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Piloting the addition of Contingency Management to best practice counselling as an adjunct treatment for rural and remote disordered gamblers.

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Title: Piloting the addition of Contingency Management to best practice counselling as an adjunct treatment for rural and remote disordered gamblers.

Authors: Darren R. Christensen[1], Chad S. G. Witcher[2], Trent Leighton[1], Rebecca Hudson-Breen[3], & Samuel Ofori-Dei[2]

Sponsor and Correspondence: Darren Christensen; darren.christensen@uleth.ca

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Affiliations:
[1]Addictions Counselling, Faculty of Health Sciences, University of Lethbridge
[2]Public Health, Faculty of Health Sciences, University of Lethbridge
[3]University of Alberta, Educational Psychology

Roles: Darren Christensen supervises and designed the study, Chad Witcher supervises the qualitative evaluation and contributed to the study design, Trent Leighton supervises the graduate student counsellors and contributed to the study design, and Rebecca Hudson-Breen counselled participants and contributed to the study protocol. Samuel Ofori-Dei contributed to the writing of the protocol manuscript and assists with the data collection.

ABSTRACT

Introduction: Problematic gambling is a significant Canadian public health concern that causes harm to the gambler, their families, and society at large. However, a significant minority of gambling treatment seekers drop out prior to the issue being resolved, where those with the most severe gambling problems have the highest drop-out rates. The aim of this study is to investigate the effects of internet-delivered Cognitive Behavioural Therapy (CBT) and internet-delivered CBT and CM (CM+) to rural and remote Albertan gamblers**.** Contingency Management (CM) is a successful treatment approach for substance dependence that uses small incentives to reinforce abstinence. This approach may be suitable for the treatment of gambling disorder. Further, internet delivered CM may hold particular promise in rural contexts, as these communities typically struggle to access traditional clinic based counselling opportunities.

Methods and analysis: 54 adults with gambling disorder will be randomised into one of two conditions; Contingency Management and Cognitive Behavioural Therapy (CM+), or Cognitive Behavioural Therapy alone (CBT). Gambling will be assessed at intake, every treatment session, post-treatment and follow-up. The primary outcome measures are treatment attendance, gambling abstinence, gambling, gambling symptomology, and gambling urge. In addition, qualitative interviews assessing study experiences will be conducted with the supervising counsellor, graduate student counsellors, and a sub-set of treatment-seekers. This is the first study to use contingency management as a treatment for gambling disorder in a rural and remote population.

Ethics and dissemination: This study is approved by the University of Lethbridge Human Subject Research committee (#2016-080). The investigators plan to publish the results from this study in academic peer-reviewed journals. Summary information will be provided to the funder. Trial registration number: NCT02953899 (ClinicialTrials.gov); Pre-results

Strengths and Limitations:

- First study to investigate the effect of providing counselling and contingency management for the treatment of gambling disorder in a rural and remote population.

- Internet delivery may provide a cost-efficient approach for delivery of counselling services.
- Contingency management is likely to improve treatment attendance and study retention.
- Sample size may be unpowered to detect changes in gambling behaviour and symptomology in the CBT condition.
- Irregular internet availability in rural and remote regions may impede study accessibility.

INTRODUCTION

Problematic gambling is a significant Canadian public health concern that causes harm to the gambler, their families, and society at large[1]. Approximately 4% of Albertans gamble in problematic ways resulting in significant financial losses, personal distress, broken relationships, and in some cases, suicide[2, 3]. However, the numbers of Albertans seeking treatment for problem gambling appears to be declining, despite the relatively consistent problem gambling prevalence rates[2]. Further, 33% - 50% of gambling treatment seekers drop out from treatment prior to resolving the issue, where those with the most severe gambling problems have the highest drop-out rates[4]. One possible reason for these issues is the lack of immediate benefits clients gain from treatment attendance.

Contingency Management (CM) is a treatment approach that has superior retention and treatment efficacy compared to traditional approaches for substance and alcohol dependence[5]. CM uses motivational incentives, typically vouchers that are exchangeable for retail goods and services, to reward participants for providing evidence of the target behaviour. Conversely, rewards are withheld when the participant fails to perform the target behaviour. CM has been successfully used in several countries for various addictive substances[6, 7].

Meta-analyses have consistently found CM studies to report improved clinical outcomes and large treatment effect sizes[8, 9]. Further, CM studies typically report a greater likelihood of program completion than standard care[10], where the positive effects of CM persist for participants many months after treatment completion[11]. Researchers are now suggesting that contingencies are important factors in the treatment of gambling[12-14], as the variable but regular receipt of gambling wins are associated with the development of problematic gambling[15], where CM uses the same approach to reverse these associations.

The CM procedure has three basic components 1) target behaviours are identified, 2) reinforcers (sometimes called motivational incentives or rewards) are provided when evidence for the target behaviours are produced, 3) reinforcers are unavailable when a participant fails to perform the target behaviour[16]. Further, CM treatment efficacy is improved by increasing the rate of reinforcers for continued performance of the target behaviour and resetting of the rate after a lapse[11], delivering the reinforcer immediately after providing evidence of the target behaviour[17], and increasing the magnitude of the reinforcer[18, c.f. 19].

The only previously published study of CM for the treatment of problematic gambling found significant reductions in gambling frequency, time spent gambling, money spent gambling, and net losses[12]. However, the target behaviours for reinforcement were participant selected goals, and typically were non-abstinence related. Although this approach is congruent with CM approaches for the treatment of

other behaviours[20], the typical CM approach in substance abuse treatment is to select abstinence as the target behaviour[21].

This study is based on the dosing schedule of pharmacological treatments for substance use where participants can attend three[22] or sometimes daily dosing sessions[23], but instead of dosing, participants in this study can have up to three counselling or counselling and CM sessions. Although the above procedure requires significant participant commitment, it has important theoretical and practical advantages. For example, the theory of behavioural momentum suggest rates of the behaviour are a function of reinforcement history[24], where higher rates of reinforcement are related to greater persistence of the target behaviour despite disruptors[25]. Consequently, we believe a greater opportunity to earn reinforcement will allow the possibility to result in higher reinforcement rates and greater persistence of performing the target behaviour (i.e., abstinence from gambling). Moreover, as gambling and substance use are often comorbid[26], where a common link between the two is impulsivity[27], we anticipate that some participants will show elevated impulsivity scores and have com-morbid substance use. Consequently, we will not exclude participants with these issues unless these issues interfere with treatment.

We believe investigating the effects of internet-delivered treatments are particularly relevant for rural populations[28], as these communities typically struggle to access counselling opportunities[29], where the rates of problematic gambling are sometimes higher for rural persons than the Albertan average[2]. Further, given that most telemedicine applications in Alberta are focused on delivering training or non-clinical services[29], and that the government of Alberta may legalize on-line gambling in the near future, gambling harm is likely to increase for rural and remote Albertans[30]. Also, as gambling disorder and the internet are ubiquitous phenomena in western countries, this study may be relevant to other rural and remote jurisdictions. However, to our knowledge, no previous on-line CM treatment for problem gambling has been previously reported. This suggests the current study is likely to offer new insights and treatment opportunities to communities struggling to access gambling counselling services.

AIM, HYPOTHESIS, OUTCOMES, AND PREDICTIONS

The aim of this study is to investigate the effects of internet-delivered Cognitive Behavioural Therapy (CBT) and internet-delivered CBT and CM (CM+) to rural and remote Albertan gamblers. The hypothesis of this study is that people with gambling disorder struggle to remain in treatment and stay abstinent from gambling because, typically, the benefits of counselling only accrue over several sessions while, with gambling, there is always the immediate possibility of winning which is oftentimes more attractive than non-gambling to those with gambling problems. The primary outcome measures are evidence of gambling abstinence, gambling, gambling symptomology, and gambling urge. We will also measure changes from pre-treatment to post-treatment in gambling urge, gambling losses, substance use, and impulsivity. Our predictions are: 1) The CM+ group will attend more treatment sessions than the CBT group, 2) The CM+ group will report a greater number of abstinent sessions compared to the CBT group, 3) and that gambling abstinence is related to gambling urge, impulsivity, and substance use.

METHOLODOGY

Design

The chosen methodology is a randomised clinical trial (pre-post) where participants are randomly allocated by a computer algorithm into one of two conditions; CM+, or CBT alone

for the treatment of gambling disorder. Allocation is made after the consent process. Dr. Christensen will administer the allocation process. Counselling will be provided free using Skype or Facetime video-conferencing internet applications. Participation in each condition will last 14 weeks: 12 weeks for treatment, and 2 weeks of assessments (one week prior to treatment and one week post treatment). Pre-treatment assessments (including demographic information) will take approximately 30-45 minutes, as will the post-treatment assessments. The progress check-ups by the Principal Investigator will take 5 to 10 minutes. These will only be conducted at the 4th week of counselling. A subset of treatment seekers, counsellors, and community/project stakeholders will also be chosen to participate in qualitative interviews to explore their experiences as well as their perceptions regarding the utility of the program for Albertans living in rural and remote areas. The qualitative interviews will take approximately 30-60 minutes.

