Augmenting an online self-directed intervention for gambling disorder with a single motivational interview

Submission date 02/07/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[X] Protocol
Registration date 07/07/2020	**Overall study status** Completed	[ ] Statistical analysis plan
		[X] Results
Last Edited 24/01/2024	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data

Plain English summary of protocol
Current plain English summary as of 19/11/2020:

Background and study aims
Despite the success of gold standard cognitive-behavioural therapy (talking therapy) for problem gambling, the majority of problem gamblers do not seek or receive professional treatment. Thus, the development of less intrusive self-directed interventions has been encouraged. Bibliotherapy (book therapy) for problem gambling has shown promise, both alone and in combination with motivational interviews, but there is still a lack of online self-directed intervention research. The aim of this study is to assess the effectiveness of an online self-directed treatment program for problem gambling and gambling disorder, both alone and in combination with a single motivational interview delivered by telephone.

Who can participate?
Canadian residents aged 18 or older who are are concerned about their gambling and are not currently receiving treatment for their gambling-related concerns

What does the study involve?
Participants will first undergo an assessment to make sure they are eligible. This will include questionnaires related to demographic information and gambling behaviour over the past 3 months (e.g., What types of gambling do you engage in?"). This assessment should take about 15 minutes. If they are eligible and choose to participate, participants will then be randomly placed into one of two groups: (1) the online workbook only; or (2) the online workbook plus one digital motivational interview within the next two weeks. If placed in the group that receives a motivational interview, participants will be contacted via email to set up a time to complete a digital interview via Microsoft Teams with one of our research staff. This interview should happen within the first two weeks of consenting to participate in the study. The interview could take up to one hour and will be recorded (with consent). Regardless of which group participants are placed in, they will be directed to a website containing the online workbook, where they will set up an account. They can work through the workbook activities in any order at their own pace. Participants will be asked to complete a baseline assessment of their gambling behaviours and

general mental health, and this assessment should take approximately 10 minutes. Participants will be compensated with an e-gift card valued at CAD $10 after: a) completing the baseline assessment; b) creating an account with the online program; and c) completing the motivational interview (if assigned to that group). They will be able to choose from one of the following: Amazon, Best Buy, Boston Pizza, Ultimate Dining Card, Chapters/Indigo, Cineplex, The Keg, Starbucks, or Walmart. After 3, 6, 12, and 24 months, they will be contacted by email to complete online assessments similar to the baseline assessment. For each follow-up assessment completed, they will be compensated with a CAD $30 e-gift card. In total, they could receive five e-gift cards, worth a total value of CAD $130. The final follow-up assessment will be at 24 months after beginning the program. Every follow-up assessment is completely voluntary. When the 24 months are over and the last assessment is completed, participants will no longer have access to the online workbook. They will no longer be contacted by the research team. They will be provided with further treatment resources specific to the province you reside in, should they wish to seek further professional help.

What are the possible benefits and risks of participating?
Participants will be compensated a total of CAD $30 in e-gift cards for each follow-up assessment they complete, in addition to the CAD $10 e-gift card for completing the initial steps (i.e., completing the baseline assessment, creating an account with the online program, and completing the motivational interview if assigned to that group). Thus, a maximum total of CAD $130 in e-gift cards may be earned. It is also the hope that their gambling concerns will be reduced following this intervention. There are no risks associated with this trial, with the exception of possible discomfort due to the sharing of personal information (i.e., gambling concerns).

Where is the study run from?
The study is being run out of the Addictive Behaviours Laboratory at the University of Calgary (Canada). However, all aspects of the study are being conducted remotely online (i.e., participants do not need to visit the Addictive Behaviours Laboratory).

When is the study starting and how long is it expected to run for?
January 2020 to September 2024

Who is funding the study?
Alberta Gambling Research Institute

Who is the main contact?
Brad Brazeau
bradley.brazeau@ucalgary.ca

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Previous plain English summary:

Background and study aims
Despite the success of gold standard cognitive-behavioural therapy (talking therapy) for problem gambling, the majority of problem gamblers do not seek or receive professional treatment. Thus, the development of less intrusive self-directed interventions has been encouraged. Bibliotherapy (book therapy) for problem gambling has shown promise, both alone and in combination with motivational interviews, but there is still a lack of online self-directed

intervention research. The aim of this study is to assess the effectiveness of an online self-directed treatment program for problem gambling and gambling disorder, both alone and in combination with a single motivational interview delivered by telephone.

