Informed Consent

Official title: My Choices: Efficacy and Implementation study

NCT number: Not yet assigned

Document date: 2022-04-08

Principal Investigator: Joël Tremblay (418) 659-2170, #2820

This project has been approved by the UQTR's research ethics committee (CER-18-251-10.02) and the research ethics committee of the Centre Intégré Santé Services Sociaux Chaudière-Appalaches (MP-23-2019-550).

INFORMATION AND CONSENT FORM

Les programmes d'intervention précoce concernant l'usage à risque des substances psychoactives / des jeux de hasard et d'argent : la famille « Mes Choix »

- Efficacy and implementation assessment -

Investigators' name and role

Joël Tremblay, Ph. D.	Principal investigator	Université du Québec à Trois-Rivières (UQTR), Équipe de « Recherche et intervention sur les substances psychoactives – Québec » (RISQ)
Hélène Simoneau, Ph. D.	Co-investigator	Institut universitaire sur les dépendances
Serge Brochu, Ph. D.	Co-investigator	Université de Montréal, Équipe de RISQ
Isabelle Giroux, Ph. D.	Co-investigator	Université Laval, Centre québécois d'excellence pour la prévention et le traitement du jeu
Jean-Sébastien Fallu, Ph. D.	Co-investigator	Université de Montréal, Équipe de RISQ
Nadine Blanchette-Martin, M. Serv. Soc.	Co-investigator	Service de recherche du Centre de réadaptation en dépendance de Québec et du Centre de réadaptation en dépendance de Chaudière-Appalaches, Équipe de RISQ
Francine Ferland, Ph. D.	Co-investigator	Service de recherche du Centre de réadaptation en dépendance de Québec et du Centre de réadaptation en dépendance de Chaudière-Appalaches, Équipe de RISQ
Chantal Plourde, Ph. D.	Co-investigator	Université du Québec à Trois-Rivières, Équipe de RISQ
Myriam Laventure, Ph. D.	Co-investigator	Université de Sherbrooke, Équipe de RISQ
Thierry Favrod-Coune, M. D. Addictologue	Co-investigator	Hôpitaux universitaires de Genève, Suisse
Pascal Gache, M. D., Addictologue	Co-investigator	Genève, Suisse
Jacques Yguel, M. D., Addictologue	Co-investigator	Avesnes sur Helpe, France
Marie-Christine Fortin, M. Serv. soc.	Co-investigator	Université du Québec à Trois-Rivières

Research Project Granting Agency: Project funded through the Substance Use and Addictions Program (SUAP), a federal contribution program under the responsibility of Health Canada. Note that it is the Quebec Ministère de la santé et des services sociaux that manages the PUDS funds for Quebec institutions.

Please take the time to read and understand the following information. We invite you to ask any questions that you deem useful to the responsible investigators and the research team.

Introduction and study goals

This project aims to develop the My Choices program, which is for adults wanting to reduce their alcohol use.

Specific objectives of the research projet are :

1) Update the My Choices Alcohol program and develop the My Choices program for other substances' use;
2) Try out the My Choices program.

Participation

Your participation in the study consists of taking part to three interviews with a research assistant. The first interview is the admission interview, the other two are respectively 3 and 6

months after the admission interview. Each interview should take about 2 hours and a half and will be recorded (audio only). You will be asked to answer some questions about your alcohol use habits, as well as about your psychological well-being and your therapeutical relationship with your intervener. You will also be questioned about your expectations and your appreciation of the program. The interviews with the research assistant will take place in a local in the clinic you are receiving services or by videoconference (Zoom or Teams).

Advantages and benefits

Your participation in the research project would allow the amelioration of the services offered to the adult population wanting to reduce their alcohol use habits. Specifically, it could allow to develop a more structured intervention program that would be better suited for their needs.

Disadvantages

Answering the questionnaires may remind you of some difficult experiences (e.g. alcohol, drug, gambling, or Internet use difficulties) or it may generate cravings to use or play. However, if this is the case, we encourage you to share it with the research officer, or your counselor if applicable, and consult the list of contact information for resources that will be given to you at the end of the interview.

Another disadvantage of your participation in the research is the use of your time to participate in the interview.

Autorisation de communiquer les résultats

We ask you the right to communicate some results of your first reasearch interview to your My Choices intervener. Those results would include the types of psychoactive substances used, amount, frequency as well as the consequences and habits associated with the substances use.

Informations fournies par l'intervenant

We ask you to have access to some informations from your intervener about your My Choices follow-up. Those informations would be about your participation in the program (dates of the meetings, reference method, meeting modality, goals and number of meetings) as well as about your progression in the program (e.g. motivation, involvement, meeting goals or not, etc.). You will be able to accept or reject this item regarding the secondary analyzes, separately from the rest of the project (see at the end of this consent form).

Confidentiality

The data collected during the interview will not be accessible to anyone other than the research team members.

All information collected will be denominated (i.e. without your names and any information that could be used to identify you, only a study number will identify you) and it will be impossible to identify the answers of a specific participant.

The various data will be saved in computer files. These will be kept in secure computers and on a hard disk kept in a locked file, in a research room of the principal investigator working at UQTR or in a research room of a co-investigator working at the Service de recherche en dépendance, CIUSSS de la Capitale Nationale and at CISSS de Chaudière-Appalaches. In addition, the paper

documents will also be kept in a locked file of a research room of the UQTR or in a research room at the Service de recherche en dépendance, CIUSSS de la Capitale Nationale and at CISSS de Chaudière-Appalaches. Both computer and paper data will be accessible only by team investigators and their research officers.

