Research report

Cognitive versus exposure therapy for problem gambling: A pilot randomised controlled trial

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A Victoria free from gambling-related harm

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2. CONTENTS

3. GLOSSARY

As treated analysis: When participants in a clinical trial are analysed according to treatment actually received and not treatment allocated to when randomised.

Binary logistic regression: A regression model where the outcome of interest or dependent variable is in categorical form with two levels such as 0 = absent and 1 = present.

Bootstrap method: Builds a dataset of estimators (e.g. mean values) from repeated random sampling of the raw data and then a measure of precision is calculated. It is particularly useful for calculating robust standard errors when there is potential threat to the validity of underlying assumptions for a statistical method.

Cognitive behavioural therapy: A class of psychological therapies that focus on maladaptive thought processes (cognitive) and behaviours (behavioural) using a systematic and goal oriented approach. The therapies comprise of action-oriented techniques that can be cognitive, behavioural or a combination of these approaches.

Confounder: A factor that is associated with both therapy and outcome and can influence estimates of treatment effects if not properly adjusted for in a statistical model.

Covariance patterns: For repeated measure data, the covariance matrix contains correlations between each pair of time points. A major goal of fitting mixed-effects models is in producing a reliable estimate of these correlations and there are a number of patterns that may be considered. For example, an unstructured pattern contains unique variances and correlations between pairs of time points. Alternatively, for the toeplitz structure, time points that are the same distance apart have the same amount of correlation.

Generalised mixed-effects model: Mixed-effects models contain both fixed effects and random effects. The fixed effects are analogous to standard regression coefficients and are estimated directly. For example, treatment group, age and sex are fixed effects. Random effects are not estimated directly but are summarised according to their estimated variance. For example, the upward or downward shift in individual trajectories of recovery from illness over time from an averaged regression line is a random effect. The term 'generalised' means the outcome variable can be continuous, categorical or count data. Mixed-effects models may also be referred to as multilevel or hierarchal models.

Imputation: When missing data are replaced with estimates that are derived from available data. For example, replacing a participant's missing outcome data at a given time point with the most recently available value.

Intent-to-treat: An analytic approach where participant outcomes are analysed based on original study group assignment. The aim is to preserve the properties of randomisation regardless of what treatment condition was actually received.

Intermittent missingness: When data are missing for a participant at some point in time but available on a future occasion.

In-vivo exposure: Repeated confrontation of a patient to problematic stimuli in the real or live setting.

Likelihood-ratio test: Measuring the difference in overall goodness-of-fit between two statistical models.

Maximum likelihood estimation: A method for estimating the parameters of a statistical model that maximises the agreement with the observed data.

Mediation analysis: In a randomised controlled trial a mediation analysis may be used to determine if the translation of treatment to outcome is through a hypothesised mechanism of change variable. This modelling process tests for causal relationships that may explain the specific therapeutic benefit of a treatment.

Missing at random: When the probability of data being missing may only depend on values at a previous occasion, but not on the responses we would have observed had they not been missing. For example, a participant may be less likely to show up to future therapy based on minimal or no response to prior therapy.

Missing not at random: When the probability of missing is dependent on the variables that were not measured. For example, a participant who has relapsed at the time follow-up is due may be less likely to show up for that appointment.

Monotone missingness: When data for a participant are missing at some time onward.

Multivariate model: A statistical model where more than one factor or independent variable is assumed to be associated with the outcome or dependent variable.

Ordinal logistic regression: A regression model where the outcome of interest or dependent variable is in categorical form and has more than two levels with natural ordering. For example, a survey question where response can be either agree = 1, neutral = 2 or disagree =3 may be analysed as an ordinal outcome variable.

Pattern-mixture models: A method used to model the differences between missing and observed data to assess the sensitivity of departure from assumptions about missing data.

Per protocol analysis: An analysis that includes only those participants who adhered to the study protocol and their assigned therapy.

Phase III trial: A clinical trial designed to test the relative efficacy of an intervention against a standard or control condition.

Randomisation: Allocation of participants to two or more study groups by chance alone.

Stratified blocked randomisation: A technique to ensure a balance in study group numbers based on a pre-specified ratio such as 1:1 and a balance between groups on potential confounding variables.

Tertile: Two points that divide a distribution of data into three parts.

Univariate model: A statistical model where only one factor or independent variable is assumed to be associated with the outcome or dependent variable.

4. EXECUTIVE SUMMARY

Background

Problem gambling and gambling-related disorders are a public health concern at an international level. Because maladaptive gambling behaviour is disruptive to individuals, families, and communities there is an acute need to identify and develop effective treatments for this disorder. The current evidence-base for gambling treatments suggests that psychological interventions, particularly variations of cognitive behavioural therapy (CBT), are most promising. 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. Based on these approaches, a range of cognitive-behavioural programs for treating problem gambling have comprised of two principal treatments: cognitive therapy (CT) where cognitive restructuring plays an important role and behavioural (exposure-based) therapy (ET) that targets psychobiological related gambling pathology. However, the data from meta-analyses offered to support these interventions are clouded due to methodological limitations and no randomised studies to date have investigated the relative efficacy of these important treatments. This indicates the need for more well-designed trials in order that CT, ET, and CBT may continue to be improved and potentially reduce the high treatment drop-out rates commonly reported for problem gamblers. Also, it is important to dismantle combined CBT approaches to determine if a) each core component can be delivered independently, b) if one is more efficacious than the other, c) what are the mechanisms of change that can be isolated or shared by each technique, d) what are the most parsimonious approaches, e) what technique benefits who as determined by retention in therapy, and f) match therapy with aetiological models.

Therefore, objectives of this pilot randomised controlled trial were to establish high quality recruitment methods, treatment techniques and manuals, research protocols, data collection methods and preliminary data in preparation for applications to national or international funding bodies for phase III randomised controlled trials in the field of problem gambling practice and research. Specifically, we sought to establish high quality treatment methods and research protocols which will contribute to answering the primary research question: Among treatment seeking problem gamblers can exposure therapy alone improve gambling related outcomes over 9-months compared with cognitive therapy? Our secondary questions related to the research process i.e., what is the rate of recruitment, therapy sessions required, drop outs, data collection and data completion and level of treatment fidelity achieved by a number of clients and therapists.

Comparing benefits of cognitive and exposure therapy for problem gambling is a single-site two-group randomised, parallel design, with treatment seeking problem gamblers presenting to the Statewide Gambling Therapy Service (SGTS) in South Australia. The study aimed to recruit 130 participants: 65 to be randomised to receive up to 12 weekly, individual face-to-face cognitive therapy sessions, and 65 participants to be randomised to receive exposure therapy in an identical treatment format. The outpatient SGTS programme offers one-on-one therapy for problem gamblers in key metropolitan and rural regions that are associated with significant problem gambling activity.

Methods

Study eligibility was 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 the 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.

The trial comprised of two manualised interventions: cognitive therapy (CT) and exposure therapy (ET). Cognitive therapy focused on correcting misconceptions relating to gambling such as the basic notion of randomness. Key components of cognitive correction involved: understanding the concept of randomness, understanding the erroneous beliefs held by gamblers, awareness of inaccurate perceptions and cognitive correction of erroneous perceptions. Cognitive therapy has been empirically validated as an efficacious treatment of problem gambling. Exposure therapy was based on the theory that problem gambling is the result of the development of a psychophysiological urge to gamble in response to environmental triggers or cues. The theoretical mechanism of behavioural therapy is de-conditioning of the urge using exposure to gambling cues, and resisting gambling which results in habituation of the urge within a session and ultimately extinguishing of the urge if the exposure task is repeated. All treatment sessions were audio recorded.

The primary research question, based on an intent-to-treat principle, was: Among treatment seeking problem gamblers is exposure therapy more effective in reducing gambling severity symptoms (harm to self-subscale of the Victorian Gambling Screen (VGS)) over the 9-month study period (intervention and maintenance effects) compared with cognitive therapy? It was estimated that 50 participants were required in each group to detect a clinically meaningful difference and a further 15 participants per group to account for expected treatment dropout rate giving a total sample size of 130 participants. Primary outcome measure VGS is a self- reported questionnaire measuring the extent gambling behaviour has impeded an individual's life. The 21 items relate to the person's experiences in the previous 4 weeks and scores range from 0 = no harm to self to 60 = high harm to self. A score of 21+ identifies a person as problem gambler. Participant assessments for primary (VGS) and secondary outcomes (gambling behaviours, gambling related problems and DSM-IV diagnosis of pathological gambling) were conducted at baseline, end of treatment (intervention period) and follow-up at 1, 3 and 6 months (maintenance period).

Individuals assessed as eligible for study participation were randomly assigned to one of two treatment groups with 1:1 allocation ratio using stratified blocked randomisation. A biostatistician independently generated random sequences for each stratum and delivered these to a clinical trials call centre of a centrally located hospital pharmacy. Staff enrolling and referring participants, collecting and entering data and administering interventions did not know in advance which treatment the next participant would receive.

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

Results

Participants were recruited from 151 consecutive referrals to SGTS from April 4th, 2011 to 30th March, 2012. Of the 99 participants randomised, 49 were allocated to ET and 50 to CT. Of these, 87 participants started an intervention (CT = 44; ET = 43) and 12 participants were non-starters. Mean age of ET starters was 45.5 (SD= 12) years and 47.5 (SD=13.9) years for CT and 50% were female in both groups. Median time for participant's enrolment in the study was 40.9 weeks with 50% of participants having times between 17 and 59 weeks and 25% less than 6.9 weeks. For CT participants, VGS data were available for 70% (31/44) on at least one follow-up occasion post-treatment and 65% (28/43) for ET participants. Of all the interventions started, recorded treatment sessions of 52 out of 87 participants (25 for CT, 27 for ET) were randomly selected for independent scoring of treatment fidelity. The overall mean treatment integrity score was high for both CT (98%) and ET (99%).

Baseline characteristics for 87 participants included 81(94.2%) classified as problem gamblers when stratifying VGS at cut score 21. For DSM-IV criteria there were 83(95.4%) diagnosed as pathological gamblers when assessed by a therapist at study commencement. For participants that did not meet problem or pathological gambling criteria, three had DSM ratings of 3 and corresponding VGS scores 12, 16 and 17. One individual had a DSM score of 1 and a self-reported VGS score of 31, and two had VGS scores of 20 and 14 with corresponding DSM scores of 6 and 10 respectively.

Based on all available data, the main findings of the trial were that gambling severity symptoms in participants in both groups as measured by VGS dropped substantially from baseline (CT: M= 33.4, SD=2.0; ET: M= 33.9, SD= 2.1) to end of treatment (CT: M= 26.1, SD= 1.8; ET: M= 26.2, SD=1.8) and 6 month follow-up (CT: M= 11.4, SD= 3.0; ET: M= 10.9, SD=2.3), but the drops were very similar in both groups. The estimated mean difference between CT and ET at end of treatment was -0.18 (95% CI: -4.47 – 4.10) and 1.47 (95% CI: -4.43 – 7.38) at 6 month follow-up. Similarly, secondary measures of gambling related behaviours, psychological distress, work and social functionality, and alcohol consumption improved substantially across time, but there was no statistically significant or clinically meaningful difference between groups. For both groups, there was also a clinically significant reduction in the rate of DSM-IV diagnoses of pathological gambling from baseline to treatment end and 6 month-follow-up.

Discussion

Through this two-group randomised, parallel design, involving treatment seeking problem gamblers, we have developed high quality recruitment methods, treatment techniques, manuals, research protocol and data collection methods. The outcome data collected covered the domains of gambling behaviours, problems caused by gambling, and mechanisms of change. The robust implementation of randomisation was demonstrated by the similarity in group characteristics on potential confounding variables at study screening and baseline demographic and clinical characteristics of treatment starters. One of the key strengths of this study was that all treatment seeking problem gamblers meeting eligibility criteria received an active treatment and a

significant proportion of the sample had co-occurring gambling-related problems and this enhanced the generalisability of findings. One of the main limitations of this study was loss of power due to an under representative sample size. The incomplete uptake of trial interventions meant that randomised groups potentially had more similar experiences than intended, and resulted in outcome differences to be smaller than if there was better uptake.

The wide range of data collected in this trial has provided high quality evidence to contribute to the development of more optimal combination of cognitive-behavioural therapies. Trial findings will also inform the design of a phase III trial to investigate the relative efficacy of cognitive, behavioural (exposure-based) and combined cognitive-behavioural approaches with a standard control condition. No previous studies have compared combined cognitive and behavioural (exposure) therapies with purely cognitive and exposure therapy on their own in the field of problem gambling.

5. BACKGROUND

Problem gambling 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) and has been identified as an addictive disorder with similarities to substance use disorders in terms of neurocognitive and physiological pathways (2, 3). The ubiquity of different forms of gambling, including online and community based electronic gaming machines (EGMs), makes gambling readily accessible (4). It is also a serious public health concern at an international level where population prevalence rates average 2% or more and occurs more frequently in younger populations (5-10). Co-morbid mental health disorders such as depression and anxiety are common in both treatment seeking and general populations of problem gamblers (11).

Research into problem gambling has expanded in the past 10 to 15 years and findings have become more accessible in the public domain including those from treatment efficacy studies (4, 12). Treatment approaches are similar to those for other addictions and include psychological, peer-support, and pharmacological interventions (13, 14). To date, the best evidence for gambling treatments exists for psychological interventions where variations of cognitive behavioural therapy (CBT) have been the most researched (15). The current CBT evidence-base has been endorsed as "…trusted to guide practice in most situations" using NHMRC (National Health and Medical Research Council) assessment grades for developers of guidelines (16).

The theoretical underpinnings of CBT include cognitive and psychobiological processes which are two dominant approaches to explaining gambling disorders (17). The cognitive approach is based on the principle that problem gamblers hold erroneous perceptions of randomness; erroneous beliefs (e.g. 'luck helps me win') and inaccurate perceptions (e.g. 'gambling makes things better for me') (18, 19) which are rewarded, learned, and become habitual. Evidence for this approach has come predominantly from 'think aloud' techniques where gamblers have verbalised their perceptions and beliefs during gambling activities (20). Cognitive therapy (CT) for problem gambling focuses on teaching the concept of randomness, increasing awareness of inaccurate perceptions and restructuring erroneous gambling beliefs (18) and is a dominant mode in a number of cognitive-behavioural programs for problem gamblers (21). Cognitive restructuring plays an important role in CT and has been shown to be clinically efficacious in treating a range of mental health conditions (22).

Treatments that target gambling related psychobiological states (e.g. urge to gamble) are predominantly behavioural (exposure-based) (23-25). Exposure therapy (ET) is grounded in a classical conditioning paradigm and cue-exposure with extinction processes (e.g. elimination of gambling urge) has been proposed as more beneficial than other types of therapy (e.g. aversive therapy) in treating gambling addiction (26). Exposure therapy has been shown to be clinically effective in treating psychological conditions such as post-traumatic stress disorder (PTSD) (27) and specific phobias (28).

Both CT and ET have similar hypothesised mechanisms of therapeutic change in anxiety disorders as they do in gambling disorders (23). ET and CT have been shown to be equally effective in the treatment of PTSD, obsessive compulsive disorder (OCD) and panic disorder (PD). It has been suggested that CT is superior to ET in the treatment of

social phobia, although findings are limited due to heterogeneity between studies including therapy-specific expertise of individual research groups and modality of treatment (individual versus group) (28).