Who can participate?
Canadian residents aged 18 or older who are are concerned about their gambling and are not currently receiving treatment for their gambling-related concerns

What does the study involve?
Participants will first undergo an assessment to make sure they are eligible. This will include questionnaires related to demographic information and gambling behaviour over the past 3 months (e.g., What types of gambling do you engage in?"). This assessment should take about 15 minutes. If they are eligible and choose to participate, participants will then be randomly placed into one of two groups: (1) the online workbook only; or (2) the online workbook plus one motivational interview over telephone within the next week. If placed in the group that receives a motivational interview, participants will be contacted via email to set up a time to talk on the phone with one of our research staff. This phone call should happen within the first week of consenting to participate in the study. The phone call could take up to one hour and will be recorded (with consent). Regardless of which group participants are placed in, they will be directed to a website containing the online workbook, where they will set up an account. They can work through the workbook activities in any order at their own pace. After 3, 6, and 12 months, they will be contacted by email to complete online assessments similar to the ones completed to determine eligibility. For each follow-up assessment completed, they will be compensated with a CAD $30 e-gift card. They will be able to choose from one of the following: Amazon, Best Buy, Boston Pizza, Ultimate Dining Card, Chapters/Indigo, Cineplex, The Keg, Starbucks, or Walmart. In total, they could receive three e-gift cards, worth a total value of CAD $90. The final follow-up assessment will be at 12 months after beginning the program. Every follow-up assessment is completely voluntary. When the 12 months are over and the last assessment is completed, participants will no longer have access to the online workbook. They will no longer be contacted by the research team. They will be provided with further treatment resources specific to the province you reside in, should they wish to seek further professional help.

What are the possible benefits and risks of participating?
Participants will be compensated a total of CAD $30 in electronic gift card form for each follow-up assessment they complete, for a maximum total of CAD $90 in electronic gift cards. It is also the hope that their gambling concerns will be reduced following this intervention. There are no risks associated with this trial, with the exception of possible discomfort due to the sharing of personal information (i.e., gambling concerns).

Where is the study run from?
The study is being run out of the Addictive Behaviours Laboratory at the University of Calgary (Canada). However, all aspects of the study are being conducted remotely online (i.e., participants do not need to visit the Addictive Behaviours Laboratory).

When is the study starting and how long is it expected to run for?
The study is expected to begin on approximately July 27th, and it is expected to run for a period of 2 years

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Brad Brazeau
bradley.brazeau@ucalgary.ca

Contact information

Type(s)
Public

Contact name
Mr Brad Brazeau

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bradley.brazeau@ucalgary.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Augmenting an online self-directed intervention for gambling disorder with a single motivational interview: a randomized controlled trial

Study objectives
Current study hypothesis as of 19/11/2020:

1. Gamblers in both the internet-only (IO) and internet plus motivational interview (IMI) treatment conditions will experience a reduction in gambling frequency over the course of treatment. However, this reduction is expected to be more pronounced for those in the IMI condition

2. Gamblers in both the IO and IMI conditions will experience a reduction in gambling severity over the course of treatment. However, this reduction is expected to be more pronounced for those in the IMI condition
3. Reductions in gambling frequency and severity for both the IO and IMI conditions will be negatively correlated with time spent using the online self-help tools (i.e., more time spent online will be associated with greater reductions in gambling frequency and severity)
4. The IMI group will demonstrate greater adherence (i.e., more modules completed on the self-help website) compared to the IO group

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Previous study hypothesis:

1. Gamblers in both the internet-only (IO) and internet plus motivational interview (IMI) treatment conditions will experience a reduction in gambling frequency over the course of treatment, particularly by the 12-month follow-up period. However, this reduction is expected to be more pronounced for those in the IMI condition
2. Gamblers in both the IO and IMI conditions will experience a reduction in gambling severity over the course of treatment, particularly by the 12-month follow-up period. However, this reduction is expected to be more pronounced for those in the IMI condition
3. Reductions in gambling frequency and severity for both the IO and IMI conditions will be negatively correlated with time spent using the online self-help tools (i.e., more time spent online will be associated with greater reductions in gambling frequency and severity).
4. The IMI group will demonstrate greater adherence (i.e., more modules completed on the self-help website) compared to the IO group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/05/2020, University of Calgary Conjoint Faculties Research Ethics Board (CFREB, University of Calgary, 2500 University Dr NW, Calgary AB, T2N 1N4, Canada; +1 (0)403 220 8640; cfreb@ucalgary.ca), ref: REB20-0568

Study design
Single-centre two-arm interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet

Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gambling disorder

Interventions
Current interventions as of 19/11/2020:

This study will employ two treatment conditions: internet-only (IO); and internet plus motivational interview (IMI). Both the IO and IMI groups will receive access for 24 months to an online self-help workbook for problem gambling that is based on principles of cognitive-behavioural therapy. The internet workbook includes four modules: self-assessment, goal-setting, goal achievement, and goal maintenance. In addition to workbook access, the IMI group will receive a single motivational interview via telephone within the first week of their enrolment in the study. Participants will be randomised based on the following information collected from the eligibility screening questionnaire: biological sex (male; female), gambling severity category (mild/moderate; severe), and whether or not they have received any form of gambling treatment in the past (yes; no).

