Sunnybrook
HEALTH SCIENCES CENTRE

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: The Brain Changes in Sleep Apnea Study

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INFORMED CONSENT

You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood.

This form explains the purpose of this research study, provides information about the study procedures, possible risks and benefits, and the rights of participants.

Please read this form carefully and ask any questions you may have. You may have this form and all information concerning the study explained to you. If you wish, someone may be available to verbally translate this form into your preferred language. You may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family, or your family doctor. The study staff will tell you if there are any study timelines for making your decision. Please ask the study staff or one of the investigator(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

Participating in this study is your choice (voluntary). You have the right to choose not to participate or to stop participating in this study at any time.

INTRODUCTION

You are being asked to consider participating in this study because you have recently been diagnosed with sleep apnea and you are not yet on a CPAP or any other treatment for sleep apnea but have decided with your doctor to undergo treatment with CPAP.

Sleep is critical to human health. Adults spend a third of their lives asleep, but insufficient sleep and disrupted sleep caused by sleep apnea are common and have a major impact on brain health. However, there is much we do not know about how sleep apnea damages the brain and what we can do to fix this. The Brain Changes in Sleep Apnea Study will look at the brain health of people with sleep apnea both before and after 4 months of treatment with a CPAP machine. We want to see if brain health improves after people are put on CPAP.

WHY IS THIS STUDY BEING DONE?

The overall goal of the Brain Changes in Sleep Apnea Study is to better understand the impact of sleep apnea on brain function and the risk for brain disorders like stroke and Alzheimer's disease. The results of this study may lead to new treatments to prevent or reverse the impact of sleep apnea on brain health.

WHAT WILL HAPPEN DURING THE STUDY?

This study will take place at Sunnybrook Health Sciences Centre as well as in your own home. We will give you equipment to bring home that you will use yourself to measure your own sleep and biological rhythms. As well, you will need to make 4 study visits to Sunnybrook – 2 times before you start using a CPAP machine, and 2 times four months after you start using a CPAP machine.

In your own home, the study will involve:

1) Wearing a WatchPAT device (Figure 1 below) for 1 night of sleep. The WatchPAT measures your breathing and blood oxygen levels during the night, and it is designed to quantify sleep stages and diagnose sleep disorders. It consists of a wrist band and a probe that goes around a finger. You will bring the WatchPAT back to Sunnybrook on the day of the MRI.
2) Wearing a wristwatch-like accelerometer (Figure 2 below) 24-hours a day for 8 consecutive days, except when swimming or bathing. This tells us when you are sleeping, and how well you are sleeping. It is not a tracking device, nor does it record heart rate – it simply measures the amount you are moving at any given time. You will bring the accelerometer back to Sunnybrook on the day that you return the blood pressure monitor. You can also opt to mail back the accelerometer to Sunnybrook with a prepaid pre-addressed envelope that will be provided to you.
3) Writing down what time you go to go to sleep and what time you wake up during the 8 days that you are wearing the wristwatch-like accelerometer. You will write down the times on a paper sleep diary that we will provide for you.
4) Collecting your urine over a 24-hour period into a 4L urine collection jug that we will provide for you. You will bring the jug back to Sunnybrook on the day of the MRI.

5) Providing some basic information about yourself (demographics and medical history), your sleep habits, and your mood, using an online questionnaire.
6) Completing an online assessment of your memory and concentration.
7) Wearing a portable blood pressure monitor (Figure 3 below) continuously for 24 hours for 1 day. You will receive the monitor on the day of your MRI and will return the monitor to Sunnybrook or to a drop-off facility at Avenue and Lawrence. You can also opt to mail back the blood pressure monitor to Sunnybrook with a prepaid pre-addressed envelope that will be provided to you.

At 2 visits to Sunnybrook Health Sciences Centre, the study will involve:

1) Completing an in-person assessment of memory and concentration.
2) Providing a blood sample (equivalent to 5-6 teaspoons).
3) Having an MRI of your brain. An MRI is a test that uses a magnetic field and radio waves to create detailed pictures of the brain. The test takes about 1 hour to complete. MRI is a safe and non-invasive diagnostic imaging test. The scan involves lying still on a bed that moves into the centre of the main magnetic field. For part of the assessment, you will be asked to relax with your eyes open and to clear your mind. For a different part of the assessment, we will place a tightly fitted mask around you where your breathing air will alternate between room air and 6% carbon dioxide (CO_2). Trained research personnel will control the air supply. MRI technologists will execute all MRI scans and are trained to address participant needs and maximize comfort. You will be able to communicate with the MRI technologists and study investigators at all times.
4) Completing a pulse wave velocity test to assess your arterial stiffness.

