

Informed Consent Gambler and Partner

Official title: Integrative Couple Treatment for Pathological Gambling or Individual Treatment: A Comparison of Efficacy

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

This project has been approved by UQTR's research ethics committee (CER-10-156-06.13), the addiction research ethics committee (CÉRT 2010-112) and the research ethics committee at the Centre hospitalier universitaire de l'Université de Sherbrooke (10-171).



CONSENT FORM
**“Efficacy Study of Two Intervention Methods
for Problem Gamblers Living in a Couple”**

Version for the person who gambles

Researchers and their functions:

Joël Tremblay, PhD	Principal Investigator	Université du Québec à Trois-Rivières, <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) research team</i>
Magali Dufour, PhD	Co-Investigator	Université de Sherbrooke, <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) research team</i>
Karine Bertrand, PhD	Co-Investigator	Université de Sherbrooke, <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) research team</i>
Marianne St-Jacques, PhD	Co-Investigator	Université de Sherbrooke, <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) research team</i>
Nadine Blanchette-Martin, MSW	Co-Investigator	Centre de réadaptation en dépendance de Québec (CRDQ), Centre de réadaptation en dépendance de Chaudière-Appalaches (CRDCA), <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) research team</i>
Francine Ferland, PhD	Co-Investigator	Centre de réadaptation en dépendance de Québec (CRDQ), Centre de réadaptation en dépendance de Chaudière-Appalaches (CRDCA), <i>Recherche et intervention sur les substances psychoactives – Québec (RISQ) research team</i>
Annie-Claude Savard, PhD	Co-Investigator	Université Laval

Introduction and research objectives

The purpose of this research is to compare two intervention methods for treating couples in which one partner has a gambling problem. The first is the standard method used by the treatment centre, that is, individual and sometimes group intervention for the gambler with the possibility of individual or group intervention for the non-gambling partner. The second method consists of couples therapy developed for the treatment of alcoholism or drug abuse that has been adapted to the needs of couples where one is a problem gambler. The goal of this study is to determine whether one of these methods is more effective or if they are equally effective. Depending on the study results, treatment centres will be able to adapt their services to people with gambling problems.



Participation

In agreeing to participate in the study, you agree to be randomly allocated to one of the two treatment groups.

Treatment sessions

a) Individual/group intervention (for the gambler)

As a gambler, you will receive one of the centre's standard treatments¹ consisting of individual and sometimes group therapy. During the sessions, the therapist will help you identify the triggers and situations that put you at risk of gambling. You will address your gambling-related beliefs and attempt to find alternative ways to meet the needs you previously met through gambling. If you are allocated to this treatment group, you commit to not participating in couples therapy sessions for the duration of the research project.

b) Couples therapy

You and your partner will participate in 8-12 weekly couples therapy sessions. Each session will last one and a half hours. During the sessions, we will address the gambler's gambling problems as well as discuss how the couple can improve their communication and problem-solving skills, share more fun times together and provide each other with greater mutual support in dealing with the gambling-related problems and their impact on the couple relationship. The ultimate goal is to maximize your chances of successfully changing your gambling habits and improve the quality of your couple relationship. Following the couples therapy sessions, you will continue receiving treatment services individually or as a couple (or both), according to your respective needs and as agreed upon with the therapist.

Research sessions

In addition to the treatment sessions, there will be four evaluation sessions with a research officer. The initial evaluation lasts around two and a half hours and the other three sessions, around one hour and 45 minutes. If you consent, the first session will take place immediately after you have signed the consent form. The others will be in 3, 9 and 18 months after today's admission meeting. During the evaluation sessions, you will be asked to answer a number of questionnaires on your gambling habits, your personal state

¹ Note à l'agente de recherche : ici décrire le traitement habituel du centre



and your couple relationship. The follow-up sessions (9 and 18 months) will consist of an interview roughly 15 minutes long, which will be audio-recorded to gain a better understanding of your treatment pathway and get your feedback on the treatment received. Following your first session with the research officer, he/she will contact you within 24 to 48 hours to let you know whether or not you will be participating in the research study and, if so, tell you to which treatment group you have been allocated. A meeting will be scheduled with your assigned clinician, after which treatment will begin (individually or as a couple, depending on the method). If you are allocated to the couples therapy group, the research officer will send the clinician a summary of your evaluation results to help him/her understand your situation more clearly and avoid asking you the same information twice. In addition, at the start of each therapy session, you will be asked to answer a few short questionnaires (15 minutes each time) on your gambling habits and certain aspects of your couple relationship.

The clinician will video-record the couples therapy sessions for the purposes of supervisory meetings with the investigators to help the therapist adopt the intervention strategy that best suits your needs. Sessions may be audio-recorded only. The investigators will analyze the videotapes and audiotapes to gain a better understanding of the needs of couples where one partner has a gambling problem.