Study Setting

The project will be run from the research offices of Dr. Christensen in the Faculty of Health Sciences at the University of Lethbridge. Participants can access the counselling from any location within the Canadian Research Initiative in Substance Misuse (CRISM): Prairie Node network (a network of drug use researchers, service providers, policy makers, and people with lived experience from the Canadian provinces of Alberta, Saskatchewan, and Manitoba) or their own homes. The purpose of the CRISM network is to facilitate collaboration between interested groups and to promote evidence based practices. Qualitative interviews will take place either in person at a mutually agreed private location or by telephone.

Partner

We have partnered with the Alberta Rural Development Network (ARDN) to recruit potential participants. The ARDN is a non-government organisation that works with post-secondary institutions to improve the lives of rural and remote Albertans. The ARDN uses a strengths based approach where the strengths of rural communities, post-secondary institutions, and community based organizations are utilized to develop rural Alberta through education, research, collaboration and networking. The ARDN is involved with the creation of community-driven projects, facilitates the creation of new partnerships, shares applied research and information, and works with rural communities to identify and address gaps in knowledge, service delivery, education, and training. The ARDN will also distribute our recruitment materials to their affiliate organisations.

Subjects

The study will recruit 54 treatment-seeking participants to achieve 44 (approximately 20% drop-out, similar to a recent CM study[22] treatment seeking disordered gamblers (n=22 per group). At study completion, we will also recruit a sub-set of treatment-seekers, counsellors, and ARDN affiliates for qualitative interviews.

Sample size

As this is a pilot study it has fewer participants than a fully powered study. However, based on similar studies we *cautiously* estimate that the CM+ treatment is sufficiently powered to observe significant treatment group effects based on the difference of two dependent means, from base-line to treatment completion (i.e., d=1.02, n=22, alpha = .05, where estimated power = 99%), although the CBT alone group is likely underpowered to observe a significant difference from base-line to

treatment completion (i.e., d=.28, alpha =.05, n=22, where estimated power = 35%[8]). Further, generic and moderately powered ANOVA repeated measures analyses with a within-between interaction, are estimated to slightly increase power when compared between groups (i.e., f=.25, alpha = .05, groups = 2, power = .90, number of measurements = 12, where estimated power = 92%).

Procedure

Recruitment: Participant recruitment is facilitated by the ARDN whose projects deal with thousands of homeless and at-risk people annually. The ARDN will email Family and Community Support Services (FCSS) offices and rural community-based organisations the study flyer. The ARDN will distribute study advertising material but will not refer any individuals to the study. A brief description of the study will also be posted on-line on the University of Lethbridge website. Treatment-seeking participants will contact Dr. Christensen by email to set-up a screening interview. Screening will be conducted by a telephone or videoconferencing interview. Consent and the remaining intake questions are completed on-line using a Qualtrics survey. We will continue to recruit until we have achieved the desired study enrollment number. Dr. Witcher will contact the treatment-seekers, counsellors, and ARDN affiliates for the qualitative interviews.

Eligibility: For treatment-seeking participants to be eligible for this study they must meet all of the following criteria: 18 to 70 years of age, capable of providing written consent, and endorse four of more DSM-V gambling disorder criteria gambling disorder[31, 32], gambled within the last month, live in a rural or remote location, and speak English. Based on a screening interview between the investigator and potential participant, evidence of the following will exclude participation: Medically unmanaged psychiatric or neurological disorder(s) likely to interfere with treatment. Participants with co-morbid substance use will not be excluded. Clients of the ARDN who are deemed at-risk of homelessness (i.e., financial stress, housing affordability issues, unsafe or problematic relationships, employment difficulties, etc.) or who are homeless will be purposively given the study advertising materials by ARDN affiliates. No coercion, implied or suggested will take place, and non-participation will likely not affect access to ARDN services. Inclusion and exclusion criteria for the treatment-seekers will be determined by our screening procedures. The eligibility criteria for counsellors is that they must have counselled a treatment-seeker from treatment start to completion. The eligibility criteria for the ARDN affiliates is that they must have participated in the study.

Group Allocation: Eligible participants will be randomly allocated by a computer algorithm prior to study commencement where the groups have the same number of participants. There is no participant or counsellor blinding as counsellors inform the CM+ group of their session earnings at each session while the counsellors will inform the CBT group they will not receive study credit for session attendance or evidence of abstinence.

Contingency Management (CM+): This is a treatment where participants earn study credit for treatment attendance and for providing evidence of gambling abstinence. Abstinence is defined as either financial evidence (cash withdrawals can be satisfactorily explained) or the collaboration by the significant other than the participant has not gambled since the previous session. Study credit is added to study accounts that can be redeemed for goods and services available at a variety of on-line businesses (e.g., Amazon, Walmart, etc.). Alternatively, treatment-seeking participants can request gift cards from local businesses. Attendance at Skype/Facetime counselling sessions earns 5 points each worth $0.10, providing evidence of abstinence (e.g., bank statements where cash withdrawals can be explained to the satisfaction of the counsellor) earns 10 points each worth $0.20, while corroboration by significant others earns 5 points each worth $0.10. Subsequent consecutive

online attendance and providing evidence of abstinence increases the value of these outcomes by 1 point, where an additional $10.00 of study credit is available for each set of three non-overlapping consecutive weeks of attendance. Participants also receive a study completion bonus of $50 study credit. Submission of evidence of gambling behaviour or non-attendance at an on-line counselling session re-sets subsequent points to the starting level. Submission of abstinence evidence in three consecutive sessions will return the value of subsequent points to the earnings rate before the reset. Points, once earned, cannot be lost. The maximum possible amount that could be earned over the 12-week program is $450 in study credit. These rates of payments, bonuses, and design are similar to CM substance use treatment studies[22]. The CM procedure is implemented as part of each CBT counselling session for approximately 10 minutes at the start of the session where the counsellors explicitly state "do you have any evidence for gambling abstinence today". Counsellors maintain the tally of study credit and this is shared on a secure servers with the primary investigator. The counsellors and participant negotiate the counselling schedule. Study credit is available immediately after verification from the counsellor. The primary investigator contacts participants who have dropped out to arrange for payment of any outstanding study credit. Payments are made by gift-cards or personal cheque (if less than $10).

Cognitive Behavioural Therapy (CBT): CBT is currently considered "best practice" for the treatment of problem gambling, as noted in the National Health and Medical Research Council (Australia) endorsed Clinical Guidelines for problem and pathological gambling treatment[30]. CBT is typically a semi-structured approach for delivering cognitive behavioural therapy addressing the participant's experiences, thoughts, and emotions relating to their gambling[34]. Counsellors begin by assessing the client's problematic gambling within the context of other presenting issues, life circumstances, and individual and systemic factors[35]. Treatment plans are developed with consideration for each individual's history and needs and rely on the establishment of a collaborative therapeutic working alliance[36]. CBT may involve a variety of specific techniques or interventions tailored to each client's specific presentation, with a focus on understanding patterns involved in gambling behavior. Techniques include psychoeducation, behavioural interventions, and cognitive strategies. Psychoeducation about the etiology of problem gambling may form an important aspect of this therapy as clients are encouraged to identify patterns in their gambling behaviours, including antecedents to gambling such as certain events, mood states, or thoughts[37]. Developing positive coping strategies, including self-regulation or stress management and mindfulness-based techniques are examples of behavioural interventions. For example, clients can identify an anxious feeling that leads them to want to gamble, and can practice a mindful breathing technique to decrease anxiety[35]. Behavioural strategies may also involve exploring new activities or hobbies, and making changes in lifestyle in order to avoid certain triggers[37]. Cognitive strategies include identifying and distinguishing between thoughts and emotions, and reframing habitual thought distortions that are involved in patterns of gambling[36]. For example, thoughts such as "I will only spend twenty dollars" can be analyzed through a thought log, and replaced with more realistic thoughts. Participants are can attend on-line counselling sessions three times a week for approximately 12 weeks. However, based on a similar terrestrial CM study, participants will most likely attend only one session per week. All participants will receive individual counselling from an experienced counsellor/therapist.

Counsellor Safety Measures

Counsellors will regularly check-in with the primary investigator and also with each other across the course of the study. Significant issues will be brought to the attention of the University of Lethbridge's Human Subject Research Committee. Further, graduate student counsellors will receive bi-weekly clinical supervision from Dr. Leighton where they will discuss participant progress and study issues. In general, the graduate student counsellors have either experience in the area and/or have graduated from the University of Lethbridge undergraduate Addictions Counselling program (or equivalent). The student counsellors are also overseen by their practicum supervisor, who is a University colleague.

Counsellor Training

All counsellors have been trained in CBT through their studies in the Addiction Counselling program or previous training/experiences. Further, each counsellor is given a CBT text and the study protocol and consent form to review prior to counselling. Finally, all counsellors are given instruction on the CM procedure by the primary investigator.

Fidelity

CM program fidelity will be assessed by assessing supplied evidence of treatment attendance, financial statements, significant other reports, and inspection of CM spreadsheets and the CM calendar. Standard care fidelity will be assessed based on audio recordings of counselling sessions and assessing clinician responses for type of treatment by an experienced clinician or counsellor/therapist who is not a member of the research team. A sample CBT session from each counsellor will be obtained. A CBT check-list was developed from a recent gambling text[34]. Approximately 10% of participants will have one session assessed. The principal investigator will remove any identifying information from the audio-files before fidelity checks are made. The audio-recordings are not part of the research but part of our study adherence procedures.

