



APPENDIX D:

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Full Research Project Title: Evaluate the value of Telehomecare for Mental Health

Principal Investigator:

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Co-Investigators:

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Dr. Jay Shaw, Institute for Health System Solutions and Virtual Care, Women's College Hospital, Toronto, ON.

Study Contacts:

Ontario Shores Centre for Mental Health Sciences:

Site Principal Investigator: Beth Brannon, 905-668-5881 Ext 6159

Lakeridge Health:

Site Principal Investigator: Paul McGary, 905-576-8711 x6212

Women’s College Hospital:

Site Principal Investigator: Dr. Jennifer Hensel; Department of Psychiatry; Phone number: 416-323-6230

Sponsor: This research project is being funded by the Ontario Telemedicine Network (OTN).

INFORMED CONSENT

You are being invited to participate in a research project. This form explains the purpose of this research project and provides information about what is being studied including possible risks and benefits, and the rights of participants.



Please read this form carefully and ask any questions you may have. Please ask the research project staff to clarify anything you do not understand or would like to know more about. Make sure that all of your questions are answered to your satisfaction before deciding to participate in this research project.

Participating in this research project is your choice. You have the right to choose not to participate, or to stop participating at any time.

ABOUT THE RESEARCH PROJECT

You are being invited to participate in this research project because you have been referred to, or assessed at Ontario Shores Centre for Mental Health Sciences, Lakeridge Health, or Women's College Hospital for a mental health problem. Mental health support and counselling is often identified as one of the most unmet needs among Canadians despite it being a recommended treatment for many mental health conditions. Modern solutions such as virtual care, which includes on-line, internet-based programs and tools, are rapidly entering the health care system to fill this gap.

The Big White Wall (BWW) is an on-line community that offers mental health support in a facilitated social network environment. The BWW offers 24/7 access to:

- Self-assessment tools to track symptoms for a wide range of mental health conditions over time
- Mental health educational materials
- A social network that allows communication between yourself and people who may have similar problems
- On-line courses that teach coping skills for common mental health problems like depression and anxiety.

People use the Big White Wall to obtain support and to share with others using the Big White Wall what's troubling them, in a safe and anonymous environment. This is done with the guidance of trained mental health professionals known as 'wall guides' who monitor postings on the Big White Wall twenty-four hours per day, seven days per week. These individuals constantly review user activity and posted materials to ensure the content is appropriate and sensitive to all users. They will engage with users through instant communication to ensure that users feel like their material is being responded to. They may also participate in 'talkabouts' to guide user-generated discussion threads that are open to all users enabling peer interaction on a common experience or topic.

The BWW was developed in the UK and is now also available in New Zealand, Australia, and the USA with over 35,000 users since it started. We are testing the use of the BWW in Canada to see if it can help people with mental health problems through providing support, education and self-management tools.

The research project is funded through the Ontario Telemedicine Network. OTN provides services and technology to doctors, nurses, hospitals and other healthcare organizations and



providers to help them give patients in Ontario better access to care. OTN is overseeing all parts of this research project including providing you with a generic email account and activation code and access to the Big White Wall on-line support.

OTN received special funding from Canada Health Infoway, a federal government agency, to determine if technology can help a patient better manage their anxiety, depression or other related symptoms and in turn improve their health. Canada Health Infoway is an organization that helps to improve the health of Canadians by working with partners like OTN to speed up the development, uptake and effective use of technology across Canada.

The Women's College Hospital Institute for Health System Solutions and Virtual Care (WIHV) in Toronto is responsible for administering the research component of the project.

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Your health care provider organization is one of three organizations participating in the Project. The role of the health care provider organization is to identify patients suitable for the Project, to invite patients to participate, to provide a project staff to assist with informing patients about the Project and to work with OTN and the researchers to ensure that all aspects of the Project are implemented as planned.

Your participation in the research project and use of the Big White Wall application does not replace professional advice from your health care provider. The Big White Wall on-line support community used in this project is not an emergency service and if you are experiencing an emergency you should call 911 or go to the Emergency Department?

