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Keywords: concerned significant other, cognitive behavior therapy, pathological gambling, randomized controlled trial

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ABSTRACT

Introduction: About 2.3 % of the adult population in Sweden is considered to be problem gamblers, and it is estimated that only 5 % of those seek treatment. Problem gambling can have devastating effects on the economy, health and relationship, both for the problem gambler and their concerned significant other (CSO). No empirically supported treatment exists for the CSOs of problem gamblers. Consequently, the aim of this study is to develop and evaluate a program aimed at CSOs of treatment refusing problem gamblers. The program will be based on principles from cognitive behavioral therapy (CBT) and motivational interviewing. In order to benefit as many CSOs as possible, the program will be delivered via the internet with therapist support via encrypted email and short weekly conversations via telephone.

Methods and analysis: This will be a randomized wait-list controlled internet-delivered treatment trial. A CBT program for the CSOs of problem gamblers will be developed and evaluated. The participants will work through 9 modules over 10 weeks in a secure online environment, and receive support via secure emails and over telephone. A total of 150 CSOs over 18 years of age will be included. Measures will be taken at baseline, 3, 6 and 12 months. Primary outcomes concern gambling-related harm. Secondary outcomes include the problem gambler's treatment entry, CSO's levels of depression, anxiety, as well as relationship satisfaction and quality of life.

Ethics and dissemination: The protocol has been approved by the regional ethics board of Stockholm, Sweden. This study will add to the body of knowledge on how to protect CSOs from gambling-related harm, and how to motivate treatment-refusing problem gamblers to seek professional help. The findings of this study will be published in peer-reviewed journals, and presented at international and national conferences.

Trial registration number: ClinicalTrials.gov NCT02250586

INTRODUCTION

An estimated 70 % of the Swedish population aged 16–84 participate in gambling.[1] Most experience no negative consequences, but for a small group of people gambling is problematic. The most recent national survey estimated that around 2.3 % percent[1] of the adult population are problem gamblers. Consequently, their gambling behavior can have devastating effects on both their own and their concerned significant others (CSOs) economic status, health and relationships. A large proportion (18 %) of the adult Swedish population see themselves as CSOs of problem gamblers.[2] Moreover, the Swedish National Institute of Public Health has estimated that approximately 260 000 (~3 %) individuals cohabitate with a problem gambler, and among them 76 000 are children.[1]

The effects of problem gambling on the CSOs have been well documented in the literature.[3-6] Problem gambling causes enormous financial problems for the affected family, such as debts, losses of property, loans that are overdue, maxed credit cards and being chased by creditors.[7] As a result of these consequences some CSOs report feeling depressed, low quality of life and some even attempt suicide.[8,9] Other CSOs experience considerable anger and anxiety as a result of the problem gambler's behavior.[4,10] CSOs also report several stress-related problems, e.g. headaches, bowel problems, and sleep disturbances. [11,12] The CSO's relation to the problem gambler can also be severely affected, and many CSOs report escalating conflicts in the home, dissipation of trust and disturbed relationships with family and friends.[3,4,9,13] In a representative sample in Norway, Wenzel et al.[14] found that 63 % of the CSOs reported that the gambler had worsened the family's financial situation, and 65 % reported that the gambling had led to conflicts in the family. Many CSOs report that they are often left feeling isolated and unsupported.[15]

In Sweden it has been estimated that only about 5 % of the problem gamblers seek professional help.[1] Numerous researchers have suggested that CSOs can play a key role in getting the gambler to enter treatment, and they have highlighted the need to better equip CSOs to cope with the problem gambling.[7,13,16-23] Even though financial concerns are often the main reason that gamblers seek help,[24] many gamblers report concerns for CSOs as an important reason for entering treatment.[18,25] Additionally, as many as 50 % of problem gamblers report that they rely on informal help provided by their CSO.[16]

Research on support programs aimed at CSOs of substance abusers has shown promising results in getting treatment refusing addicts into treatment. The approach with the strongest empirical support is the *community reinforcement and family training (CRAFT)*.[26-28] The CRAFT approach has been modified and tested with CSOs of problem gamblers in two studies.[20,29] Both studies used a self-help workbook to deliver the training, and found that the program had a significant effect on the number of

days gambling, CSOs' program satisfaction and experiences of having their needs met. However, no differences were found between the CRAFT and control group on rates of treatment engagement.

Few studies have evaluated interventions that focus on working with CSOs of problem gamblers in their own right. In 2006, Rychtarik et al.[30] performed a preliminary evaluation of a coping skills training program for CSOs of pathological gamblers. They found a large reduction in symptoms of depression and anxiety in the coping skills training group relative to a wait-list control. However, they found no differences between the groups on partner gambling or treatment entry.

Most CSOs typically turn to self-help, online or telephone support before seeking professional help.[18] Thus, it is possible that an internet-delivered treatment could seem attractive to CSOs, especially since there is evidence that shame and stigma are the main barriers for CSOs in seeking help.[18,31,32] Cognitive-behavioral therapy (CBT) has been readily adapted and evaluated over the internet. These internet-delivered CBT-interventions have often achieved treatment effects that are comparable to face-to-face therapy in several studies.[33-35] Moreover, internet-delivered CBT has also been efficaciously implemented with problem gamblers.[36]

Aims and hypotheses

Earlier studies have found limited success in helping CSOs deal with their problem gambler. Protecting the CSO from gambling related harm can be achieved partly by motivating the gambler to enter treatment, and thus hopefully end the problem gambling, and partly by focusing on the CSOs needs in their own right and how to protect themselves from gambling related harm. Since the available support for CSOs is scarce in Sweden, the aim of this study is to develop and evaluate an internet-delivered CBT program for CSOs of problem gamblers. The program will be inspired by CRAFT but can rightfully be seen as a CBT program—utilizing standard CBT techniques—for CSOs of problem gamblers. Thus, this program is referred to as CBT for CSOs of problem gamblers (CBT-CSO).

