

Study Protocol

Official title: Effectiveness Study of Two Types of Intervention for People in Couple Who Have Difficulties With Their Gambling Habits or Alcohol/Drug Use

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

This project has been approved by UQTR's research ethics committee (CERPPE-21-01-10.01) and the research ethics committee of the Centre intégré de santé et de services sociaux de Chaudière-Appalaches (MP-23-2022-894).

Random distribution research design

The efficacy study, using a longitudinal mixed methods approach, is conducted with a randomization process ($n=100$ couples) whereby participants are assigned to one of two treatment groups: a) an experimental group involving couple counselling ($n = 50$), and b) a control group involving individual counselling ($n = 50$). 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

- The person has high-level problems for gambling and substance use (score ≥ 7 from CPGI for gambling, score ≥ 26 from ASSIST for alcohol/other substances).
- The primary problem is a gambling disorder.
- The person with the gambling or substance use problem is a woman
- The person with a gambling or substance use problem self-identifies as a gender minority
- Partner has a moderate problem with substance use (score between 11 to 26 from ASSIST for alcohol, score between 4 to 26 from ASSIST for other substances) or gambling (score between 3 to 7 from CPGI)
- Serious but stabilized mental health problem in the gambler or his/her partner as assessed with the following questionnaires:
 - Indication of major depression (World Health Organisation-Five Well-Being Index (WHO-5), score ≤ 50 , Topp et al., 2015)
 - Significant psychological distress detected with the Psychological Distress Index from the Quebec Health Survey – PDIQHS-14 (score ≥ 31 for women, score ≥ 27 for men, Boyer et al., 1993)
 - 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)
 - A Borderline Personality Disorder of moderate severity on the Borderline Symptom List (score ≥ 0.7 , BSL-23; Bohus et al., 2009; Kleindienst et al., 2020)

Participants

Participants will be recruited from the specialized addiction services (also called addiction rehabilitation centers) of ten Centre intégré de santé et de services sociaux/Centre intégré universitaire de santé et de services sociaux, namely those of the Capitale-Nationale, Chaudière-Appalaches, Centre-sud de l'Île de Montréal, Montérégie Ouest, Lanaudière, Laurentides, Eastern

Townships, Saguenay-Lac-St-Jean, Laval and Mauricie-Centre-du-Québec regions. These establishments serve more than 80% of the Quebec population.

Selection criteria

Inclusion Criteria:

Living in couple for at least 6 months or report being in a significant relationship for at least 2 years

The problem at treatment entry may be gambling or substance use, but it must reach a severity that warrants referral to specialized services (score ≥ 7 from CPGI for gambling or score ≥ 26 from ASSIST for alcohol/others substances).

The Gambler has engaged in gambling and substance use behaviors in the past three months (TLFB)

The gambler has not received treatment for their gambling or substance use disorder for at least 6 months (excluding Gamblers Anonymous, Alcoholics Anonymous or Narcotics Anonymous).

Partners can gamble, drink alcohol or use others substances as long as they are not highly addicted to gambling (CPGI ≥ 8) or alcohol/substances (ASSIST ≥ 26) and if the partners present a problem to one or the other, it cannot be of moderate level for both issues (score between 3 to 7 from CPGI for gambling, score between 11 to 26 from ASSIST for alcohol, score between 4 to 26 from ASSIST for other substances)

Exclusion Criteria:

Presence of serious acts of violence endangering the safety of both spouses in the last year (Conflict Tactics Scale-2) or use of services for victims of domestic violence in the past year

Disorder or serious mental health unstabilized for one of two members of the couple (History of Psychiatric Hospitalization) in the last 6 months.

Scenario with strong suicidal ideation or attempt in the last 30 days or less of two members of the couple (History of Psychiatric Hospitalization).

Antisocial personality or severe limit personality disorder of two members of the couple (Borderline and Conduct Disorder Scale, score ≥ 9 , Borderline Symptom List, score $\geq 2,8$).

Low degree of commitment in the relationship of a risk of separation (Marital Status Inventory, score ≥ 9)

Recruitment strategies

Generally, practitioners propose the study to users following routine admission evaluations in the participating centres. Individuals interested in participating sign a form authorizing a research officer to contact them. A research assistant then reaches out to gambler 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: Integrative Couple Treatment for Addiction (ICT-A)
Inspired by the "Alcohol Behavior Couple Therapy" from Epstein & McCrady, the ICT-A will be offered over 12 to 16 sessions of 90 minutes. Typically, approximately the first half of each session is dedicated to GD/SUD problems, in a predominantly cognitive behavioral model. In the second part of each session, the clinician will help the couple to improve their communication, to reduce the reinforcements (non-voluntary) of the behaviors of GD/SUD and to increase marital pleasure situations incompatible with the use of GD/SUD. Particular attention will also be paid to feelings of betrayal and interpersonal attacks to restore trust. Plus, they will receive a self-care guide.
- B) Control group: Individual treatment as usually offered
The usual treatment control group will receive individual treatment as already offered by the specialized centres in addiction.
For the person with GD/SUD, this treatment consists of 12 to 16 individual cognitive-behavioral sessions of 60 minutes. In general, the intervention aims to secure financial assets, awareness of erroneous thoughts and improvement of alternative skills to gambling in order to meet the normal demands of psychic and relational life. People undergoing this intervention will receive a self-care guide.
As for the partners randomized in this intervention, they will receive the services that are usually offered to members of the entourage of a person with GD/SUD. In groups or individually, these services are generally aimed at improving the partner's well-being and relationship with their spouse, which includes information about GD/SUD and the recovery process.

Research process

Following admission to treatment, an 18-month longitudinal follow-up will document the effects of the intervention and the maintenance of gains over time. The research assessments will therefore take place on four occasions, at intake, 6, 12 and 18 months post-admission.

The initial meeting takes place before therapy sessions begin; the second is held about six months after, and the third about 12 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 month), so the therapist can intervene as effectively as possible to help the couple.

The monetary compensation offered will be \$275 per couple, offered in the form of gift cards to a local mall (\$50 at the first intake meeting, \$75 at the three meetings 6, 12 and 18 months post-intake). Since participants are expected to attend four research meetings over a year and a half, as well as 12 to 16 treatment meetings, we believe that the \$275 per couple compensation is commensurate with the effort required.

Training for clinicians

The research team organized three day of 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

At the end of each interview (individual treatment or couple treatment), the clinician clinicians complete a checklist rating the importance of each theme during the encounter (scale of 0 to 10 where 0 = not at all, 10 = extremely).

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