Study Protocol

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

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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).

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Random distribution research design

The efficacy study, using a longitudinal mixed methods approach, is conducted with a randomization process (n=80 problem gamblers) whereby participants are assigned to one of two treatment groups: a) an experimental group involving couple counselling ($n = 44$), and b) a control group involving individual counselling ($n = 36$). After the evaluation interview, the research officer applies randomization to ensure that each participant is randomly assigned to one of the two interventions. The method used is urn randomization (Wei and Lachin, 1988), combined with stratification for covariates thought to influence treatment outcome (Hedden, Woolson and Malcolm, 2006).

Stratification criteria (covariates) for randomization

- Risky alcohol or drug use (yellow light) by player, detected with DEBA-Alcool and DEBA-Drogues
- Risky gambling patterns (yellow light) in the partner, detected with DEBA-Jeu
- Player's sex
- Serious but stabilized mental health problem in the player, as assessed with the following questionnaires:
    - Indication of major depression (score 16 or over), detected with the Center for Epidemiologic Studies Depression Scale (Radloff, 1977; French translation by Fuhrer and Rouillon, 1989)
    - Significant psychological distress (85th percentile), detected with the Psychological Distress Index used in the Québec Health Survey – PDIQHS-29 (Préville, Boyer, Potvin, Perreault and Légaré, 1992)
    - Antisocial personality disorder or moderate borderline personality disorder (score 3 to 8), detected with the Borderline Conduct Scale and Conduct Disorder Scale in the Global Appraisal of Individual Needs – Initial (GAIN-I) instrument (Chestnut Health Systems, 2002-2006; translated by Tremblay and Savard, 2011)
    - Indication of another personality disorder (score 4 and over), detected with the Standardised Assessment of Personality – Abbreviated Scale (SAPAS) (Moran, Leese, Lee, Walters, Thornicroft and Mann, 2003; translated by Gordwoon)

Participants

Participants (problem gamblers) and their spouses are recruited in various alcohol and drug rehabilitation centres in various regions of Québec. More specifically, participating centres are in Montréal (Centre de réadaptation en dépendance de Montréal – Institut universitaire sur les dépendances, Centre de réadaptation en dépendance Foster), Montérégie (Centre de réadaptation en dépendance le Virage), Laurentides (Centre de réadaptation en dépendance des Laurentides), Estrie (Centre de réadaptation en dépendance de l'Estrie), Lanaudière (Centre de réadaptation en dépendance de Lanaudière), Québec (Centre de réadaptation en dépendance de Québec) and Chaudière-Appalaches (Centre de réadaptation en dépendance de Chaudière-Appalaches); as well as at Maison Jean Lapointe.

Selection criteria

Study eligibility criteria are the following:

- The couple has lived together at least 6 months.
- Pathological gambling (5 criteria) has been diagnosed in the past 12 months, as detected with WHM-CIDI (WHO; French translation by Gagnon, Tremblay, Ménard, Ferland, B-Martin and Berthelot, 2007).
- The player has not been treated for gambling habits for at least 6 months (excluding GA).
- The player has engaged in gambling behaviours in the past 3 months.
- Both partners show sufficient levels of commitment (score 8 and under) indicating a desire to continue the relationship, as measured by the *Marital Status Inventory* (Weiss and Cerreto, 1980).

Other characteristics emerge as being less favourable to participating in conjugal treatment. Therefore, participants with the following characteristics will be excluded from the study:

- The couple has lived together less than 6 months.
- The player has been treated for gambling habits in the past 6 months (excluding GA).
- The player has stopped gambling for 3 months or more.
- The player has alcohol or drug addiction problems (red light), as detected with DEBA-Alcool or DEBA-Drogues (Tremblay, Rouillard and Sirois, 2003)
- The partner has alcohol or drug addiction problems (red light), as detected with DEBA-Alcool or DEBA-Drogues (Tremblay, Rouillard and Sirois, 2003)
- The partner has gambling problems (red light), as detected with DEBA-Jeu (Tremblay, Ménard and Ferland, 2005).
- Acts of serious violence endangering the safety of one of the partners have been committed in the past 12 months.
- One person in the couple has had serious, non-stabilized mental health problems requiring hospitalization for at least 24 hours in a psychiatric department or psychiatric emergency department <u>in the past 12 months due to a psychotic spectrum disorder</u> (schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, psychotic disorder, bipolar disorder with psychotic features, major depressive disorder with psychotic features), <u>or in the past 6 months for any other mental health problem</u> (self-reported).
- An antisocial personality disorder or severe borderline personality disorder has been diagnosed, (score 9 or over) as detected with the Borderline Conduct Scale and Conduct Disorder Scale in the Global Appraisal of Individual Needs – Initial (GAIN-I) instrument (Chestnut Health Systems, 2002-2006; translated by Tremblay and Savard, 2011).
- The partner has had strong suicidal ideation with suicide scenario or suicide attempt in the past 30 days or less.
- Both partners show low levels of commitment (score 8 and over) indicating a risk of separation, as measured by the *Marital Status Inventory* (Weiss and Cerreto, 1980)

