Protocol for a randomised trial of cognitive and exposure therapies for problem gambling

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-003244
Article Type:	Protocol
Date Submitted by the Author:	17-May-2013
Complete List of Authors:	Smith, David; Flinders University, Psychiatry Battersby, Malcolm; Flinders University, Psychiatry Harvey, Peter; Flinders University, Psychiatry Pols, Rene; Flinders University, Psychiatry Ladouceur, Robert; Université Laval, School of Psychology
Primary Subject Heading:	Addiction
Secondary Subject Heading:	Mental health
Keywords:	Impulse control disorders < PSYCHIATRY, Adult psychiatry < PSYCHIATRY, PUBLIC HEALTH

Title

Protocol for a randomised trial of cognitive and exposure therapies for problem gambling

Authors

David P Smith
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: david.smith@flinders.edu.au
Tel: +61 8 8404 2610
Fax: +61 8 8404 2101

Malcolm W Battersby
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: malcolm.battersby@flinders.edu.au
Tel: +61 8 8204 2314
Fax: +61 8 8404 2101

Peter W Harvey
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: peter.harvey@flinders.edu.au
Tel: +61 8 8204 2314
Fax: +61 8 8404 2101

Rene G Pols
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: rene.pols@flinders.edu.au
Tel: +61 8 8204 4849
Fax: +61 8 8204 6410

Robert Ladouceur
Institutional affiliation: Université Laval, School of Psychology
Address: 2325, rue des Bibliothèques, Bureau 1328, Université Laval, Québec (Québec), Canada, G1V 0A6.
Country: Canada
Email: robert.ladouceur@psy.ulaval.ca
Tel: (418) 656-3996
Fax: (418) 656-3646

Running head
Trial protocol for gambling treatments

Word count
Abstract: 235
Main text: 3,500

Declaration of interest
This work is funded by Victorian Department of Justice, Office of Gaming & Racing grant 061/09. The SGTS is funded by the Office of Problem Gambling, Department of Families and Social Inclusion, Government of South Australia. The authors have no other conflicts of interest to declare.

Article summary

Article focus

- To isolate and compare cognitive and behavioural (exposure-based) techniques to determine their relative efficacy in treating problem gambling.
- The primary research question is: Among treatment seeking problem gamblers, is exposure therapy more effective in reducing gambling severity symptoms (harm to self subscale of the VGS) over the 12-month study period (intervention and maintenance effects) compared with cognitive therapy?

Key messages

- Problem gambling is a serious public health concern at an international level and occurs more frequently in younger populations.
- The best evidence for gambling treatments is for cognitive behavioural therapy (CBT) but remains tentative.
- This study will be the first to compare cognitive and exposure therapies in this population.

Strengths and limitations

A key strength of this study is that all treatment seeking problem gamblers meeting eligibility criteria will receive an active treatment. Also, due to the broad study inclusion criteria, it is expected that a significant proportion of the sample will have co-morbid conditions (e.g. anxiety, depression, and substance abuse which will enhance the external validity of findings using an intent-to-treat design. A limitation of the design is no control group to account for non-specific treatment effects, however, a reasonable assumption is made that non-specific effects will be approximately similar between study groups due to analogous therapy structures,

therapist background and experience, and therapeutic environment. A further limitation is that this study will be conducted at a single-site the findings will have some limitations for inference to a wider population. On the other hand, benefits of being a single-site study can include more effective lines of communication and a more consistent application of research protocol.

Abstract

Background and aims: Problem gambling is a serious public health concern at an international level where population prevalence rates average 2% or more and occurs more frequently in younger populations. The most empirically established treatments to date are combinations of cognitive and behavioural techniques labelled cognitive behaviour therapy (CBT). However, there is a paucity of high quality evidence for the comparative efficacy of core CBT interventions in treating problem gamblers. This study aims to isolate and compare cognitive and behavioural (exposure-based) techniques to determine their relative efficacy.

Methods: A sample of 130 treatment seeking problem gamblers will be allocated to either cognitive or exposure therapy in a two-group randomised, parallel design. Repeated measures will be conducted at baseline, mid and end of treatment (12 sessions intervention period), and 3, 6, and 12 months (maintenance effects). The primary outcome measure is improvement in problem gambling severity symptoms using the Victorian Gambling Screen (VGS) harm to self sub-scale. The VGS measures gambling severity on an extensive continuum, therefore enhancing sensitivity to change within and between individuals over time.

Discussion: This article describes the research methods, treatments, and outcome measures used to evaluate gambling behaviours, problems caused by gambling and mechanisms of change. This study will be the first to compare cognitive and exposure therapies in this population. Findings are expected to guide consumers, clinicians, policy makers and funders in the use of these treatments for gambling disorders.

Introduction

Pathological gambling (PG) from a mental health perspective is defined by the American Psychiatric Association DSM-IV-TR as "…persistent and recurrent maladaptive gambling behaviour that disrupts personal, family and vocational pursuits" (1)**.** The term 'problem gambling' defines less severe forms of gambling disorders and has been the basis for the development of several diagnostic and screening instruments such as the Canadian Problem Gambling Index (CGPI) (2) and the Victorian Gambling Screen (VGS) (3). It is a serious public health concern at an international level where population prevalence rates average 2% or more and occurs more frequently in younger populations (4-9). Co-morbid mental health disorders such as depression and anxiety are common in both treatment seeking and general populations of problem gamblers (10).

Treatment types available for gambling disorders have similarities to those of other addictions and include psychological, peer-support, and more recently, pharmacological interventions (11, 12). To date, the best evidence for gambling treatments is psychological, where cognitive behavioural therapy (CBT) has been the most researched (13) and the evidence-base recommended as "…trusted to guide practice in most situations" based on NHMRC (National Health and Medical Research Council) grades for developers of guidelines (14).

The theoretical underpinnings of CBT include cognitions (e.g. erroneous thoughts) and psychobiological states (e.g. physiological arousal) and are two dominant approaches to explaining gambling disorders (15). Most variants of CBT for treating gambling disorders have shown to be clinically beneficial compared to no treatment, and the most rigorous clinical trials have comprised of a combined cognitive-behavioural approach (13, 16). For core techniques, findings have indicated cognitive therapy (CT) has an "added advantage" when compared

directly to no treatment, although evidence is tentative due to heterogeneity between studies (13). Cognitive restructuring plays an important role in CT and has shown to be beneficial in treating a range of mental health conditions (17).

However, the comparative efficacy of CT with other core CBT interventions such as behavioural (exposure-based) therapies that target psychobiological related gambling pathology is unknown (13). Exposure therapy (ET) is grounded in classical and operant conditioning paradigms and where cue-exposure with extinction processes has been proposed as more beneficial than other types (e.g. aversive therapy) in treating gambling addiction (18). ET has shown to be equally effective as CT in treating anxiety disorders where both techniques have similar hypothesised mechanisms of therapeutic change to those in gambling disorders (19, 20). In addictions there is no conclusive evidence for exposure based treatments due to there being few clinical trials with power (21).

As behavioural therapies in general are more parsimonious in terms of delivery than CT (22) it is important from a public health point of view to understand the relative efficacy of these core treatments. Therefore, we designed a study titled "Comparing outcomes of cognitive and exposure therapy for problem gambling" which is a randomised trial comparing efficacies of CT and ET. This trial is motivated by the uncertainty about the clinical superiority of CT over ET. Based on this uncertainty, the concept of equipoise exists and participants will, therefore, not be disadvantaged from randomisation to either treatment group. This study will be the first to compare these treatments in a population of treatment seeking gamblers.

Study design

Comparing outcomes of cognitive and exposure therapy for gambling disorders is a two-group randomised, parallel design with treatment seeking problem gamblers presenting to the

Statewide Gambling Therapy Service (SGTS) in South Australia. The study will recruit 130 participants over a 12 month period commencing April 2011. The outpatient SGTS programme offers one-on-one and group therapy for problem gamblers at three key metropolitan (Adelaide) centres, one of which will be selected as the trial site. The primary referral sources of clients presenting to SGTS are self, Gambling Helpline and related agencies and general practitioners. The service is staffed by a psychiatrist and therapists with professional registration in psychology, nursing, or social work. All therapists have graduate qualifications and clinical experience in CBT (19). Data collection will finish in July 2013.

The study was approved by the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12610000828022) at the trials inception.

Participant recruitment and random assignment

To assess study eligibility, an independent clinician will conduct semi-structured interviews with treatment seeking problem gamblers presenting to SGTS during the recruitment period. The interview will include assessment of individual demographics, recent gambling activities, and administration of the well-validated *South Oaks Gambling Screen* (SOGS) (23). The SOGS is a 20 item questionnaire based on DSM criteria for pathological gambling. A score of 5 or more is indicative of probable pathological gambler. In gambling treatment samples the scale has good reliability, exhibits high correlations with DSM-IV diagnostic criteria, and good to excellent classification accuracy (24).

Study eligibility will be based on the following inclusion criteria: 18 years of age or older; treatment seeking for problem gambling with electronic gaming machines (EGM's); not

involved in a concurrent gambling treatment program; not received psychological treatment for problem gambling in previous 12 months; willing to participate in the study; a willingness to read and respond to self-rated questionnaires written in English; willing to be randomised to one of two psychological treatments; gambled in the past month using EGM's; willing to provide follow-up data; willing to have treatment sessions audio recorded; scoring 5 or greater on the South Oaks Gambling Screen; and not suicidal or experiencing mental distress such as mania which would indicate that the problem gambler would not be able to participate fully in the treatment offered.

Individuals assessed as eligible for study participation will be randomly assigned to one of two treatment groups with 1:1 allocation ratio. Randomisation will be blocked to increase the likelihood of equal group sizes, using a standard permutated block algorithm in which block sizes will be randomly chosen from 2, 4, and 6 to protect concealment. To ensure balance on potential confounders, block randomisation within strata will be used, stratifying at median age, gender, and median SOGS scores for problem gambling severity. Based on previous SGTS data, age will be stratified as 18 - 42 years, and 43 years or more (25). Gambling severity will be stratified according to previous treatment seeking problem gamblers SOGS scores of either 5 - 11, and between 12 and 20 (26). A statistician will independently generate random sequences for each stratum using Stata version 11.1 software (27) and deliver to the clinical trials call centre of a centrally located hospital pharmacy. Staff enrolling and referring participants, collecting and entering data and administering interventions will not know in advance which treatment the next participant will receive.

Sample size

The primary research question is: Among treatment seeking problem gamblers, is exposure therapy more effective in reducing gambling severity symptoms (harm to self subscale of the

VGS) over the 12-month study period (intervention and maintenance effects) compared with cognitive therapy?

Based on a type I error rate of 5% , power of 90%, two-tailed test, and a VGS standard deviation of 10.2 units (25), to detect a significant difference of 8% (i.e. 4.8 points on the scale) in mean VGS scores between the ET and CT groups, 50 participants will be required in each group. Given the treatment dropout rate experienced in the SGTS treatment programme (approximately 30%) we therefore would need to recruit 65 participants in each group of the study giving a total sample size of 130 participants.

Therapists

Cognitive therapy will be provided by two psychotherapists with qualifications in psychology and, on average, having approximately 5 years practice experience, including 2 years in treating individuals with gambling disorders. The therapists will receive initial on-site training in CT by Robert Ladouceur, a widely published international clinician and researcher in the field of cognitive therapy for gambling disorders (28-30).

Exposure therapy will be provided by two psychotherapists with post-graduate qualifications in CBT; a registered mental health nurse and a psychology graduate. On average, therapists have 6 years clinical experience in delivering CBT treatments to clients' of SGTS including a manualised ET program. Therapists will receive on-site supervision from Malcolm Battersby who trained at the Institute of Psychiatry, London in behavioural treatments of anxiety disorders and severe neurotic conditions and is the Director of the Flinders Gambling Research Centre and SGTS (19).

Study treatments

The trial will comprise two interventions: cognitive therapy (CT) and exposure therapy (ET). Participants in both groups will receive a standard of twelve 60-minute individual treatment sessions, ranging from 4-16 depending on co-occurring conditions, conducted at weekly intervals. Both treatment manuals are intended as a session-by-session guide for therapists treating individuals with a gambling disorder where EGM's are the main form of gambling problem. The therapists will deliver treatment according to the content of each manual and sequencing of techniques in a face-to-face format. A summary of treatment sessions is provided in Table 1.

Table 1 here

Blinding

Statistical analyses will be conducted according to pre-specified guidelines. In this trial, therapists will know what treatment they are administering and participants will be provided with information that will rationalise and describe their assigned therapy protocol. Participants will be blinded to the study hypothesis in order to reduce the likelihood for self-report bias. Participant information sheets will refer to treatments as "well known and commonly used psychological treatments".

Treatment integrity

All treatment sessions will be audio recorded and 20% will be randomly selected from early, mid, and late study phases and evaluated using a checklist based on the Cognitive Therapy Scale (Table 2) (31). ET sessions will be evaluated by MB and RP who are senior consultant psychiatrists with the Flinders Gambling Research Centre and have extensive experience in

treatments for gambling disorders and other addictions (19, 32). CT sessions will be evaluated by RL and MD who are senior clinical psychologists.

Table 2 here

Measures

The administration of measures during the intervention period will be conducted prior to commencement of each treatment session and at 3 and 6 month follow-up visit with study therapist. The 12 month follow-up questionnaires will be mailed to participants. Baseline assessment will include demographic variables and data for duration of gambling problem. Validated outcome measures will cover domains of gambling behaviours, problems caused by gambling, and mechanisms of change (33). This means that for ET participants, a greater reduction in urge to gamble is expected to be associated with a clinically meaningful improvement in treatment outcomes than in CT participants. For CT participants, a more accurate set of beliefs relating to gambling is expected to be associated with a clinically meaningful improvement in treatment outcomes than in ET participants. The measures are summarised in the following sections and measurement occasions are presented in Table 3.