The aim of this study will be to investigate the effects and feasibility of an internet-delivered CBT-CSO program on 1) gambling related harm both for the CSO and the problem gambler, 2) problem gamblers' treatment-seeking rate, and 3) relationship functioning and mental health of the CSOs. It is hypothesized that: 1) the CBT-CSO program will lead to a reduction in gambling related harm, 2) the CBT-CSO program will reduce the CSO's anxiety and depressive feelings, 3) the CBT-CSO program will decrease the amount of time and money the problem gambler spend on gambling, 4) the CBT-CSO program will increase the CSO's relationship satisfaction with the problem gambler.

METHODOLOGY

The study will be a randomized controlled trial with two arms: 1) the CBT-CSO program and 2) a wait-list control. The wait-list group will be offered the CBT-CSO program after 10 weeks.

Study population

Participants will be recruited nationwide through the Swedish National Gambling Helpline and via media and internet advertisements.

Eligibility criteria

Inclusion: 1) The CSO and the gambler are at least 18 years old, 2) the CSO is a parent, child, sibling, friend or partner of the gambler. 3) The CSO must have had a relationship with the gambler for at least 3 months. 4) Neither the CSO nor the gambler has had any treatment in the past 3 months (that is related to gambling). 5) The gambler is currently not in treatment or actively seeking treatment. 6) The CSO is able to read and answer questions in Swedish, and is willing to have phone contact with a counselor each week. 7) The gambler is rated by the CSO as having gambling problems (score 8 or greater) on the Problem Gambling Severity Index (PGSI)[37]. 7) CSOs on psychotropic medication must have been on a stable dose for at least 3 months. *Exclusion*: 1) Presence of current psychotic- or bipolar disorder in the CSO or gambler. 2) CSO meets PGSI criteria (8 or greater) for ongoing problem gambling.

Counselors

The study's counselors will be at least master level clinical psychology students on their last semester, or experienced staff from the National Helpline that are trained in motivational interviewing (MI; Rollnick and Miller [38]). They will assist the CSOs via both encrypted e-mails and scheduled weekly telephone calls. The lengths of the calls will be a maximum of 15 minutes per week. The purpose of these calls is to provide positive feedback and answers questions the CSO might have regarding the content of the modules. The counselors will receive training in the study-manual and weekly supervision by an experienced CBT-therapist (c.f., Carlbring, et al. [39]).

Blinding

Participants will not be blinded. Baseline assessment occurs prior to randomization, and follow-up assessment will be self-reported via the internet.

Trial arms

CBT-CSO

The CBT-CSO program will be based on concepts from CBT and MI.[40] CBT-CSO will be similar to the CRAFT approach in many regards, since both approaches utilize generic CBT techniques, such as psychoeducation, functional analysis and positive

reinforcement. However, CRAFT was not developed with CSOs of problem gamblers in mind. Consequently, our approach will incorporate a greater focus on communication training and relationship functioning—using techniques from MI and *integrative behavioral couples therapy (IBCT)*[41] and focus less on functional analysis relative to the CRAFT-approach.

The program will be given as guided self-help with guidance given via a secure email system and telephone. There are 9 modules, which all contain homework exercises and about 5-10 pages of text. Table 1 provides a summary of the 9 modules.

[INSERT TABLE 1 ABOUT HERE]

All CSOs will receive help from their counselor in locating professional gambling treatment as close to their home as possible. The National Gambling Helpline has a registry of available treatment options in Sweden, which is regularly kept up to date. In parallel to this study we are also running a trial on internet CBT for problem gamblers. The CSOs' gamblers who wish to enter treatment will be offered the program used in the parallel study.

Wait-list condition

The participants allocated to the control condition will be put on a waiting list and offered the treatment after 10 weeks. The CSOs will receive information about available treatment options—in their area and web-based—for the problem gambler.

Outcome measures and data collection

See Table 2 for a list of measures and when they will be collected. All outcomes will be self-reported via the internet. The primary outcome concern gambling behavior and consequences for the problem gambler and CSO. Gambling behavior will be reported by the CSO, and will be measured by the timeline followback method for the last 30 days, and continuously during the study. CSOs will be asked to report days gambling and money spent. Previous studies have found fair agreement between CSOs and problem gamblers report,[42] indicating that CSOs report of gambling behavior is reasonably valid and reliable as a proxy measure of problem gambling behavior. The Inventory of Consequences Scale for the Gambler and CSO (ICS)[42] will be used to measure gambling consequences in general. The scale was adopted from the substance abuse field and consists of three subscales: 1) consequences for the gambler, 2) negative emotional consequences for the CSO and 3) negative behavioral consequences for the CSO. The scale has demonstrated good psychometric properties in a preliminary study.[42] The CSOs will also be asked to report whether and when the problem gambler decided to enter treatment. Treatment engagement is defined as completing at least one treatment session or agreeing to call the National Gambling Helpline. We choose the include calls to the Helpline since they work with motivational interviewing,

and research has shown that such brief interventions can reduce gambling problems.[43]

PHQ-9 [44] and GAD-7 [45] will be used to measure symptoms of depression and anxiety. PHQ-9 contains 9 items, scored 0-3 with a total score between 0 and 27.[46] GAD-7 is frequently used to assess general anxiety, and contains 7 items (scored 0-3). Both PHQ-9 and GAD-7 are well-established measures with demonstrated good validity and reliability even when administered via the internet.[46-48] Relationship satisfaction will be measured by the generic version of the relationship assessment scale.[49] RAS consists of 7 items and has shown good psychometric properties with CSOs of problem gamblers.[42] The short version of WHO Quality of Life Questionnaire will be used to measure CSOs quality of life, it consists of 26 items and has demonstrated good reliability and validity.[50]

[INSERT TABLE 2 ABOUT HERE]

Planned missingness design

The study will utilize a planned missingess design for the weekly measures.[52] This is to decrease the number of items each participants must answer each week, but still retain a good temporal resolution. Each participant will be randomized to one of two measurement schemes. Table 3 outlines the two variants.

