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Effects of added involvement from concerned significant others in internet-delivered CBT treatments for problem gambling: study protocol for a randomised controlled trial

Anders Nilsson,[1] Kristoffer Magnusson,[1] Per Carlbring,[2] Gerhard Andersson,[1,3] Clara Hellner Gumpert[1]

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[1]Department of Clinical Neuroscience, Stockholm Center for Psychiatry Research and Education, Karolinska Institutet, Stockholm, Sweden
[2]Department of Psychology, Stockholm University, Stockholm, Sweden
[3]Department of Behavioral Sciences and Learning, Linköping University, Linköping, Sweden

Correspondence to
Anders Nilsson;
Anders.nilsson.2@ki.se

ABSTRACT

Introduction: Problem gambling is a public health concern affecting ~2.3% of the Swedish population. Problem gambling also severely affects concerned significant others (CSOs). Several studies have investigated the effect of individual treatments based on cognitive–behavioural therapy (CBT), but less is known of the effect of involving CSOs in treatment. This study aims to compare an intervention based on behavioural couples therapy (BCT), involving a CSO, with an individual CBT treatment to determine their relative efficacy. BCT has shown promising results in working with substance abuse, but this is the first time it is used as an intervention for problem gambling. Both interventions will be internet-delivered, and participants will receive written support and telephone support.

Methods and analysis: A sample of 120 couples will be randomised to either the BCT condition, involving the gambler and the CSO, or the CBT condition, involving the gambler alone. Measures will be conducted weekly and at 3, 6 and 12 months follow-up. The primary outcome measure is gambling behaviour, as measured by Timeline Followback for Gambling. This article describes the outline of the research methods, interventions and outcome measures used to evaluate gambling behaviour, mechanisms of change and relationship satisfaction. This study will be the first study on BCT for problem gambling.

Ethics and dissemination: This study has been given ethical approval from the regional ethics board of Stockholm, Sweden. It will add to the body of knowledge as to how to treat problem gambling and how to involve CSOs in treatment. The findings of this study will be published in peer-reviewed journals and published at international and national conferences.

Trial registration number: NCT02543372; Pre-results.

Strengths and limitations of this study

- This study will be the first study investigating behavioural couples therapy for gambling.
- The interventions in this study offer support not only for problem gamblers but also for concerned significant others (CSOs) of problem gamblers, whose needs are often neglected.
- Behavioural couples therapy relies heavily on functional analysis, which is a challenge in problem gambling in which there are no physiological signs of gambling.
- This is a randomised controlled trial in which participants are recruited pairwise, which means CSOs are somewhat involved in treatment regardless of which treatment arm they are randomised into.
- Some of the outcome measures have not yet been properly validated, making it more difficult to draw conclusions.

INTRODUCTION

An estimated 70% of the Swedish population aged 16–84 years gamble, including those who gamble on very rare occasions. For the majority of people who gamble, gambling does not cause any substantial harm. For a minority of gamblers, however, gambling can have devastating effects on their economic status, health and relationships. An estimated 2.3% of the Swedish population between 16 and 84 are considered to be either problem gamblers or moderate risk gamblers,[1] according to Problem Gambling Severity Index (PGSI), defined as a score of ≥8 or 3–7, respectively.[2]

Problem gambling is characterised by the failure to control expenditure on gambling in respect to time and money, despite significant negative financial, personal and social consequences. More precisely, problem gambling is often hallmarked by gamblers using gambling as a means to escape bad mood, chasing money lost on gambling, lying to

others about the extent of gambling and relying on others' financial support.[3–6] Furthermore, problem gamblers often report symptoms that commonly occur in substance use disorders, such as preoccupation, tolerance, withdrawal, unsuccessful attempts to quit and giving up other activities because of gambling.[4 5]

While gambling disorder is diagnostically defined in DSM-5,[7] problem gambling is an informal term used in prevalence studies and clinical studies to describe a less severe form of problematic gambling, alternatively as an all-embracing term, connoting gambling disorder and less severe forms of problem gambling. The term will, henceforth, be used in the latter sense.