In order to detect change in problem gambling severity during treatment and at follow-up, the Victorian Gambling Screen (VGS) will be utilised as a primary outcome measure. The VGS is a self-reported questionnaire measuring the extent to which gambling behaviour has impeded an individual's life. The screen comprises three sub-scales (enjoyment of gambling, harm to partner and harm to self) with a total of 21 items. In this study the harm to self sub-scale will be used as primary outcome measure. Items on the self-harm subscale relate to the person's experiences in the previous 4 weeks and has been validated for use in Australia in a clinical

population of problem gamblers (34). Total scores for the 15 items range from 0 = no harm to self to 60 = high harm to self and a score of 21+ identifies a person as problem gambler. Concurrent validity indicates the scale correlates very highly with the SOGS but extends the score range. The VGS has also shown similar properties in construct validity as the Canadian Problem Gambling Index (CPGI) on a number of problem gambling correlates (e.g. 'self-rating of problem', and 'wanted help') (22).

Secondary outcome measures will include DSM-IV-TR diagnostic criteria relating to the extent of persistent and recurrent maladaptive gambling behaviour and will be administered by study therapists. A total score is obtained by summing across the ten responses of "yes" or "no". A score of five or more indicates pathological gambling (1). All other secondary measures are self-reported. Gambling related cognitions will be measured using a 23 item scale (GRCS) that records common thoughts associated with problem gambling where each item is rated on a 1-7 Likert scale (35). The urge to gamble will be assessed using a 6 item instrument (GUS) where each item is rated on a Likert (1-7) scale (36, 37). Participants' experiences of psychological distress will be recorded using a 10 item global measure (K10) with each item rated on a 1-5 Likert scale (38). To measure an individual's perspective of their functional ability/ impairment relating to work and social activities a 5 item scale (WSAS) will be used where each item is rated on a 0-8 Likert scale (39). Participant levels of alcohol use will be assessed based on a 10 item scale where questions 1 to 3 measure quantity and frequency of alcohol use, questions 4 to 6 measure possible dependence on alcohol and questions 7 to 10 measure alcohol-related problems (47, 48).

Following an explanation of treatment rationale and protocol in session one, participants will be asked to rate their confidence in treatment (from 0= *extremely unconfident* to 6= *extremely*

confident) and belief in treatment logic (from 0= *extremely illogical* to 6= *extremely logical*) at commencement of session two. At treatment completion participants will again be asked to rate their views on confidence and logic of treatment, and satisfaction with treatment received (from 0= *extremely unsatisfied* to 6= *extremely satisfied*). To assess a participant's degree of confidence in their perceived ability to execute control of gambling behaviours during treatment and follow-up, a measure of self-efficacy will be utilised. Participants will describe up to three personally relevant high-risk situations and then rate the extent of their belief that they could refrain from gambling excessively in these situations on a scale of 0-10. Self-reported measures of behaviours relating to problematic gambling will include: frequency of gambling in previous week and month; number of hours spent on gambling activities in previous week and month; and amount spent on gambling activities in previous week and month.

Table 3 here

Treatment drop-out

Treatment drop-out will be determined using two general approaches (40). The first approach will be based on therapists' judgement of participant progress up to the point of self-initiated termination. Secondly, attendance at a pre-specified number of sessions will also be examined. A previous study involving SGTS participants engaged in ET determined an appropriate cut-off number of sessions for classification as drop-out as 3 or less including the first screening attendance (25). Similarly, in a randomised trial evaluating CT, participants who attended an initial study screening and 2 treatment sessions or less were classified as drop-outs (29). The degree of concordance between these two classification methods for drop-out will then be assessed and any discrepancies will be resolved by discussion between clinical supervisors and

therapists. The level of treatment adherence for each participant will inform secondary data analyses discussed in the following section.

Data analyses

The primary analysis will be an intent-to-treat (ITT) to detect any statistically significant differences in VGS scores over time for the treatment and follow-up period between cognitive and exposure therapy. To account for participant attrition and lack of treatment adherence the ITT analysis will be supplemented with an 'as treated' and 'per protocol' analysis. The 'as treated' approach will be useful for identifying associations between clusters of participant characteristics and treatment outcomes from an observational perspective. The 'per protocol' analysis will enable an evaluation of treatment efficacies in the sub-sample of participants that adhere to their assigned treatment protocol (41) . Secondary measures will be analysed using the same approach as outlined above.

Generalised linear mixed models will be used for repeated measures of primary and secondary continuous and categorical outcomes. Preliminary models will assess for Therapist and Therapist X Treatment Group effects and will be included in main analyses if statistically significant. Fixed effects in models will include intervention group, time in continuous form (intervention period and maintenance effects), and interaction between group and time. Random effects will be at study participant level and represent an upward or downward shift in the outcome measure from an overall regression line and rate of change over time. Linear combinations of regression coefficients will be tested for treatment group effect at completion of intervention period and for maintenance effects and estimates will be presented along with confidence intervals. Predicted estimates of treatment outcomes at each time point will be calculated using fitted models of the data in order to examine patterns of individual change

within each group. To interpret effect sizes and precision for categorical outcomes, odds ratios and confidence intervals will be calculated.

To determine mechanisms of therapeutic change based on the intended effects of each treatment, a mediation analysis will be conducted using mixed-effects modelling. The analysis will follow the traditional requirements for testing mediation: (1) testing for an association between treatment condition (ET and CT) and mediator (gambling urge or gambling related cognitions); (2) testing for an association between treatment outcome variable (e.g. gambling behaviours) and treatment condition; (3) testing for an association between the mediator and treatment outcome; and (4) testing if the effect of treatment condition on treatment outcome is attenuated upon the addition of the mediator to the model (42).

In order to allow accurate critical appraisal of the validity and applicability of results, reporting of this trial will comply with CONSORT (Consolidated Standards of Reporting Trials) guidelines for non-pharmacologic treatment (43).

Qualitative component

Following the treatment intervention period a sub-sample of participants will be invited to take part in semi-structured interviews to explore therapeutic change for cognitive and exposure therapies. One-on-one interviews will last for approximately one hour and be conducted in person with participants. To ensure the capture of a range of individual experiences, purposeful sampling will be used. Sampling will continue until theoretical saturation has been achieved where no new or relevant data is seen to emerge (44). Interview transcripts will be analyzed using content analysis and based on a Grounded Theory approach to develop key themes around specific and non-specific treatment effects (45).

Discussion

This study will provide high quality data for therapeutic benefits of exposure therapy compared to cognitive therapy in people seeking treatment for problem gambling using electronic gaming machines. The outcome data collected will cover the domains of gambling behaviours, problems caused by gambling, and mechanisms of change. Also, qualitative interviews will explore therapeutic change from the individual's experience and will be examined in light of conclusions drawn from quantitative models to better understand each treatments intended effects. The findings are expected to guide consumers, clinicians, policymakers and funders in the use of these treatments for gambling disorders.

The design of this trial is guided by ethical considerations in line with the community service commitment of the Statewide Gambling Therapy Service. Therefore, a key strength of this study is that all treatment seeking problem gamblers meeting eligibility criteria will receive an active treatment. Also, due to the broad study inclusion criteria, it is expected that a significant proportion of the sample will have co-morbid conditions (e.g. anxiety, depression, and substance abuse (10, 46)), which will enhance the external validity of findings using an intent-to-treat design. A limitation of the design is no control group to account for non-specific treatment effects, however, a reasonable assumption is made that non-specific effects will be approximately similar between study groups due to analogous therapy structures, therapist background and experience, and therapeutic environment.

A further limitation of the study design is that outcome data will be collected from self-report measures and therefore participants may overestimate treatment effects. Because there is a high degree of uncertainty for differential treatment effects and blinding of participants to study hypothesis, the likelihood of bias in self-ratings is expected to be minimised. Also, as this study will be conducted at a single-site the findings will have some limitations for inference to a

wider population. On the other hand, benefits of being a single-site study can include more effective lines of communication and a more consistent application of research protocol.

Conclusion

We have described the rationale and protocol for a randomised clinical trial to investigate treatment efficacy of exposure therapy compared to cognitive therapy for people with a gambling disorder in South Australia. The trial is funded, due to a limited gambling treatment evidence-base, to inform a range of stakeholders on best practice. To our knowledge, this is the first clinical trial to compare treatments with theoretical underpinnings from each of the two dominant approaches in explaining gambling disorders- cognitions (cognitive therapy) and psychobiological states (exposure therapy) in treatment seeking problem gamblers. The wide range of data collected in this trial will provide high quality evidence for these treatments and contribute to the development of more optimal combinations of cognitive and behavioural therapies.

Acknowledgements

Kirsten Dunn and Gaston Antezana are providing cognitive therapy. Jane Oakes and Amii Larsen are providing exposure therapy. Mitch Durbridge is providing on-site supervision for the cognitive therapy group and treatment integrity checks.

References

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (4th Edition, Text Revision). 4th ed. Washington DC2000.
2. Ferris J, Wynne H. The Canadian Problem Gambling Index: Final Report: Canadian Centre on Substance Abuse. 2001.
3. Ben-Tovim D, Esterman A, Tolchard B, Battersby MW. The Victorian Gambling Screen: Project report. Melbourne: Victorian Research Panel2001.
4. Becona E. Prevalence surveys of problem and pathological gambling in Europe: The cases of Germany, Holland and Spain. J Gambl Stud. 1996;12(2):179-92.
5. Bondolfi G, Osiek C, Ferrero F. Prevalence estimates of pathological gambling in Switzerland. Acta Psychiatr Scand. 2000;101(6):473-5.
6. Delfabbro P. Australasian Gambling Review: Independent Gambling Authority of South Australia2009.
7. Shaffer HJ, Hall MN. Updating and refining prevalence estimates of disordered gambling behaviour in the United States and Canada. Can J Public Health. 2001;92(3):168-72.
8. Wardle H, Sproston K, Orford J, Erens B, Griffiths MD, Constantine R, et al. The British Gambling Prevalence Survey. London: The Stationery Office 2007.
9. Wong ILK, Ernest MTS. Prevalence estimates of problem and pathological gambling in Hong Kong. The American Journal of Psychiatry. 2003;160(7):1353.
10. Lorains FK, Cowlishaw S, Thomas SA. Prevalence of comorbid disorders in problem and pathological gambling: systematic review and meta-analysis of population surveys. Addiction. 2011;106(3).
11. Daughters B, Lejuez CW, Lesieur HR, Strong DR, Zvolensky MJ. Towards a better understanding of gambling treatment failure: implications of translational research. Clin Psychol Rev. 2003;23(4):573-86.
12. Jackson A, Thomas S, Blaszczynski A. Best practice in problem gambling services. Melbourne: Gambling Research Panel2003.
13. Gooding P, Tarrier N. A systematic review and meta-analysis of cognitive-behavioural interventions to reduce problem gambling: Hedging our bets? Behav Res Ther. 2009;47(7):592-607.
14. Problem Gambling Research and Treatment Centre (PGRTC). Guideline for screening, assessment and treatment in problem gambling: Clayton:Monash University2011.
15. Clark L. Decision-making during gambling: an integration of cognitive and psychobiological approaches. Philosophical Transactions of the Royal Society B: Biological Sciences. 2010;365(1538):319.
16. Hodgins DC, Stea JN, Grant JE. Gambling disorders. The Lancet. 2011;378(9806):1874-84.
17. Beck AT, Dozois DJA. Cognitive Therapy: Current Status and Future Directions. Annu Rev Med. 2011;62(1):397-409.
18. Brown RIF. Classical and Operant Paradigms in the Management of Gambling Addictions. Behavioural Psychotherapy. 1987;15(2):111-22.
19. Battersby MW, Oakes J, Tolchard B, Forbes A, Pols R. Cognitive behavioural treatment for problem gamblers. In: Zangeneh M, Blaszczynski A, Turner NE, editors. In the pursuit of winning. New York: Springer; 2008. p. 179-97.
20. Ougrin D. Efficacy of exposure versus cognitive therapy in anxiety disorders: systematic review and meta-analysis. BMC Psychiatry. 2011;11:200.
21. Martin T, D. LaRowe S, Malcolm R. Progress in Cue Exposure Therapy for the Treatment of Addictive Disorders: A Review Update. The Open Addiction Journal. 2010;3:92-101.

22. McMillen J, Wenzel M. Measuring problem gambling: Assessment of three prevalence screens. International Gambling Studies. 2006;6(2):147-74.
23. Lesieur HR, Blume SB. The South Oaks Gambling Screen (SOGS): a new instrument for the identification of pathological gamblers. Am J Psychiatry. 1987 September 1, 1987;144(9):1184-8.
24. Stinchfield R. Reliability, validity, and classification accuracy of the South Oaks Gambling Screen (SOGS). Addict Behav. 2002;27(1):1-19.
25. Smith D, Harvey P, Battersby M, Pols R, Oakes J, Baigent M. Treatment outcomes and predictors of drop out for problem gamblers in South Australia: a cohort study. Aust N Z J Psychiatry. 2010;44:911-20.
26. Riley B, Smith D, Oakes J. Exposure therapy for pathological gambling in rural communities: a program model and early outcomes. Aust J Rural Health. 2011;19(3):142-6.
27. StataCorp. Stata: Release 11. Statistical Software. College Station, TX: StataCorp LP; 2009.
28. Ladoucer R, Sylvain C, Boutin C, Lachance S, Doucet C, Leblond J, et al. Cognitive treatment of pathological gambling. J Nerv Ment Dis. 2001;189:774-80.
29. Ladouceur R, Sylvain C, Boutin C, Lachance S, Doucet C, Leblond J. Group therapy for pathological gamblers: a cognitive approach. Behav Res Ther. 2003;41(5):587.
30. Ladouceur R, Sylvain C, Letarte H, Giroux I, Jacques C. Cognitive treatment of pathological gamblers. Behav Res Ther. 1998;36(12):1111-9.
31. Wolitzky-Taylor KB, Horowitz JD, Powers MB, Telch MJ. Psychological approaches in the treatment of specific phobias: A meta-analysis. Clin Psychol Rev. 2008;28(6):1021-37.
32. Oakes J, Battersby M, Pols R, Cromarty P. Exposure therapy for problem gambling via videoconferencing: a case report. Journal of Gambling Studies. 2008;24(1):107-19.
33. Walker M, Toneatto T, Potenza MN, Petry N, Ladouceur R, Hodgins DC, et al. A framework for reporting outcomes in problem gambling treatment research: the Banff, Alberta Consensus. Addiction. 2006;101(4):504-11.
34. Tolchard B, Battersby M. The Victorian Gambling Screen: reliability and validity in a clinical population J Gambl Stud. 2010;26:623-38.
35. Raylu N, Oei T. The Gambling Related Cognitions Scale (GRCS): development, confirmatory factor validation and psychometric properties. Addiction. 2004;99(6):757-69.
36. Raylu N, Oei T. The Gambling Urge Scale: Development, confirmatory factor validation, and psychometric properties. Psychol Addict Behav. 2004;18(2):100-5.
37. Smith DP, Pols RG, Battersby MW, Harvey PW. The Gambling Urge Scale: Reliability and validity in a clinical population. Addiction research & theory. 2012;doi:10.3109/16066359.2012.696293.
38. Andrews G, Slade T. Interpreting scores on the Kessler psychological distress scale (K10). Aust N Z J Public Health. 2001;25:494-7.
39. Mundt JC, Marks IM, Shear MK, Greist JM. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. The British Journal of Psychiatry. 2002 May 1, 2002;180(5):461-4.
40. Melville KM, Casey LM, Kavanagh DJ. Psychological treatment dropout among pathological gamblers. Clin Psychol Rev. 2007;27(8):944-58.
41. Oakes JE, Pols RG, Battersby MW, Lawn SJ, Pulvirenti M, Smith DP. A focus group study of predictors of relapse in electronic gaming machine problem gambling, part 1:factors that 'push' towards relapse. J Gambl Stud. 2011;DOI 10.1007/s10899-011-9264-y.
42. Baron RM, Kenny D. The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. J Pers Soc Psychol. 1986;51(6):1173-82.