Figure 1: WatchPAT Sleep Monitor

Figure 2: GENEActiv Accelerometer

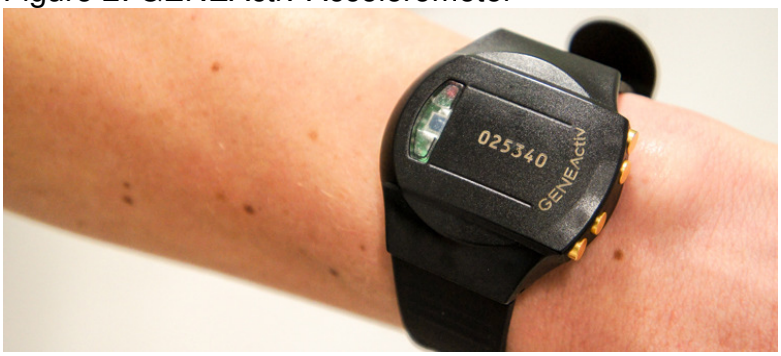

Figure 3: Spacelabs 90217 Blood Pressure Monitor

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that 80 people will participate in this study. 40 people will be patients from Sunnybrook Health Sciences Centre. The entire study is expected to take about three years to complete, and the results should be known in four years.

WHAT ARE THE RESPONSIBILITIES OF THE STUDY PARTICIPANTS?

If you decide to participate in this study, you will be asked to do the following in your own home. You will be asked to do these tests before you start using a CPAP machine, as well as four months after you start using a CPAP machine:

1) Wear a WatchPAT device for 1 night of sleep, starting the day that you receive the device. The WatchPAT measures your breathing and blood oxygen levels during the night, and it is designed to quantify sleep stages and diagnose sleep disorders. It consists of a wrist band and a probe that goes around a finger.
2) Wear a WatchPAT device for 1 night of sleep, starting the day that you receive the device. The WatchPAT measures your breathing and blood oxygen levels during the night, and it is designed to quantify sleep stages and diagnose sleep disorders. It consists of a wrist band and a probe that goes around a finger.

Wear a wristwatch-like accelerometer 24 hours a day for 8 consecutive days, starting the day that you receive the device. The device can be worn at all times except when swimming or bathing. The device tells us when you are sleeping, and how well you are sleeping. It is not a tracking device, nor does it record heart rate – it simply measures the amount you are moving at any given time.

3) Write down what time you go to go to sleep and what time you wake up during the 8 days that you are wearing the wristwatch-like accelerometer. You will write down the times on a paper sleep diary that we will provide for you.
4) Collect your urine over a 24-hour period into a 4L urine collection jug that we will provide for you. You will collect the urine during the 24-hour period before your MRI.
5) Complete an online questionnaire about your health, sleep habits, and mood.
6) Complete an online assessment of your memory and concentration.
7) You will be asked to return the WatchPAT and urine collection jug to the research team at Sunnybrook on the day you come in for an MRI.
8) Refrain from eating from midnight onward on the night before your MRI appointment.
9) Wear a portable blood pressure monitor continuously for 24 hours, starting the day you receive the device. The monitor will take measurements every 30 minutes for 24 hours. You will receive the monitor on the day of your MRI and will return the monitor to Sunnybrook. You can also opt to mail back the blood pressure monitor to Sunnybrook with a prepaid pre-addressed envelope that will be provided to you.
10) You will be asked to return the wristwatch-like accelerometer to the research team at Sunnybrook on the day you return the blood pressure monitor to Sunnybrook. You can also opt to mail back the accelerometer to Sunnybrook with a prepaid pre-addressed envelope that will be provided to you.

If you decide to participate in this study, you will be asked to do the following at 2 study visits to Sunnybrook Health Sciences Centre. You will be asked to do these tests before you start using a CPAP machine, as well as four months after you start using a CPAP machine.

1) Complete an in-person assessment of memory and concentration.
2) Provide a blood sample following an overnight fast. We will take approximately 25-30mL (5-6 teaspoons) of blood from a vein in your arm to test for levels of various fats, sugars, proteins, and other substances that measure inflammation, metabolism, and vascular health. DNA will also be extracted for genetic research to test for genes that are known to predispose people to brain blood vessel dysfunction, cognitive impairment, and sleep disruption. All testing of all samples will be done at the conclusion of the study in 2022. In the future, your blood and/or DNA may also be analyzed in ways that are currently unknown. Blood draws will be conducted by a specially trained staff member. Blood samples will be identified using a unique de-identified number only (not containing your personal health information). Your blood samples will be stored in a secure and confidential location at Sunnybrook Health Sciences Centre under the supervision of the Principal Investigator for up to 10 years following the conclusion of the study.
3) Have an MRI taken of your brain. An MRI is a test that uses a magnetic field and radio waves to create detailed pictures of the brain. The test takes about 1 hour to complete. MRI is a safe and non-invasive diagnostic imaging test. The scan involves lying still on a bed that moves into the centre of the main magnetic field. For part of the assessment, you will be asked to relax with your eyes open and to clear your mind. For a different part of the assessment, we will

place a tightly fitted mask around you where your breathing air will alternate between room air and 6% carbon dioxide (CO_2). Trained research personnel will control the air supply. MRI technologists will execute all MRI scans and are trained to address participant needs and maximize comfort. You will be able to communicate with the MRI technologists and study investigators at all times.