Numerous studies suggest not only a substantial overlap between problem gambling and substance use disorders but also symptom similarities, as well as potential parallel biological dysfunction.[5 8 9] Consequently, there is also an overlap in the type of treatments for substance use disorders and problem gambling. As a result, gambling disorder is, as of May 2013, classified as an addiction, not an impulse control disorder, in the DSM-5.[10]

A large body of research has investigated the impact of problem gambling on the gambler. Problem gambling is associated with psychological distress.[11–14] Problem gamblers have up to 10 times higher risk of having a diagnosis of substance abuse during their lifetime,[15–18] and compared to the general population, there is an increased risk for suicide attempts, suicide plans and suicide ideation among people with gambling disorder.[19–21] Problem gambling is also associated with physical health problems,[22 23] a heightened risk of committing and being exposed to acts of violence,[24 25] and a lower socioeconomic status.[1 26] In general, gambling-related harm could be defined as 'any initial or exacerbated adverse consequence due to an engagement with gambling that leads to a decrement to the health or well-being of an individual, family unit, community or population'.[27]

Despite severe consequences, only between 5% and 12% of problem gamblers ever seek treatment.[1 28] This has generally been attributed to stigma, a lack of accessibility to treatment, unwillingness to admit problem and a wish to handle problems oneself.[29–32] Furthermore, treatments for problem gambling are often characterised by high degrees of attrition and low adherence to treatment, averaging 42% attrition in psychosocial interventions.[33–35]

The Swedish National Institute of Public Health has estimated that ~260 000 people in Sweden cohabit with a problem gambler, and as many as 18% of the population could be considered a CSO of a problem gambler.[36] Problem gambling's effect on the CSOs of the gamblers has been well documented in the literature, including high levels of psychological distress.[16 36–39] Problem gambling often causes financial problems for the affected family, such as debts, overdue loans, loss of property and being chased by creditors.[40] CSOs of problem gamblers are generally worse off in terms of physical and psychological well-being, and many CSOs not only report that their relationship with the gambler is severely affected but also report disturbed relationships with family and friends.[16 41–43] Problem gamblers are also less likely to be married or have children, but this could partly be explained by the higher levels of problem gambling among young males.[1]

Various treatment programmes have been evaluated for problem gambling; many of the successful treatment approaches for problem gambling are based on evidence-based treatments for substance use disorders. These treatments are primarily based on cognitive–behavioural therapy (CBT) or motivational interviewing. In a Cochrane review[44] of psychological treatments for pathological and gambling disorder, the authors found support for the efficacy of CBT. On the basis of seven randomised controlled trials (RCTs), they concluded that CBT reduced gambling behaviours (gambling symptom severity; Cohen's d pretest and post-test: −1.82; 95% CI −2.61 to −1.02) and depression and anxiety symptoms compared to a control condition. However, on the basis of GRADE guidelines, they ranked the quality of evidence as low to very low, due to the methodological flaws of the studies and the significant statistical heterogeneity in the estimates. Other meta-analyses, applying slightly different methods, have also found CBT to be an efficient treatment for problem gambling.[45 46] Two RCT studies for problem gambling have been performed in Sweden, both found support for the efficacy of CBT.[47 48]

CSOs of gamblers can potentially play an important role in recovery. Researchers have found that gamblers report concerns not only for their next of kins as an important reason for seeking treatment[42 49–51] but also for remaining in treatment.[52] However, research on couple-based or family-based approaches for problem gambling has been scarce, mostly based on systemic marital therapy. But several studies suggest that merely having a CSO improved odds of successful treatment, and that including CSOs in treatment also increased retention in treatment.[49 53] However, a recent study of group CBT treatment in which family members were invited to participate in the treatment found that family involvement was actually associated with a higher rate of relapse.[54] This prompted the authors to recommend that separate interventions should be given to gamblers and to CSOs. Also, studies have shown that CSOs, in general, have limited understanding of, and a lack of awareness of the extent of, the problem gambling,[55] and that this can sometimes enable further gambling.[37] This is likely partly due to the secretive nature of problem gamblers, where the gambling is often kept hidden.[42] Owing to stigma and shame, problem gamblers are often reluctant to talk to CSOs about their gambling problems.[56]

Statistics from the Swedish National Helpline reveal that approximately half of the contacts are with CSOs, which indicate that there is a demand for support for

CSOs.[57] Partners and parents made up the majority of the contacts, 30% and 36% respectively, while siblings, other family members and friends made up roughly 10% each of the contacts. Children of problem gamblers made up <5%. An earlier study of CSO support groups in Sweden, based on Community Reinforcement and Family Training, showed similar results with parents and partners making up the majority of participants.[58] Several studies have investigated the impact of coping-skills training for CSOs, in which the gambler is not involved in treatment. While it has failed to have a substantial effect on the gambling behaviour of the gambler, it has an effect on the psychological distress of the CSOs and relationship satisfaction.[59–61]