43. Boutron IMDP, Moher DP, Altman DGD, Schulz KFPMBA, Ravaud PMDP, for the CG. Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration. Ann Intern Med. 2008;148(4):295-309.
44. Crabtree B, DiCicco-Bloom B. The qualitative research interview. Med Educ. 2006;40:314-21.
45. Charmaz K. Grounded theory, objectivist and constructivist methods. In: Denzin NK, Lincoln YS, editors. Handbook of Qualitative Research. Second ed: Sage, Thousand Oaks.; 2000.
46. Ibanez A, Blanco C, Donahue E, Lesieur HR, Perez de Castro I, Fernandez-Piqueras J, et al. Psychiatric Comorbidity in Pathological Gamblers Seeking Treatment. Am J Psychiatry. 2001 October 1, 2001;158(10):1733-5.

Table 1.Intervention schedule

Weekly Sessions	Cognitive Therapy (CT)	Exposure Therapy (ET)
Session 1:	Pre-treatment assessment to identify problem gambling and any co-morbid conditions. Rationale and protocol of cognitive therapy explained.	Pre-treatment assessment to identify problem gambling and any co-morbid conditions. Rationale and protocol of exposure therapy explained.
Session 2:	Development of participant's measurable problems and goals. Analysis of a gambling session to identify erroneous thoughts. Commence daily self-monitoring diary.	Development of participant's measurable problems and goals. Establish cash restrictions to ensure participant has no cash. First exposure task set using images. Commence daily self-monitoring diary.
Session 3:	Psycho-education: clarification of the concept of chance and establish the distinction between games of skill and games of chance.	Review participant's attempt at first exposure task. Finalise cash restriction strategies if not already in place. In-session imagery exposure task with therapist guidance.
Session 4:	Psycho-education/cognitive awareness: introduce ABCD (situation, thoughts, behaviour, consequences) model and exercises to focus on the gambling thoughts or 'inner dialogue'.	Review imagery exposure task. Finalise cash restriction strategies if not already in place. Imagery exposure task with therapist guidance.
Session 5:	Identifying erroneous thoughts or 'gambling traps' that lie behind emotions taking over reason using ABCD model. Participants are encouraged to challenge these thoughts, perceptions, and beliefs in this session.	Review imagery exposure task. Introduction of next exposure task involving image and sounds of gambling-related cues.
Session 6:	Identifying erroneous cognitions. Practical exercise to help participant organise and act upon thoughts	Introduction to first of the in-vivo exposure tasks. This task to take place outside of participant's usual gambling venue(s). The participant utilises principles of exposure therapy from imaginal tasks to assist in identifying what is happening to them at the time of the in-vivo task.
Session 7:	Identifying erroneous cognitions. Practical exercise to help participant organise and act upon thoughts (continued).	Fine tuning of in-vivo exposure task outside of venue. Introduction to in-vivo exposure task to take place inside venue without cash.
Session 8:	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling	Fine tuning of in-vivo exposure task inside venue without cash. Introduction to next in-vivo task taking place inside a gambling venue with a small amount of cash.
Session 9:	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling (continued).	Fine tuning of in-vivo exposure task inside venue with a small amount of cash. Introduction to next in-vivo task taking place inside a gambling venue changing a small amount of cash for Poker machine coins.
Session 10	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling (continued).	Review in-vivo exposure tasks. Introduction to next in-vivo task taking place inside a gambling venue changing a small amount of cash for coins and placing in Poker machine.
Sessions 11- 12	Explore gambling relapse and develop relapse prevention strategies.	Explore gambling relapse and develop relapse prevention strategies.

Table 2.Treatment integrity checklist items

Item	Response options	Cognitive Therapy	Exposure Therapy
1	Yes/No/or N/A (not applicable)	*Eliciting automatic thoughts:* Gambling related	*Cash Management:* Effective plan established and agreed by the client
2	Yes/No/or N/A	*Case conceptualisation:* Linking beliefs and thoughts with behaviour, eliciting feedback from client regarding validity and usefulness	*Case conceptualisation:* linking autonomic responses with behaviour, eliciting feedback from client regarding validity and usefulness
3	Yes/No/or N/A	*Sharing conceptualisation with client:* Used meaningful examples	*Sharing conceptualisation with client:* Used meaningful examples
4	Yes/No/or N/A	*Eliciting core beliefs/schemata:* Gambling related	*Eliciting autonomic symptoms, thoughts, and behaviours:* Gambling related
5	Yes/No/or N/A	*Addressing key issues*: Raised key issues and related them to cognition and behaviour	*Setting and conduct of exposure tasks* : Appropriately graded, focussed, prolonged, and repeated; agreed by the client; relevant to therapy goals
6	Yes/No/or N/A	*Guided discovery:* Socratic questioning, reflective/confronting (e.g. what would that mean?)/interpretive responses to guide client's understanding	*Addressing key issues*: Raised key issues and related them to urge and behaviour
7	Yes/No/or N/A	*Asking for alternative thoughts:* Alternative views/explanations appropriately followed through	*Habituation:* Evidence that the therapist assisted client to identify and habituate to spontaneous urges
8	Yes/No/or N/A	*Use of alternative cognitive techniques:* Appropriately selected and applied, relevant to therapy goals	*Use of alternative behavioural techniques:* Appropriately selected and applied, relevant to therapy goals
9	0-10 Likert scale	Overall rating of integrity	Overall rating of integrity
10	Unlimited free form text	*Overall use of appropriate technique (specifically, please comment on any area of the session which may not have adhered to the allocated therapeutic approach)*	*Overall use of appropriate technique (specifically, please comment on any area of the session which may not have adhered to the allocated therapeutic approach)*

Table 3.Measurements

Measurements	Intervention period				Maintenance period		
	Baseline	**Sessions 2-12**	**Mid-treatment**	**End of treatment**	**3 month**	**6 month**	**12 month**
Demographics	X						
Duration of gambling problem	X						
AISS	X						
VGS	X		X	X	X	X	X
DSM-IV-TR	X			X		X	
Mechanisms of change							
GRCS	X	X	X	X	X	X	X
GUS	X	X	X	X	X	X	X
Self-efficacy	X	X	X	X	X	X	X
Problems caused by gambling							
K10	X			X	X	X	X
WSAS	X			X	X	X	X
AUDIT	X			X	X	X	X
Gambling behaviours							
frequency†	X		X	X	X	X	X
hours‡	X		X	X	X	X	X
amount§	X		X	X	X	X	X
Treatment views							
Confidence about treatment		X*		X			
Treatment is logical		X*		X			
Satisfied with treatment				X			

Abbreviations: AISS, Arnett Inventory of Sensation Seeking Traits; VGS, Victorian Gambling Screen; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Text Revision (4th Edition); GRCS, Gambling Related Cognitions Scale; GUS, Gambling Urge Scale; K10, Kessler 10 Scale; WSAS, Work and Social Adjustment Scale; AUDIT, Alcohol Use Disorders Identification Test.
†Days per month in which gambling takes place
‡Time spent thinking about or engaged in the pursuit of gambling in previous month
§Expenditure in previous month
*Session 2 only

Protocol for a two- group randomised, parallel trial of cognitive and exposure therapies for problem gambling

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-003244.R1
Article Type:	Protocol
Date Submitted by the Author:	22-May-2013
Complete List of Authors:	Smith, David; Flinders University, Psychiatry Battersby, Malcolm; Flinders University, Psychiatry Harvey, Peter; Flinders University, Psychiatry Pols, Rene; Flinders University, Psychiatry Ladouceur, Robert; Université Laval, School of Psychology
Primary Subject Heading:	Addiction
Secondary Subject Heading:	Mental health
Keywords:	Impulse control disorders < PSYCHIATRY, Adult psychiatry < PSYCHIATRY, PUBLIC HEALTH

Title

Protocol for a two- group randomised, parallel trial of cognitive and exposure therapies for problem gambling

Authors

David P Smith
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: david.smith@flinders.edu.au
Tel: +61 8 8404 2610
Fax: +61 8 8404 2101

Malcolm W Battersby
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: malcolm.battersby@flinders.edu.au
Tel: +61 8 8204 2314
Fax: +61 8 8404 2101

Peter W Harvey
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: peter.harvey@flinders.edu.au
Tel: +61 8 8204 2314
Fax: +61 8 8404 2101

Rene G Pols
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: rene.pols@flinders.edu.au
Tel: +61 8 8204 4849
Fax: +61 8 8204 6410

Robert Ladouceur
Institutional affiliation: Université Laval, School of Psychology
Address: 2325, rue des Bibliothèques, Bureau 1328, Université Laval, Québec (Québec), Canada, G1V 0A6.
Country: Canada
Email: robert.ladouceur@psy.ulaval.ca
Tel: (418) 656-3996
Fax: (418) 656-3646

Running head
Trial protocol for gambling treatments

Word count
Abstract: 235
Main text: 3,500

FundingThis work is funded by Victorian Department of Justice, Office of Gaming & Racing grant 061/09. The SGTS is funded by the Office of Problem Gambling, Department of Families and Social Inclusion, Government of South Australia. The authors alone are responsible for the design, implementation and reporting of results for this study. Competing interests
None

Article summary

Article focus

- To isolate and compare cognitive and behavioural (exposure-based) techniques to determine their relative efficacy in treating problem gambling.
- The primary research question is: Among treatment seeking problem gamblers, is exposure therapy more effective in reducing gambling severity symptoms (harm to self subscale of the VGS) over the 15-month study period (intervention and maintenance effects) compared with cognitive therapy?

Key messages

- Problem gambling is a serious public health concern at an international level and occurs more frequently in younger populations.
- The best evidence for gambling treatments is for cognitive behavioural therapy (CBT) but remains tentative.
- This study will be the first randomised, parallel trial to compare cognitive and exposure therapies in this population.

Strengths and limitations

- A key strength of this study is that all treatment seeking problem gamblers meeting eligibility criteria will receive an active treatment. Also, due to the broad study inclusion criteria, it is expected that a significant proportion of the sample will have co-morbid conditions (e.g. anxiety, depression, and substance abuse which will enhance the external validity of findings using an intent-to-treat design.
- A limitation of the design is no control group to account for non-specific treatment effects, however, a reasonable assumption is made that non-specific effects will be approximately similar between study groups due to analogous therapy structures, therapist background and experience, and therapeutic environment.

Abstract

Background and aims: Problem gambling is a serious public health concern at an international level where population prevalence rates average 2% or more and occurs more frequently in younger populations. The most empirically established treatments to date are combinations of cognitive and behavioural techniques labelled cognitive behaviour therapy (CBT). However, there is a paucity of high quality evidence for the comparative efficacy of

core CBT interventions in treating problem gamblers. This study aims to isolate and compare cognitive and behavioural (exposure-based) techniques to determine their relative efficacy.

Methods: A sample of 130 treatment seeking problem gamblers will be allocated to either cognitive or exposure therapy in a two-group randomised, parallel design. Repeated measures will be conducted at baseline, mid and end of treatment (12 sessions intervention period), and 3, 6, and 12 months (maintenance effects). The primary outcome measure is improvement in problem gambling severity symptoms using the Victorian Gambling Screen (VGS) harm to self sub-scale. The VGS measures gambling severity on an extensive continuum, therefore enhancing sensitivity to change within and between individuals over time.

Discussion: This article describes the research methods, treatments, and outcome measures used to evaluate gambling behaviours, problems caused by gambling and mechanisms of change. This study will be the first randomised, parallel trial to compare cognitive and exposure therapies in this population.

Ethics and dissemination: The study was approved by the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee. Study findings will be disseminated through peer-reviewed publications and conference presentations.

Trial registration: Australian New Zealand Clinical Trials Registry: ACTRN12610000828022

Introduction

Pathological gambling (PG) from a mental health perspective is defined by the American Psychiatric Association DSM-IV-TR as "…persistent and recurrent maladaptive gambling behaviour that disrupts personal, family and vocational pursuits" (1)**.** The term 'problem gambling' defines less severe forms of gambling disorders and has been the basis for the development of several diagnostic and screening instruments such as the Canadian Problem Gambling Index (CGPI) (2) and the Victorian Gambling Screen (VGS) (3). It is a serious

public health concern at an international level where population prevalence rates average 2% or more and occurs more frequently in younger populations (4-9). Co-morbid mental health disorders such as depression and anxiety are common in both treatment seeking and general populations of problem gamblers (10).

Treatment types available for gambling disorders have similarities to those of other addictions and include psychological, peer-support, and more recently, pharmacological interventions (11, 12). To date, the best evidence for gambling treatments is psychological, where cognitive behavioural therapy (CBT) has been the most researched (13) and the evidence-base recommended as "…trusted to guide practice in most situations" based on NHMRC (National Health and Medical Research Council) grades for developers of guidelines (14).

