Is virtual reality useful to treat pathological gambling?

Submission date	Recruitment status No longer recruiting	Prospectively registered		
15/01/2015		[] Protocol		
Registration date	Overall study status	Statistical analysis plan		
31/03/2015	Completed	[X] Results		
Last Edited 18/10/2019	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

Pathological gambling is characterized by a loss of control over gambling, deception about the extent of one's involvement with gambling, family and job disruption, theft, and chasing losses, or the effort to win back money lost while gambling. About 1% of the adult population is said to be a pathological gambler. Scientific data suggest that combined cognitive and behavioural therapies (CBT) are "somewhat" successful in treating this addiction. An important issue in treating pathological gambling is that, despite understanding the negative consequences of their behaviour, problem, gamblers continue experiencing an overwhelming craving to gamble. In CBT sessions, patients remain emotionally detached from the gambling situation and the associated cravings. Being in the safety of the psychologist's office makes it difficult to evoke all high risk situations and associated behaviours and thoughts, as well as practicing skills that would prevent them from gambling when they feel a craving to do so. An alternative solution would be to use virtual reality (VR) to help people to walk away when faced with a situation where they may be tempted to gamble (relapse prevention). In a previous study, called "My turn to play", gamblers were enrolled in a an inpatient CBT program where they could choose between being exposed to one of two situations (an easy one and a more difficult one) that may encourage them to gamble (gambling stimuli) where they could practice CBT relapse prevention exercises either through the 7 steps of the virtual environment or an individualized typical situation. It was found that being exposed to a more intense gambling stimuli during the relapse prevention exercises was more successful.

VR has not yet been tested to see how successful it could be when combined with CBT. Before launching a large, expensive trial, this study sets out to answer:

1. Can VR help identify high risk situations and dysfunctional beliefs, early in the treatment

2. Can VR be useful for relapse prevention exercises, late in the treatment

3. Does using VR raise ethical issues with patients during the treatment (e.g., uncontrollable urges to gamble)?

Who can participate? French speaking pathological gamblers aged 18-75.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (experimental

group) attend one VR session which identifies situations where the participant is at high risk of being compelled to gamble and one VR session where they practice relapse prevention exercises. Those in group 2 (control) attend similar sessions but use their own imagination to visualize situations rather than VR. All participants are treated with a standardized cognitive-behavioural program run by experienced therapists. Adherence to the research protocol is assessed regularly by independent raters who review videotapes of therapy sessions. Diagnostic interviews and questionnaires are completed before and after the treatment, and at follow-up sessions 6 months and then 12 months later.

What are the possible benefits and risks of participating?

The fact that participants are exposed to virtual environments that includes gambling machines can trigger the desire to gamble. In the worst case scenario, this desire will not be any stronger than that triggered by real gambling machines. It is important to mention that the first source of motivation to play is to win. In this project, participants cannot get real gains since it is all in virtual reality. We recruit participants located in inpatient therapy centers that specializes in the treatment of pathological gambling in order to ensure there is always a therapist present in case of a problem. These centres have accommodations on site for clients that requires a safe environment away from gambling. Participants are informed of what is expect and are free to refuse or guit the project at any time. The Gambling Craving Scale measures desire to gamble and will allow the therapist to know, after each virtual reality sessions if the participant's desire to gamble is high and will be able to stop the sessions. Possible adverse effects of participating in the study are mild symptoms of cybersickness. Cybersickness is similar to motion sickness and typically occurs during or after an immersion in a virtual environment. The temporary side effects associated to cybersickness include (1) visual symptoms (eyestrains, blurred vision, and headaches), (2) disorientation (vertigo, imbalance) and (3) nausea (vomiting, dizziness). If cybersickness occurs and become uncomfortable for the participant, the session will end immediately. All participants will be asked to remain in the therapist's office 15 minutes after the session before leaving, as a preventive measure. If symptoms do not subside after 15 minutes (although it never happened before in many years of experiments), the assistant or therapist will take appropriate actions, such as waiting longer in the waiting room, going to rest in their room at the inpatient clinic, or bring the participant directly to the local emergency room (which is extremely unlikely).

Where is the study run from? Laval University - School of Psychology and two drug addiction centres (Canada)

When is the study starting and how long is it expected to run for? June 2013 to March 2017

Who is funding the study? Quebec Research Fund - Society and Culture (Canada)

Who is the main contact? Dr Stephane Bouchard stephane.bouchard@uqo.ca

Contact information

Type(s) Scientific **Contact name** Dr Stéphane Bouchard

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

FRQSC (Funding): 2014-JU-171635 and UQO Ethic committee no: 1778

Study information

Scientific Title

Testing the usefulness of virtual reality (VR) in the treatment of pathological gambling with a randomized controlled trial

Acronym

VR_GAMBLE

Study objectives

In comparison with traditional CBT treatment, Immersions in virtual environments that induces desire to gamble will:

1. Facilitates the identification of high risk situations and dysfunctional beliefs, early in treatment 2. Facilitates self-efficacy perceptions and relapse prevention exercises, late in the treatment and at 6 and 12 month follow-ups

