

Information & Consent Form for the Wellbeing for Chronic Health Conditions Course Screening

Please take the time to carefully read the following information. If any information is unclear or for technical assistance, please email us at Online.Therapy.USER@uregina.ca or phone 306-337-3331.

Project Title: Internet-delivered Cognitive Behaviour Therapy for Chronic Health Conditions: Open Trial

Principal Investigator:
Heather Hadjistavropoulos, PhD, R. D. Psych Professor, Department of Psychology University of Regina Contact # (306) 585-5133 E-mail: heather.hadjistavropoulos@uregina.ca
Co-investigators
Blake Dear, PhD, University of Regina Nickolai Titov, PhD, Macquarie University

Online Therapy Team:	
Marcie Nugent, MSW, Operations Director Kelly Adlam, MSW, Clinical Research Associate Lee Bourgeault, MA, Clinical Research Associate Emma Valli, BSW, Clinical Research Associate Vanessa Heron, MEd, Clinical Research Associate Giuliano LaPosta, BA (Hon) Research Associate Andrew Wilhelms, BA (Hon) Research Associate Vanessa Peynenburg, PhD, Research Associate Ram Sapkota, PhD, Senior Research Associate Lacey Sabine, BSW, Research Associate Kathryn Dickerson, BSW, Research Associate MacKenzie Martin-Proskie, BSW, Community Online Therapist Aaron Ingrouville, BSW, Community Online Therapist Katherine Owens, PhD, Community Supervisor Janet Tzupa, BSW, Community Online Therapist	Online Therapy Unit Department of Psychology University of Regina Contact: (306): 337-3331 Email: Online.Therapy.USER@uregina.ca

Purpose of the Screening:

The purpose of the screening is to assess your present concerns and determine whether you are eligible for the Wellbeing for Chronic Health Conditions Course and the associated research project. This consent form is in regards to the Wellbeing for Chronic Health Conditions Screening only. For your information, however, we also describe the Wellbeing for Chronic Health Conditions and the Wellbeing for Chronic Health Conditions Research below. If you are accepted into treatment, a second consent form will be presented at that time.

Purpose & Nature of the Chronic Health Conditions Course:

The Wellbeing for Chronic Health Conditions Course is a transdiagnostic internet-delivered cognitive behaviour therapy (ICBT) course designed to assist people managing diverse chronic health conditions and diverse symptoms of depression and anxiety.

The course involves clients reviewing course materials online and then practicing cognitive, behavioural, and physical strategies for managing symptoms.

- The course materials are delivered gradually over 8 weeks and take about 1 hour to review and then additional time (1-3 hours) to practice strategies taught in the course.
- Clients are able to email or phone a provider, who offers support and answers questions, up to once per week.
- All providers have received training and supervision in ICBT and have a background in psychology or social work; providers are registered or certified to practice in Saskatchewan or are graduate students under supervision of a registered/certified professional. All providers use the Online Therapy Unit website to deliver services, although they may work from offices located in different parts of Saskatchewan.
- All clients who take part in the Wellbeing for Chronic Health Conditions Course are asked to complete questionnaires before treatment (~30 minutes), weekly during treatment (~5 minutes), and then at 8 weeks after treatment, and 3 months after treatment (20-30 minutes).

Purpose of the Chronic Conditions Course Research:

- While we have learned a lot about the effectiveness of Wellbeing for Chronic Health Conditions Course 2018, there is still more for us to learn about how to best deliver ICBT. At this time, the Online Therapy Unit is examining how to improve the delivery of online therapy for Chronic Health Conditions.

Procedure/ Format of the Screening:

- **Brief Online Screening (5 minutes):** After you consent, you will be asked some brief questions to determine if you are eligible for the Wellbeing for Chronic Health Conditions Course. If you are not eligible, the Online Screening will stop and you will be given information about why you are not eligible. You can contact the office to discuss your eligibility further if you wish.
- **Full Online Screening (20 to 30 minutes):** If you meet basic eligibility for the Wellbeing for Chronic Health Conditions Course, you will be asked to provide personal information

such as name, address, telephone number, and email address before continuing. This information is necessary for our staff to contact you to discuss the results of the Full Online Screening. In the Full Online Screening you will be presented with questions asking about your background, mental health symptoms, health, relationships, occupation, and treatment history. We will request, but not require, the name and contact information for an emergency medical contact, such as your physician. At this stage, this provider will only be contacted if we are concerned about your safety, or, with your additional consent, to discuss your care.