WHY IS THIS RESEARCH PROJECT BEING DONE?

The purpose of this research project is to determine whether the use of an on-line community (the BWW) can improve mental health self-management and recovery among individuals seeking mental health care. In addition to this, we hope that this research can help us understand the challenges involved in making this kind of on-line community available to Ontarians.

WHAT WILL HAPPEN DURING THIS RESEARCH PROJECT?

If you consent to participate in this research project, you will be randomly (by chance) placed in one of two research project groups. Random placement into a group is almost like flipping a coin. The first group will have access to the BWW immediately after agreeing to participate and will have continuous access for a period of 3 months, while the second group will get access to the BWW 3 months after agreeing to participate and then have access for a total period of 3 months. Neither you, nor the research project staff can influence which group you are in. You will have a 2 in 3 (67%) chance of being placed in the group who will receive immediate access to the BWW. We will tell you which group you are in after you agree to participate. If you agree, your primary care provider will be notified that you are participating in the research project.

There are additional components to this research project, namely:



- Registering on the BWW as a user.
- You will be able to access the on-line support through the internet on a personal computer or mobile device.
- You will be provided with a generic email account by OTN and an activation code to link to the BWW. The generic email account serves to limit identifying information about you being transmitted to and stored in the UK. Once logged in to the BWW you assume an online identity which is anonymous to other users of BWW and to the 'wall guides' monitoring the BWW.
- You will receive personalized email notifications from Big White Wall. If you do not want to receive these emails, you have the ability to turn off the email notifications within your Big White Wall profile.
- Completing a series of questionnaires expected to take approximately 15-25 minutes. Questionnaires will cover topics such as your experiences and perspectives on the technology that you are using, and your health status, outcomes, and behaviours post-intervention. You may do this over the phone now, or request that the questionnaires be sent to your email address. Regardless of which group you are in, you will be sent emails with links to complete additional questionnaires on-line at 3 and 6 months' time from now. If you do not wish to communicate by email and/or do the questionnaires on-line, you will be able to complete the questionnaires with a member of the research team over the phone and they will enter your responses directly in the secure on-line questionnaire database. Each set of questionnaires may be completed all at once or you may stop and continue at a later time, as long as you complete them all within 2 weeks of receiving the email link.
- Providing consent for the research project team to access your personal healthcare information using your OHIP number. Personal healthcare information collected will include how often/when you accessed the healthcare system, what services you used, and overall individual costs using methods developed for use with Ontario data.
- The study staff will also collect baseline socio demographic information such as your:
 - Gender
 - Ethnicity
 - Education
 - Household income
 - Marital status
 - Age at which first experienced mental health problem. Answering baseline socio demographic questions is optional.

You will have access to BWW for a 3 month period. Once this 3 month period is over, you will no longer have access to BWW. BWW will send you email notifications when your access is close to expiring.

Please note, as this app is online, you will incur normal charges as per your internet services provider for the time spent online

HOW MANY PEOPLE WILL TAKE PART IN THIS RESEARCH PROJECT?

Up to 1000 people will participate in this research project across 3 participating health care sites in Ontario. The length of time you will be in the research project is 6 months. The entire research project for all participants is expected to take about 12 months to complete and the results should be known in 2 years.

WHAT ARE THE RESPONSIBILITIES OF RESEARCH PROJECT PARTICIPANTS?

If you decide to participate in this research project, the research project team will collect some information from you now and again at 3 and 6 months. At the end of the research project, the research project team would like to use your OHIP number to link to your individual health administrative data at the Institute for Clinical Evaluative Sciences (ICES). This health data includes health care visits such as use of the emergency room and visits with your doctors. ICES retains health data indefinitely and follows processes and procedures approved by the Privacy Commissioner of Ontario to ensure personal health information is protected at all times.

A direct link to the on-line questionnaires will be sent to your email address at the 3 month and 6 months time points during your participation. You can complete them at your leisure from anywhere you can access the internet.