Measures

Participants will be tested pre- and post-treatment using a variety of demographic, clinical, psychological, and behavioural measures. Please see Table 1 for when an item is administered.

*DSM-V Gambling Disorder Criteria***.** This is a series of nine criteria from the Diagnostic and Statistical Manual for Mental Disorders-V criteria[32]. It specifies gambling disorder severity into three categories; mild, moderate, and severe, and if appropriate, the type of remission and temporal clustering of criteria endorsement.

Barrat Impulsivity Scale (BIS[37]). Barratt and colleagues developed this test to measure an impulsivity construct that is orthogonal to anxiety but related to similar personality traits, such as extraversion and sensation seeking. The BIS-11 is made up of three subscales: attentional impulsiveness (e.g. I get easily bored when solving thought problems), motor impulsiveness (e.g. I do things without thinking), and non-planning impulsiveness (e.g. I am more interested in the present than the future). Patton et al.[37] reported good internal consistency scores for the BIS-11 total score (0.79 to 0.83) for clinical and non-clinical populations.

Gambling Urges Scale (GUS[38]). Raylu and Oei adapted an alcohol-related urge scale to assess gambling urges with the intent to provide a quick screening tool. They created a 6-item Gambling Urge Questionnaire and analysed the responses from 968 community-based participants. Factor analysis using half of the sample indicated a 1-factor solution that accounted for 55.18% of the total variance. This was confirmed using confirmatory factor

analysis with the other half of the sample. Reports of the concurrent, predictive, and criterion-related validity of the GUS suggest that the GUS is a valid and reliable instrument for assessing gambling urges[38].

Delay Discounting (DD[39]). This task assesses participant's "impulsive" versus "far-sighted" behavioural strategies. Participants are presented with a series of hypothetical scenarios in which they determine the relative value of a delayed "reward" (e.g., delayed money) to an immediate "reward" using different delays (e.g., 1 day to 25 years) and magnitudes (e.g., $31, $85). For example, a participant may be asked to choose between hypothetical alternatives such as $55 in 7-days' time and $20 immediately. Measures of discounting rate are obtained.

The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST[40]). The ASSIST was recently developed for the World Health Organization (WHO) by an international group of substance abuse researchers to screen for problem or risky use of tobacco, alcohol, cannabis, cocaine, amphetamine-type stimulants, sedatives, hallucinogens, inhalants, opioids and 'other drugs' that do not fall into the previous 9 categories. The ASSIST was found to have high Internal Consistency (alpha > 0.80), correlated well against similarly worded items of other questionnaires, and good concurrent validity with a range of substance use and dependence measures[40].

Gambling Symptom Assessment Scale (G-SAS[41]). This is a 12-item self-rated Likert scale (0-4) designed to assess the change of gambling symptoms during treatment. It detects changes in gambling duration and urges, thoughts and preoccupation, control, emotional distress, and adverse personal consequences as a result of gambling in the last seven days. Test-retest reliability showed good correlation (n = 58; r = .70), and item consistency (Alpha = 0.89), while convergent validity compared favourably with another gambling index over a 10 week period (n = 48; r scores were .68 to .82)[41].

Gambling: At each session counsellors will report session attendance, evidence of abstinence, and collaboration by significant others of gambling abstinence. The counsellor will also record participant self-reports of net gambling losses, time spent gambling, and frequency of gambling sessions.

Table 1: Assessment Schedule

			Week											
Item	**Screening**	**Assessment: On-line Survey**	**1**	**2**	**3**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**Trial End**
Consent		✓												
D	✓	✓												
DSM-V	✓													
BIS		✓												✓
GUS		✓												✓
DD		✓												✓
G-SAS		✓												✓
ASSIST		✓												✓
G	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Key:
D: demographics
DSM-V: Gambling Disorder
BIS: Barrat Impulsivity Scale
GUS: Gambling Urges Scale
DD: Delay Discounting
G-SAS: Gambling Symptom Assessment Scale
ASSIST: The Alcohol, Smoking and Substance Involvement Screening Test
G: Evidence of Gambling Behaviour

Compensation

All treatment seeking participants will receive a $25 study credit for completing pre-treatment measures and an additional $50 study credit for completing post-treatment measures. These monies are paid in physical gift cards or as on-line credit at selected on-line stores (they cannot be used as cash), and are in addition to the earnings received by the CM+ group. All unexpended study credit lower than the minimum gift card amount of $10 will be credited to participants into their nominated store account or a personal cheque will be posted to them. Alternatively, treatment-seeking participants can request gift cards from local businesses. Treatment-seeking participants can indicate their preference on a consent form. Counsellors and ARDN affiliates will not receive compensation for answering the study evaluation questions. Treatment-seekers who participate in the qualitative evaluation component will receive a nominal payment of a $10 gift card.

Data Management

Participant, counsellor, and affiliate information will be held in secure locked cabinets or on password protected computers. The counselling location is in Dr Christensen's research room (Markin Hall 4132, University of Lethbridge), while the screening is conducted in Dr. Christensen's office (3011 Markin Hall, University of Lethbridge). The counselling is conducted on-line using free videoconferencing applications where participants are advised of the study risks, including data interception, and the procedures we use to mitigate risks. All identifiable data will be retained for 5 years and then shredded or deleted. Non-identifiable data will be kept by the principal investigator. Only the research team will have access to the data. The monitoring of the data will be the responsibility of the investigators.

Ethics and Dissemination

Treatment-seeking participants will respond to study advertisements distributed by the Alberta Development Network, advertisements in rural media, and study information from self-exclusion packages and rural casinos. Treatment-seeking participants contact Dr Christensen for a screening interview. The consent process occurs immediately after screening (or when the participant is available) where the study is explained by Dr. Christensen. Treatment-seeking participants will be informed of the right to withdraw from the study throughout the consent process and this right is included in the consent form. Treatment-seeking participants who wish to withdraw from the study will have their information destroyed except for their eligibility criteria and pre-treatment scores. This caveat is described in the consent form. If treatment-seeking participants express an interest in the study they are then directed to the Qualtrics site where they will complete a consent form on-line before entering into the pre-treatment measures. Treatment-seeking participants will type their name stating they consent to participate in the study. Treatment-seeking participants are then contacted by email to set-up their first counselling session. Treatment-seeking participants are randomly assigned to the CM+ or CBT group after consent. We report the random assignment of treatment-seeking participants to the treatment groups in the consent form and in the consent process to fully disclose our procedures to potential participants. All treatment-seeking participants receive free counselling and are compensated for completing the study assessments. Counsellors who notice distress in treatment-

seekers will stop counselling and seek to provide help or arrange alternative help for the participant (this is part of our protocol).

A sub-set of treatment-seekers, counsellors and ARDN affiliates will be contacted by Dr. Witcher to participate in qualitative interviews. Dr Witcher will conduct the qualitative interviews. Treatment-seekers who consent to the main study will also be asked to consent to follow-up procedures including a qualitative interview. Only those treatment-seekers that indicate their consent for the qualitative interview will be contacted. Dr. Witcher will contact the counsellors if they are willing to participate in an interview to discuss their experiences as counsellors in the study. ARDN Executive Director Dee Ann Benard will provide a list of ARDN affiliates to Dr Witcher where he will contact the affiliates to see if they are willing to participate in an interview to discuss their experiences as affiliates in the study. Dr. Witcher will obtain written consent from the counsellors and ARDN affiliates before the interview. For the telephone interviews, Dr Witcher will post a self-addressed envelope containing the consent form and wait for the return of a signed consent form before interviewing the participant. The investigators will provide annual reports to the University of Lethbridge Human Subject Ethics committee and report any adverse events to this committee. Amendments will be submitted to this committee.

Participant anonymity will be partially protected as the study team members will have access to the participants' identities. Participant identities will only be shared to outside groups when the participant consents to release of their identities to non-Alberta Health Service (AHS) providers. No release of information will be requested from AHS. The clinician/therapist scoring treatment fidelity will be provided with a redacted audio-recording of the standard treatment sessions. The principal investigator will digitally redact the audio-recorded sessions using audacity (a free audio editor). Papers emanating from this study will only report aggregate data so no individual can be identified from this information. Referrals will consist of providing the participant with the contact information of services appropriate for their needs. Further, as the consent information and assessment data are held on secure Qualtrics servers and the counselling is delivered on internet applications there is a very unlikely possibility that this information can be intercepted or accessed. This information is explained in the treatment-seeking participant consent form.

Participant information will be held in locked rooms and cabinets that only the study team has access to (i.e., Markin Hall rooms M4132 and M3011) and on password protected computers in those rooms. Only the investigators will have access to this data except when a participant consents to release information to Non-AHS health service providers. The information that may be released are study participation, the purpose of the study, nature of study participation, and participant progress. The release of information process will be explained in the consent process and is included on the consent form. Consent and assessment data will be held on the secure Qualtrics website and this is explained in the consent process and is stated in the consent form. All data will be retained for 5 years and then shredded or deleted. All investigators will have the final de-identified dataset. Sharing of the de-identifiable requires consent from all investigators. No investigators will share the identifiable dataset.

