

INFORMATION AND CONSENT FORM

“Effectiveness study of two types of interventions for couples experiencing difficulties related to gambling and drug and alcohol use”

Version for the person with a substance use or gambling problem

Names and functions of the researchers:

Joël Tremblay, Ph.D.	Principal investigator	Université du Québec à Trois-Rivières (UQTR), <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) team</i>
Magali Dufour, Ph.D.	Co-investigator	Université du Québec à Montréal, RISQ team
Karine Bertrand, Ph.D.	Co-investigator	Université de Sherbrooke, RISQ team
Marianne St-Jacques, Ph.D.	Co-investigator	Université de Sherbrooke, RISQ team
Nadine Blanchette-Martin, M. Serv. Soc.	Co-investigator	CIUSSS de la Capitale-Nationale/CISSS de Chaudière-Appalaches Addiction Research Service, CISSS-CA Research Center, RISQ team
Francine Ferland, Ph.D.	Co-investigator	CIUSSS de la Capitale-Nationale/CISSS de Chaudière-Appalaches Addiction Research Service, CISSS-CA Research Center, RISQ team
Catherine Arseneault, Ph.D.	Co-investigator	Université de Montréal, RISQ team
Chantal Plourde, Ph.D.	Co-investigator	UQTR, RISQ team
Mélissa, Côté, Ph.D.	Co-investigator	Université Laval, RISQ team
Paul Greenman, PhD	Co-investigator	Université du Québec en Outaouais

You are invited to participate in a research project. Please take the time to read and understand the following information.

This information and consent form describes the research project goal, procedures, harms and benefits, as well as your right to end your participation in the project at any time. Finally, it provides contact information of people with whom you may communicate if needed.

Introduction and research goals

The goal of this study is to compare two intervention modalities for people living as a couple who have difficulty controlling their gambling and drug and alcohol use habits. One of the two modalities is the center’s regular treatment modality, i.e., individual, and sometimes group modality for the person with a substance use or gambling problem along with an offer of individual or group sessions for their partner. The second modality is a couples treatment developed for couples where a member has problematic gambling and drug and alcohol use habits. This study aims to determine whether one of the two modalities is more effective than the other or if they are equivalent. Depending on the results of this study, specialized addiction treatment centers may be able to tailor their services to the needs of couples where there is a member who gambles or uses substances.

Nature and duration of participation in the research project

By agreeing to participate in the project, you agree to be randomly assigned to one of the two treatment modalities.

Principal investigator: Joël Tremblay (418) 659-2170, ext. 2820

Version 08-04-2024 Approved by the Research Ethics Committee of the CISSS-CA 7-02-2023

Local adaptations for the CISSS-MO 9-02-2023

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Participant initials:



Treatment sessions

a) Individual or group modality

In this modality, as a person with a substance use or gambling problem, you will receive a regular form of treatment that consists of individual and sometimes group sessions. Your treatment will be provided at the service center where you sought help. If needed and exceptionally, in accordance with public health rules, videoconference sessions that respect the safety rules of the CISSS/CIUSSS where you will receive treatment may be conducted. During these sessions, your counsellor will help you identify triggers and risk situations related to your gambling and substance use habits. You will address your gambling-related beliefs and work on alternative ways to fulfil the needs you used to meet through gambling or using substances. If you are assigned to this modality, you agree to not participate in any couples therapy sessions for the duration of the research project. A total of 12 to 16 one-hour sessions will be offered.

b) Couples modality

In this modality, you will participate with your partner in 12 to 16 couples sessions of 1 hour and 15 minutes each. The sessions will take place once a week. You will receive this treatment at the service center where you sought help. During these sessions, both your gambling and substance use difficulties will be addressed. In addition, your communication and problem-solving skills as a couple, the moments of pleasure that you share, and the possibilities of mutual support regarding your gambling and substance use difficulties will be discussed. The aim is to optimise your chances of success in changing your gambling and substance use habits, but also to improve the quality of your relationship with your partner. After the couples sessions conducted for this study have ended, treatment may continue according to your respective needs, individually or as a couple (or both), upon agreement with your counsellor. In addition, you will be given a support and reflection guide containing information on the experience of partners, known strategies to help restore communication skills, and strategies for better taking care of yourself.