If you agree to participate in this research project, you have the option of being selected to participate in two interviews to find out from you about your experience with the BWW. The research team would like to know whether you believe it to be useful in your health care and the management of your symptoms. The interviews will take approximately 30 to 60 minutes each and will take place via Personal Videoconferencing (PCVC) or via telephone. Please indicate your decision at the end of this process. If selected, you will be contacted at a separate time with more information about this part of the research project.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS RESEARCH PROJECT?

There are no known major risks to you from participating in this research project. If you were recruited from a waitlist, participation in the research project will not affect your position on the list or time to services. If you are currently receiving help for your mental health problems, you will continue to meet with your health care provider as planned. The questionnaires may be inconvenient or cause some distress and you have the option to discontinue at any time or opt not to complete them. They may also be completed over several days, rather than all at once. There is a risk that you will be distressed by something you encounter during your use of the BWW. The BWW is monitored by trained therapists called ‘wall guides’ who are available to respond if something problematic is experienced on the site. Once your access to BWW expires at the end of your 3-month period, there is a risk that you might miss having access to it if you found the program beneficial. Since this is a trial project, we are unable to offer patients continued use of the BWW beyond the 3-month period. If you require additional mental health support after the 3-month period, please contact your health care provider for advice.



Please note that the BWW on-line support community used in this project is not an emergency service and if you are experiencing an emergency you should call 911 or go to the Emergency Department.

You will be told about any new information that might affect your willingness to continue to participate in this research project as soon as the information becomes available to the research project staff. You will be able to maintain anonymity on the site through a unique non-identifiable user ID.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS RESEARCH PROJECT?

You may or may not benefit directly from using the BWW. Based on the results of previous studies involving this and other similar on-line communities, we hope that many people will experience benefits in a range of outcomes. Your input will also tell us how this and similar on-line communities can be used to help people like yourself who are experiencing mental health problems.

CAN PARTICIPATION IN THIS RESEARCH PROJECT END EARLY?

You can choose to end your participation at any time. If you choose to withdraw, your choice will not have any effect on your current or future receipt of health care services. If you choose to withdraw voluntarily from the research project, you are encouraged to contact the research project team by telephone about your decision. If you withdraw your consent, the information about you and your mental health problem(s) that was collected before you left the research project will still be used. No new information about you will be collected without your permission.

The research project staff may decide to remove you from this research project without your consent. If you are removed from the research project, the investigator will discuss the reason(s) with you.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS RESEARCH PROJECT?

There is no cost of participating.

ARE RESEARCH PROJECT PARTICIPANTS PAID TO PARTICIPATE IN THIS RESEARCH PROJECT?

You will not be paid to participate in this research project.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?



The information you provide to Big White Wall will be limited. The data collected such as your age and education level is used to recommend what portions of the Big White Wall may be most helpful to you and is kept separate and behind firewalls. This minimal information collected will be stored on an encrypted server in compliance with applicable laws.

Your health care organization will provide OTN with minimal information about you only to allow OTN to set up your generic email account and activation code.

OTN will keep minimal information about you, securely, for the purpose of creating a generic email account and emailing you the email account and access code to your personal email. This information will be kept by OTN for 15 years. OTN is required to comply with provincial privacy legislation. OTN is also required to ensure any third party vendors (such as Big White Wall) also comply with this legislation. OTN uses a variety of physical, administrative and technical methods to protect patient information including assessing, monitoring, reviewing and updating our practices regularly to ensure the ongoing privacy and security of that information. OTN is required to conduct privacy and security assessments as a requirement of the funding we receive from Canada Health Infoway. We are required to provide the findings of this assessment to the participating health care provider organizations and to ensure that all organizations involved in the Project are fulfilling their privacy and security obligations.

Agreements are in place with Big White Wall, WIHV and your health care provider organization which requires them to fulfill their privacy and security obligations

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

If you decide to participate in this research project, the research project staff will collect only the information they need for this research project. You have the right to access, review and request changes to your personal health information.