The theoretical underpinnings of CBT include cognitions (e.g. erroneous thoughts) and psychobiological states (e.g. physiological arousal) and are two dominant approaches to explaining gambling disorders (15). Most variants of CBT for treating gambling disorders have shown to be clinically beneficial compared to no treatment, and the most rigorous clinical trials have comprised of a combined cognitive-behavioural approach (13, 16). For core techniques, findings have indicated cognitive therapy (CT) has an "added advantage" when compared directly to no treatment, although evidence is tentative due to heterogeneity between studies (13). Cognitive restructuring plays an important role in CT and has shown to be beneficial in treating a range of mental health conditions (17).

However, the comparative efficacy of CT with other core CBT interventions such as behavioural (exposure-based) therapies that target psychobiological related gambling pathology is unknown (13). Exposure therapy (ET) is grounded in classical and operant

conditioning paradigms and where cue-exposure with extinction processes has been proposed as more beneficial than other types (e.g. aversive therapy) in treating gambling addiction (18). ET has shown to be equally effective as CT in treating anxiety disorders where both techniques have similar hypothesised mechanisms of therapeutic change to those in gambling disorders (19, 20). In addictions there is no conclusive evidence for exposure based treatments due to there being few clinical trials with power (21).

As behavioural therapies in general are more parsimonious in terms of delivery than CT (22) it is important from a public health point of view to understand the relative efficacy of these core treatments. Therefore, we designed a study titled "Comparing outcomes of cognitive and exposure therapy for problem gambling" which is a randomised trial comparing efficacies of CT and ET. This trial is motivated by the uncertainty about the clinical superiority of CT over ET. Based on this uncertainty, the concept of equipoise exists and participants will, therefore, not be disadvantaged from randomisation to either treatment group. This study will be the first to compare these treatments in a population of treatment seeking gamblers.

Study design

Comparing outcomes of cognitive and exposure therapy for gambling disorders is a two-group randomised, parallel design with treatment seeking problem gamblers presenting to the Statewide Gambling Therapy Service (SGTS) in South Australia. The study will recruit 130 participants over a 12 month period commencing April 2011. The outpatient SGTS programme offers one-on-one and group therapy for problem gamblers at three key metropolitan (Adelaide) centres, one of which will be selected as the trial site. The primary referral sources of clients presenting to SGTS are self, Gambling Helpline and related agencies and general practitioners. The service is staffed by a psychiatrist and therapists with professional

registration in psychology, nursing, or social work. All therapists have graduate qualifications and clinical experience in CBT (19). Data collection will finish in July 2013.

The study was approved by the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12610000828022) at the trials inception. The research officer will give participants an information statement regarding the study and ask for written informed consent before data collection begins.

Participant recruitment and random assignment

To assess study eligibility, an independent clinician will conduct semi-structured interviews with treatment seeking problem gamblers presenting to SGTS during the recruitment period. The interview will include assessment of individual demographics, recent gambling activities, and administration of the well-validated *South Oaks Gambling Screen* (SOGS) (23). The SOGS is a 20 item questionnaire based on DSM criteria for pathological gambling. A score of 5 or more is indicative of probable pathological gambler. In gambling treatment samples the scale has good reliability, exhibits high correlations with DSM-IV diagnostic criteria, and good to excellent classification accuracy (24).

Study eligibility will be based on the following inclusion criteria: 18 years of age or older; treatment seeking for problem gambling with electronic gaming machines (EGM's); not involved in a concurrent gambling treatment program; not received psychological treatment for problem gambling in previous 12 months; willing to participate in the study; a willingness to read and respond to self-rated questionnaires written in English; willing to be randomised to

one of two psychological treatments; gambled in the past month using EGM's; willing to provide follow-up data; willing to have treatment sessions audio recorded; scoring 5 or greater on the South Oaks Gambling Screen; and not suicidal or experiencing mental distress such as mania which would indicate that the problem gambler would not be able to participate fully in the treatment offered.

Individuals assessed as eligible for study participation will be randomly assigned to one of two treatment groups with 1:1 allocation ratio. Randomisation will be blocked to increase the likelihood of equal group sizes, using a standard permutated block algorithm in which block sizes will be randomly chosen from 2, 4, and 6 to protect concealment. To ensure balance on potential confounders, block randomisation within strata will be used, stratifying at median age, gender, and median SOGS scores for problem gambling severity. Based on previous SGTS data, age will be stratified as 18 - 42 years, and 43 years or more (25). Gambling severity will be stratified according to previous treatment seeking problem gamblers SOGS scores of either 5 - 11, and between 12 and 20 (26). A statistician will independently generate random sequences for each stratum using Stata version 11.1 software (27) and deliver to the clinical trials call centre of a centrally located hospital pharmacy. Staff enrolling and referring participants, collecting and entering data and administering interventions will not know in advance which treatment the next participant will receive.

Sample size

The primary research question is: Among treatment seeking problem gamblers, is exposure therapy more effective in reducing gambling severity symptoms (harm to self subscale of the VGS) over the 12-month study period (intervention and maintenance effects) compared with cognitive therapy?

Based on a type I error rate of 5% , power of 90%, two-tailed test, and a VGS standard deviation of 10.2 units (25), to detect a significant difference of 8% (i.e. 4.8 points on the scale) in mean VGS scores between the ET and CT groups, 50 participants will be required in each group. Given the treatment dropout rate experienced in the SGTS treatment programme (approximately 30%) we therefore would need to recruit 65 participants in each group of the study giving a total sample size of 130 participants.

Therapists

Cognitive therapy will be provided by two psychotherapists with qualifications in psychology and, on average, having approximately 5 years practice experience, including 2 years in treating individuals with gambling disorders. The therapists will receive initial on-site training in CT by Robert Ladouceur, a widely published international clinician and researcher in the field of cognitive therapy for gambling disorders (28-30).

Exposure therapy will be provided by two psychotherapists with post-graduate qualifications in CBT; a registered mental health nurse and a psychology graduate. On average, therapists have 6 years clinical experience in delivering CBT treatments to clients' of SGTS including a manualised ET program. Therapists will receive on-site supervision from Malcolm Battersby who trained at the Institute of Psychiatry, London in behavioural treatments of anxiety disorders and severe neurotic conditions and is the Director of the Flinders Gambling Research Centre and SGTS (19).

Study treatments

The trial will comprise two interventions: cognitive therapy (CT) and exposure therapy (ET). Participants in both groups will receive a standard of twelve 60-minute individual treatment

sessions, ranging from 4-16 depending on co-occurring conditions, conducted at weekly intervals. Both treatment manuals are intended as a session-by-session guide for therapists treating individuals with a gambling disorder where EGM's are the main form of gambling problem. The therapists will deliver treatment according to the content of each manual and sequencing of techniques in a face-to-face format. A summary of treatment sessions is provided in Table 1.

Table 1 here

Blinding

Statistical analyses will be conducted according to pre-specified guidelines. In this trial, therapists will know what treatment they are administering and participants will be provided with information that will rationalise and describe their assigned therapy protocol. Participants will be blinded to the study hypothesis in order to reduce the likelihood for self-report bias. Participant information sheets will refer to treatments as "well known and commonly used psychological treatments".

Treatment integrity

All treatment sessions will be audio recorded and 20% will be randomly selected from early, mid, and late study phases and evaluated using a checklist based on the Cognitive Therapy Scale (Table 2) (31). ET sessions will be evaluated by MB and RP who are senior consultant psychiatrists with the Flinders Gambling Research Centre and have extensive experience in treatments for gambling disorders and other addictions (19, 32). CT sessions will be evaluated by RL and MD who are senior clinical psychologists.

Table 2 here

Measures

The administration of measures during the intervention period will be conducted prior to commencement of each treatment session and at 3 and 6 month follow-up visit with study therapist. The 12 month follow-up questionnaires will be mailed to participants. Baseline assessment will include demographic variables and data for duration of gambling problem. Validated outcome measures will cover domains of gambling behaviours, problems caused by gambling, and mechanisms of change (33). This means that for ET participants, a greater reduction in urge to gamble is expected to be associated with a clinically meaningful improvement in treatment outcomes than in CT participants. For CT participants, a more accurate set of beliefs relating to gambling is expected to be associated with a clinically meaningful improvement in treatment outcomes than in ET participants. The measures are summarised in the following sections and measurement occasions are presented in Table 3.

In order to detect change in problem gambling severity during treatment and at follow-up, the Victorian Gambling Screen (VGS) will be utilised as a primary outcome measure. The VGS is a self-reported questionnaire measuring the extent to which gambling behaviour has impeded an individual's life. The screen comprises three sub-scales (enjoyment of gambling, harm to partner and harm to self) with a total of 21 items. In this study the harm to self sub-scale will be used as primary outcome measure. Items on the self-harm subscale relate to the person's experiences in the previous 4 weeks and has been validated for use in Australia in a clinical population of problem gamblers (34). Total scores for the 15 items range from 0 = no harm to self to 60 = high harm to self and a score of 21+ identifies a person as problem gambler. Concurrent validity indicates the scale correlates very highly with the SOGS but extends the

score range. The VGS has also shown similar properties in construct validity as the Canadian Problem Gambling Index (CPGI) on a number of problem gambling correlates (e.g. 'self-rating of problem', and 'wanted help') (22).

Secondary outcome measures will include DSM-IV-TR diagnostic criteria relating to the extent of persistent and recurrent maladaptive gambling behaviour and will be administered by study therapists. A total score is obtained by summing across the ten responses of "yes" or "no". A score of five or more indicates pathological gambling (1). All other secondary measures are self-reported. Gambling related cognitions will be measured using a 23 item scale (GRCS) that records common thoughts associated with problem gambling where each item is rated on a 1-7 Likert scale (35). The urge to gamble will be assessed using a 6 item instrument (GUS) where each item is rated on a Likert (1-7) scale (36, 37). Participants' experiences of psychological distress will be recorded using a 10 item global measure (K10) with each item rated on a 1-5 Likert scale (38). To measure an individual's perspective of their functional ability/ impairment relating to work and social activities a 5 item scale (WSAS) will be used where each item is rated on a 0-8 Likert scale (39). Participant levels of alcohol use will be assessed based on a 10 item scale where questions 1 to 3 measure quantity and frequency of alcohol use, questions 4 to 6 measure possible dependence on alcohol and questions 7 to 10 measure alcohol-related problems (47, 48).

Following an explanation of treatment rationale and protocol in session one, participants will be asked to rate their confidence in treatment (from 0= *extremely unconfident* to 6= *extremely confident*) and belief in treatment logic (from 0= *extremely illogical* to 6= *extremely logical*) at commencement of session two. At treatment completion participants will be asked to rate their level of satisfaction with treatment received (from 0= *extremely unsatisfied* to 6= *extremely*

satisfied). To assess a participant's degree of confidence in their perceived ability to execute control of gambling behaviours during treatment and follow-up, a measure of self-efficacy will be utilised. Participants will describe up to three personally relevant high-risk situations and then rate the extent of their belief that they could refrain from gambling excessively in these situations on a scale of 0-10. Self-reported measures of behaviours relating to problematic gambling will include: frequency of gambling in previous month; number of hours spent on gambling activities in previous month; and amount spent on gambling activities in previous month.

Table 3 here

Follow-up

High rates of treatment and follow up attrition occur for problem gamblers (40). To improve completion rates of self-rated questionnaires at follow-up for both treatment completers and treatment drop outs, study participants will be offered honorarium gift vouchers to the value of $10 at treatment completion; $20 at 3 months follow-up; $25 at 6 months follow-up; and $30 at 12 months follow-up. For follow-up assessments, a relatively large time window will be allowed to ensure maximum data collection and questionnaires will be administered by post to limit burden to participants that may result from attending appointments at the study-site during follow-up (41).

Treatment drop-out

Treatment drop-out will be determined using two general approaches (40). The first approachwill be based on therapists' judgement of participant progress up to the point of self-initiated termination. Secondly, attendance at a pre-specified number of sessions will also be

examined. A previous study involving SGTS participants engaged in ET determined an appropriate cut-off number of sessions for classification as drop-out as 3 or less including the first screening attendance (25). Similarly, in a randomised trial evaluating CT, participants who attended an initial study screening and 2 treatment sessions or less were classified as drop-outs (29). The degree of concordance between these two classification methods for drop-out will then be assessed and any discrepancies will be resolved by discussion between clinical supervisors and therapists. The level of treatment adherence for each participant will inform secondary data analyses discussed in the following section.

Data analyses

The primary analysis will be an intent-to-treat (ITT) to detect any statistically significant differences in VGS scores over time for the treatment and follow-up period between cognitive and exposure therapy. To account for participant attrition and lack of treatment adherence the ITT analysis will be supplemented with an 'as treated' and 'per protocol' analysis. The 'as treated' approach will be useful for identifying associations between clusters of participant characteristics and treatment outcomes from an observational perspective. The 'per protocol' analysis will enable an evaluation of treatment efficacies in the sub-sample of participants that adhere to their assigned treatment protocol (42) . Secondary measures will be analysed using the same approach as outlined above.

Generalised linear mixed models will be used for repeated measures of primary and secondary continuous and categorical outcomes. Preliminary models will assess for Therapist and Therapist X Treatment Group effects and will be included in main analyses if statistically significant. Fixed effects in models will include intervention group, time in continuous form (intervention period and maintenance effects), and interaction between group and time.

Random effects will be at study participant level and represent an upward or downward shift in the outcome measure from an overall regression line and rate of change over time. Linear combinations of regression coefficients will be tested for treatment group effect at completion of intervention period and for maintenance effects and estimates will be presented along with confidence intervals. Predicted estimates of treatment outcomes at each time point will be calculated using fitted models of the data in order to examine patterns of individual change within each group. To interpret effect sizes and precision for categorical outcomes, odds ratios and confidence intervals will be calculated.

To determine mechanisms of therapeutic change based on the intended effects of each treatment, a mediation analysis will be conducted using mixed-effects modelling. The analysis will follow the traditional requirements for testing mediation: (1) testing for an association between treatment condition (ET and CT) and mediator (gambling urge or gambling related cognitions); (2) testing for an association between treatment outcome variable (e.g. gambling behaviours) and treatment condition; (3) testing for an association between the mediator and treatment outcome; and (4) testing if the effect of treatment condition on treatment outcome is attenuated upon the addition of the mediator to the model (43).