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Comité d'Éthique à la Recherche de l'Université du Québec en Outaouais, 05/06/2013, ref:1778 2. Université Laval, 28/04/2014, ref: 2014-024

Study design

Two arms non-inferiority randomized control trial in two centers offering inpatients psychological services for pathological gambling

Primary study design

Interventional

Secondary study design

Study setting(s) Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Treatment and relapse prevention for adults suffering from pathological gambling

Interventions

After receiving an appropriate diagnosis and completing the ethics procedures, participants will be randomly assigned to one of the following two conditions:

1. Experimental (Virtual Reality (VR) Condition):

1.1. One session identifying high risks situations with exercises in VR.

1.2. One session practicing relapse prevention with exercises in VR.

2. Control condition:

2.1. One session identifying high risks situations with exercises in imagination.

2.2. One session practicing relapse prevention with exercises in imagination.

A standardized treatment will be conducted inside a traditional (cognitive-behavioral therapy) program delivered by experienced therapists in each centers. Treatment fidelity will be enhanced by the use of treatment manuals and weekly supervisions. Adherence to the research protocol will be assessed regularly by independent raters who will review videotapes of therapy sessions.

Intervention Type

Behavioural

Primary outcome measure

Pre, 2-week post, 6 and 12 month follow-up:

1. Indice Canadien du Jeu Excessif (ICJE; McCready & Adlaf, 2006): will be administered to document the program effectiveness.

2. Perception d'Efficacité Personnelle (Sylvain et al., 1997): based on the description of three situations assessing excess risk in gambling. Participants can rate how much they can control their gambling behaviors in these situations.

Note that there is a 2-week period between post and the end of the treatment. This period of time allows the participant to finish their program and return into their familiar environment.

Secondary outcome measures

Pre, 2-week post, 6 and 12 month follow-up:

1. Fréquence de jeu (Sylvain et al., 1997) : Gambling Frequency is a questionnaire that indicates gambling frequency during the last week. They also note the amount spent and how long they

played.

2. Gambling Craving Scale (GACS; Young & Wohl, 2009) This 9-item questionnaire has three subscales measuring anticipation, desire to gamble et and relief. Each subscale has three items and participants have to answer to questions on a scale of 1 (strongly disagree) to 7 (strongly agree).

3. Mon Traitement (Bouchard et al., 2012) : My treatment is a scale composed of two types of information : (a) presence at the end of the day of desire to gamble and possible cybersickness following virtual reality sessions, and (b) assiduity in therapy sessions and motivation to continue treatment.

Note that there is a 2-week period between post and the end of the treatment. This period of time allows the participant to finish their program and return into their familiar environment.

Overall study start date

05/06/2013

Completion date

30/03/2017

Eligibility

Key inclusion criteria

40 participants suffering from pathological gambling (according to DSM-V diagnostic critera) will be recruited in two treatment centers that offers a closed-inpatient setting (Centre Casa and Maison Jean Lapointe), allowing a more secure environment for trying a treatment that involves voluntary interventions related to the desire to gamble. In each centers, participants will be randomly assigned to one of the two experimental conditions.

1. Ambulatory man and woman

2. At least 18 years old and at most 75 years old

3. French speaking

4. Receiving a principal diagnosis of Pathological gambling based on DSM-5 diagnostic criteria. Assessed with a semi-structured diagnostic interview (EDTJ)

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants N=40 (n=20 in each condition)

Key exclusion criteria

1. Having a principal diagnosis other than Pathological gambling

2. Currently suffering from a severe organic disease, dementia, mental retardation,

schizophrenia, amnesia, substance abuse, borderline personality disorder, psychosis or bipolar disorder

3. Active suicidal ideations

Date of first enrolment 01/12/2013

Date of final enrolment

15/12/2015

Locations

Countries of recruitment Canada

Study participating centre University of Quebec at Outaouais (Université du Québec en Outaouais (UQO)) Department of Psychology (Dept. psychologie) C.P.1250 succ. Hull Gatineau Canada J8X 3X7

Study participating centre Laval University - School of Psychology (Université Laval - École de psychologie) Pavillon Félix-Antoine-Savard 2325 rue des Bibliothèques Québec Canada G1V 0A6

Study participating centre Maison Jean Lapointe 367, rue Marguerite-D'Youville Montreal Canada H2C 2C4

Study participating centre Centre CASA 4965, Lionel-Groulx Saint-Augustin-de-Desmaures Canada G3A 1V3

Sponsor information

Organisation Fonds de Recherche du Québec - Société et culture (FRQSC)

Sponsor details 140, Grande Allée Est, bureau 470 Québec Canada G1R 5M8 (418) 643-7582 frq.sc@frq.gouv.qc.ca

Sponsor type

Government

Website http://www.frqsc.gouv.qc.ca

ROR https://ror.org/00shpc021

Funder(s)

Funder type Not defined

Funder Name Quebec Research Fund - Society and Culture (Canada)

Results and Publications

Publication and dissemination plan

To be confirmed at a later date but we intend to publish results in conferences and scientific journals.

Intention to publish date

IPD sharing plan summary Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	24/02/2017	18/10/2019	Yes	No