- **Telephone Screening (20 to 30 minutes):** Following the completion of the Online Screening, you will schedule a time for a staff member to contact you by phone to discuss the results of the Online Screening and let you know if you are eligible for the Wellbeing for Chronic Health Conditions Course and our research project. Online Therapy Staff may ask you some brief clarifying questions if more information is needed regarding your responses to the Online Screening. You may also use this time to ask any questions you may have about the program or research.

Please note: The Wellbeing for Chronic Health Conditions Course is not for everyone. Participation in the Online Screening does not guarantee participation in the course.

Funded by:

The research has received funding from the Government of Saskatchewan, Ministry of Health.

Potential Risks:

You may find that sharing information can result in an increase in your emotions. It is also possible that after undergoing the screening it will be determined that the Wellbeing for Chronic Health Conditions Course is not a good fit for you. If this happens, Online Therapy staff will discuss alternate treatment options with you. In general, your physician is a good source of information about services that may be available to you. Note that there are some risks with respect to confidentiality of information which are described below.

Potential Benefits:

It is our hope that by undergoing the screening you will be able to access and benefit from the Wellbeing for Chronic Health Conditions Course; alternatively, if the course is not a good fit for you, we will do our best to discuss more appropriate alternative services for you.

Compensation:

No compensation will be provided for taking part in the screening.

Voluntary Participation & Right to Withdraw:

Participation in the screening process is entirely voluntary and you can answer only those questions that you are comfortable with. Should you choose not to participate in the screening, or if you wish to stop the screening at any time after starting, you may do so without explanation or generally without consequences. The one exception, however, is that if certain questions are not answered it may not be possible for us to offer you the Wellbeing for Chronic Health Conditions

Course (e.g., your provider requires certain information, such as your name and contact information, in order to offer you services).

Your right to withdraw your Online Screening data from the research results will apply until one week after you complete the Online Screening. After this date, it is possible that some results have been analyzed, written up and/or presented, and it may not be possible to withdraw your data. If you want your Online Screening data to be excluded from research results, please contact the Online Therapy Unit at the contact information above and your data will be removed from the research database. It is not possible to exclude Online Screening data from clinical files until 7 years after services have been provided as this represents a record of care.

Confidentiality:

The responses you provide are confidential and will not be released to any outside source including your employer, except in situations in which there is:

1. potential, imminent harm to yourself or others; or
2. suspected neglect or harm to a child, including the witnessing of violence; or
3. a court order to release client information; or
4. where required by legislation.

Risks to Privacy:

There are unique risks that may compromise your privacy that exist with any internet-based service, including that the responses to the questionnaires are temporarily stored on your computer connected to the internet in the browser's history and cache.

Methods Used to Protect Your Information:

The Online Therapy staff has taken precautions to protect the security of your information. Both the University of Regina server and REDCap servers are protected with generally available security technologies, including firewalls and data encryption. In addition, information transmitted from your machine to the server is encrypted using secure socket layer technology (SSL).

Things You Should Do to Protect Your Information:

It is important for all users of internet-delivered services to take additional security precautions when submitting sensitive information electronically to ensure the safety of your information.

1. Use your home computer instead of a computer in a shared space, such as a library or office.
2. When you leave your computer or are done working with the web application, ensure you have exited the Online Screening.
3. Since your internet browser stores information in its memory, or disk cache, you can clean the cache or browser history after you use the computer to ensure the information has been discarded. Certain browsers have "Privacy" modes that can be enabled. Once in this mode, the user's interactions are not saved to browser history, and no data is stored in browser cache. Once the browser is closed or this mode is exited, there are no browser records of any of the interactions that occurred while in the "Privacy" mode. Firefox has this feature and is, therefore, highly recommended when completing the Online Screening. Browsers that do not

have this mode, or users that do not use this feature, must manually purge their browser history and cache to prevent others from seeing their web interactions.