In order to allow accurate critical appraisal of the validity and applicability of results, reporting of this trial will comply with CONSORT (Consolidated Standards of Reporting Trials) guidelines for non-pharmacologic treatment (44).

Qualitative component

Despite the growing evidence-base for cognitive and behavioural therapies for problem gambling, the processes and mechanisms of therapeutic change have not been explored from

the participant's perspective and experience. . Therefore, following the treatment intervention period a sub-sample of participants will be invited to take part in semi-structured interviews to explore therapeutic change for cognitive and exposure therapies. One-on-one interviews with participants will be conducted in person by the study research officer for approximately one hour and audio recorded.. To ensure the capture of a range of individual experiences, purposeful sampling will be used. Sampling will continue until theoretical saturation has been achieved where no new or relevant data is seen to emerge (45). All recordings will be transcribed to a document then verified for consistency by the research officer and uploaded to NVivo software (46) for data management. Interview transcripts will be analyzed using direct content analysis to report participant's experiences at the semantic level around specific and non-specific treatment effects. Initial coding will be conducted by the research officer and guided by existing theory and research (47). A second researcher will then cross-check the coding in order to reduce potential subjectivity in the analysis.

Discussion

This study will provide high quality data for therapeutic benefits of exposure therapy compared to cognitive therapy in people seeking treatment for problem gambling using electronic gaming machines. The outcome data collected will cover the domains of gambling behaviours, problems caused by gambling, and mechanisms of change. Also, qualitative interviews will explore therapeutic change from the individual's experience and will be examined in light of conclusions drawn from quantitative models to better understand each treatments intended effects. The findings are expected to guide consumers, clinicians, policymakers and funders in the use of these treatments for gambling disorders.

The design of this trial is guided by ethical considerations in line with the community service commitment of the Statewide Gambling Therapy Service. Therefore, a key strength of this

study is that all treatment seeking problem gamblers meeting eligibility criteria will receive an active treatment. Also, due to the broad study inclusion criteria, it is expected that a significant proportion of the sample will have co-morbid conditions (e.g. anxiety, depression, and substance abuse (10, 48)), which will enhance the external validity of findings using an intent-to-treat design. A limitation of the design is no control group to account for non-specific treatment effects, however, a reasonable assumption is made that non-specific effects will be approximately similar between study groups due to analogous therapy structures, therapist background and experience, and therapeutic environment.

A further limitation of the study design is that outcome data will be collected from self-report measures and therefore participants may overestimate treatment effects. Because there is a high degree of uncertainty for differential treatment effects and blinding of participants to study hypothesis, the likelihood of bias in self-ratings is expected to be minimised. Also, as this study will be conducted at a single-site the findings will have some limitations for inference to a wider population. On the other hand, benefits of being a single-site study can include more effective lines of communication and a more consistent application of research protocol.

Conclusion

We have described the rationale and protocol for a randomised clinical trial to investigate treatment efficacy of exposure therapy compared to cognitive therapy for people with a gambling disorder in South Australia. The trial is funded, due to a limited gambling treatment evidence-base, to inform a range of stakeholders on best practice. To our knowledge, this is the first clinical trial to compare treatments with theoretical underpinnings from each of the two dominant approaches in explaining gambling disorders- cognitions (cognitive therapy) and psychobiological states (exposure therapy) in treatment seeking problem gamblers. The wide range of data collected in this trial will provide high quality evidence for these treatments and

contribute to the development of more optimal combinations of cognitive and behavioural therapies.

Acknowledgements

Kirsten Dunn and Gaston Antezana are providing cognitive therapy. Jane Oakes and Amii Larsen are providing exposure therapy. Mitch Durbridge is providing on-site supervision for the cognitive therapy group and treatment integrity checks.

References

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (4th Edition, Text Revision). 4th ed. Washington DC2000.
2. Ferris J, Wynne H. The Canadian Problem Gambling Index: Final Report: Canadian Centre on Substance Abuse. 2001.
3. Ben-Tovim D, Esterman A, Tolchard B, Battersby MW. The Victorian Gambling Screen: Project report. Melbourne: Victorian Research Panel2001.
4. Becona E. Prevalence surveys of problem and pathological gambling in Europe: The cases of Germany, Holland and Spain. J Gambl Stud. 1996;12(2):179-92.
5. Bondolfi G, Osiek C, Ferrero F. Prevalence estimates of pathological gambling in Switzerland. Acta Psychiatr Scand. 2000;101(6):473-5.
6. Delfabbro P. Australasian Gambling Review: Independent Gambling Authority of South Australia2009.
7. Shaffer HJ, Hall MN. Updating and refining prevalence estimates of disordered gambling behaviour in the United States and Canada. Can J Public Health. 2001;92(3):168-72.
8. Wardle H, Sproston K, Orford J, Erens B, Griffiths MD, Constantine R, et al. The British Gambling Prevalence Survey. London: The Stationery Office 2007.
9. Wong ILK, Ernest MTS. Prevalence estimates of problem and pathological gambling in Hong Kong. The American Journal of Psychiatry. 2003;160(7):1353.
10. Lorains FK, Cowlishaw S, Thomas SA. Prevalence of comorbid disorders in problem and pathological gambling: systematic review and meta-analysis of population surveys. Addiction. 2011;106(3).
11. Daughters B, Lejuez CW, Lesieur HR, Strong DR, Zvolensky MJ. Towards a better understanding of gambling treatment failure: implications of translational research. Clin Psychol Rev. 2003;23(4):573-86.
12. Jackson A, Thomas S, Blaszczynski A. Best practice in problem gambling services. Melbourne: Gambling Research Panel2003.
13. Gooding P, Tarrier N. A systematic review and meta-analysis of cognitive-behavioural interventions to reduce problem gambling: Hedging our bets? Behav Res Ther. 2009;47(7):592-607.
14. Problem Gambling Research and Treatment Centre (PGRTC). Guideline for screening, assessment and treatment in problem gambling: Clayton:Monash University2011.
15. Clark L. Decision-making during gambling: an integration of cognitive and psychobiological approaches. Philosophical Transactions of the Royal Society B: Biological Sciences. 2010;365(1538):319.
16. Hodgins DC, Stea JN, Grant JE. Gambling disorders. The Lancet. 2011;378(9806):1874-84.
17. Beck AT, Dozois DJA. Cognitive Therapy: Current Status and Future Directions. Annu Rev Med. 2011;62(1):397-409.
18. Brown RIF. Classical and Operant Paradigms in the Management of Gambling Addictions. Behavioural Psychotherapy. 1987;15(2):111-22.
19. Battersby MW, Oakes J, Tolchard B, Forbes A, Pols R. Cognitive behavioural treatment for problem gamblers. In: Zangeneh M, Blaszczynski A, Turner NE, editors. In the pursuit of winning. New York: Springer; 2008. p. 179-97.
20. Ougrin D. Efficacy of exposure versus cognitive therapy in anxiety disorders: systematic review and meta-analysis. BMC Psychiatry. 2011;11:200.
21. Martin T, D. LaRowe S, Malcolm R. Progress in Cue Exposure Therapy for the Treatment of Addictive Disorders: A Review Update. The Open Addiction Journal. 2010;3:92-101.

22. McMillen J, Wenzel M. Measuring problem gambling: Assessment of three prevalence screens. International Gambling Studies. 2006;6(2):147-74.
23. Lesieur HR, Blume SB. The South Oaks Gambling Screen (SOGS): a new instrument for the identification of pathological gamblers. Am J Psychiatry. 1987 September 1, 1987;144(9):1184-8.
24. Stinchfield R. Reliability, validity, and classification accuracy of the South Oaks Gambling Screen (SOGS). Addict Behav. 2002;27(1):1-19.
25. Smith D, Harvey P, Battersby M, Pols R, Oakes J, Baigent M. Treatment outcomes and predictors of drop out for problem gamblers in South Australia: a cohort study. Aust N Z J Psychiatry. 2010;44:911-20.
26. Riley B, Smith D, Oakes J. Exposure therapy for pathological gambling in rural communities: a program model and early outcomes. Aust J Rural Health. 2011;19(3):142-6.
27. StataCorp. Stata: Release 11. Statistical Software. College Station, TX: StataCorp LP; 2009.
28. Ladoucer R, Sylvain C, Boutin C, Lachance S, Doucet C, Leblond J, et al. Cognitive treatment of pathological gambling. J Nerv Ment Dis. 2001;189:774-80.
29. Ladouceur R, Sylvain C, Boutin C, Lachance S, Doucet C, Leblond J. Group therapy for pathological gamblers: a cognitive approach. Behav Res Ther. 2003;41(5):587.
30. Ladouceur R, Sylvain C, Letarte H, Giroux I, Jacques C. Cognitive treatment of pathological gamblers. Behav Res Ther. 1998;36(12):1111-9.
31. Wolitzky-Taylor KB, Horowitz JD, Powers MB, Telch MJ. Psychological approaches in the treatment of specific phobias: A meta-analysis. Clin Psychol Rev. 2008;28(6):1021-37.
32. Oakes J, Battersby M, Pols R, Cromarty P. Exposure therapy for problem gambling via videoconferencing: a case report. Journal of Gambling Studies. 2008;24(1):107-19.
33. Walker M, Toneatto T, Potenza MN, Petry N, Ladouceur R, Hodgins DC, et al. A framework for reporting outcomes in problem gambling treatment research: the Banff, Alberta Consensus. Addiction. 2006;101(4):504-11.
34. Tolchard B, Battersby M. The Victorian Gambling Screen: reliability and validity in a clinical population J Gambl Stud. 2010;26:623-38.
35. Raylu N, Oei T. The Gambling Related Cognitions Scale (GRCS): development, confirmatory factor validation and psychometric properties. Addiction. 2004;99(6):757-69.
36. Raylu N, Oei T. The Gambling Urge Scale: Development, confirmatory factor validation, and psychometric properties. Psychol Addict Behav. 2004;18(2):100-5.
37. Smith DP, Pols RG, Battersby MW, Harvey PW. The Gambling Urge Scale: Reliability and validity in a clinical population. Addiction research & theory. 2012;doi:10.3109/16066359.2012.696293.
38. Andrews G, Slade T. Interpreting scores on the Kessler psychological distress scale (K10). Aust N Z J Public Health. 2001;25:494-7.
39. Mundt JC, Marks IM, Shear MK, Greist JM. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. The British Journal of Psychiatry. 2002 May 1, 2002;180(5):461-4.
40. Melville KM, Casey LM, Kavanagh DJ. Psychological treatment dropout among pathological gamblers. Clin Psychol Rev. 2007;27(8):944-58.
41. National Research Council. The Prevention and Treatment of Missing Data in Clinical Trials. Panel on Handling Missing Data in Clinical Trials. Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC, The National Academies Press 2010.
42. Oakes JE, Pols RG, Battersby MW, Lawn SJ, Pulvirenti M, Smith DP. A focus group study of predictors of relapse in electronic gaming machine problem gambling, part 1:factors that 'push' towards relapse. J Gambl Stud. 2011;DOI 10.1007/s10899-011-9264-y.

43. Baron RM, Kenny D. The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. J Pers Soc Psychol. 1986;51(6):1173-82.
44. Boutron IMDP, Moher DP, Altman DGD, Schulz KFPMBA, Ravaud PMDP, for the CG. Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration. Ann Intern Med. 2008;148(4):295-309.
45. Crabtree B, DiCicco-Bloom B. The qualitative research interview. Med Educ. 2006;40:314-21.
46. NVivo qualitative data analysis software. 10 ed: QSR International Pty Ltd. ; 2012.
47. Charmaz K. Grounded theory, objectivist and constructivist methods. In: Denzin NK, Lincoln YS, editors. Handbook of Qualitative Research. Second ed: Sage, Thousand Oaks.; 2000.
48. Ibanez A, Blanco C, Donahue E, Lesieur HR, Perez de Castro I, Fernandez-Piqueras J, et al. Psychiatric Comorbidity in Pathological Gamblers Seeking Treatment. Am J Psychiatry. 2001 October 1, 2001;158(10):1733-5.

Table 1.Intervention schedule

Weekly Sessions	Cognitive Therapy (CT)	Exposure Therapy (ET)
Session 1:	Pre-treatment assessment to identify problem gambling and any co-morbid conditions. Rationale and protocol of cognitive therapy explained.	Pre-treatment assessment to identify problem gambling and any co-morbid conditions. Rationale and protocol of exposure therapy explained.
Session 2:	Development of participant's measurable problems and goals. Analysis of a gambling session to identify erroneous thoughts. Commence daily self-monitoring diary.	Development of participant's measurable problems and goals. Establish cash restrictions to ensure participant has no cash. First exposure task set using images. Commence daily self-monitoring diary.
Session 3:	Psycho-education: clarification of the concept of chance and establish the distinction between games of skill and games of chance.	Review participant's attempt at first exposure task. Finalise cash restriction strategies if not already in place. In-session imagery exposure task with therapist guidance.
Session 4:	Psycho-education/cognitive awareness: introduce ABCD (situation, thoughts, behaviour, consequences) model and exercises to focus on the gambling thoughts or 'inner dialogue'.	Review imagery exposure task. Finalise cash restriction strategies if not already in place. Imagery exposure task with therapist guidance.
Session 5:	Identifying erroneous thoughts or 'gambling traps' that lie behind emotions taking over reason using ABCD model. Participants are encouraged to challenge these thoughts, perceptions, and beliefs in this session.	Review imagery exposure task. Introduction of next exposure task involving image and sounds of gambling-related cues.
Session 6:	Identifying erroneous cognitions. Practical exercise to help participant organise and act upon thoughts	Introduction to first of the in-vivo exposure tasks. This task to take place outside of participant's usual gambling venue(s). The participant utilises principles of exposure therapy from imaginal tasks to assist in identifying what is happening to them at the time of the in-vivo task.
Session 7:	Identifying erroneous cognitions. Practical exercise to help participant organise and act upon thoughts (continued).	Fine tuning of in-vivo exposure task outside of venue. Introduction to in-vivo exposure task to take place inside venue without cash.
Session 8:	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling	Fine tuning of in-vivo exposure task inside venue without cash. Introduction to next in-vivo task taking place inside a gambling venue with a small amount of cash.
Session 9:	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling (continued).	Fine tuning of in-vivo exposure task inside venue with a small amount of cash. Introduction to next in-vivo task taking place inside a gambling venue changing a small amount of cash for Poker machine coins.
Session 10	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling (continued).	Review in-vivo exposure tasks. Introduction to next in-vivo task taking place inside a gambling venue changing a small amount of cash for coins and placing in Poker machine.
Sessions 11- 12	Explore gambling relapse and develop relapse prevention strategies.	Explore gambling relapse and develop relapse prevention strategies.