Cognitive-behavioural therapies (CBT) for problem gambling typically comprise a combination of ET and CT techniques based on an ostensible evidence-base (e.g. (29-31)). Whilst CBT in general has shown to be clinically superior to control conditions such as wait-list groups (30) and self-help groups (e.g. gamblers anonymous (GA)) (32), there remains uncertainty as to the validity of evidence for core components of this approach. For example, the most recent review of CBT for gambling disorders suggested CT had an "added advantage" relative to other treatment elements. However, evidence was tentative due to heterogeneity between studies and this may have attenuated the effects of other treatments with comparable importance (15).

A more recent Cochrane review (2012) of psychological therapies specific to gambling disorders further supported the clinical efficacy of CBT (21). Of the 12 studies included for meta-analysis, 3 were focused on CT (18, 33, 34). However, studies with a focus on an exposure-based approach were excluded (35-37) as they did not meet eligibility criteria of having a control condition such as "no treatment controls, referral to Gamblers Anonymous and non-specific treatment component controls". It has been suggested that behavioural therapies are, in general, more parsimonious in terms of delivery than CT (38). Therefore it is important that the evidence for these core treatment approaches is elucidated.

The best evidence to inform clinical practice has come from 'gold standard' randomised clinical trials (RCTs) (39). However, clear conclusions are often difficult to draw due to a common lack of transparency in reporting RCT findings which "compounds problems arising from poor methodology" (40). In response to this and in order to improve the reporting of parallel group randomisation trials and enable readers to critically appraise the validity of findings, an international group of experts including journal editors, clinical epidemiologists and statisticians developed CONsolidated Standards Of Reporting Trials (CONSORT) (41). Since inception in 1996, the checklist has been shown to be associated with significant improvement in reporting of RCTs (42) and has evolved with revisions in 2001 (43) and 2010 (40). CONSORT has been extended for appraisal of cluster randomised trials (44), non-inferiority and equivalence randomised trials (45), non-pharmacological treatments (46) and is endorsed by "many journals, influential editorial groups, such as the World Association of Medical Journals, and translated into several languages" (http://www.consort-statement.org/).

The objective of the following systematic review was to examine the existing evidence from randomised clinical trials on the following research question. Among problem gamblers (population) how accurate and valid is the evidence-base on cognitive and exposure-based therapies in terms of the CONSORT checklist for randomised trials of non-pharmacologic treatment (46).

6. SYSTEMATIC LITERATURE REVIEW

Methods

Data Sources
The search for primary studies used the OVIDSP interface with two databases (MEDLINE and psycINFO) from inception to September 2012. A list of keywords and MeSH terms were generated to identify studies of cognitive and/or behavioural treatments for gambling disorders. The Cochrane Library was also searched for reviews involving psychological treatments of gambling disorders. The results from the search were then merged within reference management software (EndNote X4).

Study selection
The titles and abstracts of the studies identified through the aforementioned searches were assessed by one researcher. Eligibility criteria for initial study inclusion were based on the Cochrane Handbook for Systematic Reviews (47) in the following order of importance: published, or in press, in a refereed journal; participants were treated for a primary gambling disorder including pathological gambling and problem gambling in either an inpatient or outpatient setting; at least one intervention comprising a cognitive, behavioural, or combined cognitive-behavioural approach; allocation of participants to either treatment and control or to two or more active treatments including non-inferiority, equivalence, factorial, cluster, and crossover trials. No criterion relating to random allocation of participants was included at initial screening due to the potential of being unstated in a study abstract or title.

The full text of selected reports were then retrieved and independently examined by two researchers for compliance with eligibility criteria for inclusion in the final review. The criteria were specific to the administration of an exposure therapy (ET) or cognitive therapy (CT) approach to a primary gambling disorder. Only randomised trials involving at least one of these approaches were included. Modality of treatment delivery was limited to face-to-face, either individual or group format and conducted in outpatient or inpatient settings. No limitations were placed on the theoretical nature of comparative treatments or control conditions.

All full-text articles that met eligibility criteria were independently appraised by two researchers. The CONSORT guidelines for randomised trials of non-pharmacologic treatment (46) were used in conjunction with more recent CONSORT guidelines for reporting parallel group randomised trials (40) in order to critically assess the accuracy and validity of results reported within each study. CONSORT statements for parallel group randomised trials as well as extensions are available at http://www.consort-statement.org/. For each study included in this review, individual CONSORT items were rated as either ‘absent’, ‘present with some limitations’, or ‘present’.

Results of search

The search resulted in a deduped set of 104 citations. Systematic searches yielded 7 papers (RCTs) for CONSORT evaluation (Figure 1). One study comprised of a treatment with both cognitive restructuring and behavioural components (problem-solving training and social-skills training) (34). However, authors made explicit that the central focus of

treatment was correction of erroneous gambling related cognitions and therefore the study was included in this review.

The 7 included studies are summarised in Table 1. Three were conducted in Australia using imaginal desensitisation (ET) and published between 1983 and 1991(35-37), one in Spain (1996) comprising of individual and combined cognitive restructuring (CT) and in-vivo exposure with response prevention (ET) (48) and three in Canada with a main focus on cognitive restructuring (CT) between 1997 and 2003 (18, 33, 34). The mode of delivery for all ET interventions was individual format and three of these were conducted in an inpatient psychiatric facility (35-37). Cognitive treatments were delivered in outpatient settings for both individual (18, 34) and group (33, 48) formats. All trials reported that participants were randomly allocated to either a treatment or control group. Participants across the studies were drawn from populations with a spectrum of gambling disorders. All CT interventions were based on clinician diagnosed pathological gambling at study screening (18, 33, 34, 48) as was one of the ET interventions (48). The remaining ET interventions were conducted on the strength of self- reported problem gambling (35-37). The proportion of males across study samples ranged from 44.4% to 100% with an overall average of 81.6%. The main type of gambling reported was gaming machines in three studies (18, 34, 48), horse and dog racing in two studies (35, 36), and no information was provided in two studies (33, 37).

Figure 1. Selection of studies

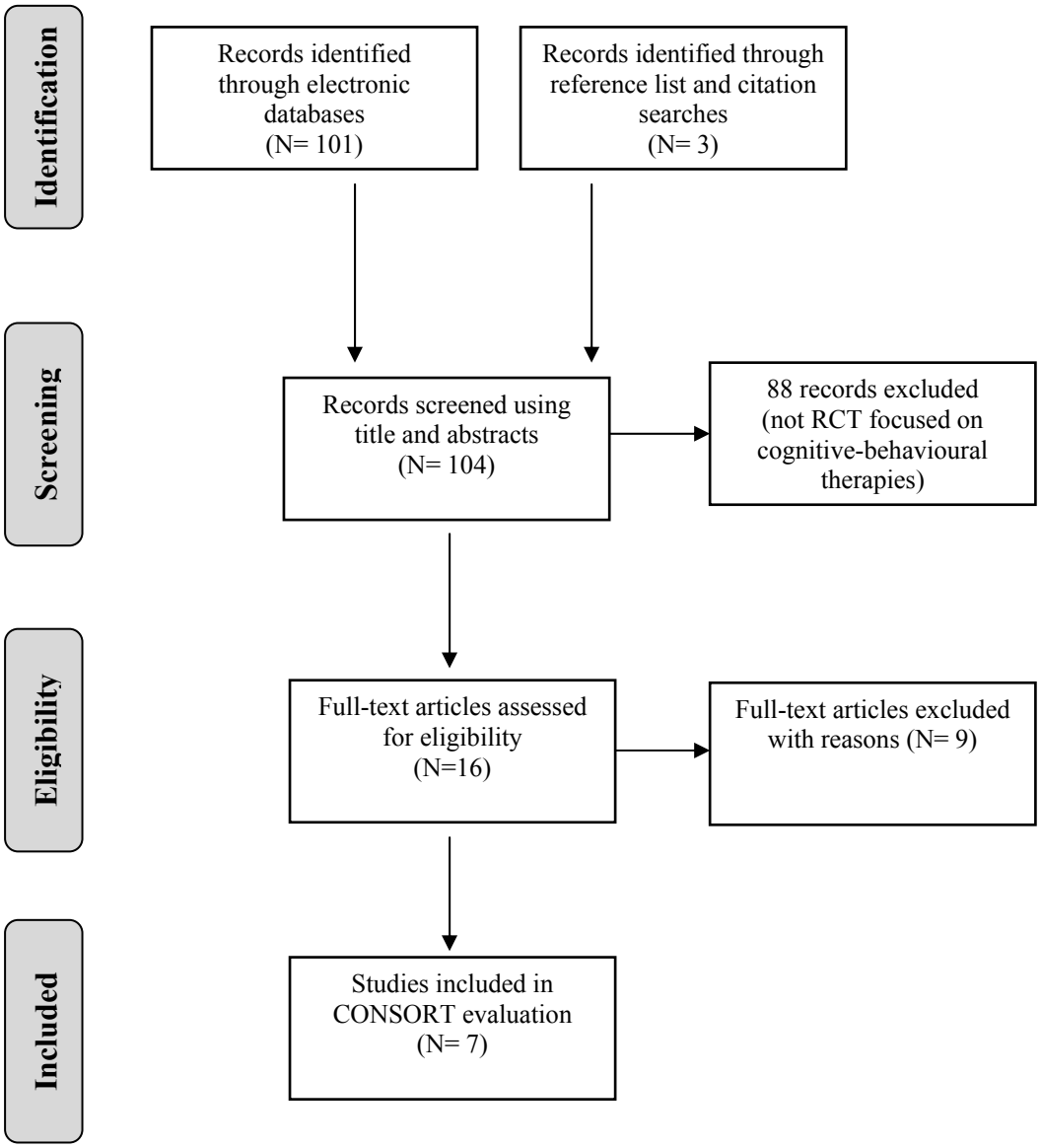


Table 1. Summary of included studies

Study	Population, setting, design	Inclusion criteria	Primary gambling type	Conditions	Outcomes
McConaghy et al. (1983)(35)	Age, mean (range), years: 35 (20 - 63) % female: 20 Population: Compulsive gamblers requesting behavioural therapy. Country: Australia Design: Two group, randomised trial. Time points: Baseline, 1 and 12 months	Persons who: • considered they were unable to control their gambling; • wished to gain control or cease gambling; • were not overtly psychotic.	60% (12/20) horse and dog racing. Other gambling forms were gaming machines, card games in casinos, and two-up.	Therapy types: Imaginal desensitisation. Mode of therapy: Individual Session no: Treatments administered during one week's admission to a psychiatric unit. Two sessions on first day and three on subsequent four days. Session duration: 15 minutes	• Urge to gamble • Gambling behaviour • STAI
McConaghy et al (1988)(36)	Age, mean (range), years: 35 (18 - 58) % female: 5 Population: Persons who were seeking treatment for problem gambling. Country: Australia Design: Two group, randomised trial. Time points: Baseline, 1 and 12 months.	Persons who: • considered they were unable to control their gambling; • wished to gain control or cease gambling; • were not overtly psychotic.	70% (14/20) gambled mainly or exclusively on horse and dog racing. 20% (4/20) gambled on both horse and dog racing and poker machines. 10% (2/20) on poker machines.	Therapy types: Imaginal desensitisation Mode of therapy: Individual Session no: Treatments administered during one week's admission to a psychiatric unit. Two sessions on first day and three on subsequent four days. Session duration: 15 minutes	• Urge to gamble • Gambling behaviour • STAI
McConaghy et al (1991) (37)	Age, mean, years: 42.5 % female: 9.2 Population: Persons who were seeking treatment for problem gambling. Country: Australia Design: Two group, randomised trial. Time points: Baseline, one follow-up between 2 - 9 years.	Persons who: • considered their problem sufficiently serious to make a commitment to 5-day inpatient stay; • were not untreated for active psychosis.	NA	Therapy types: Imaginal desensitisation Mode of therapy: Individual Session no: Treatments administered during one week's admission to a psychiatric unit. Two sessions on first day and three on subsequent four days. Session duration: 20 minutes	• EPQ • STAI • SCL-90 • BDI • Gambling behaviour and related problems.

Echeburua et al. (1996)(48)	Age, mean(SD), years: 35 (11) % female: 55.6 Population: Pathological gamblers Country: Spain Design: Four group, randomised trial. Time points: Baseline, 3 weeks in-treatment, post treatment, 1, 3, 6, and 12 month follow-up for experimental groups. Baseline and 6 months for wait-list control group.	• Diagnosis of pathological gambling. • Scored 8 or more on the South Oaks Gambling Screen (SOGS). • Not suffering from another psychopathological disorder. • Gamble primarily with slot machines.	Gaming machines.	Therapy types: a) Individual stimulus control and exposure with response prevention. b) Group cognitive restructuring. c) Combined treatment A+B Mode of therapy: Individual, group and combined formats. Session no: 6 for individual treatments and 12 for combined treatment. Session duration: Exposure therapy, 65 minutes. Cognitive therapy, 60 minutes.	• Gambling behaviours and related thoughts • STAI • BDI • Adaptation Scale
Sylvain et al. (1997)(34)	Age range, mean (SD), years: treatment group: 37.6 (10.3) control group: 42.6 (12.1) % female: 0 Population: Pathological gamblers Country: Canada Design: Two group, randomised trial. Time points: Baseline, end of treatment, 6 and 12 month follow-up.	• Primary diagnosis of pathological gambling • Answer "yes" to the following question: "Are you willing to make an effort to reduce or stop gambling?" In addition, they had to rate their motivation to change at 7 or more on a scale of 0 to 10.	Video poker machines.	Therapy type: Cognitive Mode of therapy: Individual Session no: One or two weekly sessions until participants developed an adequate perception of gambling and chance and ceased gambling. Session duration: 60 to 90 minutes	• DSM-III-R • SOGS • Perception of control • Desire to gamble • Self-efficacy perception • Frequency of gambling
Ladouceur et al. (2001)(18)	Age, mean (SD), years: treatment group: 40.8 (10.2) control group: 43.4 (10.2) % female: 17.2 Population: Pathological gamblers contacting study treatment centre and referred by other health professionals. Country: Canada Design: Two group, randomised trial. Time points: Baseline, end of treatment. 6 and 12 month follow-up for treatment group.	• Primary diagnosis of pathological gambling. • No evidence of immediate suicidal intent. • No evidence of current or past schizophrenia, bipolar disorder or organic mental disorder. • Willing to undergo randomisation.	85% gaming machines. Other forms included cards, horse races, sports, blackjack, bingo, skill games, and keno.	Therapy type: Cognitive Mode of therapy: Individual Session no: Maximum of 20 weekly sessions. Session duration: 60 minutes	• DSM-IV • Self-efficacy perception • Perception of control • Desire to gamble • SOGS • Frequency of gambling
Ladouceur et al. (2003)(33)	[a]Age, mean (SD), years: treatment group: 42.56 (10.48)	• Primary diagnosis of pathological gambling.	NA	Therapy type: Cognitive Mode of therapy: Group	• DSM-IV • Self-efficacy

	control group: 44.56 (10.7) % female: 22 Population: Pathological gamblers contacting study treatment centre and referred by other health professionals. Country: Canada Design: Two group, randomised trial. Time points: Baseline, end of treatment. Six, 12 and 24 month follow-up for treatment group.	• No evidence of current or past schizophrenia, bipolar disorder or organic mental disorder. • Willing to undergo randomisation.	Session no: 10 weekly sessions. Session duration: 120 minutes	perception • Perception of control • Desire to gamble • Frequency of gambling

Abbreviations: DSM-III-R, Diagnostic and Statistical Manual of Mental Disorders (3rd edition, revised);DSM-IV, Diagnostic and Statistical Manual of Mental Disorders (4th edition); STAI, Spielberger State-Trait Anxiety Inventory; EPQ, Eysenck Personality Questionnaire; SCL-90, Symptom Checklist-90; BDI, Beck Depression Inventory; SOGS, South Oaks Gambling Screen.