No information that identifies a participant will be released into the public domain. Participants have the right to review their information at any stage of the study. They can also withdraw from the study at any stage where only the treatment-seeker eligibility and intake data will be included in the study. These caveats are included in the consent form.

All participants can request a lay summary of the results by contacting the principal investigator. His contact information is on the consent form. Treatment-seeking participants will be sent an electronically signed copy of the consent form. In addition, treatment-seeking participants will have access to a generic study consent form for the duration of the study on the Qualtrics study website. Treatment-seeking participants can also contact the primary researcher for a copy of the consent form. Counsellors and ARDN affiliates who participated in the qualitative interviews will receive a copy of the signed consent form. The investigators intend to publish from the de-identifiable dataset in peer-reviewed academic journals. The investigators will also present summary information to the funder.

At treatment completion, participants will be referred to the free AHS help-line where they can receive counselling and psychoeducation services from local state run counselling services. Data on participant attendance in post-treatment services will be systematically collected at follow-up.

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Statistical Analysis

Participants will be primarily compared on study attendance and retention measures and gambling behaviour (predictions one and two) using parametric analyses (i.e., t-tests), we will also analyse abstinence using repeated measures, descriptive scores of participant demographics, and where appropriate, non-parametric tests (e.g., survival plots for study retention). Additionally, comorbid variables will be treated as covariates in subsequent ANCOVA analyses (prediction three). We will also test whether there is a relationship between abstinence and, study retention and session attendance. Further, clinical outcomes will be analysed based on counsellor type: graduate student or faculty member. Although we anticipate no missing data, where necessary, we will use data appropriate imputation methods (i.e., median values for quantitative scores). When participants fail to attend a scheduled session this is evidence of a break in their continuous treatment sessions and when they fail to produce evidence of gambling abstinence this is evidence of gambling behaviour.

Qualitative Analysis

Regarding the qualitative data obtained, thematic analysis procedures will be utilized to generate themes with respect to perceptions of success and perceived constraints or challenges from study participants, counsellors, and stakeholders.

Study Evaluation

A unique aspect of the study is its focus on Albertans residing in rural and remote areas. To properly situate our findings in terms of other contingency management and internet-delivered treatment studies, and potentially inform other studies in rural and/or remote areas, we will conduct a mixed methods feasibility assessment. For example, quantitative data will be obtained with respect to recruitment and participation rates (analyzed by location, demographics, and co-morbidity variables), and rates of retention/program completion. Further, we will conduct a cost-

benefit analysis investigating the relative benefits or costs per participant from this study. Our analyses will also describe the management and support systems necessary to implement this project in other agencies. Post-treatment, Dr Witcher will contact a sub-set of treatment-seeking participants, as well as counsellors, and ARDN affiliates regarding perceptions of success and perceived constraints or challenges to treatment.

DISCUSSION

This will be the first randomised controlled study examining the added impact of contingency management to cognitive behavioural therapy using internet delivered counselling by videoconference for the treatment of gambling disorder. Further, this study is also unique as it targets rural and remote Albertans. Contingency management appears well suited to the treatment of gambling disorder as gambling is maintained in part by the association between gambling and immediate reinforcement where CM competes with these associations by immediately reinforcing gambling abstinence, thereby reversing these associations[14]. However, this assertion needs further evidence for us to have confidence that the CM procedure competes with gambling and reverses the association between gambling and reinforcement.

Persons with gambling disorder typically experience shame and stigma[42]. Therefore, internet delivered treatments are likely to appeal to those who are hesitant about attending traditional counselling programs[42], and may alleviate participant concerns regarding community members noticing their attendance at counselling services. Furthermore, as our target group is rural and remote Albertans, participants need not travel to access counselling and health services that are typically located in urban settings, often at some distance to rural people. Similarly, the ease of access provided by the internet to rural persons is also likely to improve participant attendance and retention[43, 44].

Another important aspect of this study is the opportunity for participants to attend up to three sessions per week and receive reinforcement from the demonstration of more than one behaviour. By comparison, traditional gambling counselling typically only occurs once a week where treatment gains are sometimes slow to start and accumulate[45]. However, as this study provides reinforcement from multiple sources, has a relatively intense reinforcement schedule, and bonuses for sustained performance, it is designed to motivate continuing and consecutive abstinence. This reinforcement schedule is congruent to another operant behavioural theory similar to contingency management: behavioural momentum. Behavioural momentum was developed from discriminant-operant relations where the rate of reinforcement and reinforcement histories influence response rates. The relationship between rate of reinforcement and behaviour is thought to be analogous to the second law of motion in Newtonian physics (i.e., the velocity of an object in motion is proportional to the magnitude of the opposing force and opposite to the mass of the object[25]), where voluntary behaviour (i.e., gambling abstinence) is analogous to 'velocity' and the reinforcement history is similar to the 'mass' of an object[46]. Theoretically, as the rate of reinforcement increases so does the performance of the target behavior; increasing the likelihood the target behaviour will be repeated and reducing the effects of the disrupter (i.e., in this case the disruptor is the reinforcing effects from gambling). The assumption is, as the performance of sustained abstinence increases, so does the 'mass' for abstinence and the 'velocity' of future abstinence. Numerous studies show evidence of behavioural momentum when the target behaviour is sufficiently strong enough to successfully compete with the alternative[24]. Consequently, as participants can attend up to three times as many counselling

sessions as treatment as usual, and can obtain reinforcements from multiple sources, this study is designed to generate greater behavioural 'mass' than traditional counselling, hopefully resulting in better attendance and retention and higher rates of abstinence post-treatment than the CBT only group.

LIMITATIONS

As previously noted, the study is powered to observe an effect for the CM+ group, but as previous meta-analyses report, the effect size for the CBT group is likely to show no significant effect. Further, as treatment is delivered using the internet, if a participant cannot reliably access the internet this is likely to impede treatment adherence. However, if participants have legitimate issues accessing the internet they will not be penalized, rather we will re-schedule sessions when the participant regains a stable internet connection. In addition, if the study credit is less powerful than gambling, study credit will not be able to successfully compete with gambling. Also, if participants have no verifiable records to report abstinence (e.g., they have no bank accounts), they will not be able to earn study credit based on financial records. Moreover, as only one study reported CM as a treatment for gambling[12], our results need to be interpreted with caution. Also, as the CM procedure outlined here is based on the pharmacological substance use literature[22], any material difference between disorders may require alternative implementations for CM to be successful[31], and this must be considered when reviewing our results. Finally, participants are randomly allocated to the CM+ or CBT groups, possible confounding variables might bias group allocation. Consequently, we will check for known confounders in the analyses (i.e., gender, gambling severity, primary gambling activity).

CONCLUSIONS

CM is an effective treatment approach for improving treatment attendance and retention where the provision of small incentives improves attendance and retention rates and can successfully compete with drug-taking[22, 43]. Recently, this approach has been proposed as a treatment for gambling disorder[14, 16] as gambling disorder treatment programs often have high treatment drop-out rates[4], where reinforcing gambling abstinence may be more rewarding for the gambler than gambling[14]. Further, treatment attendance and retention rates may additionally rise when treatment is delivered using computer or internet approaches[16, 47]. These issues are especially relevant for rural and remote Albertans who face significant challenges accessing counselling services[29]. Consequently, this study may provide important evidence for addressing gambling treatment attendance and retention issues, as well assessing the efficacy of using the internet and video conferencing to provide treatment to rural and remote persons.

Contributorship Statement: All investigators have made or will make significant contributions to the design or implementation of the study. All investigators contributed to the writing of the protocol manuscript. Roles: Dr. Darren R Christensen supervises and designed the study, Dr. Chad S. G. Witcher supervises the qualitative evaluation and contributed to the study design, Dr. Trent Leighton supervises the graduate student counsellors and contributed to the study design,

Dr. Rebecca Hudson-Breen counselled participants and contributed to the study protocol, Mr. Samuel Ofori-Dei contributed to the writing of the protocol manuscript and assists with the data collection.
Competing Interests: There are no competing interests.
Funding: This work was supported with finance by the CRISM: Prairie Node. The funder made design suggestions in the application process. It will have no further role in the study.
Data Sharing Statement: All investigators will have the final de-identified dataset. Sharing of the de-identifiable requires consent from all investigators. No investigators will share the identifiable dataset**.**
Date: 21/07/2017
Version No: 2

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	2-6
Protocol version	3	Date and version identifier	15
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14-15
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14-15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2-3
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3-4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	1-11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3, 7-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4-5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	5
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	5
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	5
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	5

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	10-12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12-13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12-13
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	DMC not required. Oversight provided by the UoL ethics committee.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13-14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13-14
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13-14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13-14

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5, 13-14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13-14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13-14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14-15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached document
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Piloting the addition of contingency management to best practice counselling as an adjunct treatment for rural and remote disordered gamblers: study protocol

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Keywords:	gambling, protocol, contingency management, on-line, behavioural momentum, treatment

Title: Piloting the addition of Contingency Management to best practice counselling as an adjunct treatment for rural and remote disordered gamblers.

