

PARTICIPANT INFORMATION SHEET

Title of Study: **WITHME – Water immersion therapy for mental health**

Principal Investigator: **Nicholas Ravanelli, PhD, CSEP-CEP
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Co-Investigators: **Diane K. Whitney, MD, FRCPC, BCETS
Program Director NOSM Psychiatry Program**

**Sarah Habinski, MD
PGY2 Psychiatry Resident, Northern Ontario School
of Medicine**

Dear potential participant:

The following study is being conducted by Dr. Nicholas Ravanelli (PhD), Dr. Diane Whitney (MD) & Dr. Sarah Habinski (MD) to investigate the utility of a simple at-home lower-limb water immersion therapy to alter symptoms and cardiovascular markers associated with mental illness. In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This document gives you detailed information about the research study. Please take your time to make your decision. Feel free to discuss it with your friends and family, and health care providers.

Why is this study being done?

Common mental health disorders like depression and generalized anxiety affect approximately 1 in 5 Canadians. The risk of developing common mental health illnesses like depression and generalized anxiety has increased due to the ongoing COVID-19 pandemic which has imposed additional life stressors and disrupted daily living for many. Heat therapy has been shown to reduce depressive symptoms and recent evidence suggests it can improve cardiovascular health and function. As such, this study will evaluate whether a simple at-home mild heat therapy intervention, in addition to ongoing mental health treatment, can reduce negative symptoms associated with mental health disorders.

What is the purpose of this study?

The purpose of this study is to evaluate whether 8-weeks of lower-limb lukewarm or hot water immersion therapy can attenuate or improve symptoms associated with common mental health disorders.

How many participants will be in this study?

A total of 150 participants above the age of 18 will be recruited for this study and randomly allocated to either a control group, lukewarm water immersion, or hot water immersion. All participants must be currently engaged in mental health support services, and continue throughout their participation in this study.

What will be my responsibilities if I take part in the study?

If you volunteer to participate in this study, various demographic information will be collected including age, sex, height, weight, education level, employment, and a short health questionnaire (~15 minutes to complete). Additionally, you will be asked to complete 3 validated questionnaires (~10 minutes to complete) to assess symptoms of depression (Patient Health Questionnaire – 9 item), anxiety (Generalized Anxiety Disorder – 7 Item), and post-traumatic stress disorder (PCL-5 – 20 item). Following these preliminary questionnaires, you will be randomly allocated to one of three groups: control, lukewarm water, or hot water. If allocated to the control group, you will be asked to maintain your regular lifestyle habits for 8-weeks. Lukewarm or hot water groups will be asked to practice 30 minutes of lower limb (e.g. mid-shin down) water immersion three times a week for 8 weeks. If randomly allocated to either the lukewarm or hot water group, you will be asked to submit your mailing address and/or contact information so that the research team can send you a waterproof digital thermometer. Lukewarm is defined as a water temperature that is not hot or cold (~31°C), whereas the hot water immersion would be defined as tolerable warm water which is not painful or burning (~39°C). This immersion session can be done anywhere in your home, either in a bucket or basin suitable to hold sufficient water to your mid-shin or in a bathtub. You will be asked to log your sessions through the online platform which will also serve as a timer for your sessions, record the water temperature using the supplied digital thermometer, and will be asked to submit a photo of your water immersion solution (this is not required and at your discretion). If allocated to either the lukewarm or hot water group, ratings of thermal sensation, comfort, preference, and acceptability will be asked after each immersion session (~2 minutes to complete). Lastly, if you own a heart rate strap (e.g. Polar H7, H9, H10), you will be asked to provide 5-minutes of resting heart rate data lying in the supine position prior to the intervention and at the end of each week, and during your water immersion sessions if allocated to the lukewarm or hot water group. If you do not have a heart rate strap, but would like to submit heart rate data, please contact Dr. Ravanelli at nravanell@lakeheadu.ca as we may be able to loan you a heart rate strap. Finally, you will be asked to complete the PHQ-9, GAD-7, and PCL-5 every 2 weeks. All activities for

this study will be accessible through the online platform. You will be contacted via an email notification when new tasks are required to be done.

What are the possible risks and discomfort?

