

Photo credit: <https://flic.kr/p/vBs8An>

IF I AM INTERESTED, WHAT SHOULD I DO NEXT?

Contact your doctor to let him or her know that you would like to learn more about the study and he will put you in contact with the researchers. Make time to talk to the researchers in detail about what is involved in the study and to find out whether you qualify to participate.

WHAT IF I AGREE TO TAKE PART, BUT THEN CHANGE MY MIND? CAN I WITHDRAW MY CONSENT?

Yes. You may withdraw from the study at any time without any penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw after having agreed to participate, you just have to contact any of the researchers involved in the study.



Sleep Lab & Sleep Disorders Center
Saskatoon Health Region's LiveWell Chronic Disease Management (CDM)

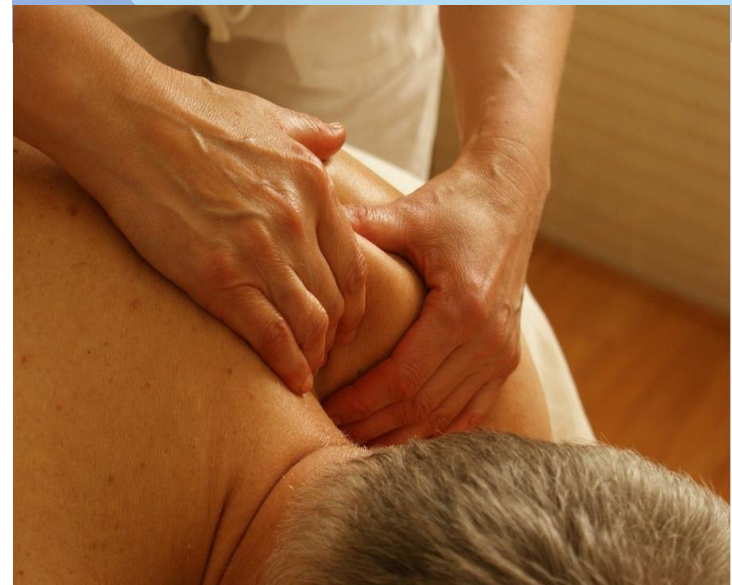
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PARTICIPANT RECRUITMENT INFORMATION



TITLE OF THE STUDY: Effects of Swedish massage on quality of life, sleep, stress, fatigue and biological markers levels in recently treated patients with breast cancer

Your doctor has given you this brochure to provide you with a general idea of what would be involved in participating in this study.

WHY HAS MY DOCTOR GIVEN ME THIS BROCHURE?

Your doctor feels that you may be an appropriate candidate for this new medical study.

WHAT IS THE PURPOSE OF THIS STUDY?

This study intends to understand the effects of Swedish massage therapy on sleep patterns, stress, quality of life, fatigue and some biological markers in patients with history of breast cancer.

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WHAT WILL I HAVE TO DO IF I PARTICIPATE IN THE STUDY?

If you meet the criteria necessary to take part in the study and choose to participate, you will receive one-hour weekly massage session for 8 weeks from a trained massage therapist.

WHAT HAPPENS ONCE THE STUDY STARTS?

If you choose to participate in this study you will be requested to:

- Commit approximately one hour per week of your time for 8 weeks.

- You will participate on the data collection process, which involves:

- Wearing a wrist monitor* (similar to a watch) to record your sleep patterns for 5 days at the beginning, middle and end of the study.
- Having your physiological parameters (blood pressure, heart rate, and oxygen saturation) assessed before and after the massage therapy.
- Having your saliva sample collected on a few occasions (the saliva will be used to measure some biomarkers that might be related to stress, fatigue and sleep).
- Answering 3 questionnaires about quality of life, fatigue and sleep at the beginning, middle and end of the study.

WILL TAKING PART IN THE STUDY HELP ME FEEL BETTER?

There is no guarantee that you will benefit from taking part in this study. You may benefit from having access to massage therapy sessions and periodic symptoms evaluation. The purpose of the study is to investigate the effects of massage therapy, so we cannot yet say whether or not it will be beneficial. However, you will be given “gold standard” medical attention and your participation will help us to learn things about complementary treatment options that could benefit others in the future facing the same situation.

***WHAT IS A WRIST MONITOR?**



Wrist monitor is a tool similar to a watch used to assess sleep. Participants will use it for at least 5 days.

This tool has an integrated accelerometer, which provides data related to daily activity and sleep pattern (such as sleep efficiency, frequency and duration).

WHAT IF I'M NOT INTERESTED IN TAKING PART IN THE STUDY? WILL THAT AFFECT MY RELATIONSHIP WITH MY DOCTOR?

Taking part in this - or any clinical trial - is entirely voluntary. You should not feel any pressure to enroll. If you are not certain that you wish to participate or if you decide not to take part, you will not suffer any penalty or lose any benefits to which you are otherwise entitled.

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