Research meetings

In addition to the treatment sessions, you will participate in four evaluation meetings with a research officer. These meetings will each last about 2 hours and 30 minutes. The first meeting could take place now, if you agree to it, after signing this consent form. This first meeting aims to evaluate your eligibility for the research project. In fact, to obtain a certain homogeneity of the couples recruited and to ensure that you receive treatment that is suited to your condition, inclusion and exclusion criteria have been elaborated. After your first meeting with the research officer, they will contact you within 24 to 48 hours to confirm whether you are eligible for the study and inform you of the treatment modality to which you will be assigned. Then, treatment may begin after making an appointment with your counsellor who will work with you (either alone or with you and your partner, depending on the assigned treatment modality). If you are

Participant initials: _____



assigned to the couples modality, the research officer will provide your counsellor with a summary of your evaluation results to help them better understand your situation and avoid asking you for the same information a second time. Also, at the beginning of each treatment session, you will be asked to complete a few brief questionnaires on your gambling and substance use habits, as well as on certain aspects of your personal life and your life as a couple (15 minutes each time). If you are not eligible for our research project, the services usually offered by the treatment center where you sought help will still be offered to you and your partner. If you are not selected for the research project, we do ask for your permission to keep the data collected during the admission meeting for our analyses.

The other research meetings will take place 6, 12, and 18 months after the admission meeting (today). During these meetings, you will answer various questionnaires on your gambling and substance use habits, your general personal state, and your life as a couple. We will also ask you open-ended questions that will allow you to tell us about your overall experience throughout the process. Your answers to these questions will be recorded and transcribed to facilitate our data analysis.

The couples sessions will be filmed by your counsellor for supervisory meetings with the researchers responsible for the study in order to help your counsellor intervene in the most helpful way possible. The sessions may also be recorded in audio format only. The video and audio recordings will also be analysed by the researchers to better understand the needs of couples where one of the members has difficulties with gambling or substance use.

Finally, we ask you to accept the possibility of being asked again to participate in a follow-up study of the intervention you will have received. This does not involve any commitment on your part other than agreeing to be contacted again by the research team.

Financial compensation

As compensation for the costs incurred by your participation in this research project, you will receive the following amounts in the form of vouchers for local department stores at the end of each meeting with the research officer:

- Admission meeting (today)	\$50 each
- Follow-up meeting, 6 months after the admission meeting	\$75 each
- Follow-up meeting, 12 months after the admission meeting	\$75 each
- Follow-up meeting, 18 months after the admission meeting	\$75 each

In total, each member of the couple will receive a financial compensation of 275\$ in the form of vouchers if you accept to take part in the three follow-up meetings. Even if you decide not to complete the couples sessions with your counsellor, we would still be interested in meeting with you so that we can get to understand your journey. If you attend the meetings with the research officer, you will receive the financial compensation as planned. If you withdraw from the project (or if your participation is terminated) before it is completed, the financial compensation will be proportional to the length of your participation. There will be no compensation for meetings that you do not attend.

Participant initials: _____



Advantages and benefits

Your participation in this project could help you overcome your difficulties with substance use and gambling, in addition to helping your partner via the couples or individual sessions that will be offered to them. Also, your participation in the study will contribute to the advancement of knowledge in the field of intervention with people living as a couple who experience difficulties related to gambling or substance use habits, because this will help us identify the most effective treatment modalities for these people.