Table 2.Treatment integrity checklist items

Item	Response options	Cognitive Therapy	Exposure Therapy
1	Yes/No/or N/A (not applicable)	*Eliciting automatic thoughts:* Gambling related	*Cash Management:* Effective plan established and agreed by the client
2	Yes/No/or N/A	*Case conceptualisation:* Linking beliefs and thoughts with behaviour, eliciting feedback from client regarding validity and usefulness	*Case conceptualisation:* linking autonomic responses with behaviour, eliciting feedback from client regarding validity and usefulness
3	Yes/No/or N/A	*Sharing conceptualisation with client:* Used meaningful examples	*Sharing conceptualisation with client:* Used meaningful examples
4	Yes/No/or N/A	*Eliciting core beliefs/schemata:* Gambling related	*Eliciting autonomic symptoms, thoughts, and behaviours:* Gambling related
5	Yes/No/or N/A	*Addressing key issues*: Raised key issues and related them to cognition and behaviour	*Setting and conduct of exposure tasks* : Appropriately graded, focussed, prolonged, and repeated; agreed by the client; relevant to therapy goals
6	Yes/No/or N/A	*Guided discovery:* Socratic questioning, reflective/confronting (e.g. what would that mean?)/interpretive responses to guide client's understanding	*Addressing key issues*: Raised key issues and related them to urge and behaviour
7	Yes/No/or N/A	*Asking for alternative thoughts:* Alternative views/explanations appropriately followed through	*Habituation:* Evidence that the therapist assisted client to identify and habituate to spontaneous urges
8	Yes/No/or N/A	*Use of alternative cognitive techniques:* Appropriately selected and applied, relevant to therapy goals	*Use of alternative behavioural techniques:* Appropriately selected and applied, relevant to therapy goals
9	0-10 Likert scale	Overall rating of integrity	Overall rating of integrity
10	Unlimited free form text	*Overall use of appropriate technique (specifically, please comment on any area of the session which may not have adhered to the allocated therapeutic approach)*	*Overall use of appropriate technique (specifically, please comment on any area of the session which may not have adhered to the allocated therapeutic approach)*

Table 3.Measurements

Measurements	Intervention period				Maintenance period		
	Baseline	**Sessions 2-12**	**Mid-treatment**	**End of treatment**	**3 month**	**6 month**	**12 month**
Demographics	X						
Duration of gambling problem	X						
AISS	X						
VGS	X		X	X	X	X	X
DSM-IV-TR	X			X		X	
Mechanisms of change							
GRCS	X	X	X	X	X	X	X
GUS	X	X	X	X	X	X	X
Self-efficacy	X	X	X	X	X	X	X
Problems caused by gambling							
K10	X			X	X	X	X
WSAS	X			X	X	X	X
AUDIT	X			X	X	X	X
Gambling behaviours							
frequency†	X		X	X	X	X	X
hours‡	X		X	X	X	X	X
amount§	X		X	X	X	X	X
Treatment views							
Confidence about treatment		X*					
Treatment is logical		X*					
Satisfied with treatment				X			

Abbreviations: AISS, Arnett Inventory of Sensation Seeking Traits; VGS, Victorian Gambling Screen; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Text Revision (4th Edition); GRCS, Gambling Related Cognitions Scale; GUS, Gambling Urge Scale; K10, Kessler 10 Scale; WSAS, Work and Social Adjustment Scale; AUDIT, Alcohol Use Disorders Identification Test.
†Days per month in which gambling takes place
‡Time spent thinking about or engaged in the pursuit of gambling in previous month
§Expenditure in previous month
*Session 2 only

Title

Protocol for a two- group randomised, parallel trial of cognitive and exposure therapies for problem gambling

Authors

David P Smith
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: david.smith@flinders.edu.au
Tel: +61 8 8404 2610
Fax: +61 8 8404 2101

Malcolm W Battersby
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: malcolm.battersby@flinders.edu.au
Tel: +61 8 8204 2314
Fax: +61 8 8404 2101

Peter W Harvey
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: peter.harvey@flinders.edu.au
Tel: +61 8 8204 2314
Fax: +61 8 8404 2101

Rene G Pols
Institutional affiliation: Flinders University, Department of Psychiatry
Address: Flinders Human Behaviour and Health Research Unit, GPO Box 2100, Adelaide SA 2001
Country: Australia
Email: rene.pols@flinders.edu.au
Tel: +61 8 8204 4849
Fax: +61 8 8204 6410

Robert Ladouceur
Institutional affiliation: Université Laval, School of Psychology
Address: 2325, rue des Bibliothèques, Bureau 1328, Université Laval, Québec (Québec), Canada, G1V 0A6.
Country: Canada
Email: robert.ladouceur@psy.ulaval.ca
Tel: (418) 656-3996
Fax: (418) 656-3646

Running head
Trial protocol for gambling treatments

Word count
Abstract: 235
Main text: 3,500

FundingDeclaration of interest
This work is funded by Victorian Department of Justice, Office of Gaming & Racing grant 061/09. The SGTS is funded by the Office of Problem Gambling, Department of Families and Social Inclusion, Government of South Australia. The authors alone are responsible for the design, implementation and reporting of results for this study. The authors have no other conflicts of interest to declare.

Competing interests
The authors have no other conflicts of interest to declare.
None

Article summary

Article focus

- To isolate and compare cognitive and behavioural (exposure-based) techniques to determine their relative efficacy in treating problem gambling.
- The primary research question is: Among treatment seeking problem gamblers, is exposure therapy more effective in reducing gambling severity symptoms (harm to self subscale of the VGS) over the 152-month study period (intervention and maintenance effects) compared with cognitive therapy?

Key messages

- Problem gambling is a serious public health concern at an international level and occurs more frequently in younger populations.
- The best evidence for gambling treatments is for cognitive behavioural therapy (CBT) but remains tentative.
- This study will be the first randomised, parallel trial to compare cognitive and exposure therapies in this population.

Strengths and limitations

- A key strength of this study is that all treatment seeking problem gamblers meeting eligibility criteria will receive an active treatment. Also, due to the broad study inclusion criteria, it is expected that a significant proportion of the sample will have co-morbid conditions (e.g. anxiety, depression, and substance abuse which will enhance the external validity of findings using an intent-to-treat design.
- A limitation of the design is no control group to account for non-specific treatment effects, however, a reasonable assumption is made that non-specific effects will be

Formatted: Bulleted + Level: 1 + Aligned at: 0.25" + Indent at: 0.5"

approximately similar between study groups due to analogous therapy structures, therapist background and experience, and therapeutic environment. ~~A further limitation is that this study will be conducted at a single site the findings will have some limitations for inference to a wider population. On the other hand, benefits of being a single site study can include more effective lines of communication and a more consistent application of research protocol.~~

Abstract

Background and aims: Problem gambling is a serious public health concern at an international level where population prevalence rates average 2% or more and occurs more frequently in younger populations. The most empirically established treatments to date are combinations of cognitive and behavioural techniques labelled cognitive behaviour therapy (CBT). However, there is a paucity of high quality evidence for the comparative efficacy of core CBT interventions in treating problem gamblers. This study aims to isolate and compare cognitive and behavioural (exposure-based) techniques to determine their relative efficacy.

Methods: A sample of 130 treatment seeking problem gamblers will be allocated to either cognitive or exposure therapy in a two-group randomised, parallel design. Repeated measures will be conducted at baseline, mid and end of treatment (12 sessions intervention period), and 3, 6, and 12 months (maintenance effects). The primary outcome measure is improvement in problem gambling severity symptoms using the Victorian Gambling Screen (VGS) harm to self sub-scale. The VGS measures gambling severity on an extensive continuum, therefore enhancing sensitivity to change within and between individuals over time.

Discussion: This article describes the research methods, treatments, and outcome measures used to evaluate gambling behaviours, problems caused by gambling and mechanisms of change. This study will be the first randomised, parallel trial to compare cognitive and exposure therapies in this population. ~~Findings are expected to guide consumers, clinicians, policy makers and funders in the use of these treatments for gambling disorders.~~

Ethics and dissemination: The study was approved by the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee. Study findings will be disseminated through peer-reviewed publications and conference presentations.

Trial registration: Australian New Zealand Clinical Trials Registry: ACTRN12610000828022

Formatted: Don't adjust space between Latin and Asian text, Don't adjust space between Asian text and numbers

Formatted: Font: (Default) Times New Roman, 12 pt

Formatted: Font: (Default) Times New Roman, 12 pt

Introduction

Pathological gambling (PG) from a mental health perspective is defined by the American Psychiatric Association DSM-IV-TR as "…persistent and recurrent maladaptive gambling behaviour that disrupts personal, family and vocational pursuits" (1)**.** The term 'problem gambling' defines less severe forms of gambling disorders and has been the basis for the development of several diagnostic and screening instruments such as the Canadian Problem Gambling Index (CGPI) (2) and the Victorian Gambling Screen (VGS) (3). It is a serious public health concern at an international level where population prevalence rates average 2% or more and occurs more frequently in younger populations (4-9). Co-morbid mental health disorders such as depression and anxiety are common in both treatment seeking and general populations of problem gamblers (10).

Treatment types available for gambling disorders have similarities to those of other addictions and include psychological, peer-support, and more recently, pharmacological interventions (11, 12). To date, the best evidence for gambling treatments is psychological, where cognitive behavioural therapy (CBT) has been the most researched (13) and the evidence-base recommended as "…trusted to guide practice in most situations" based on NHMRC (National Health and Medical Research Council) grades for developers of guidelines (14).

The theoretical underpinnings of CBT include cognitions (e.g. erroneous thoughts) and psychobiological states (e.g. physiological arousal) and are two dominant approaches to explaining gambling disorders (15). Most variants of CBT for treating gambling disorders have shown to be clinically beneficial compared to no treatment, and the most rigorous clinical trials have comprised of a combined cognitive-behavioural approach (13, 16). For core techniques, findings have indicated cognitive therapy (CT) has an "added advantage" when compared

directly to no treatment, although evidence is tentative due to heterogeneity between studies (13). Cognitive restructuring plays an important role in CT and has shown to be beneficial in treating a range of mental health conditions (17).

However, the comparative efficacy of CT with other core CBT interventions such as behavioural (exposure-based) therapies that target psychobiological related gambling pathology is unknown (13). Exposure therapy (ET) is grounded in classical and operant conditioning paradigms and where cue-exposure with extinction processes has been proposed as more beneficial than other types (e.g. aversive therapy) in treating gambling addiction (18). ET has shown to be equally effective as CT in treating anxiety disorders where both techniques have similar hypothesised mechanisms of therapeutic change to those in gambling disorders (19, 20). In addictions there is no conclusive evidence for exposure based treatments due to there being few clinical trials with power (21).

As behavioural therapies in general are more parsimonious in terms of delivery than CT (22) it is important from a public health point of view to understand the relative efficacy of these core treatments. Therefore, we designed a study titled "Comparing outcomes of cognitive and exposure therapy for problem gambling" which is a randomised trial comparing efficacies of CT and ET. This trial is motivated by the uncertainty about the clinical superiority of CT over ET. Based on this uncertainty, the concept of equipoise exists and participants will, therefore, not be disadvantaged from randomisation to either treatment group. This study will be the first to compare these treatments in a population of treatment seeking gamblers.

Study design

Comparing outcomes of cognitive and exposure therapy for gambling disorders is a two-group randomised, parallel design with treatment seeking problem gamblers presenting to the

Statewide Gambling Therapy Service (SGTS) in South Australia. The study will recruit 130 participants over a 12 month period commencing April 2011. The outpatient SGTS programme offers one-on-one and group therapy for problem gamblers at three key metropolitan (Adelaide) centres, one of which will be selected as the trial site. The primary referral sources of clients presenting to SGTS are self, Gambling Helpline and related agencies and general practitioners. The service is staffed by a psychiatrist and therapists with professional registration in psychology, nursing, or social work. All therapists have graduate qualifications and clinical experience in CBT (19). Data collection will finish in July 2013.

The study was approved by the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee and registered with the Australian New Zealand Clinical Trials Registry (ACTRN12610000828022) at the trials inception. The research officer will give participants an information statement regarding the study and ask for written informed consent before data collection begins.

Participant recruitment and random assignment

To assess study eligibility, an independent clinician will conduct semi-structured interviews with treatment seeking problem gamblers presenting to SGTS during the recruitment period. The interview will include assessment of individual demographics, recent gambling activities, and administration of the well-validated *South Oaks Gambling Screen* (SOGS) (23). The SOGS is a 20 item questionnaire based on DSM criteria for pathological gambling. A score of 5 or more is indicative of probable pathological gambler. In gambling treatment samples the scale has good reliability, exhibits high correlations with DSM-IV diagnostic criteria, and good to excellent classification accuracy (24).

Study eligibility will be based on the following inclusion criteria: 18 years of age or older; treatment seeking for problem gambling with electronic gaming machines (EGM's); not involved in a concurrent gambling treatment program; not received psychological treatment for problem gambling in previous 12 months; willing to participate in the study; a willingness to read and respond to self-rated questionnaires written in English; willing to be randomised to one of two psychological treatments; gambled in the past month using EGM's; willing to provide follow-up data; willing to have treatment sessions audio recorded; scoring 5 or greater on the South Oaks Gambling Screen; and not suicidal or experiencing mental distress such as mania which would indicate that the problem gambler would not be able to participate fully in the treatment offered.

Individuals assessed as eligible for study participation will be randomly assigned to one of two treatment groups with 1:1 allocation ratio. Randomisation will be blocked to increase the likelihood of equal group sizes, using a standard permutated block algorithm in which block sizes will be randomly chosen from 2, 4, and 6 to protect concealment. To ensure balance on potential confounders, block randomisation within strata will be used, stratifying at median age, gender, and median SOGS scores for problem gambling severity. Based on previous SGTS data, age will be stratified as 18 - 42 years, and 43 years or more (25). Gambling severity will be stratified according to previous treatment seeking problem gamblers SOGS scores of either 5 - 11, and between 12 and 20 (26). A statistician will independently generate random sequences for each stratum using Stata version 11.1 software (27) and deliver to the clinical trials call centre of a centrally located hospital pharmacy. Staff enrolling and referring participants, collecting and entering data and administering interventions will not know in advance which treatment the next participant will receive.