Authors: Darren R. Christensen[1], Chad S. G. Witcher[2], Trent Leighton[1], Rebecca Hudson-Breen[3], & Samuel Ofori-Dei[2]

Sponsor and Correspondence: Darren Christensen; darren.christensen@uleth.ca

Funder: CRISM Prairie Node

Affiliations:
[1]Addictions Counselling, Faculty of Health Sciences, University of Lethbridge
[2]Public Health, Faculty of Health Sciences, University of Lethbridge
[3]University of Alberta, Educational Psychology

Roles: Darren Christensen supervises and designed the study, Chad Witcher supervises the qualitative evaluation and contributed to the study design, Trent Leighton supervises the graduate student counsellors and contributed to the study design, and Rebecca Hudson-Breen counselled participants and contributed to the study protocol. Samuel Ofori-Dei contributed to the writing of the protocol manuscript and assists with the data collection.

ABSTRACT

Introduction: Problematic gambling is a significant Canadian public health concern that causes harm to the gambler, their families, and society at large. However, a significant minority of gambling treatment seekers drop-out prior to the issue being resolved, where those with higher impulsivity scores have the highest drop-out rates. The aim of this study is to investigate the effects of internet-delivered Cognitive Behavioural Therapy (CBT) and internet-delivered CBT and CM (CM+) to rural and remote Albertan gamblers**.** Contingency Management (CM) is a successful treatment approach for substance dependence that uses small incentives to reinforce abstinence. This approach may be suitable for the treatment of gambling disorder. Further, internet delivered CM may hold particular promise in rural contexts, as these communities typically struggle to access traditional clinic based counselling opportunities.

Methods and analysis: 54 adults with gambling disorder will be randomised into one of two conditions; Contingency Management and Cognitive Behavioural Therapy (CM+), or Cognitive Behavioural Therapy alone (CBT). Gambling will be assessed at intake, every treatment session, post-treatment, and follow-up. The primary outcome measures are treatment attendance, gambling abstinence, gambling, gambling symptomology, and gambling urge. In addition, qualitative interviews assessing study experiences will be conducted with the supervising counsellor, graduate student counsellors, and a sub-set of treatment-seekers. This is the first study to use contingency management as a treatment for gambling disorder in a rural and remote population.

Ethics and dissemination: This study is approved by the University of Lethbridge Human Subject Research committee (#2016-080). The investigators plan to publish the results from this study in academic peer-reviewed journals. Summary information will be provided to the funder. Trial registration number: NCT02953899 (ClinicialTrials.gov); Pre-results

Strengths and Limitations:

- First study to investigate the effect of providing counselling and contingency management for the treatment of gambling disorder in a rural and remote population.

- Internet delivery may provide a cost-efficient approach for delivery of counselling services.
- Contingency management is likely to improve treatment attendance and study retention.
- Sample size may be unpowered to detect changes in gambling behaviour and symptomology in the CBT condition.
- Irregular internet availability in rural and remote regions may impede study accessibility.

INTRODUCTION

Problematic gambling is a significant Canadian public health concern that causes harm to the gambler, their families, and society at large[1]. Approximately 4% of Albertans gamble in problematic ways resulting in significant financial losses, personal distress, broken relationships, and in some cases, suicide[2, 3]. However, the numbers of Albertans seeking treatment for problem gambling appears to be declining, despite the relatively consistent problem gambling prevalence rates[2]. Further, 33% - 50% of gambling treatment seekers drop out from treatment prior to resolving the issue, where those with higher impulsivity scores are more likely to drop-out [4]. One possible reason for these issues is the lack of immediate benefits clients gain from treatment attendance.

Contingency Management (CM) is a treatment approach that has superior retention and treatment efficacy compared to traditional approaches for substance and alcohol dependence[5]. CM uses motivational incentives, typically vouchers that are exchangeable for retail goods and services, to reward participants for providing evidence of the target behaviour. Conversely, rewards are withheld when the participant fails to perform the target behaviour. CM has been successfully used in several countries for various addictive substances[6, 7].

Meta-analyses have consistently found CM studies to report improved clinical outcomes and large treatment effect sizes[8, 9]. Further, CM studies typically report a greater likelihood of program completion than standard care[10], where the positive effects of CM persist for participants many months after treatment completion[11]. Researchers are now suggesting that contingencies are important factors in the treatment of gambling[12-14], as the variable but regular receipt of gambling wins are associated with the development of problematic gambling[15], where CM uses the same approach to reverse these associations.

The CM procedure has three basic components 1) target behaviours are identified, 2) reinforcers (sometimes called motivational incentives or rewards) are provided when evidence for the target behaviours are produced, and 3) reinforcers are unavailable when a participant fails to perform the target behaviour[16]. Further, CM treatment efficacy is improved by increasing the rate of reinforcers for continued performance of the target behaviour and resetting of the rate after a lapse[11], delivering the reinforcer immediately after providing evidence of the target behaviour[17], and increasing the magnitude of the reinforcer[18, c.f. 19].

The only published study of CM as a treatment of problematic gambling found significant reductions in gambling frequency, time spent gambling, money spent gambling, and net losses[12]. However, the target behaviours for reinforcement were participant selected goals, and typically were non-abstinence related. Although this approach is congruent with CM approaches for the treatment of other behaviours[20], the typical CM approach in substance abuse treatment is to select abstinence as the target behaviour[21].

This study is based on the dosing schedule of pharmacological treatments for substance use where participants can attend three[22] or sometimes daily dosing sessions[23], but instead of dosing, participants in this study can have up to three counselling or counselling and CM sessions. Although the above procedure requires significant participant commitment, it has important theoretical and practical advantages. For example, the theory of behavioural momentum suggests rates of behaviour are a function of reinforcement history[24], where higher rates of reinforcement are related to greater persistence of the target behaviour despite disruptors[25]. Consequently, we believe a greater opportunity to earn reinforcement will allow the possibility of higher reinforcement rates and greater performance of the target behaviour (i.e., abstinence from gambling). Moreover, as gambling and substance use are often comorbid[26], where a common link between the two is impulsivity[27], we anticipate that some participants will show elevated impulsivity scores and have co-morbid substance use. Consequently, we will not exclude participants with these issues unless these issues interfere with treatment.

We believe investigating the effects of internet-delivered treatments are particularly relevant for rural populations[28], as these communities typically struggle to access counselling opportunities[29], where the rates of problematic gambling are sometimes higher for rural persons than the Albertan average[2]. Further, given that most telemedicine applications in Alberta are focused on delivering training or non-clinical services[29], and that the government of Alberta may legalize on-line gambling in the near future, gambling harm is likely to increase for rural and remote Albertans[30]. Also, as gambling and the internet are ubiquitous phenomena in western countries, this study may be relevant to other rural and remote jurisdictions. However, to our knowledge, no previous on-line CM treatment for problem gambling has been previously reported. This suggests the current study is likely to offer new insights and treatment opportunities to communities struggling to access gambling counselling services.

AIM, HYPOTHESIS, OUTCOMES, AND PREDICTIONS

The aim of this study is to investigate the effects of internet-delivered Cognitive Behavioural Therapy (CBT) and internet-delivered CBT and CM (CM+) to rural and remote Albertan gamblers. The hypothesis of this study is that people with gambling disorder struggle to remain in treatment and stay abstinent from gambling because, typically, the benefits of counselling only accrue over several sessions while, with gambling, there is always the immediate possibility of winning which is oftentimes more attractive than non-gambling to those with gambling problems. The primary outcome measures are evidence of gambling abstinence, gambling, gambling symptomology, and gambling urge. We will also measure changes from pre-treatment to post-treatment in gambling urge, gambling losses, substance use, and impulsivity. Our predictions are: 1) The CM+ group will attend more treatment sessions than the CBT group, 2) The CM+ group will report a greater number of abstinent sessions compared to the CBT group, 3) and that gambling abstinence is related to gambling urge, impulsivity, and substance use.

METHOLODOGY

Design

The chosen methodology is a randomised clinical trial (pre-post) where participants are randomly allocated by a computer algorithm into one of two conditions; CM+, or CBT alone for the treatment of gambling disorder. Allocation is made after the consent process. Dr. Christensen will administer the allocation process. Counselling will be provided free using

Skype or Facetime video-conferencing internet applications. Participation in each condition will last 14 weeks: 12 weeks for treatment, and 2 weeks of assessments (one week prior to treatment and one week post treatment). Pre-treatment assessments (including demographic information) will take approximately 30-45 minutes, as will the post-treatment assessments. The progress check-ups by the Principal Investigator will take 5 to 10 minutes. These check-ups will be conducted on the 4th week of counselling. A subset of treatment seekers, counsellors, and community/project stakeholders will also be chosen to participate in qualitative interviews to explore their experiences as well as their perceptions regarding the utility of the program for Albertans living in rural and remote areas. The qualitative interviews will take approximately 30-60 minutes.