Inconveniences and risks

The treatment provided may not allow you to achieve the desired success. However, the treatment center where you will receive services assures you that beyond the research meetings, you will be able to continue to receive services, whether individual or for couples, for as long as necessary. If, during the meetings (and even beyond), a major crisis was to arise (suicidal emergency, relationship breakdown, etc.), the counsellors will use all the necessary resources as they do in such clinical situations. If necessary, participation in the meetings will simply be stopped.

Confidentiality

During your participation in this project, the responsible researcher and their personnel will collect and record your data in a research file. Only the information necessary to meet the scientific goals of this project will be collected. All information collected during the course of this project will be denominated (your name and all identifying information will be removed and only a research number will identify you) and it will be impossible to identify the responses of any specific participant. The various data will be transcribed into computer files. These data will then be stored in a directory accessible only by the team researchers and their research officers. Only the information necessary to meet the scientific goals of this project will be collected.

The paper copies of the questionnaires and the video and audio recordings will be kept in a locked filing cabinet in the principal investigator’s research facility at the Université du Québec à Trois-Rivières, Quebec campus, or at the research facilities of the addiction research services of the CIUSSS de la Capitale-Nationale and the CISSS de Chaudière-Appalaches. The paper copies of the questionnaires, the audio and video recordings, and the denominated computer files will be kept for a period of 7 years after the end of this project, then destroyed. During this period, we may use the data to redo various analyses based on these interviews. Since the field of research with couples where one member gambles or uses substances is not very well developed, we are interested in reanalysing the interviews based on new knowledge that we may acquire later. Only research directed or co-directed by the principal investigator will be authorized to run secondary analyses with the data. After 7 years, the paper questionnaires will be disposed of in a specific area designed for the destruction of confidential documents (shredding) in the offices of the Université du Québec à Trois-Rivières. Video and audio recordings will also be physically destroyed.

Participant initials:



This research project is part of a larger research program that focuses on the role that family and friends play in the treatment of gamblers. With your permission, the data collected in this research project may be used for secondary analyses in a limited number of research projects conducted by the team of researchers responsible for this project (including the students they supervise). By secondary analyses, we mean, for example, further validation of questionnaires used in the project, the pooling of data from two similar studies in order to increase the number of participants, the analysis of specific subgroups (male versus female gamblers), and so on. All information collected is obviously denominated, which means that there will be no way to identify you (names are removed and only a number will identify each participant). The secondary analyses will be carried out within the data conservation period (7 years). Each secondary analysis will require the approval of an ethics committee. All research reports will be presented in such a way that no participant can be identified in any way.

If, during an evaluation or an intervention, the research officers or counsellors become aware of a situation of child abuse or serious child neglect, the researchers, the research officers, and the counsellors will be required to denounce the situation in accordance with the *Youth Protection Act*. This measure also applies to treatment outside of any research project. Also, if during an evaluation or an intervention, the research officers or counsellors are informed of a situation of domestic violence that endangers the safety of one of the members of the couple, the research officers and the counsellors will be required to denounce the situation to the responsible authorities.

For monitoring and control purposes, your research file may be consulted by a person mandated by the CISSS de Chaudière-Appalaches Research Ethics Committee or by the institution, or by a person appointed by an authorized organisation. All these people and organisations adhere to a confidentiality policy.

You have the right to consult your research file to verify the information collected and have it corrected, if needed, for as long as the researcher responsible for the project or the institution possess this information. However, to preserve the scientific integrity of the research project, you may not have access to some of this information until after your participation has ended.

Access to clinical records

We ask that you grant us access to the data in your clinical records from the center where you are being treated. More specifically, we would like to know what services you will have received throughout the follow-up of the research project, i.e., until the date of the last research meeting scheduled for approximately 18 months after the beginning of treatment. Also, when necessary, we ask to have access to relevant information to contact you as part of the research follow-up. In addition, we want to photocopy the questionnaires and assessments that you completed with the staff during the admission meeting and throughout the process.