More attention has been paid to CSO's involvement in clinical trials with alcohol and substance abusers. One of the more promising approaches is behavioural couples therapy (BCT),[62] which has shown results by working with the person with an addiction and their spouse.[63] BCT integrates interventions that focus on addiction and interventions that focus on relationship functioning, thus the addict and the spouse are in treatment concurrently. BCT has two main goals: (1) build support for abstinence and (2) improve relationship functioning. The hypothesised mechanism of change is that improved relationship functioning will promote relationship behaviours that are conducive with abstinence. A meta-analysis of 12 RCTs of BCT, of which 8 studies targeted alcohol problems and 4 targeted other substances, showed better outcomes for BCT than for individual-based treatments with a mean overall effect size (Cohen's d) of 0.44 in favour of BCT.[64] BCT is arguably the relational therapy aimed at reducing substance abuse that has the most solid evidence base. It has been tested for a variety of relational types (eg, heterosexual couples, same-sex couples and parent–child relationship), as well as for different substances (eg, alcohol, illegal drugs and methadone).[65] Given the general similarities in treatment approaches for substance abuse and problem gambling, there is reason to examine the potential role BCT could have in treating problem gambling. There is already preliminary support for the notion that CSO involvement in problem gambling treatment produces better treatment outcomes and better retention in treatment, and coping-skills training increases relationship satisfaction and reduces distress in CSOs of problem gamblers. Since BCT targets abstinence and relationship functioning, it seems appropriate to investigate the potential effects of BCT for problem gambling.

In 2014, ~36% of gambling revenues in Sweden came from internet-based gambling, according to the Swedish Gambling Authority.[66] Reports from the Swedish National Gambling Helpline reveal that internet casinos, internet poker and internet-delivered sports betting have become the three most prevalent problem games among callers.[67] In combination with a general lack of treatment seeking among problem gamblers due to stigma, as well as a lack of treatment options, we believe that there are reasons to try to provide the treatment over the internet, which is anonymous, flexible and accessible nationwide. This has also been the reason given by gamblers and CSOs in similar trials to access internet-based interventions.[68 69] A growing number of the contacts to the National Helpline are made by chat and email, which indicates that internet-based support is seen as a viable treatment option.[57] A study from 2008 on internet-based CBT treatment for problem gambling significantly reduced problem gambling as well as comorbid conditions, with sustained effect sizes at 36-month follow-up.[48 70]

AIM AND HYPOTHESIS

The aim of this study was to investigate the effects of internet-delivered CBT and internet-delivered BCT on problem gambling, relationship functioning and mental health for individuals with gambling problem and their CSO.

The main focus of the study will be on the hypothesised effect of the addition of CSO involvement on individual treatment outcomes. The primary outcome measure is gambling behaviour, as measured by Timeline Followback for Gambling (G-TLFB).[71] Furthermore, the study will investigate the effect of the treatments on the secondary outcomes, depression, anxiety, treatment adherence, attrition, relationship satisfaction and alcohol use for the gambler and the CSO. Also, the study will analyse the relationship between a number of mediating and moderating variables on gambling outcomes.

We hypothesise that (1) BCT will yield greater reductions on gambling measures than individual CBT, (2) BCT will yield a lower drop-out rate compared to individual CBT, (3) BCT will be superior to individual CBT in increasing relationship satisfaction, (4) relationship functioning will mediate change in gambling behaviour for the gambler randomised to the BCT group and (5) reduction in gambling behaviour for the gambler will mediate change in relationship functioning in the CBT group.

Study design

This study will be a RCT with two treatment conditions: (1) internet-delivered CBT with telephone support and (2) internet-delivered BCT with telephone support. The study intends to further develop, evaluate and compare two different treatments for problem gambling, the CBT condition and the BCT condition. The main difference between the two treatments is the involvement required from a CSO of the gambler. Participants will be randomised into one of the two conditions. The treatments will be delivered via the internet, which makes the treatments available for a larger group of people and potentially lowers some of the barriers to seek help for problem gambling. The study will adhere to the recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[72]

Participants and procedure

Participants will be recruited nationwide by means of advertisements on our homepage, in printed media and on Facebook and Google, and through the Swedish National Gambling Helpline. In addition, we will use our professional networks across the country to inform about the study. Application is done online, where prospective participants will also find further information on the study as well as the questionnaires serving as screening instruments. Before final inclusion, participants are required to provide written, informed consent. The written consent will be handled by a research assistant independent from the study, and stored in a safe.