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

- Members of the research project team at the Women's College Hospital and St. Michael's Hospital in Toronto and their representatives at Lakeridge Health, Ontario Shores and Women's College Hospital;
- Representatives of the Women's College Hospital, Women's College Hospital Research Institute, or the Women's College Hospital Research Ethics Board, because they oversee the ethical conduct of research studies at Women's College Hospital; and
- Representatives of Health Canada and other regulatory bodies.

Access to your personal health information will take place under the supervision of the research project's Principal Investigator.

“Research project data” is information about you that is collected for the research project, but that does not directly identify you. Your research project data will include information about your use of the BWW and results of questionnaires you complete on the site. These results will not have your identifying data and will be sent by BWW to WIHV. Your data will be added to the research project data from all other research project participants and sent to Women’s College Hospital after research project completion for analysis. Any research project data about you that is sent outside of the hospital will not contain your name or address, or any information that directly identifies you. Research project data that is sent outside of the hospital will be used only for the research purposes explained in this consent form.

The investigator(s), research project 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 the risk of identifying you from the research project data is very small, it can never be completely eliminated.

The research project’s Principal Investigator will keep any personal health information about you in a secure and confidential location for 7 years after publication and then destroy it according to Women’s College Hospital policy.

When the results of this research project are published, your identity will not be disclosed.

BWW will be provided access to de-identified, aggregate data around things like how often you used the on-line community so that they may improve their product. They will not be given any information that can be used to identify you personally.

You have the right to be informed of the results of this research project once the entire research project is complete. If you would like to be informed of the results of this research project, please contact the project manager at 416-323-6400 x5126.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?

There are no conflicts of interest to declare related to this research project.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH PROJECT?

You have the right to receive all information that could help you make a decision about participating in this research project. You also have the right to ask questions about this research project 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 research project.

If you have any questions about this research project you may contact the person in charge of this research project, Dr. Sacha Bhatia at the Women's College Hospital, at 416-323-6400 x5126.

Alternatively, you may call the project staff located at your hospital location with any questions you may have while using Big White Wall or to withdraw from the project:



Ontario Shores Centre for Mental Health Sciences: 905-706-4761

Lakeridge Health: 905-213-0722

Women's College Hospital: 416-323-6400 x 5989

Should you have any questions or concerns regarding your rights as a participant in this research study, or if you wish to speak with someone who is not related to the study, you may contact: Chair of the Women's College Hospital REB, Dr. Nancy Walton, or the Research Ethics Co-ordinator, Ms. Melissa Sidhu, at 416-351-3732 ext. 2325.



DOCUMENTATION OF INFORMED CONSENT

Full Research project Title: Evaluate the value of Telehomecare for Mental Health

Name of Participant: _____

Participant ID: _____

Participant

By signing this form, I confirm that:

- This research project has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research project
- I have been informed of the risks and benefits
- I have been informed of any alternatives to participating in this research project
- I have been informed of the rights of research project participants
- I understand that I have the right to withdraw from the research project at any time.
- I have read all of the pages of this consent form or they have been read to me
- I am responsible for the use and access to the Big White Wall on-line support community and services given to me.
- I understand that the research project is not an emergency service nor should it replace the medical advice of my healthcare provider.
- I authorize access to my personal health information, medical record and research project data as explained in this form
- I have agreed, or agree to allow the person I am responsible for, to participate in this research project
- I understand that my primary care provider may be informed of my participation in this research project

The following components are optional and not required in order to participate in the research project.

- I **agree** that the research project team may contact my primary care provider(s) to inform them of my involvement in the research project
- I **agree** to provide my OHIP number to allow the research project team to access my health administrative data from ICES at the conclusion of the research project, and link it to the data collected about me during the research project.
- I **agree** to be contacted to complete the second part of this research project, which involves an interview process to find out from me about the BWW as described in this consent form.



Please indicate your preferred method of contact:

Email Phone

We may leave a voice message:

YES NO

Email or Telephone: _____

Person obtaining consent

By signing this form, I confirm that:

- This research project and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered

Name of Person obtaining
consent (print)

Signature

Date

If applicable:

Consent obtained by telephone

Date: _____ Initial: _____