Each person will receive financial compensation for each session with the research officer. The compensation will take the form of coupons worth the following amounts, redeemable at a shopping centre in your region:

- Admission meeting (today).....	\$50 each
- Follow-up session, 3 months after the admission meeting	\$50 each
- Follow-up session, 9 months after the admission meeting	\$75 each
- Follow-up session , 18 months after the admission meeting	\$75 each

If you agree to take part in all three follow-up sessions, each person in the couple will receive a total of \$250 in coupons. Even if you drop out of the couples therapy sessions, we would still like to meet with you to understand your pathway. If you attend the sessions with the research officer, you will receive the financial compensation provided for. If you choose to withdraw from the research project at any point in time, you will already have received the financial compensation for each session with the research officer you attended. You will not receive financial compensation for sessions you did not attend.

Advantages and benefits

The goal of intervention is first and foremost to help the gambler overcome his/her gambling problem as well as help his/her partner through the couples or individual



therapy sessions. Participating in this research project will thus help improve your personal well-being or your couple relationship and help you get to know yourself better. In addition, your participation will contribute to advancing knowledge about interventions for problem gamblers who are part of a couple by helping us identify the most effective treatment methods.

Inconveniences and risks

Remember that the primary goal of intervention is to help the gambler overcome his/her gambling problem as well as help his/her partner through the couples or individual therapy sessions. As with any treatment, though, the intervention may not have the desired outcome. However, the treatment centre where you are receiving services promises that you can continue receiving individual or couples therapy for as long as necessary beyond the sessions under this research project. If a crisis situation (suicidal emergency, breakup, etc.) arises during (or even after) the research sessions, the therapists will use all the resources necessary to deal with it, just as they do in every clinical situation. If necessary, participation in the couples therapy sessions will simply stop.

If, during the course of evaluation or intervention, a research officer or therapist becomes aware of a situation of child abuse or serious neglect, the investigator, research officer or clinician is required to report the situation under the *Youth Protection Act*. The same applies during treatment received outside of any research project. Similarly, if, during the course of evaluation or intervention, a research officer or therapist becomes aware of a situation of spousal abuse that threatens the safety of the victim, the research officer or therapist must report the situation to the responsible authorities.

Confidentiality

We ask that you give us access to your clinical records at your treatment centre. Specifically, we want to know what services you received during the follow-up phase of the research project, that is, up until the date of your last evaluation session approximately 18 months after treatment begins. We would also like to have access to the relevant information so we can contact you during the follow-up phase of the research where necessary. In addition, we would like to photocopy the questionnaires and evaluations you answered with clinicians at the time of admission and during the research project.

All identifying information will be removed from the data collected during the research project (you will be identified only by a code number). It will be impossible to associate answers with a given participant. All of the data will be entered in computer files and saved in a directory that can be accessed solely by members of the research team and their research officers.



The paper copies of questionnaires as well as videotapes and audiotapes will be kept in a locked filing cabinet, in the principal investigator's research room at the Université du Québec à Trois-Rivières, at the Centre universitaire de Québec. The paper copies of questionnaires, videotapes, audiotapes and computer files with identifying information removed will be kept for seven years after the end of the research project and then destroyed. During that seven-year period, we will be able to analyze interview data anew. As very little research has been conducted on couples in which one member has a gambling problem, we are interested in reanalyzing the interview data as new knowledge comes to light. Secondary data analysis will be conducted only as part of research led or jointly led by the principal investigator. At the end of the seven years, the paper questionnaires will be shredded in a dedicated room at the Université du Québec à Trois-Rivières for destroying confidential documents. Video and audio recordings will be physically destroyed.

This research project falls within a broader research program on the role of families and friends in the treatment of pathological gamblers. With your consent, the data collected during this research project may be used for secondary analyses in the context of a few research projects conducted by members of the current research team (including students they supervise). "Secondary analysis" means, for example, more-in-depth validation of questionnaires used in this project, grouping of data from two similar studies to increase the number of participants, analysis of specific sub-groups (male gamblers versus female gamblers), and so forth. Identifying information will be retracted of course, so there will be no way of identifying you (names will be removed, with participants being identified only by a code number). Secondary analyses will be conducted within the seven-year data preservation period, and every secondary analysis will be subject to ethics approval. All research reports will be presented in such a way that it is impossible to recognize any participant.

Lastly, we are asking for your consent to be contacted regarding participation in a follow-study on the treatment received. You will be under no obligation; your consent means only that you agree to be contacted by the research team.

Dissemination of results

The results of this study will be presented in the form of a research report, conferences and scientific articles, always respecting the confidentiality of data. Your name will not be mentioned and the necessary steps will be taken to ensure that you cannot be identified.