After signing up online, the prospective participants will be contacted by telephone by a therapist in order to ensure that they are eligible for inclusion. The telephone calls will function as a complement to ensure that the participants fulfil the eligibility criteria, that they understand the aim and design of the study, as well as to clarify any ambiguity in their replies to the screening instruments. After the 12-week treatment period, participants are asked to fill out follow-up screenings at post-treatment, and at 3, 6 and 12 months after treatment.

The gambler and the CSO will be screened separately. The first participant was accepted for the trial on the same day as the study was registered on ClinicTrails.gov, 3 September 2015.

Eligibility criteria

In order to participate in the study, (1) the gambler and the CSO must be living in Sweden and (2) be at least 18 years old. Further, (3) the gambler must meet the criteria for problem gambling according to PGSI, defined as a score of >8,[73] and (4) the gambler and the CSO must be able and willing to access a Swedish website and provide follow-up data on gambling. (5) The gambler and the CSO must have a personal relationship, defined as the CSO being a parent, child, sibling, friend or partner of the gambler and they must have had a relationship for at least 3 months. (6) Participants may not participate in any other treatment for problem gambling and the CSO may not meet the PGSI criteria for ongoing problem gambling. (7) Participants displaying symptoms of severe psychiatric disorders, such as psychotic or bipolar disorders or severe suicidality judged to require further treatment, will be excluded and referred to better-suited treatment options. This is also the case should a participant show such symptoms during treatment. (8) Participants will also be required to fill out a computerised screening battery measuring gambling behaviour, psychological distress and relationship satisfaction.

Randomisation

When eligibility assessment is completed, participants will be randomised to one of the two study arms. Since the gambler and the CSO participate in the study together, they will be randomised as one unit. The allocation sequence will be generated, using a true random number generator (http://www.random.org). A research assistant who is independent from the study will perform the treatment allocation.

Trial arms

After randomisation, the participants will gain access to a treatment website containing their respective treatment programme. The BCT and the CBT programmes are divided into one chapter, called module, each week, containing text material, short films and three to five exercises related to a specific treatment component. Each module is on average 5–10 pages long, and the exercises vary in time and effort required to complete them. In the BCT condition, the gambler and the CSO will be given 10 modules each. In the CBT condition, the gambler will be given 10 modules, but the CSO will not be given any modules. In order to investigate the effect of added CSO involvement, the content in the treatment modules for the gamblers is constructed to be as similar as possible, regardless of trial arm (see table 1). This means that the gamblers in the CBT arm will receive some treatment content that is not always part of standard CBT form problem gambling, particularly communication skills training. The main difference between the content in the two arms for the gamblers is that the content in the BCT arm is aimed at involving the CSO, while the content in the CBT arm assumes the gambler is working by himself or herself.

There are also some minor differences in the order in which the content appears in the modules.

Each treatment programme contains 10 modules, thus lasting 10 weeks. Participants will, however, be given the opportunity to complete the programme during a 12-week time frame in order to increase flexibility. The modules will be complemented with scheduled telephone and written support from their assigned therapist. The written communication will be administered via an online messaging system that is built into the treatment platform. All data are encrypted in the database, and a cryptographic protocol (Secure Sockets Layer) will be used to provide privacy and data integrity for the participants.

Interventions

Cognitive–behavioural therapy

The CBT intervention will be based on existing CBT treatments for problem gambling. The intervention will include cognitive strategies for handling gambling cognitions (eg, irrational thoughts on one's own control of chance) and cravings related to gambling. Behavioural interventions—such as behavioural activation and functional analysis of one's gambling behaviour to identify and manage specific triggers and possible reinforcers of gambling behaviour—will form a significant part of the intervention. The programme also includes exercises and text specifically aimed at controlling impulsivity,