[INSERT TABLE 3 ABOUT HERE]

Process measures

In order to better understand what mechanisms mediate change during the study, data on treatment involvement will be collected, in addition to the weekly measures. Treatment involvement will be measured as data 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.

Planned subgroup contrasts

It is hypothesized that the following factors will predict treatment response: 1) type of relationship with the problem gambler (parent, romantic partner or other) and 2) if the CSO live with the problem gambler.

Randomization

CSOs will be randomized to one of the two treatment arms (1:1 ratio) after eligibility and pretest assessment is completed. The allocation sequence will be generated by a

computer random number generator. To ensure balanced groups block randomization will be used. Each block's size will be randomly chosen from the set (4,6,8), and be unknown by the researchers involved in the study. A research assistant that is independent from the study will perform the treatment allocation, using sealed, sequentially numbered, opaque envelopes.

Statistical Analyses

Due to the hierarchal structure of the data, and the planned missingness design, analyses will be performed within the linear mixed models framework, such as to model the variability and dependency at the different levels. Treatment entry-rates will be analyzed using discrete-time event history models (i.e. survival analysis).[53] Survival analysis enables the evaluating of both *whether* and *when* events occur; this will be used to compare time to treatment entry and differences in treatment entry-rates in the study. Continuous outcomes will be analyzed using a linear mixed models approach.[54] Model building will follow the data-driven and theoretical approach described in Singer and Willet.[53] Time will be split into two periods by a piecewise linear function[55], this makes it possible to parsimoniously model both change during treatment and follow up data. Additionally, we hypothesize that treatment engagement will be associated with a reduction on the ICS self-report, and will test this hypothesis by joint modeling.[56] Furthermore, for the analysis of the timeline followback reports (count data), it is anticipated that the data will be positively skewed and bounded at zero. Hence, generalized linear mixed models will be fitted, specifically zero-inflated Poisson models. In the case of overdispersion zero-inflated negative binomial regression models will be fit.[57]

Handling of Attrition

All randomized CSOs will be included in the statistical analyses, i.e. an intention-to-treat analysis will be used.[58] 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.[59] Unfortunately it is impossible to prove that the responses are MAR, consequently pattern-mixture methods will be used in order to perform sensitivity analyses.[60]

Sample size

The study's sample size is based on power calculations for the primary outcome (Inventory of Consequences Scale for the Gambler and CSO [ICS]). Since no good parameter estimates are available for this study, standardized coefficients are used. Power is estimated for the primary between-groups comparison directly post treatment. A linear mixed model with random intercept and slopes is assumed. First, it is assumed that the between-groups standardized mean difference (Cohen's *d*) will be at least 0.5 at posttest, standardized using the standard deviation at baseline. Moreover, the individual

heterogeneity in change is likely to be large. Therefore, individual change at post treatment is estimated to have a standard deviation of 0.8 around the standardized average estimate (i.e. variance due to random slopes). Meaning that the 95 % prediction interval for individual treatment response is expected to vary between ± 1.6 around the average change. Assuming a standardized within groups difference of 1, these estimated numbers implies that about 10 % of the participants will be unimproved or have negative outcomes (given by the cumulative distribution function of the Gaussian distribution). Moreover, at post treatment we estimate that 75 % of the variance will be between subjects and 25 % residual variance. A shift in this ratio towards more residual variance will decrease power. Given these estimates 75 participants are needed per group to achieve approximately 80 % power, with $\alpha = 0.05$ (this power calculation used equation 2 in Ard and Edland[61]).

Moreover, based on the treatment entry numbers reported in previous studies,[20,29] it is estimated that treatment entry-rate for the wait-list group will be 15 %. Thus, using formulas to calculate power for a test of two independent proportions,[62] it is estimated that 75 CSOs per group will achieve 80 % power ($\alpha = 0.05$) if the treatment entry-rate in the CBT-CSO group is 35 %. With such few events the power for a test of two proportions and a survival analysis are essentially identical. Hence, power is not reported for a survival analysis.

DISCUSSION

This study will test the efficacy of a CBT-based program for CSOs of problem gamblers. Currently, there exists no empirically supported assistance available to CSOs of problem gamblers. Thus, the development and evaluation of internet-based assistance for these CSOs is deemed to be exceptionally important—especially due to the notable negative consequences suffered by these CSOs. Moreover, the implications of potentially getting treatment refusing gamblers to seek treatment earlier cannot be overstated. Our prediction is that the present study will improve our knowledge of how to get problem gamblers to enter treatment earlier, how to reduce their harmful gambling behavior and how to help their CSOs cope with the gambling—and consequently improve the quality of life for the gambler, the CSOs, and reduce the impact of gambling on the community at large. Moreover, no studies have been conducted with this population in Sweden. This study will therefore provide important information on the feasibility of providing internet-based support to CSOs' of treatment refusing problem gamblers.

Since the intervention will be internet-delivered the potential for wide distribution is evident. This opens the potential to provide assistance to all CSOs in Sweden, especially to the majority of CSOs that live in cities without the existence of any peer-support groups or professional help.

ETHICS AND DISSEMINATION

The protocol has been approved by the regional ethics board of Stockholm, Sweden. Written informed consent will be obtained from all participants, and all participants will be informed that they can withdraw from the trial at any time.

The results of this trial will be submitted for publication in peer-reviewed journals, no matter the results. Findings will also be disseminated at gambling conferences aimed at both researches and practitioners. Moreover, after the study is completed, it is possible for an institution like the Helpline to incorporate the CBT-CSO method in their regular operations.