[a]Mean (SD) age reported for treatment completers only.

Validity of evidence

A number of methodological shortcomings were identified in the literature which focussed on ET and CT approaches of treatment specific to problem gambling. That is, 71% of the CONSORT items rated as 'absent' were specific to the methods section across the studies. None of the studies under examination provided sufficient information about randomisation to allow the reader to assess whether the treatment groups were approximately comparable in terms of known and unknown prognostic factors such as severity of gambling behaviours or co-morbid conditions. Also, sample sizes were generally small and although three of the studies (35, 36, 48) reported participant groups that were exactly equivalent in numbers, no information was provided on how this was achieved (e.g. blocked randomisation). Such limitations pose a major threat to internal validity and generalisability of trial findings.

The methodological deficits identified were further compounded by the absence of reported sample size calculations and clear differentiation between primary and secondary outcome measures. As different hypotheses and outcome measures require different sample sizes to achieve sufficient power, any conclusions drawn from these studies are limited in terms of causal inferences.

Implications

The results of this review have important implications for the application of cognitive-behavioural therapies in gambling disorders. Whilst the evidence-base has recommended CBT to address gambling disorders in "most situations" (16), the data from meta-analyses offered to support this recommendation are clouded due to methodological limitations. Despite the partial evidence for CT and ET, a range of cognitive-behavioural programs that involve a combination of these techniques have become available in recent years (29-31). These findings indicate the need for more well-designed trials in order that CT, ET, and CBT approaches may continue to be improved and potentially reduce the high dropout rates commonly reported for problem gamblers (49).

Study objectives

To further improve the evidence-base for specific CBT techniques in treating gambling disorders (12, 50-52), we designed a study titled "Cognitive versus Exposure Therapy for Problem Gambling: A Pilot Randomised Controlled Trial" which is a randomised trial comparing efficacies of CT and ET to improve gambling related symptoms. The trial was motivated by the uncertainty about the clinical superiority of CT over ET. Based on this uncertainty, the concept of equipoise existed and participants were not disadvantaged from randomisation to either treatment group. The study is the first randomised trial to compare these treatments in a population of treatment seeking gamblers.

The objectives of this pilot randomised controlled trial were to establish high quality recruitment methods, treatment techniques and manuals, research protocols, data collection methods and preliminary data in preparation for phase III randomised controlled trials in the field of problem gambling practice and research. Specifically, we sought to establish high

quality treatment methods and research protocols to contribute to answering the primary research question:

> Among treatment seeking problem gamblers can exposure therapy alone improve gambling related outcomes over 9 months compared with cognitive therapy?

Our secondary questions related to the research process i.e., what is the rate of recruitment, therapy sessions required, drop outs, data collection and data completion and level of treatment fidelity achieved by a number of clients and therapists.

7. RESEARCH METHODS

Study design

Comparing outcomes of cognitive and exposure therapy for problem gamblers 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 aimed to recruit 130 participants: 65 to be randomised to receive up to 12 weekly, individual face-to-face cognitive therapy sessions, and 65 participants to be randomised to receive exposure therapy in an identical treatment format. The outpatient SGTS programme offers one-on-one and group therapy for problem gamblers in key metropolitan and rural regions that are associated with significant problem gambling activity. 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 (23).

The study received approval from the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee, and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12610000828022) at the trials inception. Participants were given an information statement regarding the study and asked to provide written informed consent before data collection began. Participants were offered the alternative therapy to their randomised treatment if they had not experienced a clinically meaningful improvement on outcome measures by 6 month follow-up as determined jointly by the participant and therapist.

Participant recruitment and random assignment

Participants were recruited over a 12 month period that commenced April 2011. To assess study eligibility, an independent clinician conducted semi-structured interviews with treatment seeking problem gamblers presenting to SGTS during the recruitment period. The interview included assessment of individual demographics, recent gambling activities, and administration of the well-validated *South Oaks Gambling Screen* (SOGS) (53). 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 (54).

Study eligibility was 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 the 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 were randomly assigned to one of two treatment groups with 1:1 allocation ratio. From the trial outset, randomisation was blocked to increase the likelihood of equal group sizes, using a standard permutated block algorithm in which block sizes were randomly chosen from 2, 4, and 6 to protect concealment. To ensure balance on potential confounders, block randomisation within strata was used, stratifying at median age, gender, and median SOGS scores for problem gambling severity. Based on previous SGTS data, age was stratified as 18 - 42 years, and 43 years or more (55). Recent population data for South Australia showed a median age of 39.5 years (56). Gambling severity was stratified according to previous treatment seeking problem gamblers SOGS scores of either 5 - 11, and between 12 and 20 (57). A biostatistician independently generated random sequences for each stratum using Stata version 11.1 software (58) and delivered these to the clinical trials call centre of a centrally located hospital pharmacy. Staff enrolling and referring participants, collecting and entering data and administering interventions did not know in advance which treatment the next participant would receive.

Sample size calculation

The primary research question was: Among treatment seeking problem gamblers is exposure therapy more effective in reducing gambling severity symptoms (harm to self-subscale of the VGS) over the 9-month study period (intervention and maintenance effects) compared with cognitive therapy?

In our sample size calculations, we assumed a correlation between follow-up measures of r = 0.7 (59). Based on a type I error rate of 5% , power of 90%, two-tailed test, and a VGS standard deviation of 10.2 units (55), 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 were required in each group. Given the treatment dropout rate experienced in the SGTS treatment programme (approximately 30%) we therefore needed to recruit 65 participants in each group of the study giving a total sample size of 130 participants. A recent meta-analysis of 25 studies on cognitive-behavioural interventions for problem gambling found that attrition over the studies ranged from 0 to 45.7% with a medium of 14.0% (15). Also, total sample sizes in these studies varied considerably with a range of 5 to 169 and median of 43 for studies with a specified baseline sample size.

Study treatments

The trial comprised of two interventions: cognitive therapy (CT) and exposure therapy (ET) and are described in the following sections and a summary of treatment sessions provided in Table 2.

CT. Cognitive therapy focused on correcting misconceptions relating to gambling such as the basic notion of randomness. Key components of cognitive correction involved: (i) understanding the concept of randomness: the therapist explained the concept of randomness with examples, such as the independence and impossibility of controlling outcomes in tossing a coin; (ii) understanding the erroneous beliefs held by gamblers: the therapist

explained how the illusion of control contributed to the maintenance of gambling habits, and then corrected these erroneous beliefs; (iii) awareness of inaccurate perceptions: the problem gamblers were informed that erroneous perceptions, mainly making links between independent events, predominate when gambling, and weretaught to distinguish between adequate and inadequate verbalisations; and (iv) cognitive correction of erroneous perceptions: the therapist was trained the problem gambler to correct inadequate verbalisations and faulty beliefs (33). Cognitive therapy has been empirically validated as an efficacious treatment of problem gambling (60). Previous studies have indicated that cognitive factors play a significant role in problem gambling pathways (61).

ET. Exposure therapy was based on the theory that problem gambling is the result of the development of a psychophysiological "urge" to gamble in response to environmental triggers or cues, analogous to craving in substance addiction. The theoretical mechanism of behavioural therapy is de-conditioning of the urge using exposure to gambling cues, and response prevention (resisting gambling) which results in habituation of the urge within a session and ultimately extinguishing of the urge if the exposure task is repeated. Remission of problem gambling occurs by eliminating the gambling "urge" rather than through a reduction in gambling cognitions (23, 24). The initial procedure comprised of a therapist guiding the client through a scene, usually audiotaped and then instructing the client to imagine a typical gambling scenario (imaginal exposure). The client was asked to rate his or her urge to gamble at regular intervals while verbalising the scenario and stay with the urge until habituation occurred. Once the client had habituated to the urge in imagination, clients habituated to their urge to gamble using a variety of live tasks at gambling venues (in-vivo exposure) to challenge the triggers of their urges (23).

Participants in each treatment group were to receive up to 12 60-minute individual treatment sessions conducted at weekly intervals. Both treatments were manualised in order to facilitate replication and clinical application. The SGTS had already developed treatment methods and a treatment manual for the conduct of ET for up to 12 individual weekly sessions which was in use by therapists (24, 62). The therapists at SGTS had previous experience in administering CT in groups that is facilitated by a manual which outlined procedures over 12 weekly sessions and was based on a workshop attended by one of our senior therapists presented by Robert Ladouceur, a widely published international clinician and researcher in the field of cognitive therapy for gambling disorders (18, 33, 61). The CT manual for individual therapy in this study was developed in collaboration with Robert Ladouceur and based on his cognitive-behavioural manual with co-author Stella Lachance (2007) (63).

For this study, both CT and ET manuals were intended as a session-by-session guide for therapists treating individuals with a gambling disorder where electronic gaming machines were the main form of gambling problem. It was intended that therapists deliver treatment according to each manuals content and sequencing of techniques in a face-to-face format. Due to the expected heterogeneity often experienced in individuals with a gambling disorder, there was flexibility for duration and frequency of techniques within treatment sessions. Participants in both treatment groups were given home exercises set with rationale and instructions and a review of these were conducted at the beginning of each session. Also, handouts summarising main session points were provided to participants. Each treatment was presented in a practical manner and technical language was used with parsimony.

Participants in both ET and CT groups were provided with a screening interview at study commencement. The interview comprised of a gambling focused cognitive behavioural assessment including DSM-IV-TR criteria for identifying a gambling disorder. Participants were also assessed for any co-morbid mental health problems such as alcohol dependence, anxiety and depression. At the beginning of each session an agenda for the session was negotiated and the time available for the session clarified. The last two sessions for each treatment group l comprised of relapse prevention strategies.

Masking

Statistical analyses were conducted according to pre-specified guidelines (provided in Section 3.8). In this trial, therapists knew what treatment they were administering and participants were provided with information that rationalised and described their assigned therapy protocol. As all participants were assigned to an active treatment of unknown efficacy relative to the alternate treatment, the potential for "overly optimistic responses" may have been reduced (64). Also, it was intended that participants were masked to the study hypothesis in order to further limit the likelihood for self-report bias. Participant information sheets referred to treatments as "well known and commonly used psychological treatments". A robust level of masking was expected as both treatments were well established psychological treatments with similar intervention structures including a manualised approach, same number of sessions and homework tasks. To avoid contamination of masking, SGTS administration staff was instructed to not reveal specific treatment labels to any participants and therapists to not reveal the alternative treatment label. Independent evaluators assessed the degree to which masking to the study hypothesis was achieved by addressing the questions: *Did the participant mention their therapy by name and/or the other study therapy* and, *did the therapist mention the other study therapy?* This evaluation was conducted as part of treatment integrity checks which are discussed in the following section.

Table 2. 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.

Training and Treatment integrity

In order to train and supervise cognitive therapists for the intervention, Professor Robert Ladouceur visited the research team at the beginning of the project and again later in the project once recruitment and intervention was underway. Professor Ladouceur's initial visit concentrated on refining the skills of the newly recruited cognitive therapists in order for them to deliver a consistent, manualised treatment program. In addition, the treatment manuals were modified and refined and the combined team of cognitive and exposure therapists worked together to plan the overall intervention strategy. Once therapists were trained, Professor Ladouceur assumed a supervisory / mentoring role and also contributed to the reviewing audio tapes of treatment sessions to ensure that treatment processes adhered to the prescribed manualised treatment protocols designed for the intervention program.

It was intended that all treatment sessions were to be audio recorded and 20% randomly selected from early, mid, and late study phases and evaluated by two independent clinicians for each study group. A preliminary checklist for treatment fidelity was developed based on the Cognitive Therapy Scale (CTS) which is an 11-item instrument with good reliability when used by experienced clinicians (65). The CTS provided a framework for the first version of a checklist and then using an iterative process between study therapists and clinical supervisors, consensus was achieved for a final checklist (Table 3). Items 1 to 8 relate to case conceptualisation for each therapy and item 9 relates to overall integrity. Inter-rater reliability was assessed within each therapy and evaluators were to also conduct integrity checks of the alternative treatment to further enhance validity of treatment integrity checks.

Measures

Baseline assessment included demographic variables such as gender, age, marital status, highest education level, employment status, and living arrangements. Data for duration of gambling problem was also collected. As previous studies have identified a significant association between treatment drop out and impulsivity/sensation seeking personality traits (55, 66, 67), the *Arnett Inventory of Sensation Seeking* (AISS) was administered at baseline. This was to enable a better understanding of any relationships between treatment drop out within treatment groups and personality traits under controlled study conditions. The AISS is a 20 item self-report questionnaire that measures sensation seeking personality trait. Within the tool there are two subscales, intensity and novelty, consisting of 10 items each. The scale has been shown to be free from social desirability bias (68).

This study utilised validated problem and pathological gambling screening instruments. In accordance with the minimum features required for reporting treatment efficacy in gambling research, measures covered the domains of *gambling behaviours*, such as financial losses; *problems caused by gambling*, for example psychological distress; and *mechanisms of change* where the hypothesised mechanisms of treatment actions were assessed. This meant for ET participants, a greater reduction in urge to gamble was 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. A reasonable assumption was made that non-specific effects were approximately similar

between study groups due to similar therapy structures, therapist's background and experience, and therapeutic environment. The administration of measures during intervention period was to be conducted prior to commencement of each treatment session. The specific measures are summarised in the following sections and measurement occasions are presented in Table 4.

Table 3. 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)*

Primary outcome measure

Victorian Gambling Screen (VGS): In order to detect change in problem gambling severity on a continuum during treatment and at follow up, the VGS was utilised as a primary outcome measure. The VGS is a self- reported questionnaire measuring the extent 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. For purposes of this study, only the 'harm to self' sub-scale was used as an outcome measure. Items on the self-harm subscale relate to the person's experiences in the previous 4 weeks and therefore enhance sensitivity to treatment outcomes on a continuum. This sub-scale has

been validated for use in Australia by Ben-Tovim, Esterman, Tolchard, Battersby & Flinders Technologies (2001) (69). Reliability and validity of the VGS have been confirmed in a clinical population of problem gamblers (70). The harm to self sub-scale scores range from 0 = no harm to self to 60 = high harm to self. Concurrent validity indicates the scale correlates very highly with the South Oaks Gambling Screen (SOGS) (R = 0.97), 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'; 'wanted help'; and 'suicidal tendencies') (71). A score of 21+ on the VGS identifies a person as problem gambler. An outcome study involving treatment seeking problem gamblers found a significant reduction (improvement) in VGS scores with concurrent improvements on other psychometric measures including cognitions, urges, psychological disturbance, and work and social functioning (55).

Secondary outcome measures

DSM-IV-TR (Diagnostic and Statistical Manual of Mental Disorders, Text Revision) criteria for pathological gambling: Diagnostic criteria relating to the extent of persistent and recurrent maladaptive gambling behaviour was measured using ten questions with response options of "yes" or "no". A total score is obtained by summing across the ten responses. A score of five or more indicates pathological gambling (1).

Gambling behaviours: Measures relating to behaviours with problematic forms of gambling included: 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.