Table 1 Description of the content in the treatment modules

Module	CBT gambler	BCT gambler	BCT CSO
1	Introduction Psychoeducation (17 773 characters, 3 videos, 2 exercises)	Introduction Psychoeducation (17 970 characters, 3 videos, 2 exercises)	Introduction Psychoeducation (21 404 characters, 3 videos, 2 exercises)
2	Behavioural analysis Economic recovery plan (10 949 characters, 1 video, 4 exercises)	Behavioural analysis Economic recovery plan (10 921 characters, 1 video, 4 exercises)	Behavioural analysis Economic recovery plan Enabling 16 024 characters, 1 video, 6 exercises)
3	Motivation enhancement Behavioural activation (13 825 characters, 1 video, 8 exercises)	Motivation enhancement Behavioural activation (14 586 characters, 1 video, 8 exercises)	Behavioural activation Shared activities (13 819 characters, 0 videos, 8 exercises)
4	Cognitive restructuring (12 481 characters, 2 videos, 5 exercises)	Cognitive restructuring (12 574 characters, 2 videos, 5 exercises)	Motivation enhancement (6804 characters, 0 videos, 8 exercises)
5	Values and goals (8832 characters, 1 video, 7 exercises)	Values and goals (10 618 characters, 1 videos, 9 exercises)	Economic recovery (9956 characters, 0 videos, 7 exercises)
6	Economic recovery (10 043 characters, 0 videos, 7 exercises)	Communication skills training (21 071 characters, 1 videos, 6 exercises)	Communication skills training (22 074 characters, 1 videos, 6 exercises)
7	Communication skills training (12 993 characters, 1 video, 5 exercises)	Communication skills training (11 951 characters, 1 video, 4 exercises)	Communication skills training (11 648 characters, 1 video, 4 exercises)
8 Extent:	Communication skills training (11 972 characters, 1 video, 4 exercises)	Reinforce positive behaviours (8976 characters, 1 video, 5 exercises)	Reinforce positive behaviours (8899 characters, 1 video, 5 exercises)
9 Extent:	Relapse prevention (11 827 characters, 1 video, 6 exercises)	Relapse prevention (13 979 characters, 1 video, 8 exercises)	Relapse prevention (11 034 characters, 1 video, 6 exercises)
10 Extent:	Repetition (6982 characters)	Repetition (6813 characters)	Repetition (6811 characters)

BCT, behavioural couples therapy; CBT, cognitive–behavioural therapy; CSO, concerned significant other.

such as identifying triggers and inhibiting and handling impulses. The interventions will also include motivation enhancement, psychoeducation about problem gambling and relapse prevention, as well as communication skills training. The content in the CBT treatment is largely based on the manual from previous studies on internet-based CBT for problem gambling,[48] and a Swedish CBT manual for the treatment of problem gambling.[74]

Moreover, the gamblers will receive weekly telephone calls and written support by CBT therapists (see below). The telephone calls will last a maximum of 10 min/week. The main purpose is not only to offer relevant feedback on the exercises in the modules but also to guide the participants through the modules, in case the participant does not fully grasp its content, as well as reminding participants to complete and intensify work on the programme, if needed. Furthermore, the gamblers will have access to a moderated internet forum where they can discuss problem gambling with other gamblers. The CSOs in the CBT condition will not receive any modules of their own, nor will they receive any telephone or written support from the therapists.

Behavioural couples therapy

The BCT condition will be based on existing BCT treatments for alcohol and substance abuse,[75] but it will also lend components regarding acceptance and perspective taking from integrative behavioural couples therapy (IBCT),[76] and the above-mentioned Swedish manuals for CBT treatment for problem gambling.[48 74] IBCT is, sometimes, described as a further development of BCT,[77] but it has yet to be tested for the treatment of abuse of any kind. Since neither treatment has been tested for problem gambling, our treatment is modified to suit problem gamblers and their partners. More specifically, BCT for CSOs relies heavily on functional analysis to establish the links between the antecedents, abuse and consequences of an abusing partner. Problem gambling, however, produces no physiological signs, making functional analysis more challenging. For example, while BCT for alcohol abuse states that sober behaviour should be rewarded by the CSO, it is almost impossible for a CSO of a problem gambler to know when the gambler is 'sober'. Thus, the programme has been adapted to suit CSOs of problem gamblers where functional analysis is a tool to understand why the gambler gambles and to help the gambler identify situations where he or she is prone to gamble, as well as how it could be handled. The CSO modules lends components regarding gambling from a Swedish CBT-based CSO manual,[78] and an internet-based study on support for CSOs of problem gamblers.[79] BCT has also been developed with married or cohabiting couples in mind,

while this study accepts any type of personal relationship, for example, parents–child, friends or siblings. The modules in this study are constructed to be suitable for any type of CSO, for example, by giving a variety of examples and by phrasing examples with 'Many CSOs feel….' 'Some CSOs have experienced…'.