Dissemination of results

The results of this study will be presented in the form of a research report, conferences, and scientific papers, all while protecting data confidentiality, which means that your name will not be mentioned, and the necessary measures will be taken so that you cannot be identified.

Participant initials: _____



Voluntary participation and right to withdraw

Your participation in this study is entirely voluntary. Therefore, you are completely free to accept or to refuse to participate. You may also withdraw from this research project at any time and without giving any reason for doing so by informing your counsellor, the research officer, or the principal investigator whom you may reach at the number on the bottom of this page.

Your withdrawal from the study will not result in any form of pressure from the researchers or the participating counsellors, nor to any prejudice or loss of benefits to which you are normally entitled, such as treatment for your gambling and substance use habits offered as standard at the center where you are in treatment.

In case of prejudice

If you should suffer any harm whatsoever as a result of your participation in the research project, you are protected by the laws in force in Quebec. By agreeing to participate in this study, you are not waiving any of your rights nor are you releasing the researchers or the institution where this research project is being conducted from their civil and professional responsibilities.

Resource persons

For any additional information, you may contact the principal investigator, Dr. Joël Tremblay Joel.Tremblay@uqtr.ca or the research project coordinator, Ms. Myriam Beaulieu Myriam.Beaulieu@uqtr.ca.

For any questions regarding your rights as a participant in this research project or if you have any complaints or comments, you may contact the institutions’s Service Quality and Complaints commissioner:

For the Virage service point of the CISSS de la Montérégie Ouest, Centre de réadaptation en dépendance, Mr. Jean Pinsonneault, the local Service Quality and Complaints commissioner can be reached at 1-800-694-9920, extension 2280 or insatisfactions-plaintes.ciessmo16@ssss.gouv.qc.ca

Ethics monitoring of the research project

The CISSS de Chaudière-Appalaches Research Ethics Committee approved this research project and will monitor it in participating public health and social services institutions. For any information, you may contact the Research Ethics Committee coordinator or their representative at 418 835-7121, extension 11256.

Declaration of the researcher or of the person obtaining the participant’s consent

I explained the research project and this information and consent form to the participant, and I answered their questions.

Participant initials: _____



Research officer name

Research officer signature

Date

Participant initials:

Appendix: Participation summary table

	Treatment sessions			
	Individual modality		Couples modality	
	<i>Person with a gambling or substance use problem</i>	<i>Partner</i>	<i>Person with a gambling or substance use problem</i>	<i>Partner</i>
Research meetings				
First evaluation/research meeting (between 2 and 2.5 hours)	x	x	x	x
Beginning of treatment	12 to 16 individual sessions with a counsellor	Services usually offered to loved ones, if desired	12 to 16 couples sessions with the same counsellor for both members of the couple	
6 months after the research evaluation (2.5 hours)		x		x
12 months after the research evaluation (2.5 hours)		x		x
18 months after the research evaluation (2.5 hours)		x		x

INFORMATION AND CONSENT FORM

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Partner version

Names and functions of the researchers:

Joël Tremblay, Ph.D.	Principal investigator	Université du Québec à Trois-Rivières (UQTR), <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) team</i>
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Nature and duration of participation in the research project

By agreeing to participate in the project, you agree to be randomly assigned to one of the two treatment modalities.



Treatment sessions

c) Individual or group modality

In this modality, as a partner, you will have access to services that are regularly offered to the people in the life of a person with a substance use or gambling problem. Depending on your needs, you may participate in individual or group sessions that aim to help you improve your personal well-being and better understand how your partner’s gambling and substance use habits develop. If you are assigned to this modality, you agree to not participate in any couples therapy sessions for the duration of the research project.

