the phone, but you can also choose to complete some information online as described.
5. *You will receive an information package by mail soon after enrolling or 6 months later.*
6. And, you give permission for the researchers to use your personal information (Medicare number or name and address) to include specific de-identified data from your personal health record in the study. This will not require any additional time on your part for study participation.

    De-identified *means that your name and any other information that could identify you will be removed before researchers may see the information.*

Option B *(Limited participation – no personal health record data)*: If you choose this option:

Option B is the same as option A with the exception of item 6. However, you will not be asked for your Medicare number and no data will be collected from your personal health record.

Option C *(Limited participation – no contact at 6 months*) If you choose this option:

1. You agree to be contacted once by a member of the research team.
2. Shortly after enrolling, you will be asked to respond to a series of questions. This will take 30-60 minutes.
3. You give permission for the researchers to use your personal information (Medicare number or name and address) to include specific de-identified data from your personal health record in the study. This will not require any additional time on your part for study participation.
4. You will receive an information package by mail soon after enrolling or 6 months later.

5. Details on the Type of Information Collected

This study includes questionnaires that ask about the following:

- *Your sleep*
- *Daytime sleepiness*
- *Health quality*
- *Sleeping pill use*
- *Use of other sleep treatments*
- *Experiences of falls*
- *Symptoms of anxiety*
- *Visits with your doctor & pharmacist*
- *Website visits to an insomnia treatment resource*

If you choose Option A or C permitting researchers to access your de-identified personal health information, the following information will be included in the data analysis:

- *Sleeping pill use*
- *Hospital stays*

The researchers will collect these data from your personal health record at the end of your participation in the study. The information collected will include sleeping pill use and hospital stays from 3 months before your enrollment date in the study and up to 6 months after your date of enrollment.

All participants will be asked to provide personal (age, sex), health (physical and mental health conditions), and medication use information at the start of the study.

6. Possible Benefits, Risks and Discomforts of Participating

The **benefits** of receiving an information package on sleep and sleeping pills by mail are not known. You may learn things about how to improve your sleep that you didn't know. You will also get information about sleeping pills that you may not have known before. Participating in the study might not benefit you, but we could learn things that will benefit others.

The **risks** related to what you are being asked to do in this study are expected to be very low. We do not expect you to experience any problems as a result of participating in the appointments planned for this study. However, some people may find it difficult to complete all questions over the phone during a single appointment. It is also possible that you could experience a mild level of distress related to answering these questions.

You may find that the information contained in the mailed study packages prompts you to look into changing how you manage your sleep. This could include making changes to the sleeping pills you take, for example the dose you take, for how long you take it, and the type you take. You are advised to discuss this with your health care provider (e.g., prescriber or pharmacist). They can help you determine what is most appropriate for you. The information provided in the mailed packages is not in any way a substitute or replacement for the health advice that you get from your health care provider.

7. How your personal information will be protected

Questionnaire/Survey Information

Your participation in this research will be known only to members of the research team. The information that you provide to us will be kept confidential. Only the research coordinator and research assistant based in Fredericton and the two lead researchers based in Halifax will have access to this information.

All members of the research team have an obligation to protect your personal information and keep research information confidential. All identifying information (including your name and contact information) will be securely stored separately from your research information. When you agree to participate in the study you will be assigned a study participant number. We will use this number, rather than your name, in our study records so that the research information we have about you contains no names.

During the study

- all electronic records will be kept secure in an encrypted file at Dalhousie University that is accessible to the researchers only.
- all paper records will be kept secure in a locked filing cabinet located in the study research office at the University of New Brunswick in Fredericton.

Once the study is over

- We will keep the electronic study data in an encrypted computer file for 10 years. This computer file will not include any personal identifiers (e.g. names, emails, etc.) of study participants. Names and contact information will *not* be included.
- We will also keep a separate computer file with your study number, your name and contact information. This file will be kept for 3 years and will only be accessed if we choose to conduct new research related to this study. If that occurs, we will contact you to ask for your consent to participate in this new research.
- When these time periods expire, research computer files will be destroyed in accordance with the most up-to-date methods agreed upon by the research ethics board of Dalhousie University.
- Permanently and irreversibly deleting these files will involve overwriting the data file with random characters up to 10 times on the hard disk of the computer storing this information.
- All paper files related to this study will be irreversibly destroyed by confidential shredding.

There are limits to participant confidentiality. If a member of the research team becomes concerned about the neglect or abuse of a participant, we have a duty to report this to the appropriate authority in New Brunswick.

Personal Health Information from Health Records

If you provide the researchers with permission to access your personal health information this will be done in a way that does not connect your name with the health information collected.