The main difference between the CBT condition and the BCT condition is the involvement of the CSO in the BCT condition. The CSO will be expected to take active part in a substantial portion of the treatment for the gambler. The main focus for the CSO will be on psychoeducation about problem gambling, functional analysis of gambling behaviour and functional coping strategies for CSOs of problem gamblers. The BCT condition will also include communication skills training. Five of the modules will be individual modules constructed to suit either the CSO or the gambler, four modules will essentially share the same content and one module will be a repetition of previous modules. They will be encouraged by their therapist to discuss the content in the modules. The gambler and the CSO will have access to the same type of internet forums as in the CBT condition. They will also receive weekly telephone calls and written support from a CBT therapist. The telephone calls will last a maximum of 10 min/week and person. The gambler and the CSO have their own unique account on the platform, and they are not able to read each other's content and answers. However, several of the modules require the gambler and the CSO to work together and share content with each other. The therapist will not share information given from the gambler to the CSO and vice versa.

Therapists

The study's counsellors will be at least master level clinical psychology students, or experienced staff from the Swedish National Gambling Helpline, who have training in motivational interviewing.[80] They will assist the participants via written support and scheduled weekly telephone calls. The counsellors will receive training in the study manual and in internet-delivered therapy before treatment start. They will also receive biweekly supervision by an experienced CBT therapist.

Blinding

Participants will not be blinded; however, neither of the two study arms will be described as potentially superior. Baseline assessment occurs prior to randomisation, and follow-up assessment will be self-reported via the internet.

Measures

Inclusion measure

PGSI will be used in order to ensure that the participants meet the criteria for problem gambling. PGSI consists of nine items and measures the presence of problem gambling the last 12 months.[81] In order to be included in the study, gamblers must meet the criteria for problem gambling, defined as a score of >8, and CSOs must meet the criteria for non-problem gambling, defined as a score of 0.

Outcome measures

Outcomes will be measured through self-report instruments, filled out by the gambler and the CSO. The gambler and the CSO will not be able to gain access to information provided by the other. All instruments will be administered online, through the internet treatment platform. All instruments will be administered pretreatment, post-treatment and at 3-month, 6-month and 12-month follow-up. G-TLFB and Relationship Assessment Scale-Generic (RAS-G) will also be measured weekly throughout treatment.

The primary outcome measure will be G-TLFB,[71] measuring days spent and money lost on gambling, in accordance with the Banff statement that specifies that net losses and time spent on gambling are the most important aspects of change in gambling behaviour.[82] G-TLFB will measure gambling last month at pretreatment and at follow-up measurements. The gambler and the CSO estimate the gambler's gambling by filling out the G-TLFB.

The National Opinion Research Center DSM-IV Screen for Gambling Problems (NODS), modified to assess the last month instead of the last year, will also be used to measure gambling problems. NODS is a 17-item questionnaire, and has been found to have acceptable psychometric properties and corresponds to the diagnostic definition of pathological gambling in DSM-IV.[6 83] NODS has been used in previous Swedish treatment studies,[47 48] and using NODS will make it easier to compare the results from different studies. NODS will be filled out only by the gambler, and not by the CSO separately.

Secondary outcomes

Secondary outcomes will include measures on gambling consequences, psychological distress, dissociative experiences while gambling, alcohol consumption, relationship satisfaction and attrition. Unless otherwise stated, the gambler and the CSO fill out all measures. The self-report measures will provide information not only on treatment outcome but also on the reliability of the gambling behaviour information provided by the CSO.

Inventory of Consequences of Gambling for the Gambler and CSO[84] consists of 44 items regarding consequences of gambling for the gambler as well as for the CSO.