4. Use a secure internet connection (private home or work network) instead of a public Wi-Fi network. If you are connected to an unsecured public wireless network, using a Virtual Private Network (VPN) service (e.g., Norton Secure VPN, TunnelBear) to encrypt all of the data you send online will ensure your privacy and anonymity are protected.
5. Enable either the firewall software that came with your operating system (e.g. Windows firewall), or install a reputable third party software, such as ZoneAlarm. Firewalls protect your computer and information from network attacks and threats.
6. Use anti-virus software to both prevent and recover from virus programs. While most anti-virus software is for purchase, there are free software options available to download. However, one must still be cautious in order to avoid downloading and installing malicious software that appears to be legitimate.
7. Malware-detection software (such as Spybot: Search and Destroy, Microsoft Security Essentials) can be used to scan your computer for software and files that may be leaking your personal information to third parties.
8. Ensure your software (operating system updates, anti-virus software) is updated with the latest version as developers are continually patching security holes and vulnerabilities with software upgrades.

Use of Information Collected through the Screening:

1. Information gathered through the Online Screening will be used to determine your eligibility for participation in the Wellbeing for Chronic Health Conditions Course. If you are not eligible for the Wellbeing for Chronic Health Conditions Course, it will be used to attempt to provide you with options available to you in your community.
2. If you are accepted for the Wellbeing for Chronic Health Conditions Course, the Online Screening will be given to your provider and be part of your clinical record of care. The clinical record is kept securely by Online Therapy Unit providers.
3. To be used in de-identified form (identifying information removed) by researchers to evaluate the Online Screening and Online Therapy Courses and to help guide the development of future screening tools, online therapy courses, and advance ICBT as a whole. Any publications stemming from the evaluation of this information will examine all respondents as a whole and you will not be personally identified.

Storage of Online Screening Information:

1. Your responses to the Online Screening will be collected by REDCap and then stored on the secure server housed at the Saskatchewan Health Authority. This server is located in Canada and information on the server is covered by the Canadian *Privacy Act*.
2. In the event that you take part in a treatment study, your responses from the Online Screening will be retrieved from REDCap by Online Therapy Unit clinical staff and stored on the Online Therapy Unit secure server at the University of Regina with your course data as your clinical file. This clinical file is similar to the file your doctor would keep for you. This file

will be kept for 10 years consistent with clinical practice standards. After this time, the clinical file will be destroyed using industry standards for the destruction of personal data.

3. The de-identified research data will be retained by the research team. You can withdraw your data from the research database up until you completed treatment. After this time, data may have been pooled and used in publication and therefore it may not be possible to withdraw your data.

Research Data Sharing and Open Science

Open Science is a movement to make scientific research accessible to all levels of society through collaborative networks. In the spirit of Open Science, de-identified data from this study may be shared with authorized researchers and the research community at large to advance science and health. If you decide to be in this study, any information that is collected that can identify you will remain confidential and any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public. Any data that is transmitted to researchers outside of Saskatchewan will be subject to the privacy legislation and ethical requirements of that researcher's jurisdiction however, every effort will be made by the principal investigator to ensure your privacy will be respected. Please note that the Open Science initiative does not charge a fee to access data from other researchers' studies, as the philosophy behind Open Science is to share data with researchers and encourage collaboration. The researchers of this study will not have any monetary benefits by sharing data with other scientists.

Study Results:

To obtain results from research on the Wellbeing for Chronic Health Conditions Course please visit www.onlinetherapyuser.ca where the results of our research will be posted once they are available. We expect results to be available by May 2025.

Questions or Concerns:

Please contact any member of our team using the information at the top of page 1.

This project has been approved on ethical grounds by the U of R Research Ethics Board. Any questions regarding your rights as a participant may be addressed to the committee at 306-585-4775 or research.ethics@uregina.ca. Out of town participants may call collect.

Continued or Ongoing Consent:

Once you complete the Online Screening and book your Telephone Screening appointment, someone from our team will contact you to discuss your results. If the Wellbeing for Chronic Health Conditions Course is recommended for you, we will provide with additional information and a consent form related to the treatment.

Consent:

- ☐ I understand that by submitting this form, **I GIVE MY FREE AND INFORMED CONSENT** and I understand the above conditions of participation in the Wellbeing for Chronic Health Conditions Course Screening.