Study Setting

The project will be run from the research offices of Dr. Christensen in the Faculty of Health Sciences at the University of Lethbridge. Participants can access the counselling from any location within the Canadian Research Initiative in Substance Misuse (CRISM): Prairie Node network (a network of drug use researchers, service providers, policy makers, and people with lived experience from the Canadian provinces of Alberta, Saskatchewan, and Manitoba) or from their own computer. The purpose of the CRISM network is to facilitate collaboration between interested groups and to promote evidence based practices. Qualitative interviews will take place either in person at a mutually agreed private location or by telephone.

Partner

We have partnered with the Alberta Rural Development Network (ARDN) to recruit potential participants. The ARDN is a non-government organisation that works with post-secondary institutions to improve the lives of rural and remote Albertans. The ARDN uses a strengths based approach where the strengths of rural communities, post-secondary institutions, and community based organizations are utilized to develop rural Alberta through education, research, collaboration and networking. The ARDN is involved with the creation of community-driven projects, facilitates the creation of new partnerships, shares applied research and information, and works with rural communities to identify and address gaps in knowledge, service delivery, education, and training. The ARDN will also distribute our recruitment materials to their affiliate organisations.

Subjects

The study will recruit 54 treatment-seeking participants to achieve 44 (approximately 20% drop-out, similar to a recent CM study[22]) treatment seeking disordered gamblers (n=22 per group). At study completion, we will also recruit a sub-set of treatment-seekers, counsellors, and ARDN affiliates for qualitative interviews.

Sample size

As this is a pilot study it has fewer participants than a fully powered study. However, based on similar studies we *cautiously* estimate that the CM+ treatment is sufficiently powered to observe significant treatment group effects based on the difference of two dependent means, from base-line to treatment completion (i.e., d=1.02, n=22, alpha = .05, where estimated power = 99%), although the CBT alone group is likely underpowered to observe a significant difference from base-line to treatment completion (i.e., d=.28, alpha =.05, n=22, where estimated power = 35%[8]).

Further, generic and moderately powered ANOVA repeated measures analyses with a within-between interaction, are estimated to slightly increase power to observe a significant difference in treatment effects between groups (i.e., f=.25, alpha = .05, groups = 2, power = .90, number of measurements = 12, where estimated power = 92%).

Procedure

Recruitment: Participant recruitment is facilitated by the ARDN whose projects deal with thousands of homeless and at-risk people annually. The ARDN will email Family and Community Support Services (FCSS) offices and rural community-based organisations the study flyer. The ARDN will distribute study advertising material but will not refer any individuals to the study. A brief description of the study will also be posted on-line on the University of Lethbridge website. Treatment-seeking participants will contact Dr. Christensen by email to set-up a screening interview. Screening will be conducted by a telephone or videoconferencing interview. Consent and the remaining intake questions are completed on-line using a Qualtrics survey. We will continue to recruit until we have achieved the desired study enrollment number. Dr. Witcher will contact the treatment-seekers, counsellors, and ARDN affiliates for the qualitative interviews.

Eligibility: Treatment-seeking participants must meet all of the following criteria: 18 to 70 years of age, capable of providing written consent, and endorse four of more DSM-V gambling disorder criteria [31, 32], gambled within the last month, live in a rural or remote location, and speak English. Based on a screening interview between the investigator and potential participant, evidence of the following will exclude participation: Medically unmanaged psychiatric or neurological disorder(s) likely to interfere with treatment. Participants with co-morbid substance use will not be excluded. Clients of the ARDN who are deemed at-risk of homelessness (i.e., financial stress, housing affordability issues, unsafe or problematic relationships, employment difficulties, etc.) or who are homeless will be purposively given the study advertising materials by ARDN affiliates. No coercion, implied or suggested will take place, and non-participation will likely not affect access to ARDN services**.** Inclusion and exclusion criteria for the treatment-seekers will be determined by our screening procedures. The eligibility criteria for counsellors is that they must have counselled a treatment-seeker from treatment start to completion. The eligibility criteria for the ARDN affiliates is that they must have participated in the study.

Group Allocation: Eligible participants will be randomly allocated by a computer algorithm prior to study commencement where the groups have the same number of participants. There is no participant or counsellor blinding as counsellors inform the CM+ group of their session earnings at each session while the counsellors will inform the CBT group they will not receive study credit for session attendance or evidence of abstinence.

Contingency Management (CM+): This is a treatment where participants earn study credit for treatment attendance and for providing evidence of gambling abstinence. Abstinence is defined as either financial evidence (cash withdrawals can be satisfactorily explained) or the collaboration by the significant other than the participant has not gambled since the previous session. Study credit is added to study accounts that can be redeemed for goods and services available at a variety of on-line businesses (e.g., Amazon, Walmart, etc.). Alternatively, treatment-seeking participants can request gift cards from local businesses. Attendance at Skype/Facetime counselling sessions earns 5 points each worth $0.10, providing evidence of abstinence (e.g., bank statements where cash withdrawals can be explained to the satisfaction of the counsellor) earns 10 points each worth $0.20, while corroboration by significant others earns 5 points each worth $0.10. Subsequent consecutive online attendance and providing evidence of abstinence increases the value of these outcomes by 1 point, where an additional $10.00 of study credit is available for each set of three non-

overlapping consecutive weeks of attendance. Participants also receive a study completion bonus of $50 study credit. Submission of evidence of gambling behaviour or non-attendance at an on-line counselling session re-sets subsequent points to the starting level. Submission of abstinence evidence in three consecutive sessions will return the value of subsequent points to the earnings rate before the reset. Points, once earned, cannot be lost. The maximum possible amount that could be earned over the 12-week program is $450 in study credit. These rates of payments, bonuses, and design are similar to CM substance use treatment studies[22]. The CM procedure is implemented as part of each CBT counselling session for approximately 10 minutes at the start of the session where the counsellors explicitly state "do you have any evidence for gambling abstinence today". Counsellors maintain the tally of study credit and this is shared on a secure servers with the primary investigator. Study credit is available immediately after verification from the counsellor. The CM component ends and the CBT session starts when the counsellor states to the client "Now, let us begin with our session". The primary investigator contacts participants who have dropped out to arrange for payment of any outstanding study credit. Payments are made by gift-cards or personal cheque (if less than $10). The counsellors and participant negotiate the counselling schedule.

Cognitive Behavioural Therapy (CBT): CBT is currently considered "best practice" for the treatment of problem gambling, as noted in the National Health and Medical Research Council (Australia) endorsed Clinical Guidelines for problem and pathological gambling treatment[33]. CBT is typically a semi-structured approach for delivering cognitive behavioural therapy addressing the participant's experiences, thoughts, and emotions relating to their gambling[34]. Counsellors begin by assessing the client's problematic gambling within the context of other presenting issues, life circumstances, and individual and systemic factors[35]. Treatment plans are developed with consideration for each individual's history and needs and rely on the establishment of a collaborative therapeutic working alliance[36]. CBT may involve a variety of specific techniques or interventions tailored to each client's specific presentation, with a focus on understanding patterns involved in gambling behavior. Techniques include psychoeducation, behavioural interventions, and cognitive strategies. Psychoeducation about the etiology of problem gambling may form an important aspect of this therapy as clients are encouraged to identify patterns in their gambling behaviours, including antecedents to gambling such as certain events, mood states, or thoughts[37]. Developing positive coping strategies, including self-regulation or stress management and mindfulness-based techniques are examples of behavioural interventions. For example, clients can identify an anxious feeling that leads them to want to gamble, and can practice a mindful breathing technique to decrease anxiety[35]. Cognitive strategies include identifying and distinguishing between thoughts and emotions, and reframing habitual thought distortions that are involved in patterns of gambling[36]. For example, thoughts such as "I will only spend twenty dollars" can be analyzed through a thought log, and replaced with more realistic thoughts. Participants are can attend on-line counselling sessions three times a week for approximately 12 weeks. However, based on a similar terrestrial CM study, participants will most likely attend only one session per week. All participants will receive individual counselling from an experienced counsellor/therapist.

Counsellor Safety Measures

Counsellors will regularly check-in with the primary investigator and also with each other across the course of the study. Significant issues will be brought to the attention of the University of Lethbridge's Human Subject Research Committee.

Further, graduate student counsellors will receive bi-weekly clinical supervision from Dr. Leighton where they will discuss participant progress and study issues. In general, the graduate student counsellors have either experience in the area and/or have graduated from the University of Lethbridge undergraduate Addictions Counselling program (or equivalent). The student counsellors are also overseen by their practicum supervisor, who is a University colleague.

Counsellor Training

All counsellors have been trained in CBT during their studies in the University of Lethbridge's Addiction Counselling program or previous training/experiences. Further, each counsellor is given a CBT text, the CBT check-list, and the study protocol and consent form to review prior to counselling. Finally, all counsellors are given instruction on the CM procedure by the primary investigator.

Fidelity

CM program fidelity will be assessed by assessing supplied evidence of treatment attendance, financial statements, significant other reports, and inspection of CM spreadsheets and the CM calendar. Standard care fidelity will be assessed based on audio recordings of counselling sessions and assessing clinician responses for type of treatment by an experienced clinician or counsellor/therapist who is not a member of the research team. A sample CBT session from each counsellor will be obtained. The CBT check-list was developed from the CBT text[34] that counsellors receive prior to their first session. Approximately 10% of participants will have one session assessed. The principal investigator will remove any identifying information from the audio-files before fidelity checks are made. The audio-recordings are not part of the research but part of our study adherence procedures.