Gambling Related Cognitions Scale (GRCS): A self-report questionnaire that records common thoughts associated with problem gambling. The 23 items of the GRCS contribute to five subscales reflective of the broader categories of gambling related cognitions that have been described in the literature: interpretative bias (*GRCS-IB)*, illusion of control (*GRCS-IC)*, predictive control (*GRCS-PC)*, gambling-related expectancies (*GRCS-GE)* and a perceived inability to stop gambling (*GRCS-IS*), in addition to the Scale Total. Statements include items such as "Praying helps me win" and "I will never be able to stop gambling". Problem gamblers use a seven-point Likert scale (1 = strongly disagree, 2 = moderately disagree, 3 = mildly disagree, 4 = neither agree nor disagree, 5 = mildly agree, 6 = moderately agree, 7 = strongly agree) to indicate how much they agree with each of the statements. The final score is created by adding the values gained from the items, with a higher score reflecting more gambling-related cognitions. A comparison with the South Oakes Gambling screen indicated the scale has good psycho-metric properties in measuring gambling cognitions in a non-clinical sample (19).

The Gambling Urge Scale(GUS) : A self-report questionnaire measuring the extent of gambling urge. The scale consists of six items rated on a Likert (1-7) scale, including statements such as "I crave a gamble right now" and "All I want to do is gamble". A final score is generated as a total of the response to each item. Higher scores indicate greater urges to gamble. Research into concurrent, predictive and criterion-related validity of the GUS suggests the GUS is a valid and reliable instrument for assessing gambling urges among treatment seeking problem gamblers (72) and non-clinical or non-treatment seeking gamblers. Predictive validity of problem gambling has been shown using the GUS as well as the ability to differentiate between non-problem gamblers and problem gamblers (73).

Self-efficacy perception: To assess 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 was utilised. Participants described up to three personally relevant high-risk situations and then rated the extent of their belief that they could refrain from gambling excessively in these situations on a scale of 0-10.

Kessler 10 Scale (K10) : This questionnaire was developed to produce a global measure of "psychological distress", based on questions about the level of anxiety and depression symptoms that the client has been experiencing, ranging from few or minimal symptoms to extreme levels of distress (74, 75). The K10 is framed for individuals to respond in terms of how they have been feeling in the past 4 weeks. Higher scores indicate greater distress. Interpreting levels of psychological stress is guided by the stratification of scores as: 10 - 19, problem gambler may currently not be experiencing significant feelings of distress; 20 - 29, mild distress consistent with a diagnosis of a mild depression and/or anxiety; and 30 - 40, severe distress consistent with a diagnosis of a severe depression and/or anxiety disorder.

The Work and Social Adjustment Scale (WSAS): A self-report questionnaire used to measure an individual's perspective of their functional ability/ impairment. The scale contains five items to explore the degree to which the participant's gambling problem affected their ability to function in the following areas: work, home management, social leisure, private leisure and family and relationships. Each question is answered using a 0 to 8 scale ("not at all" to "very severely"), with higher scores corresponding to a higher degree of severity. Scores below 10 are indicative of a subclinical population; 10 - 20, significant functional impairment but less severe clinical symptomatology; and 20 +, moderately severe (or worse) impairment. Research into the validity of the scale suggests that WSAS correlates closely with the severity of depression and obsessive-compulsive disorder symptoms at 0.76 and 0.61 and is sensitive to patient differences and change following treatment (76).

The Alcohol Use Disorders Identification Test (AUDIT): The Self-Report Version is a non-diagnostic ten item questionnaire indicating hazardous alcohol use. Individuals are required to rate how frequently they engage in certain activities. 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. A guide to interpretation of final scores range from 0 indicating abstainer, < 8 indicating low risk alcohol use, 8+ indicating risky or harmful alcohol use, 13+ indicating alcohol dependence is likely. According to studies reporting the psycho-metric properties of the AUDIT, the scales sensitivity and specificity is at a level at least equal to, and often exceeding alternate measures. The scale also has good test-retest reliability and internal consistency (77).

Participant views about treatment: Following an explanation of treatment rationale and protocol in session one, participants were 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 were asked to rate their views on satisfaction with treatment received (from 0= *extremely unsatisfied* to 6= *extremely satisfied*).

Follow-up

To improve completion rates of self-rated questionnaires at follow-up for both treatment completers and treatment drop outs, study participants were 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. Treatment drop-out was determined using the approach based on therapist's judgement of participant progress up to the point of self-initiated termination (55).

Self-rated measures were provided to participants for completion at commencement of each treatment session and at 1, 3 and 6 month follow-up. Follow-up questionnaires were mailed to participants with a pre-paid self-addressed envelope. To improve response rates to mailed questionnaires, multiple contacts were implemented with phone calls and reminder letters (78). The purpose of the call was to see if the participant had any questions about the study and to offer the mailing out of a further set of questionnaires if needed.

Table 4. Measurements

Measurements	Intervention period			Maintenance period		
	Baseline	Sessions 2-12	End of treatment	1 month	3 month	6 month
Demographics	X					
Duration of gambling problem	X					
AISS	X					
VGS	X		X	X	X	X
DSM-IV-TR	X		X			X
Mechanisms of change						
GRCS	X	X	X	X	X	X
GUS	X	X	X	X	X	X
Self-efficacy	X	X	X	X	X	X
Problems associated with 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
hours‡	X		X	X	X	X
amount§	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

*Treatment session 2 only

Data analyses

Statistical analyses were conducted using Stata 12.0 (79) and the user-written program gllamm (generalised linear latent and mixed models) (80). For baseline demographics and clinical characteristics the mean and SD were used to summarise quantitative data for each group. Where quantitative data was asymmetrically distributed the median and inter-quartile ranges are given. For categorical data, numbers and proportions are reported.

The primary analysis was intention-to-treat (ITT) to investigate any statistically significant differences in primary and secondary outcomes over time between cognitive and exposure therapy. The ITT principal preserves the benefit of randomisation where all individuals are included in the analysis, in the groups to which they were randomised to avoid potential effects from group crossover and study drop out (81). Secondary analyses were conducted based on 'as treated' and 'per protocol' approaches. Where results did not differ between the two methods, only the ITT results are reported. For primary outcome measure VGS, the data structure was described for repeated measures including patterns of missing data: monotone and intermittent (i.e. no particular pattern). The plausibility of assumptions for missing data was investigated using a sensitivity analysis. Pattern-mixture models (PMM) were used to represent alternative missing not at random (MNAR) behaviour for a range of differences between unobserved VGS data and observed VGS data. If the treatment effects are relatively constant over the specified range then the findings are considered to be clinically plausible (82).

To investigate the association between treatment drop-out and predictor variables of participant demographics and baseline gambling related measures, we used binary logistic regression. In accordance with study protocol, classification as treatment drop-out was based on therapists' judgement of participant progress up to the point of self-initiated termination. The referent category was participants who had completed treatment based on therapists' judgement. In order to determine any association between predictor variables and number of treatment sessions attended by each participant, ordinal logistic regression analyses were conducted. We used two tertiles to categorise participants into three ordered groups as outcome. Firstly, participants receiving 3 or less treatments were categorised as treatment drop-outs in accordance with study protocol. The second and third groups were created using a median split of remaining session numbers. Both univariate and multivariate models were calculated for binary and ordinal logistic regression analysis. To account for potential bias of estimates in the final multivariate models, 95% confidence intervals and *P*- values were derived from bootstrap method with 200 resamplings.

A generalised mixed-effects model approach was used in the analysis of repeated measures for primary and secondary continuous and categorical outcomes. Mixed-effects models take into account the inter-individual differences in intra-individual change with repeated responses and use all the available data on each subject. Mixed models are also unaffected by randomly missing data and therefore do not require imputation methods (83). Fixed effects in models were intervention group (CT or ET), time in continuous form (intervention period and maintenance effects), and interaction between group and time. Random effects in the model were at study participant level, and represented an upward or downward shift in the outcome measure from an overall regression line and rate of change over time. A quadratic

term for time was also tested to allow for possible non-linear effects where rates of change in outcome measures slow down over time with a levelling-off effect.

Covariance patterns of residuals for random effects were tested using two structures: independent (residuals assumed to have one unique variance parameter per random effect and all covariances zero) and unstructured (all variances and covariances distinctly estimated). Nested models were then compared using a likelihood-ratio test to identify for any significant association between random intercept (baseline score) and random slope (rate of change over time) at the individual level. Maximum likelihood estimation (MLE) was used for comparing models. For final models, standardised residuals (difference between observed and predicted values) were calculated to identify any poorly fitting data or outliers.

Linear combinations of regression coefficients from mixed models were then tested for treatment group effect at completion of intervention and follow-up time points and estimated between-group mean differences were presented along with confidence intervals. Predicted estimates of treatment outcome at each time point were 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 ordinal and categorical outcomes, odds ratios and confidence intervals were calculated.

To determine mechanisms of therapeutic change based on each treatment's intended effects a mediation analysis was conducted using mixed-effects models under ITT principle. The mediation analysis was based on two approaches. The first approach followed these traditional requirements for testing mediation: (1) testing for an association between treatment condition (ET versus CT) and putative mediators (gambling urge and gambling related cognitions); (2) testing for an association between treatment outcome variable (perceived self-efficacy) and treatment condition; (3) testing for an association between the mediator and treatment outcome after adjusting for treatment effect; and (4) testing if the effect of treatment condition on treatment outcome is attenuated upon the addition of the mediator to the model (84). The second approach assessed indirect mediation effects using the Sobel test $Z = \alpha\beta / (\alpha^2\sigma^2_\beta + \beta^2\sigma^2_\alpha)^{1/2}$ where α is the path coefficient between the independent variable and mediator and β is the path coefficient between the mediator and the outcome variable (85).

Handling missing data

To avoid missing data, the trial adhered to the following recommended steps for handling missing data (86):

1. We attempted to follow up all randomised individuals, even if they withdrew from allocated treatment. Strategies to improve follow-up rates included minimising the number of attendances required at SGTS by sending follow-up questionnaires by post and offering incentives. A relatively large time window was also allowed for each follow-up assessment. Mixed models were used to account for the unbalanced design and time was entered into models as a continuous covariate from the date of first intervention (baseline) to date of each follow-up measurement.

2. We performed a main analysis that was valid under a plausible assumption about the missing data (MLE) and used all available data

3. Sensitivity analyses were conducted to explore the impact of departures from the assumption about missingness that was made in the main analysis.

Qualitative component

Following the treatment intervention period a sub-sample of participants was invited to take part in semi-structured interviews to explore treatment specific and non-specific effects for cognitive and exposure therapies. One-on-one interviews were planned to last for approximately one hour and conducted in person with participants. Each interview was to commence with a 'grand tour' question "Tell me about your experiences with your gambling treatment?" Open ended questions were designed to guide interviews including "What made it easy or difficult with your gambling treatment?" and "How can treatments improve for problem gamblers?" To ensure a range of individual experiences were captured, purposeful sampling was used. Sampling was to continue until theoretical saturation had been achieved where no new or relevant data were seen to emerge for each of the categories of information established from preliminary analyses, expected to be in the range of 4-8 for each group. The interviews were to be recorded using a digital voice recorder and transcribed verbatim. Data was analysed using thematic content analysis.

8. RESULTS

Participant recruitment and flow

Participant recruitment was primarily from self-referral to SGTS. A number of participants responded to a range of media announcements about the study including a television interview with the project's Chief Investigator (Table 5).

The flow of participants through each stage of the study is shown in Figure 2. Participants were recruited from 151 consecutive referrals to SGTS from April 4th, 2011 to 30th March, 2012. The main reason for study exclusion was non-EGM use as the primary form of problem gambling. From stratified blocked randomisation, 50 participants were allocated to receive cognitive therapy and 49 participants to receive exposure therapy (Table 6). Of the 99 participants randomised, 12 did not receive allocated intervention. One participant allocated to CT group received ET due to inconsistent application of study protocol. No significant differences were found between intervention starters and non-starters on stratification variables age ($P = 0.395$), SOGS scores ($P = 0.170$) or gender distribution ($P = 0.970$).

Overall, median time for participants enrolment in the study was 40.9 weeks where 50% of participants had times between 17 and 59 weeks (IQR = 42 weeks) and 25% less than 6.9 weeks. Mean follow-up time was 6.5 weeks (SD = 2.7; Range: 3.7 - 17 weeks) for one month assessment, 15.6 weeks (SD = 3.7; Range: 8.7 – 27.4 weeks) for 3 month assessment, and 29.6 weeks (SD = 5.4; Range: 19.9 – 46.1 weeks) for 6 month assessment.

Table 5. Participant recruitment

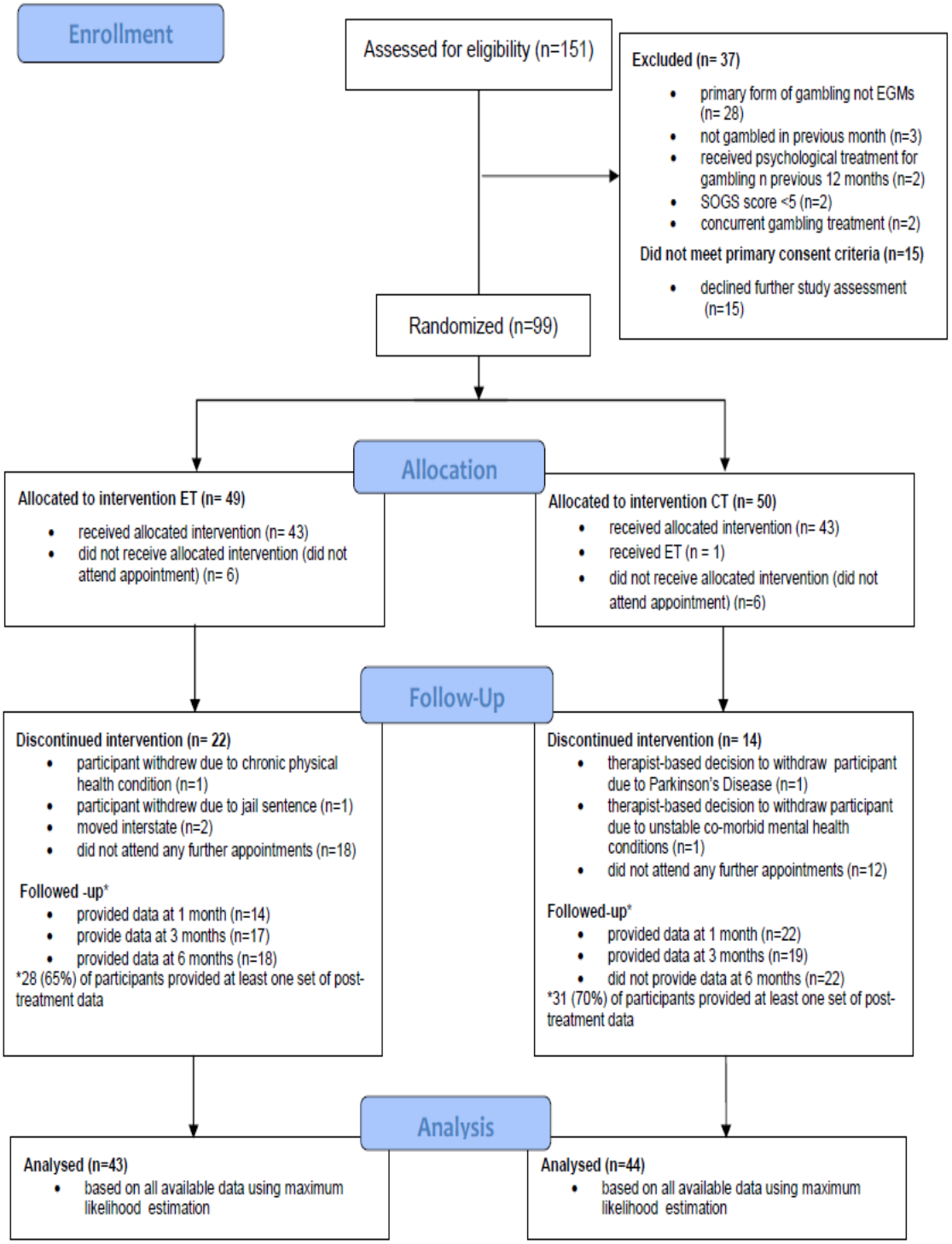
Source	Randomised but did not receive allocated intervention (n =12)	Randomised and received allocated intervention(n = 87)
Self-referred	9	68
Media announcements		
ABC radio interview with Project Investigator (21 Nov, 2011)	0	1
Channel 9 news interview with Project Investigator (9 Aug, 2011)	2	9
Flyer		
Public hospital	1	1
Medical centre	0	1
Gambling venues	0	2
Newspaper advertisements	0	5

Table 6. Distribution of participants using stratified randomisation

	Exposure Therapy (n=49)	Cognitive Therapy (n=50)
Demographic data		
Age (years)	46.17 (11.59)	45.96 (14.71)
Female	25 (51.02)	25 (50)
Clinical data		
SOGS	11.71 (2.88)	11.64 (2.57)

Abbreviations: SOGS, South Oaks Gambling Screen;
Data are mean (SD) or n (%).