In order to perform mediation analyses on how participants change their gambling behaviour, relationship functioning will be collected continuously throughout treatment, alongside data on gambling behaviour. Relationship satisfaction will be measured, using a generic version of the 7-item RAS-G.[85] Depression will be measured using Patient Health Questionnaire-9 (PHQ-9),[86] and anxiety will be measured using General Anxiety Disorder-7 (GAD-7).[87] Alcohol use will be

Table 2 Measures

Focus	Measure	Time point: Pretest	Time point: Weekly during treatment	Filled out by: Post-test, follow-ups	Filled out by: Gambler	Filled out by: CSO
Inclusion						
Gambling	PGSI	×			×	×
Background data		×			×	×
Primary outcomes						
Gambling (gambler)	NODS	×		×	×	
	G-TLFB	×	×	×	×	×
Secondary outcomes						
Alcohol consumption	AUDIT	×		×	×	×
Depression	PHQ-9	×		×	×	×
Anxiety	GAD-7	×		×	×	×
Relationship	RAS-G	×	×	×	×	×
Gambling consequences	ICS	×		×	×	×
Dissociative experience		×		×	×	
Attrition		×	×	×	×	×

AUDIT, Alcohol Use Disorders Identification Test; CSO, concerned significant other; GAD-7, General Anxiety Disorder-7; G-TLFB, Timeline Followback for Gambling; ICS, Inventory of Consequences of Gambling for the Gambler and CSO; NODS, National Opinion Research Center DSM-IV Screen for Gambling Problems; PGSI, Problem Gambling Severity Index; PHQ-9, Patient Health Questionnaire-9; RAS-G, Relationship Assessment Scale-Generic.

measured, using the well-established Alcohol Use Disorders Identification Test (AUDIT) containing 10 items regarding alcohol consumption and consequences of alcohol consumption.[88] Finally, five questions, measuring dissociative experiences taken from the Dissociative Experience Scale,[89] will be included. The questions have been modified to suit problem gambling, and have previously been used in one study.[90] Only the gambler will fill out the questions on dissociative experiences. A list of all the measures are provided in table 2.

Process measures

Treatment involvement will be measured as form completion, times spent with the treatment site and the number of page views on the site, and will be collected unobtrusively as participants visit the treatment site. To allow for moderation analysis, the following basic demographics will be collected at baseline assessment: age, sex, relationship status, employment status, income, level of education, number of children and psychiatric medication used. Descriptive data on gambling involvement and consequences will also be gathered, that is, type of gambling problems, types of gambling (eg, poker, internet casino), an estimate of length of problems, age when problem began, previous quit attempts, ever attended meetings with Gamblers Anonymous or other self-help groups, past or co-occurring addiction and previous treatments.

Statistical methods

Statistical analysis plan

It is likely that the outcome data will have excess zeroes because the majority of participants are not gambling, that is, more participants will record zeroes than what is expected by traditional statistical models. Moreover, data on gambling expenditures are likely to be heavily right skewed. Therefore, the longitudinal outcome data will be analysed by generalised linear mixed models (GLMMs).[91] GLMMs offer a flexible way to model the types of data that are likely to arise in this study.[92] For instance, we plan to analyse the G-TLFB data by modelling the likelihood of gambling over time by a logistic model, and a skewed distribution (such as γ or log-normal) for the amount of money lost on the days a participant gamble. Moreover, it is likely that these two models have correlated random effects, indicating an association between the likelihood of abstinence and the amount of money spent on gambling. These types of two-part GLMMs are often referred to as a longitudinal semi-continuous or hurdle models.[93]

We assume that the rate of change will differ between the treatment and follow-up period; thus, time will be modelled by a piecewise function.[94] Mediation will be tested using structural equation modelling.[95] To investigate the impact of different baseline characteristics on treatment outcome, the following moderators will be investigated: baseline G-TLFB scores, baseline relationship functioning and past use of treatment.

Handling of attrition

All randomised participants will be included in the statistical analyses, that is, an intention-to-treat analysis will be used.[96] If the pattern of the non-responses is attributable to observed data, then the attrition is said to be missing at random (MAR). Under the MAR assumption, the maximum likelihood approach will yield sensible parameter estimates.[97] Unfortunately, it is impossible to prove that the responses are MAR, consequently Pattern Mixture Methods will be used in order to perform sensitivity analyses.[98]