d) Couples modality

In this modality, you will participate with your partner in 12 to 16 couples sessions of 1 hour and 15 minutes each. The sessions will take place once a week. You will receive this treatment at the service center where you sought help. If needed and exceptionally, in accordance with public health rules, videoconference sessions that respect the safety rules of the CISSS/CIUSSS where you will receive treatment may be conducted. During these sessions, we will discuss both the difficulties related to your partner's gambling and drug use, and ways to improve communication and problem-solving skills in your relationship, increase shared pleasure and mutual support regarding gambling and substance use difficulties and their impact on your life as a couple. The aim is to optimise your chances of success in helping your partner as they work on changing their gambling and substance use habits, but also to improve the quality of your relationship with your partner. After the couples sessions conducted for this study have ended, treatment may continue according to your respective needs, individually or as a couple (or both), upon agreement with your counsellor. In addition, you will be given a support and reflection guide containing information on the experience of partners, known strategies for helping the recovery of a partner with a gambling or substance use problem, restoring communication skills, and better taking care of yourself.

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Participant initials: _____



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Participant initials:



Advantages and benefits

Your participation in this project could help your partner overcome their difficulties with substance use and gambling, in addition to helping you personally via the couples or individual sessions that you will be offered. Also, your participation in the study will contribute to the advancement of knowledge in the field of intervention with people living as a couple who experience difficulties related to gambling or substance use habits, because this will help us identify the most effective treatment modalities for these people.

Inconveniences and risks

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Confidentiality

During your participation in this project, the responsible researcher and their personnel will collect and record your data in a research file. Only the information necessary to meet the scientific goals of this project will be collected. All information collected during the course of this project will be denominated (your name and all identifying information will be removed and only a research number will identify you) and it will be impossible to identify the responses of any specific participant. The various data will be transcribed into computer files. These data will then be stored in a directory accessible only by the team researchers and their research officers. Only the information necessary to meet the scientific goals of this project will be collected.

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Participant initials: _____



This research project is part of a larger research program that focuses on the role that family and friends play in the treatment of gamblers. With your permission, the data collected in this research project may be used for secondary analyses in a limited number of research projects conducted by the team of researchers responsible for this project (including the students they supervise). By secondary analyses, we mean, for example, further validation of questionnaires used in the project, the pooling of data from two similar studies in order to increase the number of participants, the analysis of specific subgroups (male versus female gamblers), and so on. All information collected is obviously denominated, which means that there will be no way to identify you (names are removed and only a number will identify each participant). The secondary analyses will be carried out within the data conservation period (7 years). Each secondary analysis will require the approval of an ethics committee. All research reports will be presented in such a way that no participant can be identified in any way.

If, during an evaluation or an intervention, the research officers or counsellors become aware of a situation of child abuse or serious child neglect, the researchers, the research officers, and the counsellors will be required to denounce the situation in accordance with the *Youth Protection Act*. This measure also applies to treatment outside of any research project. Also, if during an evaluation or an intervention, the research officers or counsellors are informed of a situation of domestic violence that endangers the safety of one of the members of the couple, the research officers and the counsellors will be required to denounce the situation to the responsible authorities.

For monitoring and control purposes, your research file may be consulted by a person mandated by the CISSS de Chaudière-Appalaches Research Ethics Committee or by the institution, or by a person appointed by an authorized organisation. All these people and organisations adhere to a confidentiality policy.

You have the right to consult your research file to verify the information collected and have it corrected, if needed, for as long as the researcher responsible for the project or the institution possess this information. However, to preserve the scientific integrity of the research project, you may not have access to some of this information until after your participation has ended.

Access to clinical records

We ask that you grant us access to the data in your clinical records from the center where you are being treated. More specifically, we would like to know what services you will have received throughout the follow-up of the research project, i.e., until the date of the last research meeting scheduled for approximately 18 months after the beginning of treatment. Also, when necessary, we ask to have access to relevant information to contact you as part of the research follow-up. In addition, we want to photocopy the questionnaires and assessments that you completed with the staff during the admission meeting and throughout the process.

Dissemination of results

The results of this study will be presented in the form of a research report, conferences, and scientific papers, all while protecting data confidentiality, which means that your name will not be mentioned, and the necessary measures will be taken so that you cannot be identified.