Sample size

The primary research question is: Among treatment seeking problem gamblers, is exposure therapy more effective in reducing gambling severity symptoms (harm to self subscale of the VGS) over the 12-month study period (intervention and maintenance effects) compared with cognitive therapy?

Based on a type I error rate of 5% , power of 90%, two-tailed test, and a VGS standard deviation of 10.2 units (25), to detect a significant difference of 8% (i.e. 4.8 points on the scale) in mean VGS scores between the ET and CT groups, 50 participants will be required in each group. Given the treatment dropout rate experienced in the SGTS treatment programme (approximately 30%) we therefore would need to recruit 65 participants in each group of the study giving a total sample size of 130 participants.

Therapists

Cognitive therapy will be provided by two psychotherapists with qualifications in psychology and, on average, having approximately 5 years practice experience, including 2 years in treating individuals with gambling disorders. The therapists will receive initial on-site training in CT by Robert Ladouceur, a widely published international clinician and researcher in the field of cognitive therapy for gambling disorders (28-30).

Exposure therapy will be provided by two psychotherapists with post-graduate qualifications in CBT; a registered mental health nurse and a psychology graduate. On average, therapists have 6 years clinical experience in delivering CBT treatments to clients' of SGTS including a manualised ET program. Therapists will receive on-site supervision from Malcolm Battersby who trained at the Institute of Psychiatry, London in behavioural treatments of anxiety

disorders and severe neurotic conditions and is the Director of the Flinders Gambling Research Centre and SGTS (19).

Study treatments

The trial will comprise two interventions: cognitive therapy (CT) and exposure therapy (ET). Participants in both groups will receive a standard of twelve 60-minute individual treatment sessions, ranging from 4-16 depending on co-occurring conditions, conducted at weekly intervals. Both treatment manuals are intended as a session-by-session guide for therapists treating individuals with a gambling disorder where EGM's are the main form of gambling problem. The therapists will deliver treatment according to the content of each manual and sequencing of techniques in a face-to-face format. A summary of treatment sessions is provided in Table 1.

Table 1 here

Blinding

Statistical analyses will be conducted according to pre-specified guidelines. In this trial, therapists will know what treatment they are administering and participants will be provided with information that will rationalise and describe their assigned therapy protocol. Participants will be blinded to the study hypothesis in order to reduce the likelihood for self-report bias. Participant information sheets will refer to treatments as "well known and commonly used psychological treatments".

Treatment integrity

All treatment sessions will be audio recorded and 20% will be randomly selected from early, mid, and late study phases and evaluated using a checklist based on the Cognitive Therapy Scale (Table 2) (31). ET sessions will be evaluated by MB and RP who are senior consultant psychiatrists with the Flinders Gambling Research Centre and have extensive experience in treatments for gambling disorders and other addictions (19, 32). CT sessions will be evaluated by RL and MD who are senior clinical psychologists.

Table 2 here

Measures

The administration of measures during the intervention period will be conducted prior to commencement of each treatment session and at 3 and 6 month follow-up visit with study therapist. The 12 month follow-up questionnaires will be mailed to participants. Baseline assessment will include demographic variables and data for duration of gambling problem. Validated outcome measures will cover domains of gambling behaviours, problems caused by gambling, and mechanisms of change (33). This means that for ET participants, a greater reduction in urge to gamble is expected to be associated with a clinically meaningful improvement in treatment outcomes than in CT participants. For CT participants, a more accurate set of beliefs relating to gambling is expected to be associated with a clinically meaningful improvement in treatment outcomes than in ET participants. The measures are summarised in the following sections and measurement occasions are presented in Table 3.

In order to detect change in problem gambling severity during treatment and at follow-up, the Victorian Gambling Screen (VGS) will be utilised as a primary outcome measure. The VGS is a self-reported questionnaire measuring the extent to which gambling behaviour has impeded

an individual's life. The screen comprises three sub-scales (enjoyment of gambling, harm to partner and harm to self) with a total of 21 items. In this study the harm to self sub-scale will be used as primary outcome measure. Items on the self-harm subscale relate to the person's experiences in the previous 4 weeks and has been validated for use in Australia in a clinical population of problem gamblers (34). Total scores for the 15 items range from 0 = no harm to self to 60 = high harm to self and a score of 21+ identifies a person as problem gambler. Concurrent validity indicates the scale correlates very highly with the SOGS but extends the score range. The VGS has also shown similar properties in construct validity as the Canadian Problem Gambling Index (CPGI) on a number of problem gambling correlates (e.g. 'self-rating of problem', and 'wanted help') (22).

Secondary outcome measures will include DSM-IV-TR diagnostic criteria relating to the extent of persistent and recurrent maladaptive gambling behaviour and will be administered by study therapists. A total score is obtained by summing across the ten responses of "yes" or "no". A score of five or more indicates pathological gambling (1). All other secondary measures are self-reported. Gambling related cognitions will be measured using a 23 item scale (GRCS) that records common thoughts associated with problem gambling where each item is rated on a 1-7 Likert scale (35). The urge to gamble will be assessed using a 6 item instrument (GUS) where each item is rated on a Likert (1-7) scale (36, 37). Participants' experiences of psychological distress will be recorded using a 10 item global measure (K10) with each item rated on a 1-5 Likert scale (38). To measure an individual's perspective of their functional ability/ impairment relating to work and social activities a 5 item scale (WSAS) will be used where each item is rated on a 0-8 Likert scale (39). Participant levels of alcohol use will be assessed based on a 10 item scale where questions 1 to 3 measure quantity and frequency of alcohol use, questions 4 to

6 measure possible dependence on alcohol and questions 7 to 10 measure alcohol-related problems (47, 48).

Following an explanation of treatment rationale and protocol in session one, participants will be asked to rate their confidence in treatment (from 0= *extremely unconfident* to 6= *extremely confident*) and belief in treatment logic (from 0= *extremely illogical* to 6= *extremely logical*) at commencement of session two. At treatment completion participants will be asked to rate their level of satisfaction with treatment received (from 0= *extremely unsatisfied* to 6= *extremely satisfied*). To assess a participant's degree of confidence in their perceived ability to execute control of gambling behaviours during treatment and follow-up, a measure of self-efficacy will be utilised. Participants will describe up to three personally relevant high-risk situations and then rate the extent of their belief that they could refrain from gambling excessively in these situations on a scale of 0-10. Self-reported measures of behaviours relating to problematic gambling will include: frequency of gambling in previous month; number of hours spent on gambling activities in previous month; and amount spent on gambling activities in previous month.

Table 3 here

Follow-up

High rates of treatment and follow up attrition occur for problem gamblers (40). To improve completion rates of self-rated questionnaires at follow-up for both treatment completers and treatment drop outs, study participants will be offered honorarium gift vouchers to the value of $10 at treatment completion; $20 at 3 months follow-up; $25 at 6 months follow-up; and $30 at 12 months follow-up. For follow-up assessments, a relatively large time window will be

Formatted: Font: Bold, Not Italic
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt

allowed to ensure maximum data collection and questionnaires will be administered by post to limit burden to participants that may result from attending appointments at the study-site during follow-up (41).

Formatted: Font: 12 pt

Formatted: Font: 12 pt

Treatment drop-out

Treatment drop-out will be determined using two general approaches (40). The first approach will be based on therapists' judgement of participant progress up to the point of self-initiated termination. Secondly, attendance at a pre-specified number of sessions will also be examined. A previous study involving SGTS participants engaged in ET determined an appropriate cut-off number of sessions for classification as drop-out as 3 or less including the first screening attendance (25). Similarly, in a randomised trial evaluating CT, participants who attended an initial study screening and 2 treatment sessions or less were classified as drop-outs (29). The degree of concordance between these two classification methods for drop-out will then be assessed and any discrepancies will be resolved by discussion between clinical supervisors and therapists. The level of treatment adherence for each participant will inform secondary data analyses discussed in the following section.

Data analyses

The primary analysis will be an intent-to-treat (ITT) to detect any statistically significant differences in VGS scores over time for the treatment and follow-up period between cognitive and exposure therapy. To account for participant attrition and lack of treatment adherence the ITT analysis will be supplemented with an 'as treated' and 'per protocol' analysis. The 'as treated' approach will be useful for identifying associations between clusters of participant characteristics and treatment outcomes from an observational perspective. The 'per protocol' analysis will enable an evaluation of treatment efficacies in the sub-sample of participants that

adhere to their assigned treatment protocol (42) . Secondary measures will be analysed using the same approach as outlined above.

Generalised linear mixed models will be used for repeated measures of primary and secondary continuous and categorical outcomes. Preliminary models will assess for Therapist and Therapist X Treatment Group effects and will be included in main analyses if statistically significant. Fixed effects in models will include intervention group, time in continuous form (intervention period and maintenance effects), and interaction between group and time. Random effects will be at study participant level and represent an upward or downward shift in the outcome measure from an overall regression line and rate of change over time. Linear combinations of regression coefficients will be tested for treatment group effect at completion of intervention period and for maintenance effects and estimates will be presented along with confidence intervals. Predicted estimates of treatment outcomes at each time point will be calculated using fitted models of the data in order to examine patterns of individual change within each group. To interpret effect sizes and precision for categorical outcomes, odds ratios and confidence intervals will be calculated.

To determine mechanisms of therapeutic change based on the intended effects of each treatment, a mediation analysis will be conducted using mixed-effects modelling. The analysis will follow the traditional requirements for testing mediation: (1) testing for an association between treatment condition (ET and CT) and mediator (gambling urge or gambling related cognitions); (2) testing for an association between treatment outcome variable (e.g. gambling behaviours) and treatment condition; (3) testing for an association between the mediator and treatment outcome; and (4) testing if the effect of treatment condition on treatment outcome is attenuated upon the addition of the mediator to the model (43).

In order to allow accurate critical appraisal of the validity and applicability of results, reporting of this trial will comply with CONSORT (Consolidated Standards of Reporting Trials) guidelines for non-pharmacologic treatment (44).

Qualitative component

Despite the growing evidence-base for cognitive and behavioural therapies for problem gambling, the processes and mechanisms of therapeutic change have not been explored from the participant's perspective and experience. ~~qualitative~~. Therefore, f~~F~~ollowing the treatment intervention period a sub-sample of participants will be invited to take part in semi-structured interviews to explore therapeutic change for cognitive and exposure therapies. One-on-one interviews with participants will~~l~~ be conducted in person by the study research officer ~~last~~ for approximately one hour and audio recorded. ~~and be conducted in person with participants~~. To ensure the capture of a range of individual experiences, purposeful sampling will be used. Sampling will continue until theoretical saturation has been achieved where no new or relevant data is seen to emerge (45). All recordings will be transcribed to a document then verified for consistency by the research officer and uploaded to NVivo software (46) for data management. Interview transcripts will be analyzed using direct content analysis to report participant's experiences at the semantic level ~~and based on a Grounded Theory approach to develop key themes~~ around specific and non-specific treatment effects. Initial coding will be conducted by the research officer and guided by existing theory and research (47). A second researcher will then cross-check the coding in order to reduce potential subjectivity in the analysis.

Discussion

This study will provide high quality data for therapeutic benefits of exposure therapy compared to cognitive therapy in people seeking treatment for problem gambling using electronic gaming machines. The outcome data collected will cover the domains of gambling behaviours, problems caused by gambling, and mechanisms of change. Also, qualitative interviews will explore therapeutic change from the individual's experience and will be examined in light of conclusions drawn from quantitative models to better understand each treatments intended effects. The findings are expected to guide consumers, clinicians, policymakers and funders in the use of these treatments for gambling disorders.

The design of this trial is guided by ethical considerations in line with the community service commitment of the Statewide Gambling Therapy Service. Therefore, a key strength of this study is that all treatment seeking problem gamblers meeting eligibility criteria will receive an active treatment. Also, due to the broad study inclusion criteria, it is expected that a significant proportion of the sample will have co-morbid conditions (e.g. anxiety, depression, and substance abuse (10, 48)), which will enhance the external validity of findings using an intent-to-treat design. A limitation of the design is no control group to account for non-specific treatment effects, however, a reasonable assumption is made that non-specific effects will be approximately similar between study groups due to analogous therapy structures, therapist background and experience, and therapeutic environment.

A further limitation of the study design is that outcome data will be collected from self-report measures and therefore participants may overestimate treatment effects. Because there is a high degree of uncertainty for differential treatment effects and blinding of participants to study hypothesis, the likelihood of bias in self-ratings is expected to be minimised. Also, as this study will be conducted at a single-site the findings will have some limitations for inference to a

wider population. On the other hand, benefits of being a single-site study can include more effective lines of communication and a more consistent application of research protocol.

Conclusion

We have described the rationale and protocol for a randomised clinical trial to investigate treatment efficacy of exposure therapy compared to cognitive therapy for people with a gambling disorder in South Australia. The trial is funded, due to a limited gambling treatment evidence-base, to inform a range of stakeholders on best practice. To our knowledge, this is the first clinical trial to compare treatments with theoretical underpinnings from each of the two dominant approaches in explaining gambling disorders- cognitions (cognitive therapy) and psychobiological states (exposure therapy) in treatment seeking problem gamblers. The wide range of data collected in this trial will provide high quality evidence for these treatments and contribute to the development of more optimal combinations of cognitive and behavioural therapies.

Acknowledgements

Kirsten Dunn and Gaston Antezana are providing cognitive therapy. Jane Oakes and Amii Larsen are providing exposure therapy. Mitch Durbridge is providing on-site supervision for the cognitive therapy group and treatment integrity checks.