Recruitment strategies

Generally, practitioners propose the study to users following routine admission evaluations in the participating centres (see the research project description in Appendix A). Individuals interested in participating sign a form authorizing a research officer to contact them. A research assistant then reaches out to players who have accepted to be contacted and explains the research project in more detail to the person and the spouse; a first meeting with the couple is also set. During the meeting, once the questionnaires have been completed, randomization is carried out and the couple told about the intervention method to which they have been randomly assigned. In all cases, spouses are informed that they can get support from the entourage program (individual or group) offered in all participating centres.

In light of each centre's usual service request process, the recruitment strategy has been adapted to the realities of each one so as to facilitate referrals.

A poster describing the research project has also been produced and put up in the waiting rooms of all participating centres. A flyer based on the poster has also been made so clinicians can give out information about the study to anyone interested.

Intervention requirements

A) Experimental group: Couple therapy

Couples take part in 8 to 12 weekly counselling sessions lasting 1 1/2 hours each. During the sessions, the player's gambling problems are discussed as well as how the couple could improve communication and problem-solving skills. Other topics discussed include shared moments of pleasure and mutual support during difficult times linked to gambling and their impacts on the couple's life. The contents of couple therapy sessions are presented in Section 4, which focuses specifically on the couples therapy guide and its components.

B) Control group: Usual therapy (individual or group sessions)

Most of the time, the usual treatment provided in drug and alcohol rehabilitation centres consists of individual sessions based on the treatment method developed by the Centre québécois d'excellence en prévention et traitement du jeu – CQEPTJ (Ladouceur, Boutin, Lachance, Doucet and Sylvain, 2000). For a number of years now, practitioners in drug and alcohol rehabilitation centres have been trained to use this therapeutic model. Non-gambling partners have access to usual services offered to family members, that is, individual or group sessions aimed at this clientele.

Research process

In addition to therapy sessions, both members of the couple participate in four evaluation meetings with a research officer. The first meeting lasts about 2 1/2 hours and the other three about 1 1/2 hours. The initial meeting takes place before therapy sessions begin; the second is held about three months after therapy begins, and the third about nine months after onset of therapy. A last meeting is held 18 months after the start of participation in the project. During the sessions, participants complete a series of questionnaires on lifestyle habits, personal state, and conjugal life. Following the first meeting with the research officer, the latter contacts the couple or referring practitioner again (depending on the outcome of the evaluation meeting) within 24 hours to confirm or reject the couple's participation in the project.

If a couple is chosen for the research project, the referring practitioner contacts them to inform them of treatment plan to which they are being referred and to schedule a meeting. If the couple has not been chosen (exclusion criteria), the research assistant who conducted the admission interview contacts the couple to inform them of the decision. In this case, the referring practitioner is also notified of the meeting's outcome so the player and his or her spouse can benefit from the services which they could normally obtain in the centre where the initial request for help was made.

If a couple is assigned to couple therapy, the research officer sends a summary of the evaluation findings to the clinician to help him or her better understand the couple's situation and preclude having to ask for the same information a second time. Also, at the beginning of each treatment meeting, both members of the couple complete a few brief 15-minute questionnaires on lifestyle habits and certain aspects of conjugal life.

The clinician films the couple sessions for supervision meetings with study researchers (a session every three weeks), so the therapist can intervene as effectively as possible to help the couple.

For every meeting with the research officer, both people in the couple are given a gift certificate that can be used in a local store. The gift certificate is given at the end of each meeting with the research officer. In all, each person gets $250 in gift certificates for a box store in their region ($50 after the first meeting, $50 after the second one, $75 after the third, and $75 after the last meeting).

Training for clinicians

The research team organized four half-day training sessions for participating clinicians. During these sessions, the clinical model was presented, including training on the use of functional analysis for gambling situations and situations presenting risks of relapse, basic principles of couple therapy, strategies to improve communication, quality of negotiation, reduction of behaviours that reinforce gambling habits, and bolstering behaviours incompatible with gambling.

Treatment quality control

Administration of the couple therapy model is assessed for quality using scales developed for the current study. This strategy, often used in well-known studies (Meyers, Miller, Smith and Tonigan,

2002), employs a check list of key elements of the therapeutic approach. At the end of each interview, the clinician assesses the degree to which each essential component of the approach was used (e.g. review of gambling behaviours/cravings during the past week, work on communication skills, work on decreasing facilitating behaviours and improving gambling abstinence behaviours).

Supervision sessions are also a way to verify the quality of application of the intervention model evaluated.