

Online Screening Consent Form

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Online Screening Information

Please take the time to carefully read the following information. This information includes a description of the Online Therapy Unit, the associated research project, as well as the terms and conditions of participation. If any of the presented information is unclear, please e-mail the primary researcher for this project, Swati Mehta, at swati.mehta@uregina.ca.

If you understand and accept the terms and conditions of the Online Screening, you will be asked to give your informed consent by responding that you understand the questions following this page.

If you indicate that you do not understand the terms and conditions of the Online Screening, you will not be able to continue with the Online Screening and you will be prompted to contact the primary researcher before continuing.

This study is currently offering and evaluating an Internet-delivered Cognitive Behavioural Therapy (ICBT) course called Chronic Conditions Course for Spinal Cord Injury (SCI). Below is a brief description of this treatment.

Project Title: Evaluating an Internet-delivered Cognitive Behavioural Therapy Course for Persons with Spinal Cord Injury.

The Chronic Conditions Course for SCI Course is an 8-week Internet-delivered course designed to manage symptoms of anxiety, depression, and/or pain among persons with SCI. The program includes education, cognitive, behavioural and physical strategies, as well as relapse prevention. Participants will complete questionnaires prior to the start of the program, before each program lesson, once they have completed the program, one month after completing program, and three months after completing the program. The questionnaires will assess symptoms of anxiety, depression, pain, and quality of life. As part of the battery of questionnaires administered after the completion of the program, clients will be asked to rate their satisfaction with the program content, amount of support they received, and the overall service.

In this study, the Online Therapy Unit will be examining the overall effectiveness of the Chronic Conditions Course for SCI. Participants in the trial will receive the course with coach guidance.

The participant will review educational materials presented online which take approximately one to two hours per week, along with weekly questionnaires that take about 5 minutes. In addition, the participant will be encouraged to complete brief, weekly assignments to facilitate learning new skills. The participant will receive automated emails with reminders about working on the Course. The project coordinator will monitor weekly questionnaires and contact the participant if there is a sudden increase in symptoms of anxiety, depression, or thoughts of death. Participants will also receive a weekly check in by a program coach, either by email or by phone. The program coach will answer questions, provide encouragement, and forecast upcoming material. This contact will be approximately 10 minutes per week.

Purpose and Benefit of the Screening:

The goal of the screening is to assess your present concerns, and determine whether the Chronic Conditions Course for SCI would be best suited to your current concerns and circumstances.

- The potential benefit of participating in the Online Screening is that by answering the questions and discussing the results with a research staff member you may obtain a better understanding of your problems or concerns.
- If your screening indicates that your current concerns and circumstances are well addressed by the Chronic Conditions Course for SCI, you will be eligible to participate in the program.
- If your screening indicates that the Chronic Conditions Course for SCI is not a good fit for your concerns and circumstances, the unit staff will do their best to suggest alternative services to you.

Format of the Screening:

Pre Online Screening:

- Once you consent to the screening, you will be asked some basic eligibility questions. Your responses to these questions will trigger instant responses concerning your eligibility. If you are not eligible for the Chronic Conditions Course for SCI, the Online Screening will terminate and you will be given information about why you are not eligible. You can contact the primary researcher to discuss your eligibility further if you wish.
- We anticipate that this first part of the Online Screening will likely take 5 minutes to complete, depending on the responses you provide.

Full Online Screening:

- If you meet basic eligibility for the Chronic Conditions Course for SCI you will be asked to provide basic personal information such as name, address, telephone number, and

email address before continuing. This information is necessary for a researcher staff member to contact you to discuss the results of the Online Screening.

- You will also be presented with questions asking about your background, injury characteristics, symptoms of anxiety and depression, other mental health concerns, physical health, relationships, occupation, and treatment history.
- Questioning is dynamic in nature and your response to a question will determine if you are asked additional questions in that area.
- We anticipate that this Online Screening will likely take 15-35 minutes to complete, depending on the responses you provide.

Telephone Screening:

- Following the completion of the Online Screening, a research staff member will contact you by phone to discuss the results of the Online Screening with you and let you know if you are eligible for the Chronic Conditions Course for SCI.
- We anticipate that this Telephone Screening will likely take 20 minutes to complete, depending on the responses you provide.
- A research staff member 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 and provide additional details that were not provided online.
- If you are eligible for the Chronic Conditions Course for SCI you can decide at that time if you would like to participate in the Course.

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

Voluntary Participation & Ability to Withdraw:

- Participation in the screening is entirely voluntary. Should you choose to not participate, or if you wish to stop the screening at any time after starting, you may do so without any consequences to your present or future health care. However, once the data has been pooled for analysis after the 8-week course has been completed, withdrawal from the study will no longer be possible.

Limits of Confidentiality:

Although these circumstances are rare, there are certain limits to confidentiality that every participant must be aware of:

- If you pose an immediate threat to your life, or another individual's life, confidentiality may be broken in order to prevent harm.
- If you disclose information suggesting that any child is at risk of abuse, the Ministry of Social Services will have to be notified.
- If you become involved in a legal case, a judge has the right to subpoena any information relevant to the legal problem.

Risks:

- There are no anticipated risks associated with the screening with the exception that under the circumstances listed above it may be necessary to break confidentiality.