Withdrawal from the study

Your participation in this study is entirely voluntary. You are free to agree or refuse to take part. If you choose to participate, you can withdraw at any time. You will be under



no pressure from the participating investigators or clinicians to remain in the study. Nor will you suffer any harm or loss of benefits to which you are normally entitled, such as the standard gambling treatment services received from your treatment centre. If you decide to withdraw from the study, the forms and questionnaires you completed during the research, as well as data stored in computer files, will be destroyed.

All you have to do to withdraw from the study is verbally inform your therapist, the research officer or the principal investigator. You can reach them at the number indicated at the bottom of the page.

Compensation

If you are harmed in any way due to your participation in this research project, you will be protected under the laws of Québec. By agreeing to participate in this study, you neither waive any of your rights nor release the researchers or the institution where the research project is being conducted of their civil or professional responsibilities.

Resource persons

For additional information, please contact the principal investigator, Joël Tremblay, or the project coordinator, Mélissa Côté, by calling 418-659-2170, ext. 2822.

If you have a complaint about the research project, please contact one of the following people:

For the Centre de réadaptation en dépendance Foster: Sylvie Côté, local complaints and service quality commissioner, 450-928-5149 or 1-800-347-8051.



Parties' signatures

Participants

I hereby declare that I have read and understand the contents of this consent form. I know that I am free to participate in the project or not and that I can withdraw from it at any time, by giving notice verbally, without affecting in any way the continuation of services I am receiving from my treatment centre. I declare that the project has been explained to me and that I can decide to participate or not, with no limitations or pressure from anyone. I hereby agree to participate in this project.

I consent to interviews being video-recorded.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
I consent to interviews being audio-recorded.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
I consent to secondary analyses being conducted on data collected, but solely under the supervision of the research team.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
I consent to being contacted during the next 36 months in relation to future research projects directly related to this one.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
Please indicate how you can be reached: Telephone number: _____ Other telephone number: _____ Email: _____ Regular mail: _____ _____ Facebook: _____ _____ Text message: ____/____/_____ People we can contact to get in touch with you: 1. Person's name: _____ • Telephone number: _____ • Relationship to you (e.g. friend, brother): _____ _____ 2. Person's name: _____ • Telephone number: _____ • Relationship to you (e.g. friend, brother): _____	



If you would like to receive a summary of the research results, please indicate whether you would like it sent by email or regular mail.	<input type="checkbox"/> Email
	<input type="checkbox"/> Regular mail

Name of participant


Signature of participant

Date

Commitment of the investigator

I hereby declare that I have provided the participant with all the necessary information in writing. I declare that I have clearly indicated on the consent form, in legible form, the name and contact information of the principal investigator available to answer all of the participant's questions and that I am giving the participant a copy of this consent form, duly signed and dated.

Joël Tremblay



August 20, 2014

Name of investigator

Signature of investigator

Date

Name of research officer

Signature of research officer

Date



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Introduction and research objectives

The purpose of this research is to compare two intervention methods for treating couples in which one partner has a gambling problem. The first is the standard method used by the treatment centre, that is, individual and sometimes group intervention for the gambler with the possibility of individual or group intervention for the non-gambling partner. The second method consists of couples therapy developed for the treatment of alcoholism or drug abuse that has been adapted to the needs of couples where one is a problem gambler. The goal of this study is to determine whether one of these methods is more effective or if they are equally effective. Depending on the study results, treatment centres will be able to adapt their services to people with gambling problems.



Participation

In agreeing to participate in the study, you agree to be randomly allocated to one of the two treatment groups.

Treatment sessions

c) Individual/group intervention (for the partner)

As a partner, you will have the choice of participating in either individual or group sessions, according to your needs. The goal of the sessions is to improve your personal well-being and gain a better understanding of how your partner develops gambling habits. If you are allocated to this treatment group, you commit to not participating in couples therapy sessions for the duration of the research project.

d) Couples therapy

You and your partner will participate in 8-12 weekly couples therapy sessions. Each session will last one and a half hours. During the sessions, we will address the gambler's gambling problems as well as discuss how the couple can improve their communication and problem-solving skills, share more fun times together and provide each other with greater mutual support in dealing with the gambling-related problems and their impact on the couple relationship. The ultimate goal is to maximize your chances of successfully changing your gambling habits and improve the quality of your couple relationship. Following the couples therapy sessions, you will continue receiving treatment services individually or as a couple (or both), according to your respective needs and as agreed upon with the therapist.