4) Complete a pulse wave velocity test to assess your arterial stiffness

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no medical risks to you from participating in this study. However, you may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. If you decide to take part in this study, you should contact the study coordinator at 416-480-5143 or brainchangessleepapnea@sunnybrook.ca about any side effects or study-related injuries that you experience.

- There may be some minimal discomfort from wearing the wristwatch-like accelerometer.
- There may be some minor disturbance of your usual sleep on the nights that you are wearing the WatchPAT device.
- There may be some minor disturbance of your usual sleep on the nights that you are wearing the portable blood pressure monitor.
- Blood collection can sometimes cause bruising, pain, or very rarely, loss of consciousness.
- There is no significant risk of harm to you during the MRI scan. Rarely, some participants experience a temporary and mild tingling sensation during the MRI.
- You may experience temporary stress and/or anxiety from the MRI.
- The CO_2 challenge during the MRI scan may rarely cause difficulty breathing, high blood pressure, and/or an anxiety attack.
- You may learn something about your brain that you were unaware of, which could cause some anxiety or discomfort. If there is a significant medical problem identified, appropriate care will be arranged for you. Some minor findings in MRI scans will not be described to you as they are of no known clinical consequence.
- 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 study staff.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You will not benefit directly from participating in this study. The physical measurements collected by the Brain Changes in Sleep Apnea Study are only for research purposes. This means that the physical measurements are not diagnostic and are not designed to replace routine clinical care. Blood sample and urine collection results will not be returned to you as they are investigational. Participating in the Brain Changes in Sleep Apnea Study does not replace a visit to your doctor or healthcare professional. At the end of your participation in this study, we will mail you summaries of the recordings you complete at home (1-night WatchPAT recording, 8-day accelerometer recording, and 1-day blood pressure monitoring).

This study was designed for research, not for medical diagnosis. Given the medical nature of the assessments, however, abnormal results may potentially be observed. The MRI scan is not part of standard care practices, so under normal circumstances, individual results will not be released. In the case of unexpected MRI findings, the investigator will consult a radiologist at Sunnybrook. If the radiologist determines that further medical attention is needed, the investigator will inform you and your health care team.

Although you will not benefit directly from participating in this study, your participation may further our understanding of the impact of sleep apnea on brain function and brain diseases like stroke, dementia, and Alzheimer's disease. The results of this study may lead to new treatments to prevent or reverse the impact of sleep apnea on brain health.

CAN PARTICIPATION IN THIS STUDY END EARLY?

You can choose to end your participation at any time without having to provide a reason. However, if you choose to end your participation before completing the study, you will still be asked to return the study equipment back to the study centre. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care. If you withdraw voluntarily from the study, you are encouraged to contact the study coordinator Giselle Kraus at 416-480-5143 or brainchangessleepapnea@sunnybrook.ca. If you withdraw your consent, the information that was/were collected before you left the study will still be used. No new information about you will be collected and no further testing will be done without your permission.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?

Participation in this study will not involve additional costs to you. We will reimburse you for travel costs and/or parking on the days you come to the study centre for study visits.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?

If you become sick or injured as a direct result of your participation in this study, medical care will be provided. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available.

By signing this consent form, you do not give up any of your legal rights.

ARE THE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?

You will not be paid to participate in this study. However, if you decide to participate in this study, you will be reimbursed for travel costs and/or parking on the days you come to the study centre for study visits.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

You have the right to have any information about you and your health that is collected, used, or disclosed for this study to be handled in a confidential manner.

If you decide to participate in this study, the investigators and study staff will look at the health information and sleep study results collected as part of your clinical care in the Sunnybrook sleep clinic.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre of the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook

Access to your personal health information will take place under the supervision of the Principal Investigator of this study.

"Study data" is health information about you that is collected for the study but does not directly identify you. Any study data about you that is sent outside of the hospital will have a code and will not contain your name or address, or any information that directly identifies you. Study data that is sent outside the hospital will be used for the research purposes explained in this consent form.
The investigators, study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though risk of identifying you from the study data is very small, it can never be completely eliminated. The Principal Investigator will keep any personal health information about you in a secure and confidential location for 10 years and then destroy it according to Sunnybrook policy.

When the results of this study are published, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study.

If you have any questions about this study you may contact the study coordinator Giselle Kraus at 416-480-5143 or brainchangessleepapnea@sunnybrook.ca.

If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Vice-Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 x4276.

DOCUMENTATION OF INFORMED CONSENT

Please sign both copies of this form. Keep one for yourself, and return one to the study staff.

Full Study Title: The Brain Changes in Sleep Apnea Study

Name of Participant: _____

Participant/Substitute decision-maker

By signing this form, I confirm that:

- I have read the information provided to me. This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I understand that at the end of my participation in this study, I will receive a summary of the results of the blood pressure monitoring, actigraphy, and home sleep breathing measurements
- I authorize access to my personal health information, medical record, and research study data as explained in this form, including all demographic and health information I have provided to the Brain Changes in Sleep Apnea Study
- I have agreed to participate in this research study

_____	_____	_____
Name of participant (print)	Signature	Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____	_____	_____
Name of Person obtaining consent (print)	Signature	Date