Use of Information Collected through the Screening:

Information gathered through the screening will be used for two purposes.

1. To determine eligibility for participation in the Chronic Conditions Course for SCI.
 - If in the process of the follow-up telephone discussion of your online screening with a research staff member it is determined that participation in the Chronic Conditions Course for SCI would effectively meet your current needs, your screening will become part of your file. This file will be provided to the staff member assigned to monitor your progress if you are participating in the Chronic Conditions Course for SCI.
 - If in the process of the follow up telephone discussion of your online screening with a research staff member it is determined that the Chronic Conditions Course for SCI is not a good fit for your concerns, research staff will attempt to provide you with options available to you in your community.
2. Information gathered through the screening will also be used in de-identified form (identifying information removed) by the primary researcher to evaluate the Chronic Conditions Course for SCI and method of delivery. 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 their secure server housed at the Regina Qu'appelle Health Region until we retrieve this information. This server is located in Canada and information on that server is covered by the Canadian Privacy Act. Only the primary investigators (Drs. Heather Hadjistavropoulos and Swati Mehta) and the project coordinator (Marcie Nugent) will have access to the data through REDcap.
2. Information will be stored in REDCAP until the final follow up data for the study has been collected. Once that has happened a copy of the project will be exported and stored on a password protected removable hard drive that is kept in a locked filing cabinet in the Research offices at the Online Therapy Unit for 7 years. A second copy of the data will be de-identified and used for data analysis. All information (whether paper or online) is kept securely at the University of Regina for a period of seven years, which is consistent with standards of professional practice for psychologists in the province of Saskatchewan.

Possible Risks for Breaches of Confidentiality:

As Internet-based studies, there are unique risks that may compromise your privacy that exist with any Internet-based service. A description of these risks follows:

1. Any computer connected to the Internet will store information about visited websites on the Internet in the browser's history list and the browser's cache. The responses to the questionnaires are only temporarily stored on your computer until you close down your browser window. In other words, after you complete and submit your responses, your computer will discard this information, although some of this information may remain in your browser's cache. You may delete this information by clearing your history list and browser's cache.
2. After you complete the Online Screening, the information you provide will be sent directly to the survey software website over a secure connection. The information will then be encrypted and securely stored in the database at which point it is only accessible by the primary researcher and research staff.

Methods Used to Protect Your Information:

The primary researcher 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).

In addition to these security precautions, 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 their information.

There are various things that you can do to protect 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 after you use the computer. 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. Enable either the firewall software that came with your operating system (e.g. Windows firewall), or install a reputable 3rd party software, such as ZoneAlarm. Firewalls protect your computer and information from network attacks and threats.

5. 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.

6. 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 3rd parties.

Ethics Approval: The Chronic Conditions Course for SCI research project has been approved on ethical grounds by the Research Ethics Board (REB) of the University of Regina and Regina Qu'Appelle Health Region Research Ethics Board. Any questions regarding your rights as a participant may be addressed to that committee through the University of Regina REB at 306-585-4775 or email: research.ethics@uregina.ca. Out of town participants may call collect. Additionally, the primary researcher can be contacted with questions or concerns and details are provided below:

Swati Mehta
swati.mehta@uregina.ca
Department of Psychology
University of Regina
Regina, SK S4S 0A2

Technical Questions: If you have any technical difficulty with the screening, contact the primary researcher, Swati Mehta, at swati.mehta@uregina.ca

Implied Consent: By completing and submitting the questionnaire, YOUR FREE AND INFORMED CONSENT IS IMPLIED and indicates that you understand the above conditions of participation in this study.

We recommend that you download a copy of this consent form for your records by pressing the button below. Once you have downloaded your copy please press NEXT to continue.

DOWNLOAD

Consent Form

Project Title: Evaluating an Online Cognitive Behaviour Therapy Program for Persons with Spinal Cord Injury.

I have read the Information Page and have had any questions answered to my satisfaction.

Yes No

I am aware that I can contact the primary researcher, Swati Mehta, at swati.mehta@uregina.ca or call her office at 306-585-4203.

Yes No

I am aware that any questions regarding my rights as a participant may be addressed to the committee through the University of Regina Ethics Board at 306-585-4775 or email: research.ethics@uregina.ca. Out of town participants may call collect.

The Chronic Conditions Course for SCI has been approved on ethical grounds by the Research Ethics Board at the University of Regina.

I understand that the information I give through the online screening will only be shared with appropriate research staff and will be kept confidential unless I pose an immediate threat to my life, or another individual's life, or if I disclose information suggesting that any child is at risk of abuse.

Yes No

I understand that my participation is voluntary and that I am free to withdraw at any time.

Yes No

I understand that when the results of the study are published, I will not be personally identifiable.

Yes No

I understand that Online Therapy Unit courses are not right for everyone. After I complete the online screening, I will be contacted at the phone number I provide by the primary researcher or one of the research staff to discuss the results.

Yes No

If participant answers no to any of the above questions then the following message will be displayed:

The screening can only be completed by individuals who consent to the conditions in the screening. At this time, we suggest you contact the primary researcher, Swati Mehta, at 306-585-4203, to ask any questions that you may have regarding online screening for this study.