Figure 2. Participant flow



Note: For the purposes of this report we have included all available data up to 11th February 2013. Further follow-up data is being collected to include additional 6 and 12 month data.

Baseline characteristics

Baseline characteristics for n=87 participants are presented in Table 7. When stratifying VGS at cut score 21 there were 81(94.2%) classified as problem gamblers. For DSM-IV criteria there were 83(95.4%) diagnosed as pathological gamblers when assessed by a therapist at study commencement. For participants that did not meet problem or pathological gambling criteria, three had DSM ratings of 3 and corresponding VGS scores 12, 16 and 17. One individual had a DSM score of 1 and a self-reported VGS score of 31, and two had VGS scores of 20 and 14 with corresponding DSM scores of 6 and 10 respectively. One participant had a missing baseline value for VGS due to reporting "not applicable" to all items, however was assessed as pathological gambler based on DSM score of 9. There was a reasonably strong and positive association between SOGS scores at study screening and baseline scores for VGS ($r = 0.53$) and DSM ($r = 0.41$) ($P < 0.001$). Similarly, there was a significant association between VGS and DSM scores at baseline ($r = 0.44$) ($P < 0.001$).

The distribution of scores for psychological distress as measured by K10 were 22(25.3%) self-reporting minimal to mild levels, 19(21.8%) as moderate, and 46(52.9%) in the severe range. For participants perspective of their functional ability/impairment using WSAS it was found that 25(28.7%) were in the sub-clinical range, 40(46%) with significant impairment, and 22(25.3%) in the moderate to severe range. Self-reported alcohol consumption using AUDIT scores showed 53(60.9%) were at low risk of harm, 15(17.2%) in the hazardous range, 7(8.1%) at harmful levels, and 12(13.8%) at high risk.

Table 7. Baseline socio-demographics and clinical characteristics

	Exposure Therapy (n=43)	Cognitive Therapy (n=44)
Socio-demographic data		
Age (years)	45.50(12.04)	47.45(13.88)
Female	22(50)	22(50)
Relationship		
married/in a partnership	16(48.48)	17(51.52)
separated/divorced/single/ widowed	26(50.98)	25(49.02)
other	1(33.33)	2(66.67)
Employment		
employed	22(47.83)	24(52.17)
unemployed	19(51.35)	18(48.65)
other	2(50)	2(50)
Duration of gambling problem		
< 2 years	4(50)	4(50)
2 - 5 years	10(52.63)	9(47.37)
> 5 years	29(48.33)	31(51.67)
Clinical measures		
VGS	40.25(9.56)	41.08(11.36)
PG (DSM-IV-TR)	43(100)	40(90.91)
GRCS	77.08 (25.62)	74.14 (26.01)
GUS	15.33(12.80)	12.43(12.57)
K10	30.58(9.31)	29.91(9.42)
WSAS	16.67(9.09)	14.36(9.66)
AUDIT	6.24(6.85)	8.57(9.54)
AISS	45.24(8.86)	45.12(8.32)
Self-efficacy[b]	4.15 (3.19)	2.50 (2.55)
Gambling behaviours[a]		
Frequency		
weekly or less	13(48.15)	14(51.85)
> weekly	28(49.12)	29(50.88)
Amount spent		
$1 - $500	12(50)	12(50)
$501 - $1000	11(40.74)	16(59.26)
> $1000	18(52.94)	16(47.06)
Hours, median (IQR)	15(20)	10(22)

Abbreviations: VGS, Victorian Gambling Screen harm to self subscale; PG, Pathological gambler; 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; AISS, Arnett Inventory of Sensation Seeking Traits.
Data are mean (SD), or n (%) unless otherwise indicated.
[a]Based on gaming machine use in previous month.
[b]Mean score of up to 3 high-risk situations.

Implementation of interventions

Cognitive therapy was provided by two psychotherapists with qualifications in psychology and, on average, had approximately 5 years practice experience, including 2 years in treating individuals with gambling disorders. For treatments implemented, the case volume for CT therapist one was 28 out of 43 participants and for therapist two 15 out of 43. Exposure therapy was provided by two psychotherapists with post-graduate qualifications in CBT; a

registered mental health nurse and an honours psychology graduate. On average, therapists had 6 years clinical experience in delivering CBT treatments to clients' of SGTS including a manualised ET program. For participants who received ET, the case volume for therapist one was 27 out of 44 participants and 17 out of 44 participants for therapist two.

For the course of the study each therapist then received on-site supervision with Mitch Durbridge, a registered clinical psychologist who has been in practice for over 6 years and received extensive training in CBT protocols. The supervisor and therapists also participated in an on-site consultation meeting with Robert Ladouceur in the early phase of study recruitment and treatment administration. Thereafter, off-site consultation with Robert Ladouceur was conducted using a voice over Internet Protocol (VoIP) service. Therapists who administered ET received 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 (23).

For participants who started intervention (n=87), the median number of CT sessions was 8.5 (IQR, 4 - 11.5) and 5 for ET sessions (IQR, 3 - 9) where a marginally significant difference was found between groups ($P = 0.046$). In terms of effect size, this meant that the probability of a CT participant having a higher number of treatment sessions than an ET participant was 62.4%. A significant difference was also found between mean duration of CT sessions (51.9 minutes, SD=16.3) and mean duration of ET sessions (43.3 minutes, SD=20.9) ($P < 0.001$). There was no significant difference in median number of weeks that participants were engaged in treatment between CT (Median = 13.5; IQR, 6.9 – 21.6) and ET (Median = 9.6; IQR, 2.7 - 20.7) ($P = 0.316$). Participant views about treatment are presented in Table 8.

Table 8. Treatment details

	Exposure Therapy	Cognitive Therapy	*P*
Views before treatment[a]			
Treatment is logical	4.82(1.13)	5.11(1.22)	0.339
Confident about treatment	4.79(0.99)	5.04(1.04)	0.345
Views after treatment[b]			
Satisfied with treatment	5.32(0.91)	5.68(0.84)	0.102

Data are mean (SD).
[a]ET (n=33), CT (n=27)
[b]ET (n=34), CT (n=34)

Based on therapist's judgement, 41% (36/87) of participant's were classified as treatment drop-outs: 31.8% (14) for CT, and 51.2% (22) ET. Of these, 66.7% (24/36) attended 1 to 3 sessions, 30.6% (11/36) attended 4 to 9 sessions, and 2.8% (1/36) attended 12 sessions. For treatment completers (51/87), there was no significant difference between median number of CT sessions (Median= 9.5; IQR, 8 - 14) and ET sessions (Median=9; IQR, 7 - 11) ($P = 0.218$). Similarly, there was no significant difference in duration of treatment between CT (Median = 16.6; IQR, 11.9 - 24.1) and ET (Median = 18.1; IQR, 12.0 - 28.7) ($P = 0.893$).

Results from binary logistic regression analyses to investigate the association between treatment drop-out and independent variables involving participant demographics, treatment group and gambling related problems are provided in Table 9. For each one year increase in

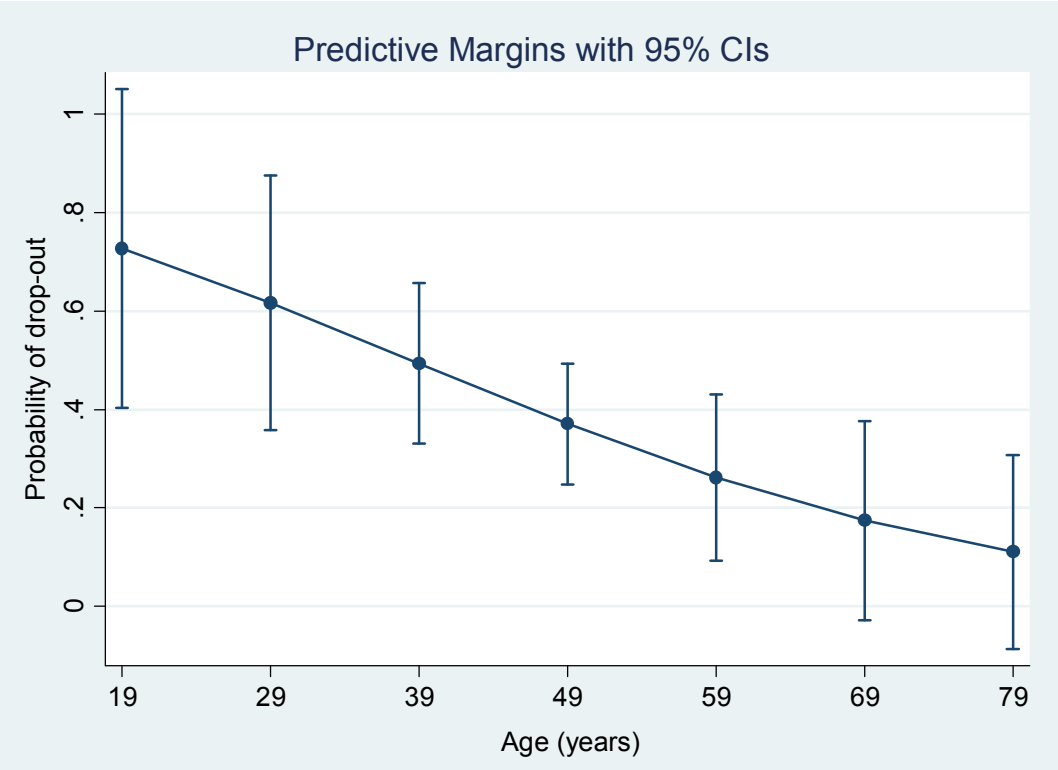
age, on average, participants were significantly less likely to drop-out from treatment in the univariate model ($P = 0.019$). In the multivariate model, age approached statistical significance with each increase of one year the odds of treatment drop-out decreased by a factor of 0.94 when holding all other variables constant ($P = 0.070$) (Figure 3). For a standard deviation increase in age, the odds of dropping out from treatment decreased by a factor of 0.48, holding all other variables constant. For psychological distress, participants with higher K10 scores were significantly more likely to drop-out from treatment in the univariate model ($P = 0.042$), but was not significant in the multivariate model ($P = 0.620$). Similarly, participants with higher levels of work and social impairment were significantly more likely to drop-out from treatment in the univariate model ($P = 0.018$), but insignificant in the multivariate model ($P = 0.661$).

Table 9. Univariate and multivariate binary logistic regression models of factors associated with treatment drop-out.

	Univariate model			**Multivariate model**[†]		
Variable	OR	95% CI	*P*	OR	Normal-based 95% CI	*P*
Gender						
female (referent)	1.00	-	-	1.00	-	-
male	1.04	0.44 - 2.44	0.928	0.82	0.18 – 3.65	0.790
Age (years)	0.96	0.92 - 0.99	0.019	0.94	0.89 - 1.00	0.070
Study group						
CT (referent)	1.00	-	-	1.00	-	-
ET	2.24	0.94 - 5.37	0.069	2.33	0.62 – 8.75	0.209
AISS	1.00	0.94 - 1.05	0.827	0.95	0.86 - 1.04	0.269
AUDIT	1.00	0.95 - 1.06	0.898	1.00	0.92 - 1.09	0.942
K10	1.05	1.00 - 1.11	0.042	1.02	0.93 - 1.12	0.620
VGS	1.02	0.98 - 1.07	0.301	1.01	0.94 - 1.09	0.770
WSAS	1.06	1.01 - 1.11	0.018	1.02	0.93 - 1.11	0.661

Abbreviations: AISS, Arnett Inventory of Sensation Seeking Traits; AUDIT, Alcohol Use Disorders Identification Test; K10, Kessler 10 Scale; VGS, Victorian Gambling Screen harm to self subscale; WSAS, Work and Social Adjustment Scale.
[†]Confidence intervals (95% CI) and *P*- values derived from bootstrap method with 200 resamplings.

Figure 3. Predictive probabilities of treatment drop-out by age



Results from ordinal logistic regression analyses to investigate the association between number of treatment sessions and independent variables are provided in Table 10. The number of treatment sessions attended by participants was stratified to create an ordinal outcome with the following ordered categories: 1 - 3 sessions (n = 25), 4 - 9 (n = 40), and 10+ (n = 22). The only significant predictor variable was treatment group ET versus CT in the univariate model *(P* = 0.029). In the multivariate model, treatment group approached statistical significance as a predictor where the odds of having more treatment sessions were 0.37 times smaller (*P* = 0.081) for ET participants, holding all other variables constant. Equivalently, the odds of having more treatment sessions were 62.5% smaller for ET than CT participants, holding all other variables constant. An alternative interpretation in terms of an increase in odds is the odds of having less treatment sessions were 2.67 times larger for ET participants than CT participants, holding all other variables constant. Equivalently, the odds of having less treatment sessions were 166.8% larger for ET than CT participants, holding all other variables constant.

Table 10. Univariate and multivariate ordinal logistic regression models for factors associated with number of treatment sessions.

	Univariate model			Multivariate model[†]		
Variable	OR	95% CI	*P*	OR	Normal-based 95% CI	*P*
Gender						
female (referent)	1.0	-	-	1.0	-	-
male	0.66	0.30 - 1.46	0.306	0.82	0.25 - 2.72	0.747
Age (years)	1.02	0.99 - 1.06	0.135	1.03	0.98 - 1.09	0.260
Study group						
CT (referent)	1.0	-	-	1.0	-	-
ET	0.41	0.18 - 0.91	0.029	0.37	0.12 – 1.12	0.081
AISS	1.00	0.96 - 1.05	0.842	1.02	0.96 - 1.09	0.475
AUDIT	1.01	0.96 - 1.06	0.711	1.01	0.94 - 1.08	0.825
K10	0.97	0.93 - 1.02	0.170	0.97	0.90 - 1.04	0.402
VGS	0.98	0.95 - 1.02	0.408	0.99	0.93 - 1.04	0.651
WSAS	0.99	0.95 - 1.03	0.686	1.04	0.97 - 1.11	0.242

Abbreviations: OR, odds ratio; CT, cognitive therapy; ET, exposure therapy; AISS, Arnett Inventory of Sensation Seeking Traits; AUDIT, Alcohol Use Disorders Identification Test; K10, Kessler 10 Scale; VGS, Victorian Gambling Screen harm to self subscale; WSAS, Work and Social Adjustment Scale.