There are no known extraneous risks associated with participation in this study. However, there may be a risk of revisiting traumatic events. As such, we have provided a list of local (e.g. Thunder Bay area) and national mental health support services in this document and as a separate link on the online platform. Moreover, participation will not affect the ongoing care you receive, and all research results shared with the co-investigators will be de-identified to ensure anonymity and confidentiality. All results submitted to this study are completely confidential and will not be provided to an external body unless requested by law.

What are the possible benefits for me and/or society?

The results of this study may provide new insight into the therapeutic use of water immersion therapy to reduce symptoms associated with mental health disorders and improve cardiovascular health. Your participation will foster new at-home strategies to compliment ongoing treatment strategies to reduce symptoms associated with poor mental health, particularly during times where access to in-person healthcare services is limited.

Will I be paid to participate in this study?

Participants who complete the 8-wk intervention study will be entered into a draw for 1 of 3 \$50 VISA gift cards.

Will there be any costs to me in this study?

There are no costs related to this study.

What will happen to my personal information?

Your age, gender, and contact information (email address) will be collected as part of this study. Your data will not be shared with anyone except with your consent or as required by law. Only the principal investigator of this study will have access to your data. All personal information such as your email address will be stored behind two alphanumeric passwords in a secure database hosted at Lakehead University. All information submitted through the online platform will be associated with your participant identification number. The list of participant keys will be kept in a separate and secure file. Any external data or images uploaded by the participant to the online platform will stored in a password protected file structure and coded with an alphanumeric name to minimize the risk of identifying the submitting user. The data for this research study will be kept for 10 years following final publication of results. By registering, you authorize such access. If the results of the study are published, your email will not be used and no information that

discloses your identity will be released or published without your specific consent to the disclosure.

Can participation end early?

You may withdraw at any time. Throughout the course of the study, you will be informed of any new information that might influence your decision to continue. If you wish to withdraw during or after the study, you have 2 options:

- 1) Continue to contribute the data collected prior to withdrawal.
- 2) Request that all your information and data be withdrawn completely from the study.

You may also refuse to answer any questions you don't want to answer and still remain in the study.

How can I receive a copy of the research results?

The results of this study will be used in the development of manuscripts intended for publication in journals. Research results will also be disseminated in the form of presentations (poster or verbal) at related conferences. You are invited to request a review of your results following the completion of the study.

If I have any questions or problems, whom can I call?

If you have any questions about the research now or later, please contact the Principal Investigator:

Dr. Nicholas Ravanelli at nravanel@lakeheadu.ca.

This study has been reviewed by the Lakehead University Research Ethics Board (REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call Lakehead University REB at 807-343-8283.

Mental Health Community Resources
*If you are in distress such that you need help immediately, please go to the
Emergency Department at the Thunder Bay Regional Health Sciences
Centre at 980 Oliver Road, or **call 911***

Immediate services:

ConnexOntario at 1-866-531-2600

Crisis Services Canada at 1-833-456-4566 (24hr) or send a text to 45645 (4 PM - 12 AM ET)

Additional Support Services:

Canadian Mental Health Association (CMHA) Thunder Bay

200 Van Norman Street
Thunder Bay, ON P7A 4B8
Tel: (807) 345-5564
E-mail: cmhatb@cmha-tb.on.ca

Thunder Bay Counselling Centre

544 Winnipeg Ave
Thunder Bay, ON P7B 3S7
Tel: (807) 684-1880

NorWest Community Health Centre

525 Simpson Street
Thunder Bay, ON P7C 3J6
Tel: (807) 622-8235
<https://www.norwestchc.org/index.php>

If you are a student at Lakehead University, Thunder Bay campus, you may also contact Student Health and Wellness at 343-8361

CONSENT STATEMENT

SIGNATURE OF RESEARCH PARTICIPANT

I agree to the following:

- ✓ I have read and understand the information contained in the Information Letter
- ✓ I agree to participate
- ✓ I understand the risks and benefits to the study
- ✓ That I am a volunteer and can withdraw from the study at any time, and may choose not to answer any question
- ✓ That the data will be securely stored at data servers at Lakehead University for a minimum period of 5 years following completion of the research project
- ✓ I understand that the research findings will be made available to me upon request
- ✓ I will remain anonymous
- ✓ All of my questions have been answered

By consenting to participate, I have not waived any rights to legal recourse in the event of research-related harm.

I have read and agree to the above information and by completing the registration, I agree to participate.