Research sessions

In addition to the treatment sessions, there will be four evaluation sessions with a research officer. The initial evaluation lasts around two and a half hours and the other three sessions, around one hour and 45 minutes. If you consent, the first session will take place immediately after you have signed the consent form. The others will be in 3, 9 and 18 months after today's admission meeting. During the evaluation sessions, you will be asked to answer a number of questionnaires on your gambling habits, your personal state and your couple relationship. The follow-up sessions (9 and 18 months) will consist of an interview roughly 15 minutes long, which will be audio-recorded to gain a better understanding of your treatment pathway and get your feedback on the treatment received. Following your first session with the research officer, he/she will contact you within 24 to 48 hours to let you know whether or not you will be participating in the



research study and, if so, tell you to which treatment group you have been allocated. A meeting will be scheduled with your assigned clinician, after which treatment will begin (individually or as a couple, depending on the method). If you are allocated to the couples therapy group, the research officer will send the clinician a summary of your evaluation results to help him/her understand your situation more clearly and avoid asking you the same information twice. In addition, at the start of each therapy session, you will be asked to answer a few short questionnaires (15 minutes each time) on your gambling habits and certain aspects of your couple relationship.

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Advantages and benefits

The goal of intervention is first and foremost to help the gambler overcome his/her gambling problem as well as help his/her partner through the couples or individual therapy sessions. Participating in this research project will thus help improve your personal well-being or your couple relationship and help you get to know yourself better. In addition, your participation will contribute to advancing knowledge about



interventions for problem gamblers who are part of a couple by helping us identify the most effective treatment methods.

Inconveniences and risks

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Withdrawal from the study

Your participation in this study is entirely voluntary. You are free to agree or refuse to take part. If you choose to participate, you can withdraw at any time. You will be under no pressure from the participating investigators or clinicians to remain in the study. Nor will you suffer any harm or loss of benefits to which you are normally entitled, such as the standard gambling treatment services received from your treatment centre. If you



decide to withdraw from the study, the forms and questionnaires you completed during the research, as well as data stored in computer files, will be destroyed.

All you have to do to withdraw from the study is verbally inform your therapist, the research officer or the principal investigator. You can reach them at the number indicated at the bottom of the page.

Compensation

If you are harmed in any way due to your participation in this research project, you will be protected under the laws of Québec. By agreeing to participate in this study, you neither waive any of your rights nor release the researchers or the institution where the research project is being conducted of their civil or professional responsibilities.

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Parties' signatures

Participants

I hereby declare that I have read and understand the contents of this consent form. I know that I am free to participate in the project or not and that I can withdraw from it at any time, by giving notice verbally, without affecting in any way the continuation of services I am receiving from my treatment centre. I declare that the project has been explained to me and that I can decide to participate or not, with no limitations or pressure from anyone. I hereby agree to participate in this project.

I consent to interviews being video-recorded.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
I consent to interviews being audio-recorded.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
I consent to secondary analyses being conducted on data collected, but solely under the supervision of the research team.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
I consent to being contacted during the next 36 months in relation to future research projects directly related to this one.	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
Please indicate how you can be reached: Telephone number: _____ Other telephone number: _____ Email: _____ Regular mail: _____ _____ Facebook: _____ _____ Text message: ____/____/_____ People we can contact to get in touch with you: 1. Person's name: _____ • Telephone number: _____ • Relationship to you (e.g. friend, brother): _____ _____ 2. Person's name: _____ • Telephone number: _____ • Relationship to you (e.g. friend, brother): _____	



<p>If you would like to receive a summary of the research results, please indicate whether you would like it sent by email or regular mail.</p>	<input type="checkbox"/> Email <input type="checkbox"/> Regular mail
<p>I consent to interviews being video-recorded.</p>	<input type="checkbox"/> YES <input type="checkbox"/> NO _____ <div style="text-align: right;">Initials</div>
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<p>Please indicate how you can be reached:</p> <p>Telephone number: _____</p> <p>Other telephone number: _____</p> <p>Email: _____</p> <p>Regular mail: _____</p> <p>Facebook: _____</p> <p>Text message: ____ / ____ / ____</p> <p>People we can contact to get in touch with you:</p> <p>1. Person's name: _____</p> <ul style="list-style-type: none"> • Telephone number: _____ • Relationship to you (e.g. friend, brother): _____ <p>2. Person's name: _____</p> <ul style="list-style-type: none"> • Telephone number: _____ • Relationship to you (e.g. friend, brother): _____ 	
<p>If you would like to receive a summary of the research results, please indicate whether you would like it sent by email or regular mail.</p>	<input type="checkbox"/> Email <input type="checkbox"/> Regular mail



Name of participant

Signature of participant

Date

Commitment of the investigator

I hereby declare that I have provided the participant with all the necessary information in writing. I declare that I have clearly indicated on the consent form, in legible form, the name and contact information of the principal investigator available to answer all of the participant's questions and that I am giving the participant a copy of this consent form, duly signed and dated.

Joël Tremblay

August 20, 2014

Name of investigator

Signature of investigator

Date

Name of research officer

Signature of research officer

Date