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Previous interventions:

This study will employ two treatment conditions: internet-only (IO); and internet plus motivational interview (IMI). Both the IO and IMI groups will receive access for 12 months to an online self-help workbook for problem gambling that is based on principles of cognitive-behavioural therapy. The internet workbook includes four modules: self-assessment, goal-setting, goal achievement, and goal maintenance. In addition to workbook access, the IMI group will receive a single motivational interview via telephone within the first week of their enrolment in the study. Participants will be randomised based on the following information collected from the eligibility screening questionnaire: biological sex (male; female), gambling severity category (mild/moderate; severe), and whether or not they have received any form of gambling treatment in the past (yes; no).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 19/11/2020:

1. Gambling severity based on the National Opinion Research Center Diagnostic Screen for Gambling Problems (NODS), collected at baseline, 3, 6, 12, and 24 months
2. Gambling frequency: average number of days gambled per month, calculated based on self-reported days gambled over the past 3 months, collected at baseline, 3, 6, 12, and 24 months

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Previous primary outcome measure:

. Gambling severity based on the National Opinion Research Center Diagnostic Screen for Gambling Problems (NODS), collected at baseline, 3, 6, and 12 months
2. Gambling frequency: average number of days gambled per month, calculated based on self-reported days gambled over the past 3 months, collected at baseline, 3, 6, and 12 months

Secondary outcome measures
Current secondary outcome measures as of 19/11/2020:

1. Gambling expenditures: average amount of money gambled per day, calculated based on self-reported money gambled every day over the past 3 months, collected at baseline, 3, 6, 12, and 24 months
2. General psychological distress based on the Kessler Psychological Distress Scale (K-10) collected at baseline, 3, 6, 12, and 24 months
3. Anxiety symptoms based on the Generalized Anxiety Disorder Scale (GAD-7) collected at baseline, 3, 6, 12, and 24 months
4. Depression symptoms based on the Patient Health Questionnaire (PHQ-9) collected at baseline, 3, 6, 12, and 24 months
5. Alcohol dependence based on the Alcohol Use Disorders Identification Test - Consumption questions (AUDIT-C) collected at baseline, 3, 6, 12, and 24 months
6. Program evaluation based on the Internet Evaluation and Utility Questionnaire (IEUQ) collected at 3, 6, 12, and 24 months
7. User data: module completion and time spent on site downloaded from the online workbook program, collected at 3, 6, 12, and 24 months

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Previous secondary outcome measures:

1. Gambling expenditures: average amount of money gambled per day, calculated based on self-reported money gambled every day over the past 3 months, collected at baseline, 3, 6, and 12 months
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4. Depression symptoms based on the Patient Health Questionnaire (PHQ-9) collected at baseline, 3, 6, and 12 months
5. Alcohol dependence based on the Alcohol Use Disorders Identification Test - Consumption questions (AUDIT-C) collected at baseline, 3, 6, and 12 months
6. Program evaluation based on the Internet Evaluation and Utility Questionnaire (IEUQ) collected at 3, 6, and 12 months
7. User data: module completion and time spent on site downloaded from the online workbook program., collected at 3, 6, and 12 months

Overall study start date
01/01/2020

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. 18 years of age or older at the point of enrolment
2. Currently residing in Canada
3. Not be currently receiving treatment for problem gambling (e.g., therapy, Gamblers Anonymous, self-help workbook, etc)
4. Currently has at least a moderate gambling problem (as determined by eligibility screening questionnaire)

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
310

Total final enrolment
322

Key exclusion criteria
1. No access to the internet
2. No access to a telephone

Date of first enrolment
19/08/2020

Date of final enrolment
17/05/2022

Locations

Countries of recruitment
Canada

Study participating centre
University of Calgary
2500 University Drive NW

Calgary
Canada
T2N 1N4

Sponsor information

Organisation
University of Calgary

Sponsor details
Research Services
2500 University Dr NW
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Canada
T2N 1N4
+1 (0)403 220 6354
rsoadmin@ucalgary.ca

Sponsor type
University/education

Website
https://www.research.ucalgary.ca/contact/research-services

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
University/education

Funder Name
Alberta Gambling Research Institute, University of Calgary

Alternative Name(s)
Alberta Gambling Research Institute, University of Alberta, Alberta Gambling Research Institute

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan
The plan is to submit a trial protocol manuscript to the journal "Trials" once recruitment begins. After data collection, analysis, and write-up, the final trial manuscript will be submitted to "Journal of Gambling Studies" for publication. Finally, the results of the trial will be presented as a peer-reviewed conference presentation at the Alberta Gambling Research Institution annual conference.

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available upon request from Brad Brazeau (bradley.brazeau@ucalgary.ca). All anonymized data will be available upon request after the study has been completed and results have been published, but identifying information will not be released. Data will be available to request for as long as the data is retained, but the timeframe for retention of anonymized data is currently unspecified. The data generated from this study will be the property of the Addictive Behaviours Laboratory. If other researchers wish to request the anonymized data for secondary analyses, they will be asked to provide a one-page summary of the rationale, analytic plan, and significance of the secondary data analyses. This summary will be evaluated by the investigators on the research team. If approved, researchers who wish to conduct secondary analyses will be asked to acknowledge the research team who collected the data in any resulting publications or presentations.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/12/2021	21/03/2022	Yes	No
Results article		04/01/2024	24/01/2024	Yes	No