In the spirit of open science an anonymized version of the dataset generated in this trial will be published in a data repository (e.g. Dryad or figshare), accompanied with the script files to reproduce the statistical analyses. In addition to the CONSORT statement the guidelines for executing and reporting internet intervention research will be adhered to.[63]

CONTRIBUTORS

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

TRIAL STATUS

Recruitment of participants started in Mars 2015.

FUNDING

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COMPETING INTERESTS

None.

PATIENT CONSENT

Written informed consent will be obtained from all participants.

ETHICS APPROVAL

The protocol was approved by the regional ethics board of Stockholm, Sweden (reference: 2014/321-31/5)

DATA SHARING STATEMENT

On completion the dataset generated in this trial will be published in a data repository (e.g. Dryad or figshare), accompanied with the script files to reproduce the statistical analyses.

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Table 1. Program contents

Module 1. Psychoeducation about gambling problems.
Module 2. Functional analysis and gambling free activities.
Module 3. Rewards and behavioral activation for both the CSO and problem gambler.
Module 4. Psychoeducation about motivation and protecting the CSOs economy.
Module 5. Common behaviors that inadvertently enable gambling.
Module 6. Communication training and principles from MI.
Module 7. Problem solving.
Module 8. Inviting the gambler into treatment.
Module 9. Repetition and evaluation.

Table 2. Outcomes and their placement during the study

Outcomes	Measure	Pretest	Weekly during treatment*	Posttest, 6, 12 months
Primary outcome				
Gambling consequences	ICS	X	X	X
Secondary outcomes				
Treatment engagement	-	X	X	X
Gambling behavior	TLFB: Days, money	X		X
Depression	PHQ-9	X	X	X
Anxiety	GAD-7	X	X	X
Relationship	RAS	X	X	X
Quality of Life	WHOQOL-Bref			

* = Not all measured are answered by all participants every week, see the section about "planned missingness design"; TLFB = Timeline followback method;[51] ICS = Inventory of Consequences Scale for the Gambler and CSO;[42] WHOQOL-Bref = WHO Quality of Life Questionnaire-BREF;[50] RAS = Relationship Assessment Scale;[49] PHQ-9 = Patient Health Questionnaire-9;[44] GAD-7 = Generalized Anxiety Disorder Scale.[45]

Table 3. Planned missingess design for the weekly measurements

	Days from randomization								
	0	7	14	21	28	35	42	49	56
Variant 1	X	O	O	O	X	O	O	O	X
Variant 2	X	O	X	O	O	O	X	O	O

A = ICS; B = PHQ-9, GAD-7, RAS and TLFB (last seven days)

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INTERNET-DELIVERED COGNITIVE-BEHAVIORAL THERAPY FOR CONCERNED SIGNIFICANT OTHERS OF PEOPLE WITH PROBLEM GAMBLING: STUDY PROTOCOL FOR A RANDOMIZED WAIT-LIST CONTROLLED TRIAL

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ABSTRACT

Introduction: About 2.3 % of the adult population in Sweden is considered to suffer from problem gambling, and it is estimated that only 5 % of those seek treatment. Problem gambling can have devastating effects on the economy, health and relationship, both for the individual that gamble and their concerned significant other (CSO). No empirically supported treatment exists for the CSOs of people with problem gambling. Consequently, the aim of this study is to develop and evaluate a program aimed at CSOs of treatment-refusing problem gamblers. The program will be based on principles from cognitive-behavioral therapy (CBT) and motivational interviewing. In order to benefit as many CSOs as possible, the program will be delivered via the internet with therapist support via encrypted email and short weekly conversations via telephone.

Methods and analysis: This will be a randomized wait-list controlled internet-delivered treatment trial. A CBT program for the CSOs of people with problem gambling will be developed and evaluated. The participants will work through 9 modules over 10 weeks in a secure online environment, and receive support via secure emails and over the telephone. A total of 150 CSOs over 18 years of age will be included. Measures will be taken at baseline, 3, 6, and 12 months. Primary outcomes concern gambling-related harm. Secondary outcomes include the treatment entry of the individual that gamble, CSO's levels of depression, anxiety, as well as relationship satisfaction and quality of life.

Ethics and dissemination: The protocol has been approved by the regional ethics board of Stockholm, Sweden. This study will add to the body of knowledge on how to protect CSOs from gambling-related harm, and how to motivate treatment-refusing individuals to seek professional help for problem gambling.

Trial registration number: ClinicalTrials.gov NCT02250586

INTRODUCTION

An estimated 70 % of the Swedish population aged 16–84 participate in gambling.[1] Most experience no negative consequences, but for a small group of people gambling is problematic. The most recent national survey estimated that around 2.3 % percent[1] of the adult population suffer from problem gambling. Consequently, their gambling behavior can have devastating effects on both their own and their concerned significant others' (CSOs) economic status, health, and relationships. A large proportion (18 %) of the adult Swedish population see themselves as CSOs of people with problem gambling.[2] Moreover, the Swedish National Institute of Public Health has estimated that approximately 260 000 (~3 %) individuals cohabitate with an individual that gamble problematically, and among them 76 000 are children.[1]

The effects of problem gambling on the CSOs have been well documented in the literature.[3-6] Problem gambling causes enormous financial problems for the affected family, such as debts, losses of property, loans that are overdue, maxed credit cards and being chased by creditors.[7] As a result of these consequences some CSOs report feeling depressed, low quality of life and some even attempt suicide.[8,9] Other CSOs experience considerable anger and anxiety as a result of the problem gambling.[4,10] CSOs also report several stress-related problems, e.g. headaches, bowel problems, and sleep disturbances. [11,12] The CSO's relation to the individual that gamble can also be severely affected, and many CSOs report escalating conflicts in the home, dissipation of trust and disturbed relationships with family and friends.[3,4,9,13] In a representative sample in Norway, Wenzel et al.[14] found that 63 % of the CSOs reported that the problem gambling had worsened the family's financial situation, and 65 % reported that the gambling had led to conflicts in the family. Many CSOs report that they are often left feeling isolated and unsupported.[15]