[†]Confidence intervals (95% CI) and *P*- values derived from bootstrap method with 200 resamplings.

Treatment fidelity

ET sessions were evaluated by Malcolm Battersby and Rene Pols who is a senior consultant psychiatrist with the Flinders Gambling Research Centre and has extensive experience in treatments for gambling disorders and other addictions (23, 24). CT sessions were evaluated by Robert Ladouceur and Mitch Durbridge.

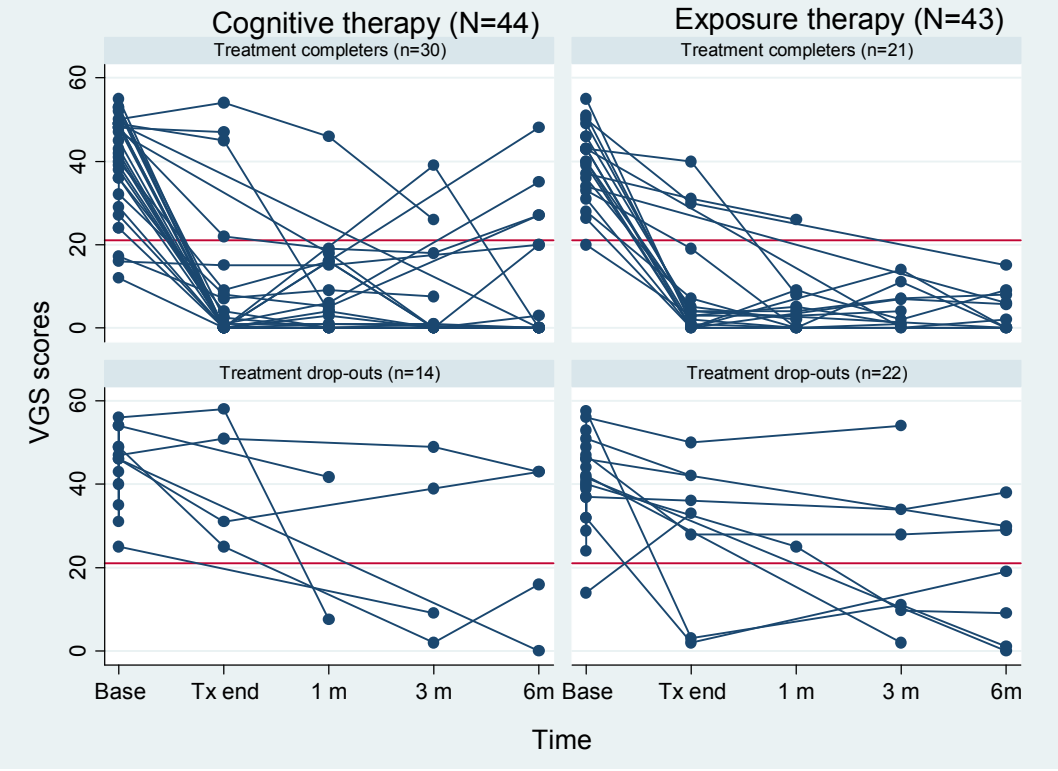
Of all the interventions started, 52 out of 87 participants (59.8%, 25 for CT, 27 for ET) were randomly selected for independent scoring of protocol adherence by therapist. In terms of unique recorded sessions, 76 out of 526 were selected (14.4%, 39 for CT, 37 for ET) and a total of 107 evaluations were conducted including 31 evaluations for inter-rater checking. The evaluations were stratified according to study phase of treatment session: 30 (28.04%) for early phase (April - August, 2011), 36 (33.5%) mid-phase (September 2011 - January 2012), and 41 (38.32%) in the final phase (February - June, 2012). For CT, 27 (25.23%) evaluations were carried out for therapist one, and 28 (26.17%) for therapist two. For ET, 27 (25.23%) evaluations were carried out for therapist one and 25 (23.36%) for therapist two.

The overall mean treatment integrity score was 98.5% for CT (SD=4.4%) and 99.5% for ET (SD=2.8%). Treatment integrity scores did not significantly differ between the two groups ($P = 0.142$). For inter-rater scores, no significant difference was also found ($P = 0.710$).

Analysis of primary treatment outcome

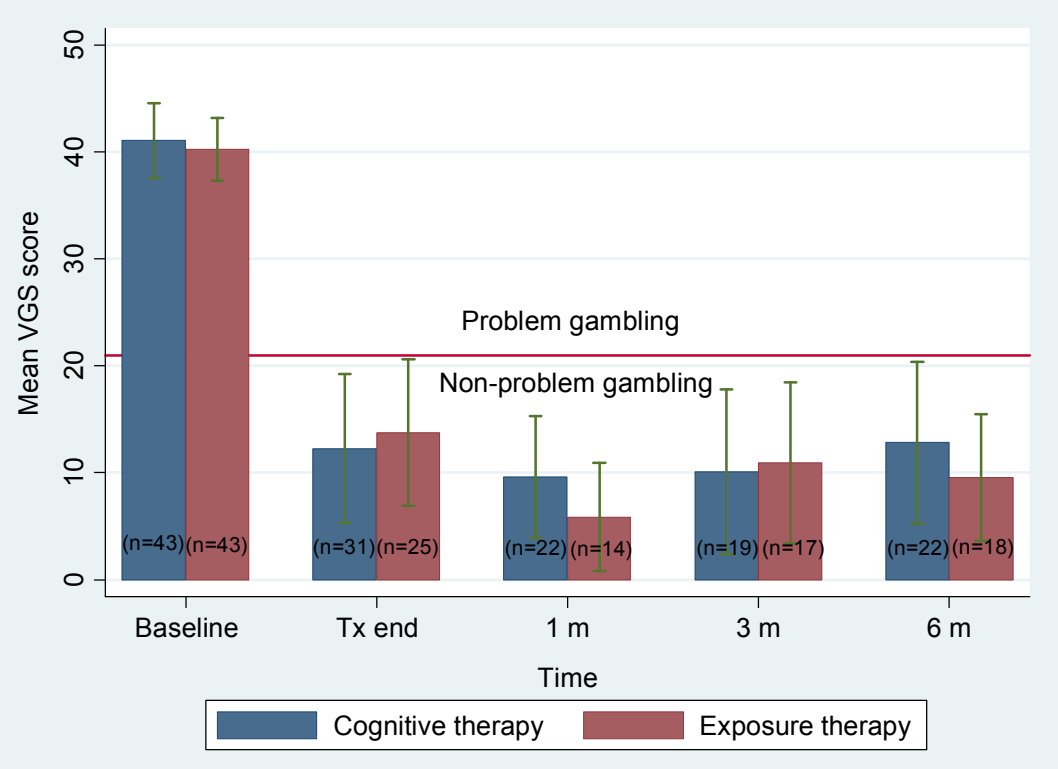
For primary outcome measure VGS, the observed trajectories of scores over time by therapy group (Figure 4) indicate that trends are generally nonlinear for treatment completers; improvement in gambling symptoms was initially fast and then slowed down. Observed mean scores by treatment group and time are shown in Figure 5. The reduction (improvement) in mean scores in both CT and ET groups show a similar trend to the individual plots in Figure 4 i.e. an initial fast improvement from baseline (problem gambling) to final treatment (non-problem gambling) and then a levelling-off effect in follow-up.

Figure 4. Individual response profiles for Victorian Gambling Screen (VGS) scores by treatment completion status, treatment group and time.[a]



Lower scores indicate a reduction (improvement) in gambling symptom severity.
Note: [a] Horizontal line is VGS cut score of 21+ (indicative of problem gambler).

Figure 5. Observed Victorian Gambling Screen (VGS) scores by time and treatment group.[a]



Lower scores indicate a reduction (improvement) in gambling symptom severity.
Note: [a] Horizontal line is VGS cut score of 21+ and indicative of problem gambler.

Patterns of missing VGS data are shown in Table 11 for CT participants and Table 12 for ET participants. For CT participants, VGS data were available for 70.5% (31/44) on at least one follow-up occasion post-treatment and 65.1% (28/43) for ET participants. In both groups, the availability of data at 6 month follow-up was, at least partly, influenced by the proximity of participant's study enrolment date to time of final data collection. At least 60% of missing data for ET and 53% CT were monotonic (i.e. missing from some time onward). These patterns suggest that, for at least half the missing data, a mechanism of missing at random (MAR) is a reasonable assumption i.e. the probability of the missing data is independent of unobserved data but may depend on observed data.

Based on intent-to-treat analyses, results from between group comparisons for VGS using linear mixed modelling are shown in Table 13. The model included both random intercept and random slope terms at the individual level (level two) and time in continuous form (level one). The average number of outcome assessments per individual was 2.9 (Range, 1 - 5) and a total of 254 observations. A better fitting model was obtained using an independent covariance structure. A likelihood-ratio test comparing the model with one-level (fixed effects) ordinary linear regression was highly significant for these data ($\chi^2 = 18.37$, df = 2, $P < 0.001$). There was no significant difference between the two groups in rate of change in scores over time ($P = 0.477$). There was a significant reduction (improvement) in VGS scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time the VGS score decreased by 1.93 (1.65 – 2.22) in CT participants and 1.87 (95% CI: 1.60 – 2.13) in ET participants. The estimated random

intercept standard deviation for VGS was 6.34 (95% CI: 4.29 – 9.38) and this considerable variation between individuals is indicated from baseline scores in Figure 4. The mean decrease in scores per week varied with a standard deviation of 0.16 per week (95% CI: 0.06 – 0.38).

Table 11. CT group: patterns of missing VGS scores

			Pattern				
Frequency	Percent (%)	Cumulative %	Baseline	Tx end	1m	3m	6m
8	18.18	18.18	X				
6	13.64	31.82	X	X	X		X
6	13.64	45.45	X	X	X	X	
6	13.64	59.09	X	X	X	X	X
5	11.36	70.45	X	X		X	X
4	9.09	79.55	X	X			
2	4.55	84.09	X				X
2	4.55	88.64	X	X			X
2	4.55	93.18	X	X	X		
1	2.27	95.45			X		
1	2.27	97.73	X			X	
1	2.27	100	X		X	X	X
44	100		X	X	X	X	X

Table 12. ET group: patterns of missing VGS scores

			Pattern				
Frequency	Percent (%)	Cumulative %	Baseline	Tx end	1m	3m	6m
12	27.91	27.91	X				
5	11.63	39.53	X	X		X	X
5	11.63	51.16	X	X	X		
5	11.63	62.79	X	X	X	X	X
3	6.98	69.77	X				X
3	6.98	76.74	X	X			
3	6.98	83.72	X	X			X
3	6.98	90.70	X	X	X	X	
1	2.33	93.02	X			X	
1	2.33	95.35	X			X	X
1	2.33	97.67	X		X	X	X
1	2.33	100	X	X		X	
43	100		X	X	X	X	X

The distribution of standardised residuals from the mixed model of VGS outcome data is shown in Figure 6. There does not seem to be any poorly fitting data, however it may still be informative to identify individuals where the difference between observed and predicted values are greater than two standard deviations (Table 14). Approximately 9% (8/87) of participants had moderately large residual values and most of these were high (worse symptoms) VGS scores post-baseline.

Table 13. Change in outcomes between exposure therapy (ET) and cognitive therapy (CT)

	Intervention								Follow-up											
	Baseline				12 weeks				1 month				3 months				6 months			
Outcome	Unadjusted estimate (SE) CT	Unadjusted estimate (SE) ET	Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE) CT	Unadjusted estimate (SE) ET	Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE) CT	Unadjusted estimate (SE) ET	Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE) CT	Unadjusted estimate (SE) ET	Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate CT	Unadjusted estimate ET	Estimated between-group difference (95% CI)[a]	*P*
VGS	33.44 (2.03)	33.90 (2.11)	-1.01 (-6.07 - 4.05)	0.696	26.09 (1.84)	26.23 (1.79)	-0.18 (-4.47 - 4.10)	0.933	23.64 (1.91)	23.68 (1.77)	0.09 (-4.18 - 4.37)	0.966	18.75 (2.22)	18.57 (1.85)	0.64 (-3.99 - 5.28)	0.625	11.40 (2.96)	10.90 (2.26)	1.47 (-4.43 - 7.38)	0.775
GUS	8.78 (1.50)	9.85 (1.40)	0.75 (-0.32-4.72)	0.712	6.79 (1.29)	7.88 (1.13)	0.98 (-2.44-4.39)	0.575	6.12 (1.26)	7.23 (1.08)	1.05 -2.26-4.37)	0.534	4.80 (1.23)	5.91 (1.05)	1.21 (-2.05-4.46)	0.468	2.81 (1.33)	3.95 (1.19)	1.43 (-2.11-4.98)	0.428
GRCS	58.06 (3.29)	61.07 (3.20)	0.80 (-8.22-9.81)	0.862	50.20 (3.04)	53.89 (3.09)	2.70 (-5.80-11.20)	0.533	47.58 (3.03)	51.50 (3.14)	3.34 -5.18-11.85)	0.443	42.34 (3.14)	46.72 (3.36)	4.60 (-4.23-13.44)	0.307	34.49 (3.57)	39.55 (3.94)	6.51 (-3.43-16.45)	0.200
K10	26.37 (1.48)	28.06 (1.46)	0.68 (-3.18-4.54)	0.731	24.15 (1.32)	24.91 (1.35)	0.66 (-2.83-4.14)	0.712	23.41 (1.29)	23.85 (1.35)	0.65 (-2.82-4.12)	0.714	21.93 (1.29)	21.75 (1.39)	0.63 (-2.98-4.25)	0.731	19.71 (1.41)	18.59 (1.56)	0.61 (-3.59-4.82)	0.776
WSAS	11.77 (1.24)	14.26 (1.30)	1.74 (-1.86-5.34)	0.343	9.67 (1.09)	11.13 (1.19)	1.43 (-1.52-4.38)	0.342	8.97 (1.06)	10.08 (1.18)	1.33 (-1.49-4.14)	0.357	7.58 (1.06)	7.99 (1.22)	1.12 (-1.61-3.84)	0.422	5.48 (1.18)	4.85 (1.39)	0.81 (-2.22-3.83)	0.602
AUDIT	8.18 (1.31)	6.23 (0.98)	-1.93 (-5.31-1.45)	0.262	7.70 (1.30)	5.93 (0.97)	-1.68 (-4.88-1.53)	0.305	7.54 (1.29)	5.84 (0.97)	-1.59 (-4.75-1.57)	0.323	7.21 (1.30)	5.64 (0.97	-1.42 (-4.50-1.66)	0.365	6.72 (1.31)	5.35 (1.0)	-1.17 (-4.18-1.84)	0.446
Self-efficacy	3.07 (0.50)	4.48 (0.47)	1.55 (0.38-2.73)	0.010	3.99 (0.43)	5.18 (0.40)	1.08 (0.01-2.16)	0.049	4.30 (0.42)	5.42 (0.39)	0.93 (-0.18-2.04)	0.102	4.91 (0.43)	5.88 (0.42)	0.62 (-0.65-1.88)	0.339	5.82 (0.49)	6.58 (0.53)	0.15 (-1.49-1.79)	0.858
Hours[b]	2.62 (0.16)	2.75 (0.13)	0.09 (0.30-0.47)	0.625	2.42 (0.15)	2.29 (0.12)	-0.02 (-0.42-0.38)	0.919	2.36 (0.16)	2.14 (0.12)	-0.06 (-0.49-0.38)	0.792	2.22 (0.17)	1.84 (0.14)	-0.13 (-0.67-0.40)	0.620	2.02 (0.20)	1.39 (0.19)	-0.25 (-0.96-0.46)	0.495

Abbreviations: VGS, Victorian Gambling Screen; GUS, Gambling Urge Scale; GRCS, Gambling Related Cognitions Scale; K10, Kessler 10 scale; WSAS, Work And Social Adjustment Scale; AUDIT, Alcohol Use Disorders Identification Test.