Voluntary participation and right to withdraw

Your participation in this study is entirely voluntary. Therefore, you are completely free to accept or to refuse to participate. You may also withdraw from this research project at any time and without giving any reason for doing so by informing your counsellor, the research officer, or the principal investigator whom you may reach at the number on the bottom of this page.

Your withdrawal from the study will not result in any form of pressure from the researchers or the participating counsellors, nor to any prejudice or loss of benefits to which you are normally entitled, such as treatment for your gambling and substance use habits offered as standard at the center where you are in treatment.

In case of prejudice

If you should suffer any harm whatsoever as a result of your participation in the research project, you are protected by the laws in force in Quebec. By agreeing to participate in this study, you are not waiving any of your rights nor are you releasing the researchers or the institution where this research project is being conducted from their civil and professional responsibilities.

Resource persons

For any additional information, you may contact the principal investigator, Dr. Joël Tremblay Joel.Tremblay@uqtr.ca or the research project coordinator, Ms. Myriam Beaulieu Myriam.Beaulieu@uqtr.ca.

For any questions regarding your rights as a participant in this research project or if you have any complaints or comments, you may contact the institutions’s Service Quality and Complaints commissioner:

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Ethics monitoring of the research project

The CISSS de Chaudière-Appalaches Research Ethics Committee approved this research project and will monitor it in participating public health and social services institutions. For any information, you may contact the Research Ethics Committee coordinator or their representative at 418 835-7121, extension 11256.

Participant initials: _____



Declaration of the researcher or of the person obtaining the participant's consent

I explained the research project and this information and consent form to the participant, and I answered their questions.

Research officer name

Research officer signature

Date

Participant initials: _____

Consent form

Participants

I have read the information and consent form. The research project and this information and consent form have been explained to me. My questions have been answered and I was given time to make my decision. After careful consideration, I consent to participate in this research project under the conditions specified in this form.

I agree to grant access to my clinical records from the center where I am being treated.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ Initials
I agree to the video recording of the couples sessions.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ Initials
I agree to the audio recording of the couples sessions.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ Initials
I agree to the audio recording of the research meetings.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ Initials
I agree to secondary analyses being conducted on any data collected, and only under the direction of the team researchers.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ Initials
I agree to possibly being contacted for future research projects that are directly related to this one over the next 36 months.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ Initials
<p>How can we reach you?</p> <p>Phone number: _____</p> <p>Secondary phone number: _____</p> <p>Email address: _____</p> <p>Full postal address: _____</p> <p>_____</p> <p>People we can contact to reach you:</p> <p>1. Name: _____</p> <ul style="list-style-type: none"> • Phone number: _____ • Nature of relationship (e.g., friend, brother): _____ <p>2. Name: _____</p> <ul style="list-style-type: none"> • Phone number: _____ • Nature of relationship (e.g., friend, brother): _____ 	
<p>I would like to receive a summary of the research project results.</p> <p>If so, how (email and/or postal address) would you like to receive this summary?</p>	<input type="checkbox"/> EMAIL <input type="checkbox"/> POSTAL MAIL

Participant name

Participant signature

Date

Participant initials:

Appendix: Participation summary table

	Treatment sessions			
	Individual modality		Couples modality	
	<i>Person with a gambling or substance use problem</i>	<i>Partner</i>	<i>Person with a gambling or substance use problem</i>	<i>Partner</i>
Research meetings				
First evaluation/research meeting (between 2 and 2.5 hours)	x	x	x	x
Beginning of treatment	12 to 16 individual sessions with a counsellor	Services usually offered to loved ones, if desired	12 to 16 couples sessions with the same counsellor for both members of the couple	
6 months after the research evaluation (2.5 hours)		x		x
12 months after the research evaluation (2.5 hours)		x		x
18 months after the research evaluation (2.5 hours)		x		x