In Sweden, it has been estimated that only about 5 % of the people with problem gambling seek professional help.[1] Numerous researchers have suggested that CSOs can play a key role in getting these people with problem gambling to enter treatment, and they have highlighted the need to better equip CSOs to cope with the problem gambling.[7,13,16-23] Even though financial concerns are often the main reason that gamblers seek help,[24] many individuals with a gambling problem report concerns for CSOs as an important reason for entering treatment.[18,25] Additionally, as many as 50 % of people with problem gambling report that they rely on informal help provided by their CSO to overcome their gambling problem.[16]

Research on support programs aimed at CSOs of people suffering from addiction has shown promising results in getting the treatment-refusing individual into treatment. The approach with the strongest empirical support is the *community reinforcement and family training (CRAFT)*.[26-28] The CRAFT approach has been modified and tested with CSOs of people with problem gambling in two studies.[20,29] Both studies used a self-

help workbook to deliver the training, and found that the program had a significant effect on the number of days gambling, CSOs' program satisfaction and experiences of having their needs met. However, no differences were found between the CRAFT and control group on rates of treatment engagement.

Few studies have evaluated interventions that focus on working with CSOs of people with problem gambling in their own right. In 2006, Rychtarik et al.[30] performed a preliminary evaluation of a coping skills training program for CSOs that had a partner with problem gambling. They found a large reduction in symptoms of depression and anxiety in the coping skills training group relative to a wait-list control. However, they found no differences between the groups on partner gambling or treatment entry. These findings should be considered highly preliminary since the study involved just 23 participants.

In 2013 The Swedish National Helpline received 600 calls (31 % of total) from CSOs.[31] Research has shown that most CSOs typically turn to self-help, online or telephone support before seeking professional help.[18] Rodda et al [32] looked at reasons why CSOs chose web-based counseling in Australia, and found that ease of access, privacy and anonymity were the main reasons. Another study on the same service[33], found that the large majority of CSOs accessing web-based counseling reported emotional distress, and impacts on relationship, social life and finances due to the problem gambling. There is also evidence that shame and stigma are the main barriers for CSOs in seeking help,[18,34,35] therefore it is possible that an internet-delivered treatment could seem attractive to these CSOs. Cognitive-behavioral therapy (CBT) has been readily adapted and evaluated over the internet. These internet-delivered CBT-interventions have often achieved treatment effects that are comparable to face-to-face therapy in several studies.[36-38] Moreover, internet-delivered CBT has also been efficaciously implemented with problem gamblers.[39]

Aims and hypotheses

Earlier studies have found limited success in helping CSOs deal with the problem gambling. Protecting the CSO from gambling-related harm can be achieved partly by motivating the individual that gamble to enter treatment, and thus hopefully end the problem gambling, and partly by focusing on the CSOs needs in their own right. Since the available support for CSOs is scarce in Sweden, the aim of this study is to develop and evaluate an internet-delivered CBT program for CSOs of people with problem gambling. The program will be inspired by CRAFT but can rightfully be seen as a CBT program—utilizing standard CBT techniques. Thus, this program is referred to as CBT for CSOs of people with problem gambling (CBT-CSO).

The aim of this study will be to investigate the effects and feasibility of an internet-delivered CBT-CSO program on 1) gambling-related harm both for the CSO and the

individual that gamble, 2) treatment-seeking rate among the people with problem gambling, and 3) relationship functioning and mental health of the CSOs. It is hypothesized that: 1) the CBT-CSO program will lead to a reduction in gambling-related harm, and a greater treatment-seeking rate, 2) the CBT-CSO program will reduce the CSO's anxiety and depressive feelings, 3) the CBT-CSO program will decrease the amount of time and money spent on gambling by the individual that gamble, 4) the CBT-CSO program will increase the CSO's relationship satisfaction with the individual with problem gambling.

The program will be compared to a wait-list control condition. This choice of comparator is justified, since not much is known about the efficacy and feasibility of these types of programs in this population.

METHODOLOGY

The study will be a randomized controlled trial with two arms: 1) the CBT-CSO program and 2) a wait-list control. The wait-list group will be offered the CBT-CSO program after 10 weeks.

Study population and recruitment

Participants will be recruited nationwide through the Swedish National Gambling Helpline and via media and internet advertisements. Advertisements will be publicized nationwide to the general population in newspapers and on Facebook. Targeted advertisements will be published via Google Adwords. Volunteers will sign up to the study via a public website. After signing up they will be invited to answer a survey of screening questions and the baseline assessment. If they are eligible they will be invited to a short telephone interview with one of the study's counselors. During this interview the volunteers are informed about the study and get the chance to ask questions. If they agree to participate in the study, the volunteers are asked to send in written informed consent via mail. After the consent is received, treatment allocation is performed, and the participant is contacted within the treatment platform.

Eligibility criteria

For brevity we will refer to the participant's related party that gamble as the identified patient (IP).

Inclusion: 1) The CSO and the IP are at least 18 years old, 2) the CSO is a parent, child, sibling, friend or partner of the IP. 3) The CSO must have had a relationship with the IP for at least 3 months. 4) Neither the CSO nor the IP has had any treatment in the past 3 months (that is related to gambling). 5) The IP is currently refusing to start treatment for gambling problems. 6) The CSO is able to read and answer questions in Swedish, and is willing to have phone contact with a counselor each week. 7) The IP is rated by the CSO as having gambling problems (score 8 or greater) on the Problem Gambling Severity Index (PGSI)[40]. 7) CSOs on psychotropic medication must have been on a

stable dose for at least 3 months. *Exclusion*: 1) Presence of current psychotic- or bipolar disorder in the CSO or IP. 2) CSO meets PGSI criteria (8 or greater) for ongoing problem gambling.