Using your Medicare number or your name and address, a special process will be followed that allows for the information you provide to the research team to be connected with the personal health information collected from health databases maintained by the province. The information is prepared and made available to researchers only in a de-identified format and may only be accessed within a secure lab facility.

The de-identified data is held by the New Brunswick Institute for Research Data and Training (NB-IRDT), a highly secure research facility located at the University of New Brunswick. NB-IRDT has the authority to hold de-identified personal health information because it serves as research data centre in the province of New Brunswick. All data held at NB-IRDT is de-identified and does not include any personal identifiers (e.g. name, address, etc.). All researchers seeking to access data at NB-IRDT must follow a

rigorous screening process including a criminal record check, privacy training and signing confidentiality agreements.

Information Packages Sent by Mail

When you receive a package by mail as a result of participating in this study, there will be no information on the envelope that indicates that you are participating in a research project.

Published Findings

We plan to publish the findings of this research in medical journals as well as at conferences. We will also post the findings on our study website. We may also speak about it to the media. We will not report results from any individual study participants. We will only report group results. This means that you will not be identified in any way in our reports.

8. Additional Study and Participation Information

Compensation / Reimbursement

There is no cost to you for being part of this study and you will not be paid or receive any kind of reimbursement for participating.

If You Decide to Stop Participating

You are free to leave the study at any time. After joining in the study, you can decide for up to 7 months if you want us to remove the information that you have provided. After that time, it will become impossible for us to remove your data because the final data set will be created using a new set of randomly generated participant codes that will not be linked to your original participant code. We will not be able to determine which data are yours.

If You Want to Obtain Results

You can learn what the study found after it is completed. This is expected to be posted by November 2022. You can find the results by visiting the study website sleepstudy.ca.

If you have questions

We are happy to talk with you about any questions or concerns you may have about your participation at any time during this research study. Use the study toll-free number which is:

1-844-929-6762

When you call you can ask to speak to the research coordinator (Kamilla Pinter), research assistant (Norma Chinho), or lead researchers (Dr. David Gardner, Dr. Andrea Murphy).

You can also contact us by email:

YAWNS@dal.ca

If you have any ethical concerns about your participation in this research, you may contact Research Ethics, Dalhousie University at (902) 494-3423 or email ethics@dal.ca (and reference REB file # 2020-5184).

9. Statements confirming choice of participation option and consent

In this section, the researcher will determine if the person is interested in participating in the study. If they are, the researcher will record their contact information, option preference for participation, and consent.

Interested in participating: Yes ☐ No ☐

Name			
Address			
Telephone #		Alt. Telephone #	
Email			
Date		Time	
Note			

Selection of participation option

Select a participation option and confirm your choice.

Your choices are:	You confirm:	**Researcher initials**
☐ Option A Full participation	☐ You understand that by making this selection you are volunteering to complete a telephone appointment soon after enrolling and also at 6 months, ☐ You understand that you are giving your consent for the researchers to access de-identified select information from your personal health information.	
☐ Option B Limited participation – no access to my personal health information records	☐ You understand that by making this selection you are volunteering to complete a telephone appointment soon after enrolling and also at 6 months.	
☐ Option C Limited participation – no 6-month contact	☐ You understand that you are giving your consent for the researchers to access select information from your personal health information, ☐ You understand that by making this selection you are volunteering to complete a telephone appointment soon after enrolling but not at 6 months.	

Completing the study questionnaires

How would you like to complete the study questionnaires?

Your choices are	**You confirm**	**Researcher initials**
☐ Option 1	☐ Telephone interview only	
☐ Option 2	☐ A combination of telephone interviews and online responses to a selection of study questions. To ensure that this is an option for you, please verify the following: ☐ You have a working computer with a reliable internet connection ☐ You understand how to use a link sent by email to open a website to start the online questionnaire. ☐ You can be on the phone and online at the same time. ☐ You will contact study staff if you have any difficulties responding to questions online.	

Consent

Please indicate whether you agree or disagree with the following statements so that the researcher may confirm you have all the information to provide your consent

	Agree/Disagree and Researcher initials	
	Agree	**Disagree**
You heard and understood the explanations about this study and you have been given the opportunity to discuss it and have your questions answered to your satisfaction.	☐	☐
You volunteer to take part in this study. You realize that you are free to withdraw from the study at any time. If you choose to leave the study you have up to 7 months from the time you enroll in the study to decide if you would like the data you provided to be removed.	☐	☐
You know how to contact the research team. You have the study phone number (1-844-929-6762).	☐	☐

Thank you for participating in the consent process to enrol in this study.