Measures

Participants will be tested pre- and post-treatment using a variety of demographic, clinical, psychological, and behavioural measures. Please see Table 1 for when an item is administered.

*DSM-5 Gambling Disorder Criteria***.** This is a series of nine criteria from the Diagnostic and Statistical Manual for Mental Disorders-5 criteria[32]. It specifies gambling disorder severity into three categories; mild, moderate, and severe, and if appropriate, the type of remission and temporal clustering of criteria endorsement. A recent archival analysis of the DSM-5 found the majority of datasets to report the DSM-5 to have excellent reliability and moderate to high validity scores[37].

Barrat Impulsivity Scale (BIS[38]). Barratt and colleagues developed this test to measure an impulsivity construct that is orthogonal to anxiety but related to similar personality traits, such as extraversion and sensation seeking. The BIS-11 is made up of three subscales: attentional impulsiveness (e.g. I get easily bored when solving thought problems), motor impulsiveness (e.g. I do things without thinking), and non-planning impulsiveness (e.g. I am more interested in the present than the future). Patton et al.[38] reported good internal consistency scores for the BIS-11 total score (0.79 to 0.83) for clinical and non-clinical populations.

Gambling Urges Scale (GUS[39]). Raylu and Oei adapted an alcohol-related urge scale to assess gambling urges with the intent to provide a quick screening tool. They created a 6-item Gambling Urge Questionnaire and analysed the responses from 968 community-based participants. Factor analysis using half of the sample indicated a 1-factor solution that accounted for 55.18% of the total variance. This was confirmed using confirmatory factor

analysis with the other half of the sample. Reports of the concurrent, predictive, and criterion-related validity of the GUS suggest that the GUS is a valid and reliable instrument for assessing gambling urges[39].

Delay Discounting (DD[40]). This task assesses participant's "impulsive" versus "far-sighted" behavioural strategies. Participants are presented with a series of hypothetical scenarios in which they determine the relative value of a delayed "reward" (e.g., delayed money) to an immediate "reward" using different delays (e.g., 1 day to 25 years) and magnitudes (e.g., $31, $85). For example, a participant may be asked to choose between hypothetical alternatives such as $55 in 7-days' time and $20 immediately. Measures of discounting rate are obtained.

The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST[41]). The ASSIST was recently developed for the World Health Organization (WHO) by an international group of substance abuse researchers to screen for problem or risky use of tobacco, alcohol, cannabis, cocaine, amphetamine-type stimulants, sedatives, hallucinogens, inhalants, opioids and 'other drugs' that do not fall into the previous 9 categories. The ASSIST was found to have high Internal Consistency (alpha > 0.80), correlated well against similarly worded items of other questionnaires, and good concurrent validity with a range of substance use and dependence measures[41].

Gambling Symptom Assessment Scale (G-SAS[42]). This is a 12-item self-rated Likert scale (0-4) designed to assess the change of gambling symptoms during treatment. It detects changes in gambling duration and urges, thoughts and preoccupation, control, emotional distress, and adverse personal consequences as a result of gambling in the last seven days. Test-retest reliability showed good correlation (n = 58; r = .70), and item consistency (Alpha = 0.89), while convergent validity compared favourably with another gambling index over a 10 week period (n = 48; r scores were .68 to .82)[42].

Gambling: At each session counsellors will report session attendance, evidence of abstinence, and collaboration by significant others of gambling abstinence. The counsellor will also record participant self-reports of net gambling losses, time spent gambling, and frequency of gambling sessions.

Table 1: Assessment Schedule

Item	Screening	Assessment: On-line Survey	Week 1	2	3	5	6	7	8	9	10	11	12	Trial End
Consent		✓												
Demographics	✓	✓												
DSM-V	✓													
BIS		✓												✓
GUS		✓												✓
DD		✓												✓
G-SAS		✓												✓
ASSIST		✓												✓
Gambling	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Key:
DSM-V: Gambling Disorder
BIS: Barrat Impulsivity Scale
GUS: Gambling Urges Scale
DD: Delay Discounting
G-SAS: Gambling Symptom Assessment Scale
ASSIST: The Alcohol, Smoking and Substance Involvement Screening Test
Gambling: Evidence of Gambling Behaviour

Compensation

All treatment seeking participants will receive a $25 study credit for completing pre-treatment measures and an additional $50 study credit for completing post-treatment measures. These monies are paid in physical gift cards or as on-line credit at selected on-line stores (they cannot be used as cash), and are in addition to the earnings received by the CM+ group. All unexpended study credit lower than the minimum gift card amount of $10 will be credited to participants into their nominated store account or a personal cheque will be posted to them. Alternatively, treatment-seeking participants can request gift cards from local businesses. Treatment-seeking participants can indicate their preference on a consent form. Counsellors and ARDN affiliates will not receive compensation for answering the study evaluation questions. Treatment-seekers who participate in the qualitative evaluation component will receive a nominal payment of a $10 gift card.

Data Management

Participant, counsellor, and affiliate information will be held in secure locked cabinets or on password protected computers. The counselling location is in Dr Christensen's research room (Markin Hall 4132, University of Lethbridge), while the screening is conducted in Dr. Christensen's office (3011 Markin Hall, University of Lethbridge). The counselling is conducted on-line using free videoconferencing applications where participants are advised of the study risks, including data interception, and the procedures we use to mitigate risks. All identifiable data will be retained for 5 years and then shredded or deleted. Non-identifiable data will be kept by the principal investigator. Only the research team will have access to the data. Data monitoring will be the responsibility of the investigators.

Ethics and Dissemination

Treatment-seeking participants will respond to study advertisements distributed by the Alberta Development Network, advertisements in rural media, and study information from self-exclusion packages and rural casinos. Treatment-seeking participants contact Dr Christensen for a screening interview. The consent process occurs immediately after screening (or when the participant is available) where the study is explained by Dr. Christensen. Treatment-seeking participants will be informed of the right to withdraw from the study throughout the consent process and this right is included in the consent form. Treatment-seeking participants who wish to withdraw from the study will have their information destroyed except for their eligibility criteria and pre-treatment scores. This caveat is described in the consent form. If treatment-seeking participants express an interest in the study they are then directed to the Qualtrics site where they will complete a consent form on-line before entering into the pre-treatment measures. Treatment-seeking participants will type their name stating they consent to participate in the study. Treatment-seeking participants are then contacted by email to set-up their first counselling session. Treatment-seeking participants are randomly assigned to the CM+ or CBT group after consent. We report the random assignment of treatment-seeking participants in the consent form and in the consent process to fully disclose our procedures to potential participants. All treatment-seeking participants receive free counselling and are compensated for completing the study assessments. Counsellors who notice distress in treatment-seekers will stop counselling

and seek to provide help or arrange alternative help for the participant (this is part of our protocol).

A sub-set of treatment-seekers, counsellors and ARDN affiliates will be contacted by Dr. Witcher to participate in qualitative interviews. Dr Witcher will conduct the qualitative interviews. Treatment-seekers who consent to the main study will also be asked to consent to follow-up procedures including a qualitative interview. Only treatment-seekers that indicate their consent for the qualitative interview will be contacted. Dr. Witcher will contact the counsellors if they are willing to participate in an interview to discuss their experiences as counsellors in the study. ARDN Executive Director Dee Ann Benard will provide a list of ARDN affiliates to Dr Witcher where he will contact the affiliates to see if they are willing to participate in an interview to discuss their experiences as affiliates in the study. Dr. Witcher will obtain written consent from the counsellors and ARDN affiliates before the interview. For the telephone interviews, Dr Witcher will post a self-addressed envelope containing the consent form and wait for the return of a signed consent form before interviewing the participant. The investigators will provide annual reports to the University of Lethbridge Human Subject Ethics committee and report any adverse events to this committee. Amendments will be submitted to this committee.

Participant anonymity will be partially protected as the study team members will have access to the participants' identities. Participant identities will only be shared to outside groups when the participant consents to release their identity to non-Alberta Health Service (AHS) providers. No release of information will be requested from AHS. The clinician/therapist scoring treatment fidelity will be provided with a redacted audio-recording of the standard treatment sessions. The principal investigator will digitally redact the audio-recorded sessions using audacity (a free audio editor). Papers emanating from this study will only report aggregate data so no individual can be identified from this information. Referrals will consist of providing the participant with the contact information of services appropriate for their needs. Further, as the consent information and assessment data are held on secure Qualtrics servers and the counselling is delivered on internet applications there is a very unlikely possibility that this information can be intercepted or accessed. This information is explained in the treatment-seeking participant consent form.

Participant information will be held in locked rooms and cabinets that only the study team has access to (i.e., Markin Hall rooms M4132 and M3011) and on password protected computers in those rooms. Only the investigators will have access to this data except when a participant consents to release information to Non-AHS health service providers. The information that may be released are study participation, the purpose of the study, nature of study participation, and participant progress. The release of information process will be explained in the consent process and is included on the consent form. Consent and assessment data will be held on the secure Qualtrics website and this is explained in the consent process and is stated in the consent form. All data will be retained for 5 years and then shredded or deleted. All investigators will have the final de-identified dataset. Sharing of the de-identifiable requires consent from all investigators. No investigators will share the identifiable dataset.