Counselors

The study's counselors will be at least master level clinical psychology students on their last semester, or experienced staff from the National Helpline that are trained in motivational interviewing (MI; Rollnick and Miller [41]). They will assist the CSOs via both encrypted e-mails and scheduled weekly telephone calls. The length of the calls will be a maximum of 15 minutes per week. The purpose of these calls is to provide positive feedback and answer questions the CSO might have regarding the content of the modules. In addition to the telephone calls the counselors also provide written feedback one time per week. They will also send short messages to reinforce the participants' efforts. The amount of time spent on sending emails is limited to 15 minutes per week. The counselors will also try to contact participants that are not responsive both via email and telephone, to see that there are no technical difficulties or other problems. The counselors will receive training in the study-manual and weekly supervision by an experienced CBT-therapist (c.f., Carlbring, et al. [42]).

Blinding

Neither participants nor counselors will be blinded to treatment allocation. Baseline assessment occurs prior to randomization, and follow-up assessment will be self-reported via the internet.

Trial arms

CBT-CSO

The CBT-CSO program will be based on concepts from CBT, integrative behavioral couples therapy (IBCT) [43] and MI.[44] CBT-CSO will be similar to the CRAFT approach in many regards, since both approaches utilize generic CBT techniques, such as psychoeducation, functional analysis and positive reinforcement. Both methods are also targeted specifically at CSOs alone, where the person with the drinking or gambling problem does not participate in the treatment. However, CRAFT was not developed with problem gambling in mind, and it relies heavily on the CSO being able to tell when a person is intoxicated. Gambling can be done anywhere and at anytime and is easy to hide. Therefore reinforcing intermittent abstinence from gambling is often very difficult. Consequently, our approach will focus less on the CSO being able to tell when the IP has gambled and more on creating an environment that encourages gambling-free activities. The aim is for the CSO and IP to engage in naturally reinforcing activities both alone and together. Thus, hopefully, reconnecting with each other and reintroducing non-gambling related reinforcers to the IP. The CSO is also introduced to concepts from motivational interviewing, such as "the stages of change", "asking for permission" and the concept of

"resistance". The purpose is to help the CSO find situations where the IP is more open to change, instead of inadvertently creating resistance. Concrete examples are given of different ways to avoid resistance, and how to lead the conversation forward. Concepts from IBCT are also integrated in to the program. For instance, "contingency based change" is one of the purposes of trying to get the CSO and IP to engage in more activities together, i.e. reinforcement from spontaneous positive behaviors. IBCT's concept of 'acceptance' is also introduced to help the CSO to better understand the IP's learning history and therefore better cope with the situation. There are also several concepts and exercises that focus on CSOs in their own right. The rationale is that the problem gambling has lead to the CSOs losing important positive reinforcers in their lifes. Therefore, there are reoccurring exercises to engage the CSO in reinforcing activities. The CSOs are prompted to schedule and log these activities. A short summary of the individual modules is provided in Table 1.

[INSERT TABLE 1 ABOUT HERE]

The program will be given as guided self-help with guidance given via a secure email system, and telephone. There are 9 modules, which all contain homework exercises and about 5-10 pages of text. Every week a new module is made available to the participant, regardless of whether the previous module has been completed. At the start of the study the participant is informed that the counselor will be aiding them for a maximum of 10 weeks. After these 10 weeks the participant will still have access to the modules but not the counselor.

All CSOs will receive help from their counselor in locating professional gambling treatment as close to their home as possible. The National Gambling Helpline has a registry of available treatment options in Sweden, which is regularly kept up to date. In parallel to this study we are also running a trial on internet CBT for people with problem gambling. The CSO's IP that wish to enter treatment will be offered the program used in the parallel study.

Wait-list condition

The participants allocated to the control condition will be put on a waiting list and offered the treatment after 10 weeks. The participants will know that they have been randomized to the control group. During these 10 weeks they will participate in the weekly assessments. The CSOs will receive information about available treatment options—in their area and web-based—for problem gambling.

Outcome measures and data collection

See Table 2 for a list of measures and when they will be collected. All outcomes will be self-reported via the internet. The primary outcome concern gambling behavior and

consequences for the IP and their CSO. This will be measured by the Inventory of Consequences Scale for the Gambler and CSO (ICS)[45]. The scale was adopted from the substance abuse field and consists of three subscales: 1) consequences for the gambler, 2) negative emotional consequences for the CSO and 3) negative behavioral consequences for the CSO. It was used in a similar study with CSOs of people who gamble.[20] Internal consistency was good ranging from $\alpha =$ 0.86 to 0.89 for the different subdomains. Test-retest reliability was excellent over 7 to 10 days (ICC = 0.93 for all domains).[45] Although, lacking an extensive psychometric evaluation these results indicate good psychometric properties in a relevant sample. Gambling behavior will be reported by the CSO, and will be measured by the timeline followback method for the last 30 days, and continuously during the study. CSOs will be asked to report days gambling and money spent. Previous studies have found fair agreement between reports from CSOs and the IP,[45] indicating that CSO's report of gambling behavior is reasonably valid and reliable as a proxy measure of problem gambling behavior. The CSOs will also be asked to report whether and when the IP decided to enter treatment. Treatment engagement is defined as completing at least one treatment session or agreeing to call the National Gambling Helpline. We choose to include calls to the Helpline since they work with motivational interviewing, and research has shown that such brief interventions can reduce gambling problems.[46]

PHQ-9 [47] and GAD-7 [48] will be used to measure symptoms of depression and anxiety. PHQ-9 contains 9 items, scored 0-3 with a total score between 0 and 27.[49] GAD-7 is frequently used to assess general anxiety, and contains 7 items (scored 0-3). Both PHQ-9 and GAD-7 are well-established measures with demonstrated good validity and reliability even when administered via the internet.[49-51] Relationship satisfaction will be measured by the generic version of the relationship assessment scale (RAS).[52] RAS consists of 7 items and has shown good psychometric properties with CSOs of problem gamblers.[45] The short version of WHO Quality of Life Questionnaire will be used to measure CSOs quality of life, it consists of 26 items and has demonstrated good reliability and validity.[53]

[INSERT TABLE 2 ABOUT HERE]

Data monitoring

Since all outcomes are collected online the risk of data loss or corruption is minimal. The data is stored encrypted and is only accessible by the people running the study. The collection and storage of data will adhere to the Swedish Personal Data Act.[54] This study will not have a formal Data Monitoring Committee and no interim analysis will be performed. Previous studies and clinical experience indicate minimal risk for the participants. Moreover, participants will be asked about any adverse events experienced during the study period.