[a]Mean group difference (95% CI) from a linear mixed model

[b]Based on gaming machine use in previous month. Hours transformed using $\log_e$ hours.

Figure 6. Standardised residuals for linear mixed model of Victorian Gambling Screen (VGS) scores.

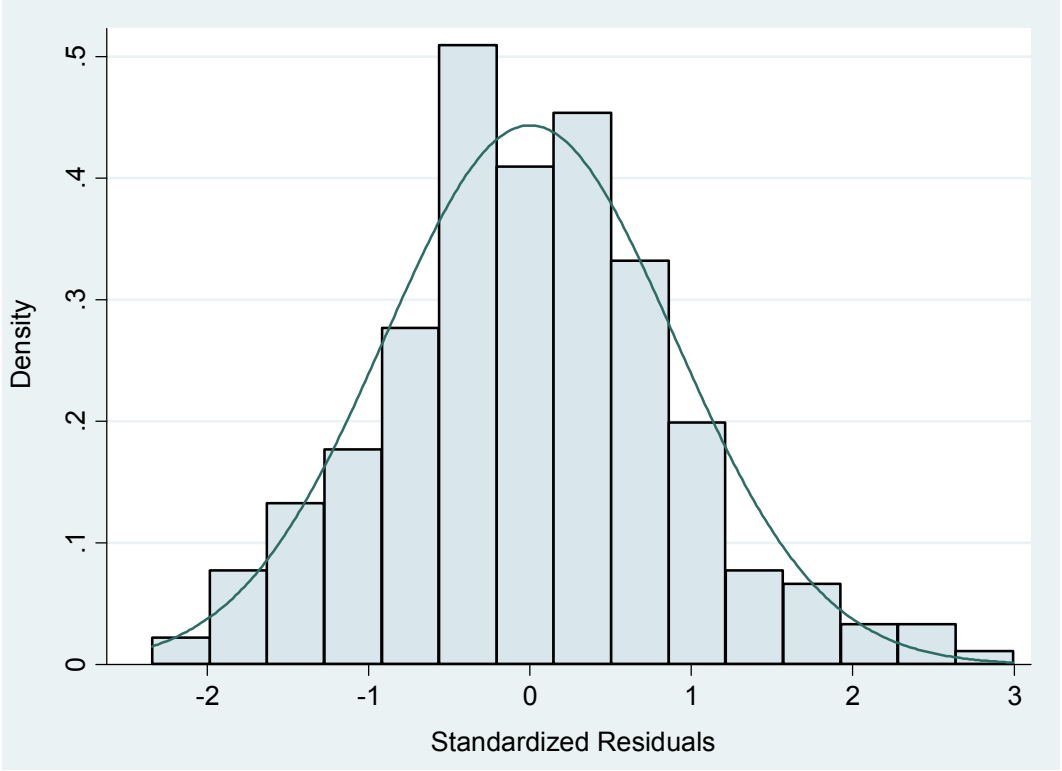


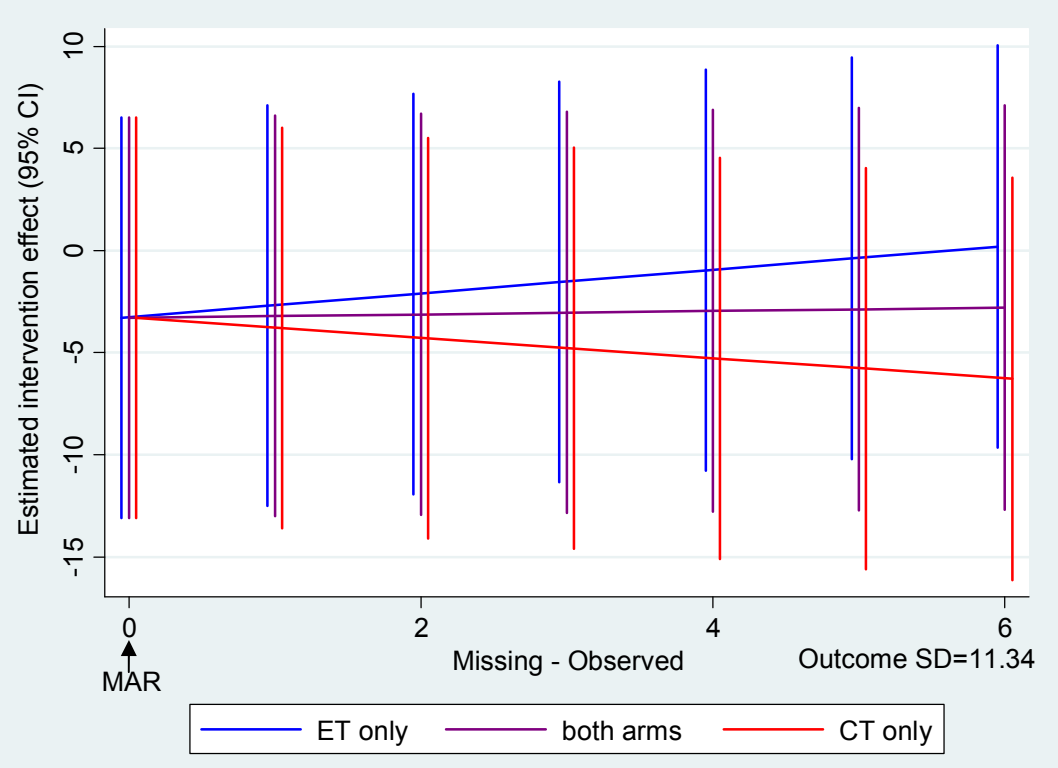
Table 14. Individual residuals greater than two standard deviations

Study participant	Group	Treatment adherence	Follow-up time	VGS
1	ET	non-completer	baseline	14
2	ET	completer	treatment-end	40
3	ET	non-completer	3 months	54
4	CT	completer	treatment-end	45
5	CT	completer	treatment-end	54
6	CT	completer	3 months	26
7	CT	completer	3 months	39
8	CT	completer	6 months	48

The above outcome analysis for VGS used maximum likelihood estimation (MLE) based on the assumption that missing data were MAR. In order to assess for departures in this assumption, three sensitivity analyses were conducted using ANCOVA (analysis of covariance) where VGS scores at 6 months was outcome, treatment group as independent variable and adjusted for baseline VGS scores. Figure 7 shows the variation in estimated intervention effects when mean unobserved VGS

outcome and mean observed VGS outcome differ over a specified range of 6 units (i.e. approximately 0.5 SD). The analysis allows for different missing data mechanisms in each group as one therapy may have been more intensive than another and so resulting in a further departure from MAR. When the difference between mean unobserved and mean observed outcome are assumed to be equal in both ET and CT groups, the treatment effects are not very sensitive to departures from MAR. For different missing data mechanisms between ET and CT groups the results are sensitive to departures from MAR with estimates ranging from - 6.28 to 0.20. Overall, sensitivity analyses suggest that trial findings are more biased if departures from MAR differ between the two groups. It is important to note that these sensitivity analyses are limited to data from one baseline and one follow-up time point and not repeated measures.

Figure 7. Sensitivity analysis for Victorian Gambling Screen (VGS) data.



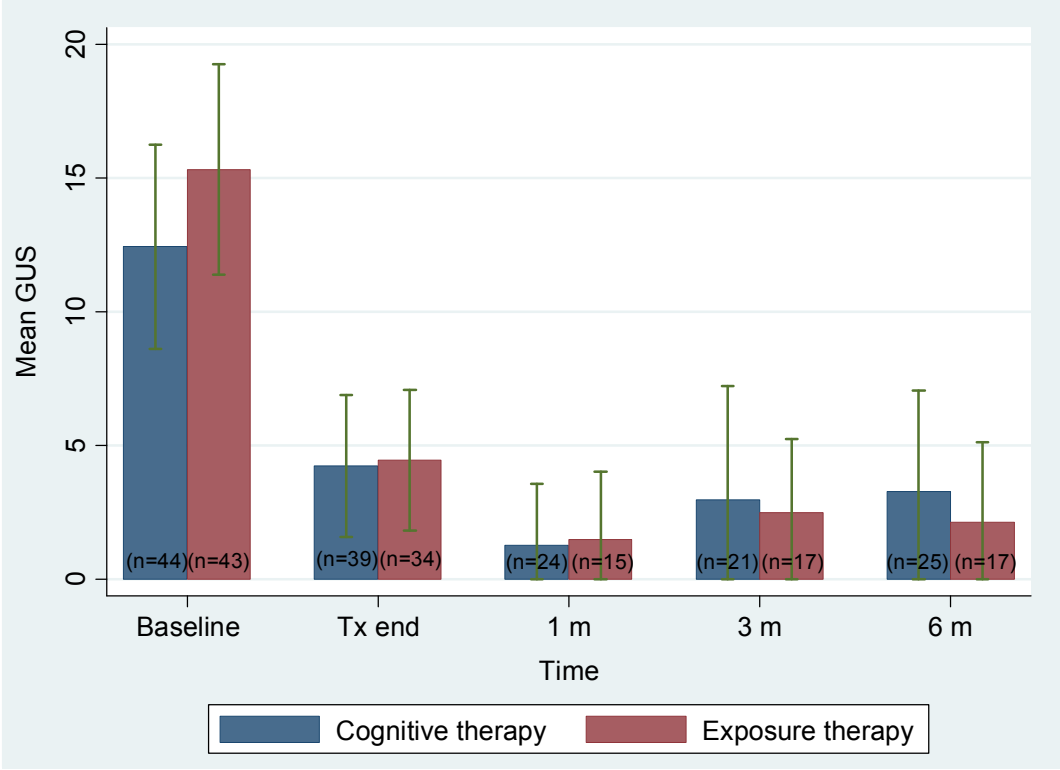
Abbreviations: ET, exposure therapy; CT, cognitive therapy; MAR, missing at random; SD, standard deviation.

Analysis of secondary treatment outcomes

Results from between group comparisons for continuous secondary outcome measures (GUS, GRCS, K10,WSAS, AUDIT, perceived self-efficacy, and hours gambled) using linear mixed modelling are shown in Table 13. The observed mean scores for urge to gamble (GUS) by treatment group and time are shown in Figure 8. The average number of outcome assessments per individual for GUS was 3.2 (Range, 1 - 5) and a total of 279 observations. A likelihood-ratio test comparing the model with one-level (fixed effects) ordinary linear regression was highly significant for these data ($\chi^2 = 67.38$, df = 3, $P < 0.001$). There was no significant difference between the

two groups in rate of change in scores over time ($P = 0.463$). There was a significant reduction (improvement) in GUS scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time the GUS score decreased by 0.64 (95% CI: 0.48 – 0.79) in CT participants and 0.69 (95% CI: 0.54 – 0.84) in ET participants. There was a substantial estimated random intercept standard deviation for GUS of 9.24 (95% CI: 7.58 – 11.27). The mean decrease in scores per week varied with a standard deviation of 0.24 per week (95% CI: 0.18 – 0.33). When models comprising of unstructured versus independent covariance patterns were compared there was a significant negative correlation between random intercept and slope (- 0.83) indicating that problem gamblers with higher baseline scores tended to have an overall faster rate of improvement (reduction) ($P < 0.001$).

Figure 8. Observed Gambling Urge Scale (GUS) scores by time and treatment group.

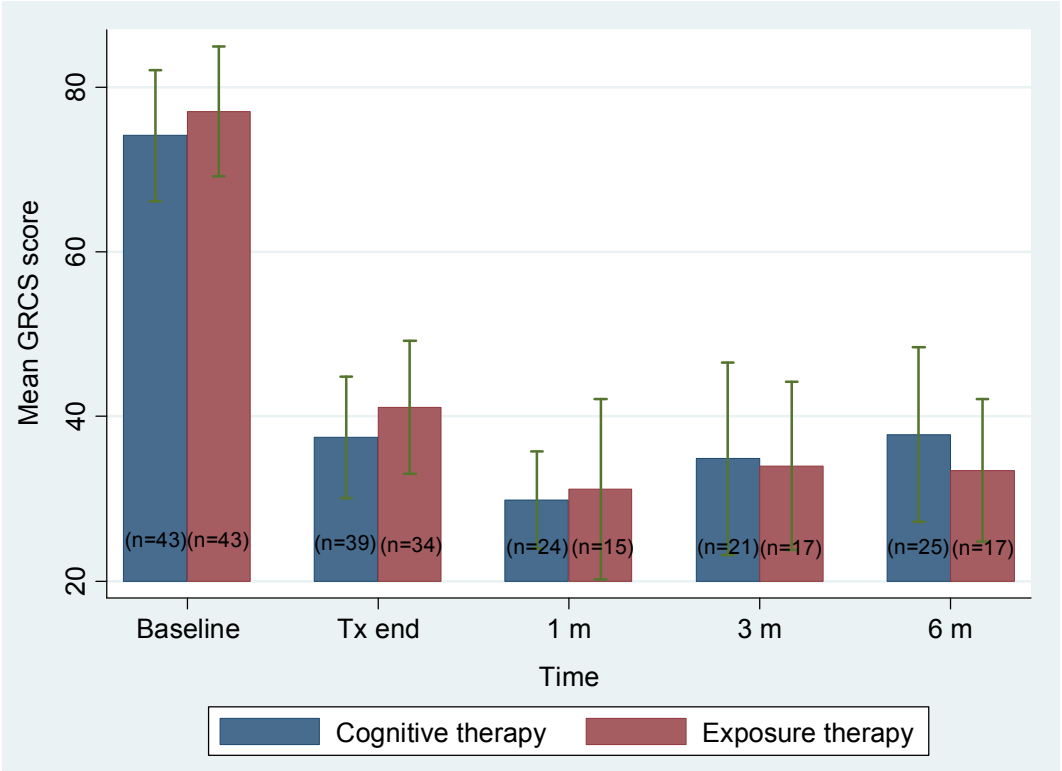


Lower scores indicate a reduction (improvement) in gambling urge.

Observed mean scores for gamble related cognitions (GRCS) by treatment group and time are shown in Figure 9. The average number of outcome assessments per individual for GRCS was 3.2 (Range, 1 - 5) and a total of 279 observations. A mixed model was found to provide a significantly better fit of the data when compared with one-level ordinary linear regression ($\chi^2 = 75.83$, df = 3, $P < 0.001$). There was no significant difference between the two groups in rate of change in scores over time ($P = 0.806$). There was a significant reduction (improvement) in scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time the GRCS score decreased by 2.57 (95% CI: 2.19 – 2.95) in CT participants and 2.53 (95% CI: 2.17 – 2.89) in ET participants. There was a

sizeable estimated random intercept standard deviation for GRCS of 19.57 (95% CI: 15.74 – 24.32). The mean decrease in scores per week varied with a standard deviation of 0.40 per week (95% CI: 0.25 – 0.62). When models comprising of unstructured versus independent covariance patterns were compared there was a significant negative correlation between random intercept and slope (- 0.54) indicating that problem gamblers with higher baseline scores tended to have an overall faster rate of improvement (reduction) in gambling cognitions ($P = 0.029$).