We may need to allow access to research data to the appropriate authorities (government agencies, research ethics committee who evaluated the project, funding agency) for auditing and internal management purposes. These organizations adhere to a strict confidentiality policy.

You can always ask the investigator to consult your research file to verify the information collected and have it corrected as needed, as long as the investigator in charge of the project holds this information. However, in order to preserve the scientific integrity of the project, you may only have access to some of this information after your research participation is complete.

When writing the research report, investigators will avoid presenting results in a way that indirectly identifies participants. Thus, the data will be presented in a consolidated manner (i.e., with information from other participants) to preserve the most complete anonymity.

Paper documents and computer files will be kept for a period of seven years from the end of the research project. After seven years, all data will be destroyed, which means erasing all computer files and their security copies, as well as shredding all paper documents, and the destruction of all digitalized copies of the recordings.

Secondary analyzes

We ask you to carry out secondary analyzes on the research data collected. This means that we are interested, in the seven years of data retention following the end of the current project, to analyze the data in more depth, or sometimes from a different angle. These secondary analyzes will be done only under the direction of the researchers of the current team, often with their students. A limited number of projects will be conducted (for example, less than ten) and each will need to be approved by the relevant research ethics boards. You will be able to accept or reject this item regarding the secondary analyzes, separately from the rest of the project (see at the end of this consent form).

Responsibility

By agreeing to participate in this project, you do not waive any of your rights or release the researchers, the granting agency and the institution from their civil and professional liability.

Dissemination of results

The results of this study will be presented in the form of a research report, lectures and scientific articles, always preserving the confidentiality of the data, which implies that your name will not be mentioned and that the necessary measures will be taken so that you can not be identified. You may receive an email summary of the results of the research project or information related to the publications related to the research project. You may accept or reject this item separately from the rest of the project (see at the end of this consent form).

Participation volontaire et droit de retrait

Participation in this study is entirely voluntary on your part. You are therefore quite free to accept or refuse to participate. In the event of your participation, you are also free, at any time, to

terminate your participation in this study. Your departure will not involve any kind of pressure from the researchers, nor any prejudice or loss of benefits to which you are normally entitled. Financial compensation will only be given if you complete the interview.

To terminate your participation in the research, simply report it verbally to the research coordinator or to the principal investigator you can reach according to the coordinates mentioned under the heading "resource persons". Your data will then be removed from the research project.

If you choose not to participate to the research project, this will not have an impact on the services you receive or might receive in your clinic. The service you will receive is the service that will be better suited for your needs among the services available in your clinic. For example, if the My Choices program is available in your clinic, you can have that program without doing the research interviews, which are only for the persons that agreed to participate in the research project.

Compensation

For your participation, you will receive financial compensation in the form of a voucher at a shopping center in your area. There will be a 50$ voucher given for each of the first two interviews, and a 75$ voucher given for the third interview. The financial compensation will be given immediately at the end of the interview or will immediately be sent by post for videoconference interviews.

For more information

For any other information, you can contact the principal investigator Mr. Joël Tremblay or the coordinator of the research project by calling (418) 663-5008 ext. 4067 or the following e-mail address: meschoix@uqtr.ca.

Ethics monitoring

The CISSS Chaudière-Appalaches Research Ethics Board (REB) has approved the project and will be monitoring the project for participating institutions in Quebec's health and social services network. If you have any questions regarding your rights as a participant, you can contact the CISSS Chaudière-Appalaches REB at the following telephone number: 418-835-7121, ext. 101360.

Complaints or questions about your rights

For any problem concerning the conditions under which your participation in this research project takes place, you may, after having discussed it with the person in charge of the project, explain your concerns to the Service Complaints and Quality Services Commissioner of your institution:

- CISSS de Chaudière-Appalaches at 1-877-986-3587.
- CIUSSS Capitale-Nationale, at 418 691-0762.
- Université du Québec à Trois-Rivières by phone at 1-800-365-0922, ext 2129 or by email CEREH@uqtr.ca.

Consent

Participant

I have read and understood the contents of this form. I know that I am free to participate in the project and that I remain free to withdraw at any time, by verbal notice, without prejudice. I certify that the project has been presented to me and that I am free to agree to participate without constraint or pressure from anyone. I agree to participate in this project.

I agree that secondary analysis be conducted on the collected data and only under the direction of the team researchers.	☐YES ☐NO _____ Initials
I agree that my My Choices intervener gives some informations to the reasearch team about my participation in the program (e.g. number of meetings, type of meeting, etc.) as well as about my goals and modifications made during my program.	☐YES ☐NO _____ Initials
I agree that the research team gives information to my My Choces intervener (type and amount of substance use, consequences and habits related to substance use as well as my motivation to start the program).	☐YES ☐NO _____ Initials
I agree to be contacted again in three months to schedule my second research interview. Phone number to join me : _____ Second phone number to join me : _____ People you can reach to join me : • Person #1 : name : _____ • Phone number : _____ • Link with this person (ex. : significant other, son, etc.) : _____ • Person #2 : name : _____ • Phone number : _____ • Link with this person (ex. : significant other, son, etc.) : _____	☐YES ☐NO _____ Initials
I am interested in receiving a summary of the results of the research project (in about two years). Here is my personal email address Or here is my complete postal address	☐YES ☐NO _____ Initials

Participant's name _____ Participant's signature _____ Date _____

Investigator's or person obtaining consent's signature

I certify that I have explained to the participant the research project and this information and consent form, and that I have answered all of the questions asked.

Name of the person obtaining consent _____ Signature of the person obtaining consent _____ Date _____

Documentation of consent obtained verbally (if applicable)

☐ VERBAL CONSENT

Means used to obtain consent

☐ BY PHONE ☐ BY VIDEOCONFERENCE

_____
Date