No information that identifies a participant will be released into the public domain. Participants have the right to review their information at any stage of the study. They can also withdraw from the study at any stage where only the treatment-seeker eligibility and intake data will be included in the study. These caveats are included in the consent form.

All participants can request a lay summary of the results by contacting the principal investigator. His contact information is on the consent form. Treatment-seeking participants will

be sent an electronically signed copy of the consent form. In addition, treatment-seeking participants will have access to a generic study consent form for the duration of the study on the study website. Treatment-seeking participants can also contact the primary researcher for a copy of the consent form. Counsellors and ARDN affiliates who participated in the qualitative interviews will receive a copy of the signed consent form. The investigators intend to publish from the de-identifiable dataset in peer-reviewed academic journals. The investigators will also present summary information to the funder.

At treatment completion, participants will be referred to the free AHS help-line where they can receive counselling and psychoeducation services from local provincial government run counselling services. Data on participant attendance in post-treatment services will be systematically collected at follow-up.

Statistical Analysis

Participants will be primarily compared on study attendance and retention measures and gambling behaviour (predictions one and two) using parametric analyses (i.e., t-tests), we will also analyse abstinence using repeated measures, descriptive scores of participant demographics, and where appropriate, non-parametric tests (e.g., survival plots for study retention). Additionally, comorbid variables will be treated as covariates in subsequent ANCOVA analyses (prediction three). We will also test whether there is a relationship between abstinence and, study retention and session attendance. Further, clinical outcomes will be analysed based on counsellor type: graduate student or faculty member. Although we anticipate no missing data, where necessary, we will use data appropriate imputation methods (i.e., median values for quantitative scores). When participants fail to attend a scheduled session this is evidence of a break in their continuous treatment sessions and when they fail to produce evidence of gambling abstinence this is evidence of gambling behaviour.

Qualitative Analysis

Regarding the qualitative data obtained, thematic analysis procedures will be utilized to generate themes with respect to perceptions of success and perceived constraints or challenges from study participants, counsellors, and stakeholders.

Study Evaluation

A unique aspect of the study is its focus on Albertans residing in rural and remote areas. To properly situate our findings in terms of other contingency management and internet-delivered treatment studies, and potentially inform other studies in rural and/or remote areas, we will conduct a mixed methods feasibility assessment. For example, quantitative data will be obtained with respect to recruitment and participation rates (analyzed by location, demographics, and co-morbidity variables), and rates of retention/program completion. Further, we will conduct a cost-benefit analysis investigating the relative benefits or costs per participant from this study. Our analyses will also describe the management and support systems necessary to implement this project in other agencies. Post-treatment, Dr Witcher will contact a sub-set of treatment-seeking participants, as well as counsellors, and ARDN affiliates regarding perceptions of success and perceived constraints or challenges to treatment.

DISCUSSION

This will be the first randomised controlled study examining the added impact of contingency management to cognitive behavioural therapy using internet delivered counselling by videoconference for the treatment of gambling disorder. Further, this study is also unique as it targets rural and remote Albertans. Contingency management appears well suited to the treatment of gambling disorder as gambling is maintained in part by the association between gambling and immediate reinforcement where CM competes with these associations by immediately reinforcing gambling abstinence, thereby reversing these associations[14]. However, this assertion needs further evidence for us to have confidence that the CM procedure competes with gambling and reverses the association between gambling and reinforcement.

Persons with gambling disorder typically experience shame and stigma[43]. Therefore, internet delivered treatments are likely to appeal to those who are hesitant about attending traditional counselling programs[43], and may alleviate participant concerns regarding community members noticing their attendance at counselling services. Furthermore, as our target group are rural and remote Albertans, participants need not travel to access counselling and health services that are typically located in urban settings, often at some distance to rural people. Similarly, the potential ease of accessibility of our internet study to rural persons is also likely to improve participant attendance and retention[44, 45].

Another important aspect of this study is the opportunity for participants to attend up to three sessions per week and receive reinforcement from the demonstration of more than one behaviour. By comparison, traditional gambling counselling typically only occurs once a week where treatment gains are sometimes slow to start and accumulate[46]. However, as this study provides reinforcement from multiple sources, has a relatively intense reinforcement schedule, and bonuses for sustained performance, it is designed to reinforce continuing and consecutive weeks of abstinence. This reinforcement schedule is congruent to another operant behavioural theory similar to contingency management: behavioural momentum. Behavioural momentum was developed from discriminant-operant relations where the rate of reinforcement and reinforcement histories influence response rates. The relationship between rate of reinforcement and behaviour is thought to be analogous to the second law of motion in Newtonian physics (i.e., the velocity of an object in motion is proportional to the magnitude of the opposing force and opposite to the mass of the object[25]), where voluntary behaviour (i.e., gambling abstinence) is analogous to 'velocity' and reinforcement history is similar to the 'mass' of an object[47]. Theoretically, as the rate of reinforcement increases so does the performance of the target behavior; increasing the likelihood the target behaviour will be repeated and reducing the effects of the disrupter (i.e., in this case the disruptor is the reinforcing effects from gambling). The assumption is, as the performance of sustained abstinence increases, so does the 'mass' for abstinence and the 'velocity' of future abstinence. Numerous studies show evidence of behavioural momentum when the target behaviour is sufficiently strong enough to successfully compete with the alternative[24]. Consequently, as participants can attend up to three times as many counselling sessions as treatment as usual, and can obtain reinforcements from multiple sources, this study is designed to generate greater behavioural 'mass' than traditional counselling, hopefully resulting in better attendance and retention and higher rates of abstinence post-treatment than the CBT only group.

LIMITATIONS

As previously noted, the study is powered to observe an effect for the CM+ group, but as previous meta-analyses report, the effect size for the CBT group is likely to show no significant effect. Further, as treatment is delivered using the internet, if a participant cannot reliably access the internet this is likely to impede treatment adherence. However, if participants have legitimate issues accessing the internet they will not be penalised, rather we will re-schedule sessions when the participant regains a stable internet connection. In addition, if the study credit is less powerful than gambling, study credit will not be able to successfully compete with gambling. Also, if participants have no verifiable records to report abstinence (e.g., they have no bank accounts), they will not be able to earn study credit based on financial records. Further, if participants are paid in cash they can circumvent our assessment procedures. Moreover, as only one study reported CM as a treatment for gambling[12], our results need to be interpreted with caution. Also, as the CM procedure outlined here is based on the pharmacological substance use literature[22], any material difference between disorders may require alternative implementations for CM to be successful[31], and this must be considered when reviewing our results. Also, the incentives might be too small to retain participants in the study during the early stages of treatment, although CM studies report this is more likely in CM alone designs[22]. Finally, as participants are randomly allocated to the CM+ or CBT groups, possible confounding variables might bias group allocation. Consequently, we will check for known confounders in the analyses (i.e., gender, gambling severity, primary gambling activity).

CONCLUSIONS

CM provides small incentives that reinforce and improve treatment attendance and retention rates[22, 44]. Recently, this approach has been proposed as a treatment for gambling disorder[14, 16], as gambling disorder treatment programs often have high treatment drop-out rates[4], where reinforcing gambling abstinence (and abstinence) may be more rewarding for the gambler than gambling[14]. Further, treatment attendance and retention rates may additionally rise when treatment is delivered using computer or internet approaches[16, 48]. These issues are especially relevant for rural and remote Albertans who face significant challenges accessing counselling services[29]. Consequently, this study may provide important evidence for addressing gambling treatment attendance and retention issues, as well assessing the efficacy of using the internet and video conferencing to provide treatment to rural and remote persons.

Contributorship Statement: All investigators have made or will make significant contributions to the design or implementation of the study. All investigators contributed to the writing of the protocol manuscript. Roles: Dr. Darren R Christensen supervises and designed the study, Dr. Chad S. G. Witcher supervises the qualitative evaluation and contributed to the study design, Dr. Trent Leighton supervises the graduate student counsellors and contributed to the study design, Dr. Rebecca Hudson-Breen counselled participants and contributed to the study protocol, Mr. Samuel Ofori-Dei contributed to the writing of the protocol manuscript and assists with the data collection.

Competing Interests: There are no competing interests.
Funding: This work was supported with finance by the CRISM: Prairie Node. The funder made design suggestions in the application process. It will have no further role in the study.
Data Sharing Statement: All investigators will have the final de-identified dataset. Sharing of the de-identifiable requires consent from all investigators. No investigators will share the identifiable dataset**.**

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	2-6
Protocol version	3	Date and version identifier	15
Funding	4	Sources and types of financial, material, and other support	1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	14-15
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	14-15
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2-3
	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3-4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	1-11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	7
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3, 7-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4-5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	5
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	5
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	5
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	5

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	10-12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12-13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12-13
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	DMC not required. Oversight provided by the UoL ethics committee.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13-14
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13-14
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	13-14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13-14

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5, 13-14
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13-14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	15
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	13-14
	31b	Authorship eligibility guidelines and any intended use of professional writers	14-15
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	15
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Attached document
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.