References

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (4th Edition, Text Revision). 4th ed. Washington DC2000.
2. Ferris J, Wynne H. The Canadian Problem Gambling Index: Final Report: Canadian Centre on Substance Abuse. 2001.
3. Ben-Tovim D, Esterman A, Tolchard B, Battersby MW. The Victorian Gambling Screen: Project report. Melbourne: Victorian Research Panel2001.
4. Becona E. Prevalence surveys of problem and pathological gambling in Europe: The cases of Germany, Holland and Spain. J Gambl Stud. 1996;12(2):179-92.
5. Bondolfi G, Osiek C, Ferrero F. Prevalence estimates of pathological gambling in Switzerland. Acta Psychiatr Scand. 2000;101(6):473-5.
6. Delfabbro P. Australasian Gambling Review: Independent Gambling Authority of South Australia2009.
7. Shaffer HJ, Hall MN. Updating and refining prevalence estimates of disordered gambling behaviour in the United States and Canada. Can J Public Health. 2001;92(3):168-72.
8. Wardle H, Sproston K, Orford J, Erens B, Griffiths MD, Constantine R, et al. The British Gambling Prevalence Survey. London: The Stationery Office 2007.
9. Wong ILK, Ernest MTS. Prevalence estimates of problem and pathological gambling in Hong Kong. The American Journal of Psychiatry. 2003;160(7):1353.
10. Lorains FK, Cowlishaw S, Thomas SA. Prevalence of comorbid disorders in problem and pathological gambling: systematic review and meta-analysis of population surveys. Addiction. 2011;106(3).
11. Daughters B, Lejuez CW, Lesieur HR, Strong DR, Zvolensky MJ. Towards a better understanding of gambling treatment failure: implications of translational research. Clin Psychol Rev. 2003;23(4):573-86.
12. Jackson A, Thomas S, Blaszczynski A. Best practice in problem gambling services. Melbourne: Gambling Research Panel2003.
13. Gooding P, Tarrier N. A systematic review and meta-analysis of cognitive-behavioural interventions to reduce problem gambling: Hedging our bets? Behav Res Ther. 2009;47(7):592-607.
14. Problem Gambling Research and Treatment Centre (PGRTC). Guideline for screening, assessment and treatment in problem gambling: Clayton:Monash University2011.
15. Clark L. Decision-making during gambling: an integration of cognitive and psychobiological approaches. Philosophical Transactions of the Royal Society B: Biological Sciences. 2010;365(1538):319.
16. Hodgins DC, Stea JN, Grant JE. Gambling disorders. The Lancet. 2011;378(9806):1874-84.
17. Beck AT, Dozois DJA. Cognitive Therapy: Current Status and Future Directions. Annu Rev Med. 2011;62(1):397-409.
18. Brown RIF. Classical and Operant Paradigms in the Management of Gambling Addictions. Behavioural Psychotherapy. 1987;15(2):111-22.
19. Battersby MW, Oakes J, Tolchard B, Forbes A, Pols R. Cognitive behavioural treatment for problem gamblers. In: Zangeneh M, Blaszczynski A, Turner NE, editors. In the pursuit of winning. New York: Springer; 2008. p. 179-97.
20. Ougrin D. Efficacy of exposure versus cognitive therapy in anxiety disorders: systematic review and meta-analysis. BMC Psychiatry. 2011;11:200.
21. Martin T, D. LaRowe S, Malcolm R. Progress in Cue Exposure Therapy for the Treatment of Addictive Disorders: A Review Update. The Open Addiction Journal. 2010;3:92-101.

22. McMillen J, Wenzel M. Measuring problem gambling: Assessment of three prevalence screens. International Gambling Studies. 2006;6(2):147-74.
23. Lesieur HR, Blume SB. The South Oaks Gambling Screen (SOGS): a new instrument for the identification of pathological gamblers. Am J Psychiatry. 1987 September 1, 1987;144(9):1184-8.
24. Stinchfield R. Reliability, validity, and classification accuracy of the South Oaks Gambling Screen (SOGS). Addict Behav. 2002;27(1):1-19.
25. Smith D, Harvey P, Battersby M, Pols R, Oakes J, Baigent M. Treatment outcomes and predictors of drop out for problem gamblers in South Australia: a cohort study. Aust N Z J Psychiatry. 2010;44:911-20.
26. Riley B, Smith D, Oakes J. Exposure therapy for pathological gambling in rural communities: a program model and early outcomes. Aust J Rural Health. 2011;19(3):142-6.
27. StataCorp. Stata: Release 11. Statistical Software. College Station, TX: StataCorp LP; 2009.
28. Ladoucer R, Sylvain C, Boutin C, Lachance S, Doucet C, Leblond J, et al. Cognitive treatment of pathological gambling. J Nerv Ment Dis. 2001;189:774-80.
29. Ladouceur R, Sylvain C, Boutin C, Lachance S, Doucet C, Leblond J. Group therapy for pathological gamblers: a cognitive approach. Behav Res Ther. 2003;41(5):587.
30. Ladouceur R, Sylvain C, Letarte H, Giroux I, Jacques C. Cognitive treatment of pathological gamblers. Behav Res Ther. 1998;36(12):1111-9.
31. Wolitzky-Taylor KB, Horowitz JD, Powers MB, Telch MJ. Psychological approaches in the treatment of specific phobias: A meta-analysis. Clin Psychol Rev. 2008;28(6):1021-37.
32. Oakes J, Battersby M, Pols R, Cromarty P. Exposure therapy for problem gambling via videoconferencing: a case report. Journal of Gambling Studies. 2008;24(1):107-19.
33. Walker M, Toneatto T, Potenza MN, Petry N, Ladouceur R, Hodgins DC, et al. A framework for reporting outcomes in problem gambling treatment research: the Banff, Alberta Consensus. Addiction. 2006;101(4):504-11.
34. Tolchard B, Battersby M. The Victorian Gambling Screen: reliability and validity in a clinical population J Gambl Stud. 2010;26:623-38.
35. Raylu N, Oei T. The Gambling Related Cognitions Scale (GRCS): development, confirmatory factor validation and psychometric properties. Addiction. 2004;99(6):757-69.
36. Raylu N, Oei T. The Gambling Urge Scale: Development, confirmatory factor validation, and psychometric properties. Psychol Addict Behav. 2004;18(2):100-5.
37. Smith DP, Pols RG, Battersby MW, Harvey PW. The Gambling Urge Scale: Reliability and validity in a clinical population. Addiction research & theory. 2012;doi:10.3109/16066359.2012.696293.
38. Andrews G, Slade T. Interpreting scores on the Kessler psychological distress scale (K10). Aust N Z J Public Health. 2001;25:494-7.
39. Mundt JC, Marks IM, Shear MK, Greist JM. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. The British Journal of Psychiatry. 2002 May 1, 2002;180(5):461-4.
40. Melville KM, Casey LM, Kavanagh DJ. Psychological treatment dropout among pathological gamblers. Clin Psychol Rev. 2007;27(8):944-58.
41. National Research Council. The Prevention and Treatment of Missing Data in Clinical Trials. Panel on Handling Missing Data in Clinical Trials. Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC, The National Academies Press 2010.
42. Oakes JE, Pols RG, Battersby MW, Lawn SJ, Pulvirenti M, Smith DP. A focus group study of predictors of relapse in electronic gaming machine problem gambling, part 1:factors that 'push' towards relapse. J Gambl Stud. 2011;DOI 10.1007/s10899-011-9264-y.

43. Baron RM, Kenny D. The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. J Pers Soc Psychol. 1986;51(6):1173-82.
44. Boutron IMDP, Moher DP, Altman DGD, Schulz KFPMBA, Ravaud PMDP, for the CG. Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration. Ann Intern Med. 2008;148(4):295-309.
45. Crabtree B, DiCicco-Bloom B. The qualitative research interview. Med Educ. 2006;40:314-21.
46. NVivo qualitative data analysis software. 10 ed: QSR International Pty Ltd. ; 2012.
47. Charmaz K. Grounded theory, objectivist and constructivist methods. In: Denzin NK, Lincoln YS, editors. Handbook of Qualitative Research. Second ed: Sage, Thousand Oaks.; 2000.
48. Ibanez A, Blanco C, Donahue E, Lesieur HR, Perez de Castro I, Fernandez-Piqueras J, et al. Psychiatric Comorbidity in Pathological Gamblers Seeking Treatment. Am J Psychiatry. 2001 October 1, 2001;158(10):1733-5.

Table 1.Intervention schedule

Weekly Sessions	Cognitive Therapy (CT)	Exposure Therapy (ET)
Session 1:	Pre-treatment assessment to identify problem gambling and any co-morbid conditions. Rationale and protocol of cognitive therapy explained.	Pre-treatment assessment to identify problem gambling and any co-morbid conditions. Rationale and protocol of exposure therapy explained.
Session 2:	Development of participant's measurable problems and goals. Analysis of a gambling session to identify erroneous thoughts. Commence daily self-monitoring diary.	Development of participant's measurable problems and goals. Establish cash restrictions to ensure participant has no cash. First exposure task set using images. Commence daily self-monitoring diary.
Session 3:	Psycho-education: clarification of the concept of chance and establish the distinction between games of skill and games of chance.	Review participant's attempt at first exposure task. Finalise cash restriction strategies if not already in place. In-session imagery exposure task with therapist guidance.
Session 4:	Psycho-education/cognitive awareness: introduce ABCD (situation, thoughts, behaviour, consequences) model and exercises to focus on the gambling thoughts or 'inner dialogue'.	Review imagery exposure task. Finalise cash restriction strategies if not already in place. Imagery exposure task with therapist guidance.
Session 5:	Identifying erroneous thoughts or 'gambling traps' that lie behind emotions taking over reason using ABCD model. Participants are encouraged to challenge these thoughts, perceptions, and beliefs in this session.	Review imagery exposure task. Introduction of next exposure task involving image and sounds of gambling-related cues.
Session 6:	Identifying erroneous cognitions. Practical exercise to help participant organise and act upon thoughts	Introduction to first of the in-vivo exposure tasks. This task to take place outside of participant's usual gambling venue(s). The participant utilises principles of exposure therapy from imaginal tasks to assist in identifying what is happening to them at the time of the in-vivo task.
Session 7:	Identifying erroneous cognitions. Practical exercise to help participant organise and act upon thoughts (continued).	Fine tuning of in-vivo exposure task outside of venue. Introduction to in-vivo exposure task to take place inside venue without cash.
Session 8:	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling	Fine tuning of in-vivo exposure task inside venue without cash. Introduction to next in-vivo task taking place inside a gambling venue with a small amount of cash.
Session 9:	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling (continued).	Fine tuning of in-vivo exposure task inside venue with a small amount of cash. Introduction to next in-vivo task taking place inside a gambling venue changing a small amount of cash for Poker machine coins.
Session 10	Develop skills for challenging and casting doubt on the erroneous thoughts that lead to excessive gambling (continued).	Review in-vivo exposure tasks. Introduction to next in-vivo task taking place inside a gambling venue changing a small amount of cash for coins and placing in Poker machine.
Sessions 11- 12	Explore gambling relapse and develop relapse prevention strategies.	Explore gambling relapse and develop relapse prevention strategies.

Table 2.Treatment integrity checklist items

Item	Response options	Cognitive Therapy	Exposure Therapy
1	Yes/No/or N/A (not applicable)	*Eliciting automatic thoughts:* Gambling related	*Cash Management:* Effective plan established and agreed by the client
2	Yes/No/or N/A	*Case conceptualisation:* Linking beliefs and thoughts with behaviour, eliciting feedback from client regarding validity and usefulness	*Case conceptualisation:* linking autonomic responses with behaviour, eliciting feedback from client regarding validity and usefulness
3	Yes/No/or N/A	*Sharing conceptualisation with client:* Used meaningful examples	*Sharing conceptualisation with client:* Used meaningful examples
4	Yes/No/or N/A	*Eliciting core beliefs/schemata:* Gambling related	*Eliciting autonomic symptoms, thoughts, and behaviours:* Gambling related
5	Yes/No/or N/A	*Addressing key issues*: Raised key issues and related them to cognition and behaviour	*Setting and conduct of exposure tasks* : Appropriately graded, focussed, prolonged, and repeated; agreed by the client; relevant to therapy goals
6	Yes/No/or N/A	*Guided discovery:* Socratic questioning, reflective/confronting (e.g. what would that mean?)/interpretive responses to guide client's understanding	*Addressing key issues*: Raised key issues and related them to urge and behaviour
7	Yes/No/or N/A	*Asking for alternative thoughts:* Alternative views/explanations appropriately followed through	*Habituation:* Evidence that the therapist assisted client to identify and habituate to spontaneous urges
8	Yes/No/or N/A	*Use of alternative cognitive techniques:* Appropriately selected and applied, relevant to therapy goals	*Use of alternative behavioural techniques:* Appropriately selected and applied, relevant to therapy goals
9	0-10 Likert scale	Overall rating of integrity	Overall rating of integrity
10	Unlimited free form text	*Overall use of appropriate technique (specifically, please comment on any area of the session which may not have adhered to the allocated therapeutic approach)*	*Overall use of appropriate technique (specifically, please comment on any area of the session which may not have adhered to the allocated therapeutic approach)*

Table 3.Measurements

	Intervention period				Maintenance period		
Measurements	**Baseline**	**Sessions 2-12**	**Mid-treatment**	**End of treatment**	**3 month**	**6 month**	**12 month**
Demographics	X						
Duration of gambling problem	X						
AISS	X						
VGS	X		X	X	X	X	X
DSM-IV-TR	X			X		X	
Mechanisms of change							
GRCS	X	X	X	X	X	X	X
GUS	X	X	X	X	X	X	X
Self-efficacy	X	X	X	X	X	X	X
Problems caused by gambling							
K10	X			X	X	X	X
WSAS	X			X	X	X	X
AUDIT	X			X	X	X	X
Gambling behaviours							
frequency†	X		X	X	X	X	X
hours‡	X		X	X	X	X	X
amount§	X		X	X	X	X	X
Treatment views							
Confidence about treatment		X*					
Treatment is logical		X*					
Satisfied with treatment				X			

Abbreviations: AISS, Arnett Inventory of Sensation Seeking Traits; VGS, Victorian Gambling Screen; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Text Revision (4th Edition); GRCS, Gambling Related Cognitions Scale; GUS, Gambling Urge Scale; K10, Kessler 10 Scale; WSAS, Work and Social Adjustment Scale; AUDIT, Alcohol Use Disorders Identification Test.
†Days per month in which gambling takes place
‡Time spent thinking about or engaged in the pursuit of gambling in previous month
§Expenditure in previous month
*Session 2 only