Planned missingness design

The study will utilize a planned missingness design for the weekly measures.[55] This is to decrease the number of items each participant must answer each week, but still retain a good temporal resolution. Each participant will be randomized to one of two measurement schemes. This design effectively leads to biweekly measures for ICS and weekly measures for PHQ-9, GAD-7, RAS, and TLFB. Table 3 outlines the two variants.

[INSERT TABLE 3 ABOUT HERE]

Process measures

In order to better understand what mechanisms mediate change during the study, data on treatment involvement will be collected, in addition to the weekly measures. Treatment involvement will be measured as data completion, time 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.

Planned subgroup contrasts

It is hypothesized that the following factors will predict treatment response: 1) type of relationship with the IP (parent, romantic partner or other) and 2) if the CSO lives with the IP.

Randomization

CSOs will be randomized to one of the two treatment arms (1:1 ratio) after eligibility and pretest assessment is completed. The allocation sequence will be generated by a computer random number generator. To ensure balanced groups block randomization will be used. Each block's size will be randomly chosen from the set (4,6,8), and be unknown by the researchers involved in the study. A research assistant that is independent from the study will perform the treatment allocation, using sealed, sequentially numbered, opaque envelopes.

Statistical analyses

Due to the hierarchical structure of the data, and the planned missingness design, analyses will be performed within the linear mixed models framework, such as to model the variability and dependency at the different levels. Treatment entry-rates will be analyzed using discrete-time event history models (i.e. survival analysis).[56] Survival analysis enables the evaluation of both *whether* and *when* events occur; this will be used to compare time to treatment entry and differences in treatment entry-rates in the study. Continuous outcomes will be analyzed using a linear mixed models approach.[57] Model building will follow the data-driven and theoretical approach described in Singer and Willet.[56] Time will be split into two periods by a piecewise linear function[58], this makes it possible to parsimoniously model both change during treatment and

follow-up data. Additionally, we hypothesize that treatment engagement will be associated with a reduction on the ICS self-report, and will test this hypothesis by joint modeling.[59] Furthermore, for the analysis of the timeline followback reports (count data), it is anticipated that the data will be positively skewed and bounded at zero. Hence, generalized linear mixed models will be fitted, specifically zero-inflated Poisson models. In the case of overdispersion zero-inflated negative binomial regression models will be fit.[60]

Handling of attrition

All randomized CSOs will be included in the statistical analyses, i.e. an intention-to-treat analysis will be used.[61] 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 and multiple imputation will yield sensible parameter estimates.[62] Unfortunately, it is impossible to prove that the responses are MAR, consequently pattern-mixture methods will be used in order to perform sensitivity analyses.[63]

Sample size

The study's sample size is based on power calculations for the primary outcome (Inventory of Consequences Scale for the Gambler and CSO [ICS]). Since no good parameter estimates are available for this study, standardized coefficients are used. Power is estimated for the primary between-groups comparison directly post treatment. A linear mixed model with random intercept and slopes is assumed. First, it is assumed that the between-groups standardized mean difference (Cohen's *d*) will be at least 0.5 at posttest, standardized using the standard deviation at baseline. Moreover, the individual heterogeneity in change is likely to be large. Therefore, individual change at post treatment is estimated to have a standard deviation of 0.8 around the standardized average estimate (i.e. variance due to random slopes). This amount of heterogeneity means that the 95 % prediction interval for individual treatment response is expected to vary between ± 1.6 around the average change. Assuming a standardized within groups difference of 1, these estimated numbers implies that about 10 % of the participants will be unimproved or have negative outcomes (given by the cumulative distribution function of the Gaussian distribution). Moreover, at post treatment we estimate that 75 % of the variance will be between subjects and 25 % residual variance. A shift in this ratio towards more residual variance will decrease power. Given these estimates 75 participants are needed per group to achieve approximately 80 % power, with $\alpha = 0.05$ (this power calculation used equation 2 in Ard and Edland[64]).

Moreover, based on the treatment entry numbers reported in previous studies,[20,29] it is estimated that the treatment entry-rate for the wait-list group will be 15 %. Thus, using formulas to calculate power for a test of two independent proportions,[65] it is estimated that 75 CSOs per group will achieve 80 % power ($\alpha = 0.05$) if the treatment

entry-rate in the CBT-CSO group is 35 %. With such few events the power for a test of two proportions and a survival analysis are essentially identical. Hence, power is not reported for a survival analysis.

DISCUSSION

This study will test the efficacy of a CBT-based program for CSOs of people with problem gambling. Currently, there are no empirically supported treatments that could be considered "well-established" (c.f., Chambless et al. [66]) available to these CSOs, regardless of the mode of delivery. Since the intervention will be internet-delivered the potential for wide distribution is evident. This opens the potential to provide assistance to all CSOs in Sweden, especially to the majority of CSOs that live in cities without the existence of any peer-support groups or professional help. Thus, the development and evaluation of internet-based assistance for these CSOs is deemed to be exceptionally important. Moreover, the implications of potentially getting treatment-refusing individuals to seek gambling treatment earlier cannot be overstated. Our prediction is that the present study will improve our knowledge of how to get people with problem gambling to enter treatment, reduce their harmful gambling behavior, and help their CSOs cope with the gambling. Thus, hopefully improve the quality of life for the people that gamble, the CSOs, and reduce the impact of problem gambling on the community at large. Moreover, no studies have been conducted with this population in Sweden. This study will therefore provide important information on the feasibility of providing internet-based support to CSOs' of treatment-refusing people with problem gambling.