Sample size

To calculate the necessary sample size, a Monte Carlo simulation was run with 1000 iterations. We based our power calculation on the odds of being abstinent post-treatment. We assumed that a BCT participant will at least have a two times greater odds of abstinence compared to a CBT participant, conditional on equal random effects. This corresponds to a marginal OR of about 1.5, indicating that if 60% is abstinent at post-treatment in the CBT group, 67% will be abstinent in the BCT group. With 12 weekly G-TLFB measurements, 60 participants per group are necessary to achieve about 90% power, with α set at 5%. This calculation assumes an intraclass correlation of about 0.65, indicating a large variation due to participants. We also investigate the impact of missing data on power. In a second simulation, we introduced a MAR missing data mechanism that let missingness depend on the participants' baseline probability of abstinence, where participants with a lower probability of abstinence tended to drop out more often. We choose to have 25% of the participants drop out around midpoint of the treatment period. Before that, the probability of not filling out the weekly G-TLFB was monotonically increasing up to 25%. Under this scenario, power dropped to 84%, thus retaining adequate statistical power under this MAR missing data assumption.

Moreover, on the other main outcome, NODS, 60 participants per group yields 80% power to detect a standardised mean difference of 0.5, on the pretest and post-test difference score in favour of BCT, with a correlation between time points of 0.5.

DISCUSSION

This study will be the first randomised controlled study examining the hypothesised added effect of including a CSO in a CBT-based treatment for problem gambling. BCT is theoretically well suited for problem gambling, given its previous effects in treating similar conditions of abuse and addiction.

internet-delivered treatments seem appropriate in treating problem gambling. Problem gambling is often burdened with stigma, making the anonymity of internet-delivered treatments suitable.[99] Furthermore, gambling in Sweden is increasingly internet-based which makes it possible to offer treatment in the environment where the problem exists. This will likely also be an advantage when recruiting participants to the study.

A challenge to most studies on addiction interventions is the high attrition rates, which also happens to have been identified as a weakness of internet-delivered treatments.[100] However, the weekly telephone calls, in combination with the involvement of a CSO, will likely increase compliance among gamblers. We also intend to include automatic reminders in the treatment platform as well as instruct therapists to contact participants who fail to submit modules on time. But we make no illusions of carrying out a study unflawed by attrition, and it is a fundamental right of participants to discontinue participation in the study without notifying therapists or researchers.

BCT relies on functional analysis to establish contingencies between gambling, its antecedents, and its immediate and long-term consequences. Since gambling does not produce any physiologic signs, gambling behaviours can largely be kept hidden, thus making functional analysis less accurate.

Owing to the broad study inclusion criteria, it is expected that a large proportion of the sample will have comorbid conditions. This will enhance the ecological validity of the study, but it could also mean that the treatment is insufficient in making a significant impact on participants. As with all psychological treatments, there is also a risk that participants do not benefit from treatment. Problem gambling and relationship dissatisfaction may actually worsen as they are brought to attention.

One benefit of this study is that it is carried out nationwide, making the sample potentially more representative of the total population. Given the general cost-effectiveness of internet-delivered treatments[101] and the generally favourable outcomes even when compared to face-to-face therapy,[102] the treatment can be implemented as part of the general health services, if proved helpful.

LIMITATIONS

There are several potential limitations with this study. First, the main focus of this study is to investigate differences in treatment outcome when a CSO is involved in treatment, compared to when the gambler participates by himself or herself. However, since this is an RCT where participants are recruited pairwise, CSOs are somewhat involved in treatment regardless of which treatment arm they are randomised into. Given that the treatment is delivered online, CSOs in the CBT condition will potentially have unrestricted access to the treatment modules given to the gambler, which are similar to the CSO modules in the BCT condition. Such a scenario would render the two treatment arms utterly similar.

Second, there is only limited research performed on some of the outcome measures used in the study, making it more difficult to draw conclusions. But, it could also give us the possibility to further develop these measures and increase the possible ways to analyse problem gambling and its consequences.

Third, CSOs in the CBT condition will not be given any treatment modules or have any contact with a therapist. This might have a discouraging effect, and it might influence the outcomes of the study. We will, however, offer the BCT treatment, given it proves superior, when follow-up measures are completed.

ETHICAL CONSIDERATIONS

This study has been given ethical approval from the regional ethics board of Stockholm, Sweden and was

given the registration number 2014/175-31/5. This study will add to the body of knowledge as to how to treat problem gambling and how to involve CSOs in treatment. The findings of this study will be published in peer-reviewed journals and published at international and national conferences.

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Contributors AN designed the study in collaboration with KM, GA, CHG and PC. AN wrote the treatment modules. AN drafted the manuscript in collaboration with KM. PC, CHG and GA reviewed and revised the manuscript. All authors have read and approved the final manuscript.

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