LIMITATIONS

There are several potential limitations to this design. First, there is only limited research done on the main outcome measure, and how well CSOs provide valid reportings of gambling behavior. Moreover, the feasibility of this type of intervention is unknown. Therefore, adherence to the program and attrition from the study are potential challenges. Lastly, the wait-list design will not enable between-group comparison for long-term follow-up measures. Thus, it will not be possible to know how the program affects relapse rates in the long-term. Dispite these limitations this study will hopefully provide preliminary evidence regarding the feasibility and efficacy of the program.

ETHICS AND DISSEMINATION

The protocol has been approved by the regional ethics board of Stockholm, Sweden. Written informed consent will be obtained via mail from all participants, and all participants will be informed that they can withdraw from the trial at any time.

The results of this trial will be submitted for publication in peer-reviewed journals, no matter the results. Findings will also be disseminated at gambling conferences aimed at both researchers and practitioners. Moreover, after the study is completed, it is possible

for an institution like the Helpline to incorporate the CBT-CSO method in their regular operations.

In the spirit of open science an anonymized version of the dataset generated in this trial will be published in a data repository (e.g. Dryad or figshare), accompanied with the script files to reproduce the statistical analyses. In addition to the CONSORT statement, the guidelines for executing and reporting internet intervention research will be adhered to.[67]

CONTRIBUTORS

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

TRIAL STATUS

Recruitment of participants started in March 2015.

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COMPETING INTERESTS

None.

PATIENT CONSENT

Written informed consent will be obtained via mail from all participants.

ETHICS APPROVAL

The protocol was approved by the regional ethics board of Stockholm, Sweden (reference: 2014/321-31/5)

DATA SHARING STATEMENT

On completion the dataset generated in this trial will be published in a data repository (e.g. Dryad or figshare), accompanied with the script files to reproduce the statistical analyses.

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Table 1. Program contents

Module	*Summary content*
1. Psychoeducation about gambling problems	• Information about the program and technical platform. • Gambling problems in general, signs of gambling, and the biopsychosocial model. • Goals, and how the gambling problem started.
2. Functional analysis and gambling free activities	• Functional analysis with exercises. • Gambling urges. • Alternatives to gambling. • Reinforcing non-gambling behavior.
3. Rewards and behavioral activation for both the CSO and problem gambler	• Helping CSOs reconnect with their values. • Behavioral activation and rewarding themselves. • Strategies that make the CSO feel worse. • Reconnecting with the gambler; doing things together.
4. Psychoeducation about motivation and protecting the CSOs economy	• CSO's motivation to support the IP. • Motivation and gambling; "stages of change". • How to talk about gambling and avoiding resistance; "asking for permission". • Protecting the CSO's economy. • Lending money and enabling.
5. Common behaviors that inadvertently enable gambling	• Enabling. • Natural negative consequences.
6. Communication training and principles from MI	• Rolling with the punches. • Effective communication; "soft disclosures". • Active listening and reflections.
7. Problem solving	• Problem solving with exercises. • Interactive log to perform the steps in problem solving.
8. Inviting the gambler into treatment	• Identifying when motivation is high. • Different treatment options. • Examples of how to use communication skills. • Support during treatment. • Relapses.
9. Repetition and evaluation	• Repetition, evaluation, and creating an action plan.

Table 2. Outcomes and their placement during the study

Outcome	Measure	Pretest	Weekly during treatment*	Posttest, 6, 12 months
Primary outcome				
Gambling consequences	ICS	X	X	X
Secondary outcomes				
Treatment engagement	-	X	X	X
Gambling behavior	TLFB: Days, money	X	X	X
Depression	PHQ-9	X	X	X
Anxiety	GAD-7	X	X	X
Relationship	RAS	X	X	X
Quality of Life	WHOQOL-Bref	X		X

* = Not all measures are answered by all participants every week, see the section about "planned missingness design"; TLFB = Timeline followback method;[68] ICS = Inventory of Consequences Scale for the Gambler and CSO;[45] WHOQOL-Bref = WHO Quality of Life Questionnaire-BREF;[53] RAS = Relationship Assessment Scale;[52] PHQ-9 = Patient Health Questionnaire-9;[47] GAD-7 = Generalized Anxiety Disorder Scale.[48]

Table 3. Planned missingness design for the weekly measurements, participants are randomly assigned to one of two measurement schemes

	Days from randomization								
	0	7	14	21	28	35	42	49	56
Scheme 1	X	O	O	O	X	O	O	O	X
Scheme 2	X	O	X	O	O	O	X	O	O

X = ICS only; O = PHQ-9, GAD-7, RAS and TLFB (last seven days)

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	_____2____
	2b	All items from the World Health Organization Trial Registration Data Set	_____2_____
Protocol version	3	Date and version identifier	_____NA_____
Funding	4	Sources and types of financial, material, and other support	_____10___
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1___
	5b	Name and contact information for the trial sponsor	_____10____
	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	_____10____
	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)	_____NA___

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	3
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	4
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)	5
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	5
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	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)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	5
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	5
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	6
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)	5-6

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	9
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	7
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	7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	5
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	6
	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	6

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	6
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	8
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	8
	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)	8
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	8
	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	8
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	8
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	8
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	11
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)	NA

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	8
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
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	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	10
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	10
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	NA
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	10
	31b	Authorship eligibility guidelines and any intended use of professional writers	10
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	10
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	NA
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	NA

*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.