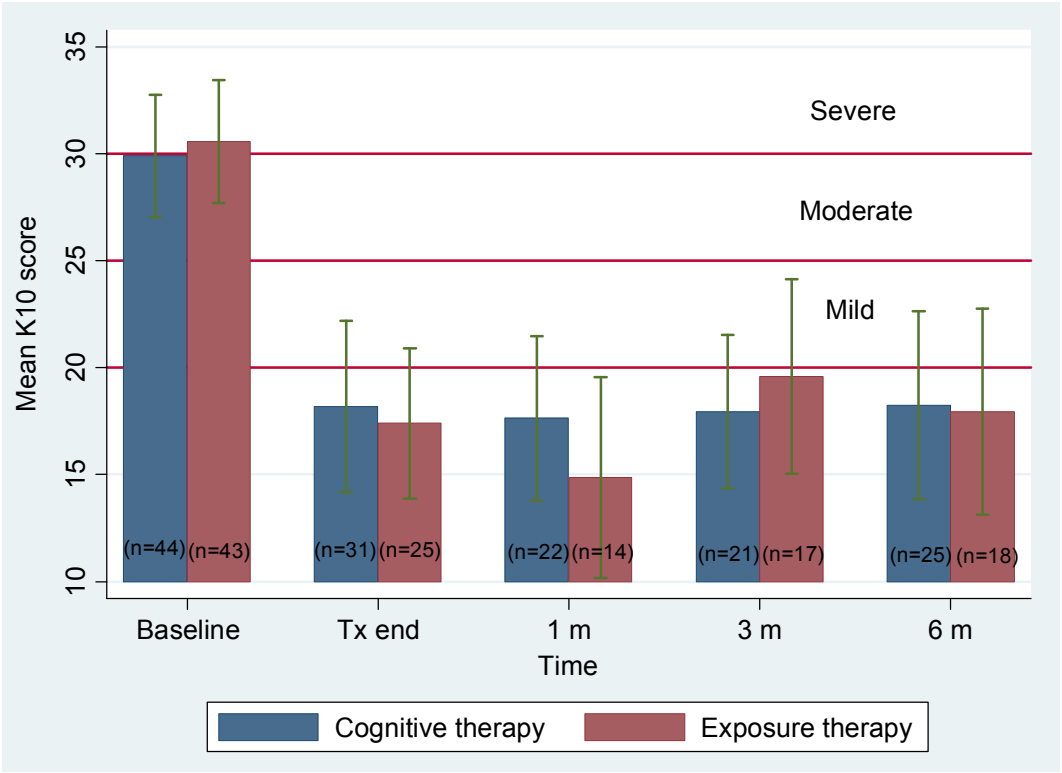
Figure 9. Observed Gambling Related Cognitions Scale (GRCS) scores by time and treatment group.



Lower scores indicate a reduction (improvement) in gambling related cognitions.

For K10 scores measuring general psychological distress there was an initial fast reduction in mean scores from baseline (moderate to severe levels) to final treatment (mild to non-significant level) and then a levelling-off effect in follow-up (Figure 10). The average number of outcome assessments per individual for GRCS was 3.0 (Range, 1 - 5) and a total of 262 observations. A likelihood-ratio test comparing the mixed model with one-level (fixed effects) ordinary linear regression was highly significant for these data ($\chi^2 = 74.63$, df = 3, $P < 0.001$). There was no significant difference between the two groups in rate of change in scores over time ($P = 0.975$). There was a significant reduction (improvement) in scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time the K10 score decreased by 0.73 (95% CI: 0.57 – 0.88) in CT participants and 0.73 (95% CI: 0.58 – 0.88) in ET participants. There was a good-sized estimated random intercept standard deviation for K10 of 7.48 (95% CI: 5.96 – 9.39). The mean decrease in scores per week varied with a standard deviation of 0.13 per week (95% CI: 0.08 – 0.23).

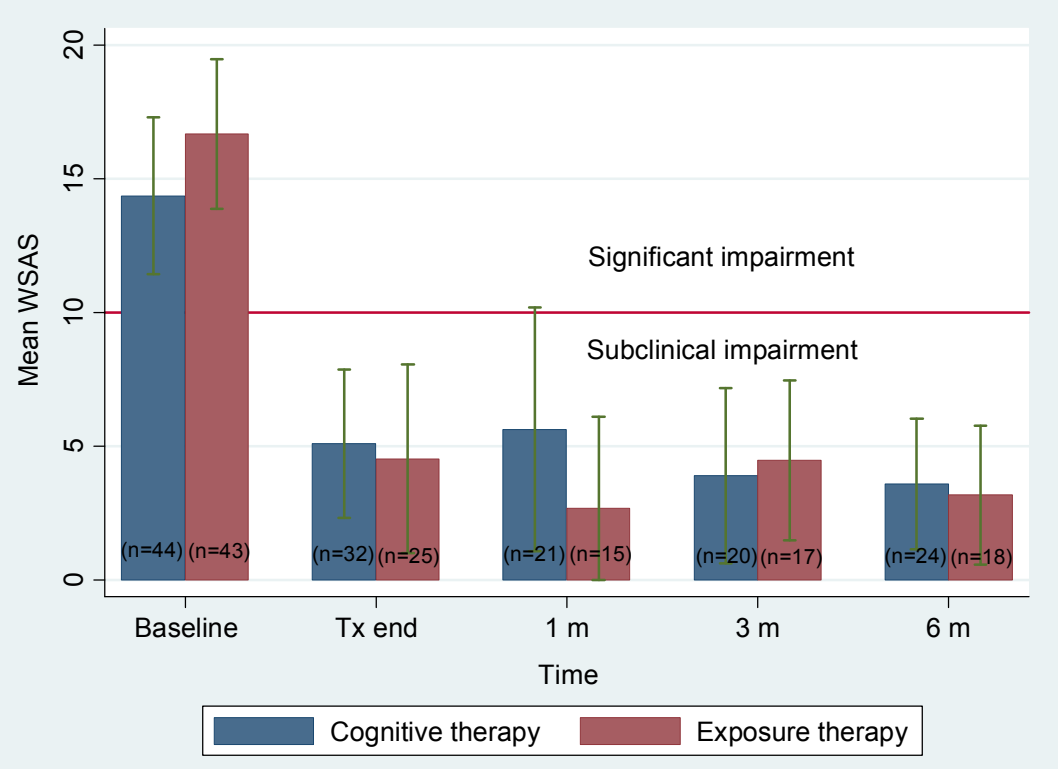
Figure 10. Observed Kessler 10 Scale (K10) scores by time and treatment group[a]



Lower scores indicate a reduction (improvement) in psychological distress.
Note: [a] Horizontal lines are K10 cut scores to interpret levels of psychological distress.

Observed mean WSAS scores by treatment group and time are shown in Figure 11. The average number of outcome assessments per individual for WSAS was 3.0 (Range, 1 - 5) and a total of 261 observations. A likelihood-ratio test comparing the model with one-level (fixed effects) ordinary linear regression was highly significant for these data ($\chi^2 = 53.16$, df = 3, $P < 0.001$). There was no significant difference between the two groups in rate of change in scores over time ($P = 0.617$). There was a significant reduction (improvement) in scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time the WSAS score decreased by 0.63 (95% CI: 0.49 – 0.77) in CT participants and 0.66 (95% CI: 0.53 – 0.79) in ET participants. The estimated random intercept standard deviation for K10 was 6.95 (95% CI: 5.54 – 8.74). The mean decrease in scores per week varied with a standard deviation of 0.13 per week (95% CI: 0.08 – 0.23).

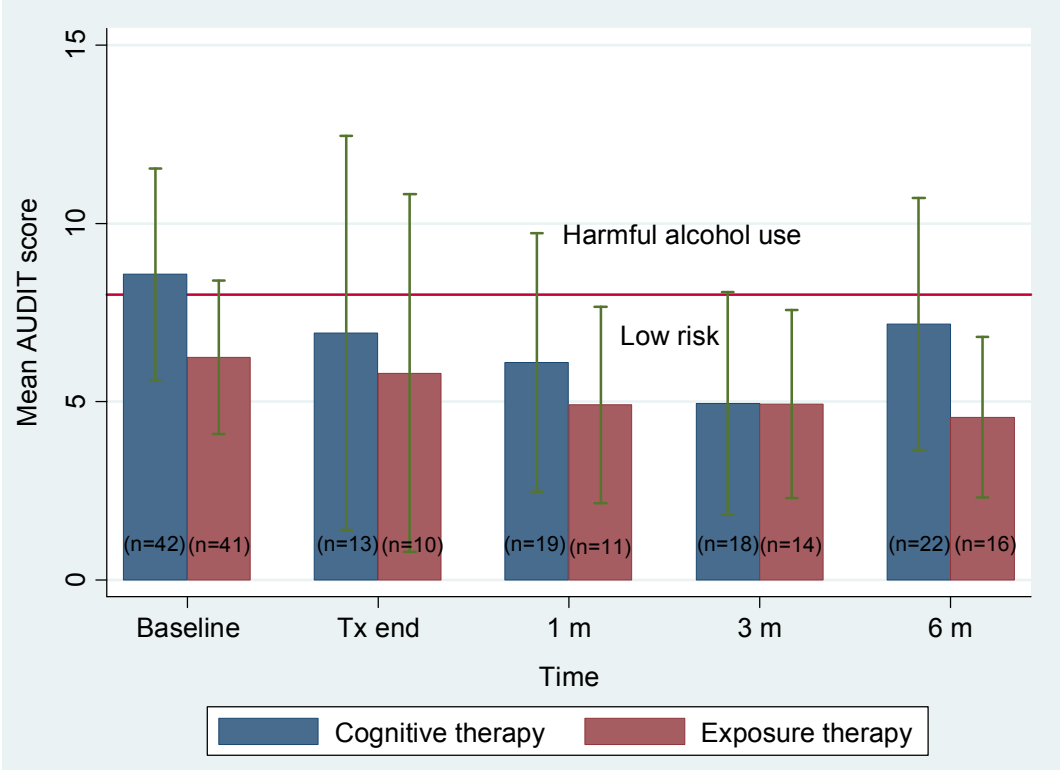
Figure 11. Observed Work and Social Adjustment Scale (WSAS) scores by time and treatment group[a]



Lower scores indicate an improvement in social and work functional ability.
Note: [a] Horizontal lines are WSAS cut scores to interpret levels of functional ability/impairment.

As shown in Figure 12, there was a modest improvement (reduction) in scores relating to alcohol use (AUDIT) where participants, on average, were in the low risk category throughout the trial. The average number of outcome assessments per individual for AUDIT was 2.4 (Range, 1 - 5) and a total of 208 observations. A likelihood-ratio test comparing the model with one-level (fixed effects) ordinary linear regression was highly significant for these data ($\chi^2 = 251.40$, df = 3, $P < 0.001$). There was no significant difference between the two groups in rate of change in scores over time ($P = 0.229$). There was a statistically significant reduction (improvement) in scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time the AUDIT score decreased by 0.10 (95% CI: 0.05 – 0.15) in CT participants and 0.08 (95% CI: 0.03 – 0.13) in ET participants. The estimated random intercept standard deviation for AUDIT was 7.82 (95% CI: 6.68 – 9.16). The mean decrease in scores per week varied with a standard deviation of 0.03 per week (95% CI: 0.01 – 0.09).

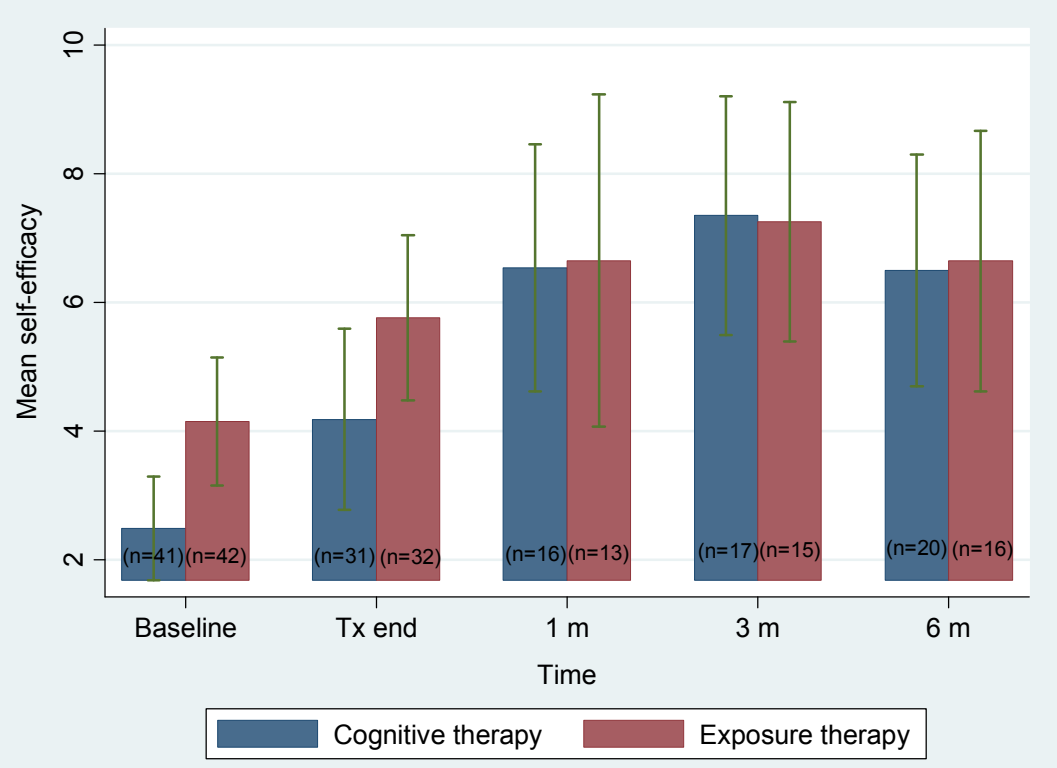
Figure 12. Observed Alcohol Use Disorders Identification Test (AUDIT) scores by time and treatment group.[a]



Lower scores indicate a reduced risk of harmful alcohol use.
Note: [a] Horizontal line is AUDIT cut score to indicate risk level from alcohol use.

For perceived self-efficacy scores there was a substantial increase (improvement) in observed mean values from baseline to one month follow-up and then a levelling-off effect (Figure 13). The average number of outcome assessments per individual for self-efficacy was 2.8 (Range, 1 - 5) and a total of 243 observations. A likelihood-ratio test comparing the mixed model with ordinary linear regression was significant for these data ($\chi^2 = 28.14$, df = 3, $P < 0.001$). There was no significant difference between the two groups in rate of change in scores over time ($P = 0.108$). There was a statistically significant increase (improvement) in scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time the self-efficacy score increased by 0.17 (95% CI: 0.10 – 0.25) in CT participants and 0.14 (95% CI: 0.07 – 0.20) in ET participants. The estimated random intercept standard deviation for self-efficacy was 1.41 (95% CI: 0.88 – 2.24). The mean decrease in scores per week varied with a standard deviation of 0.03 per week (95% CI: 0.01 – 0.07).

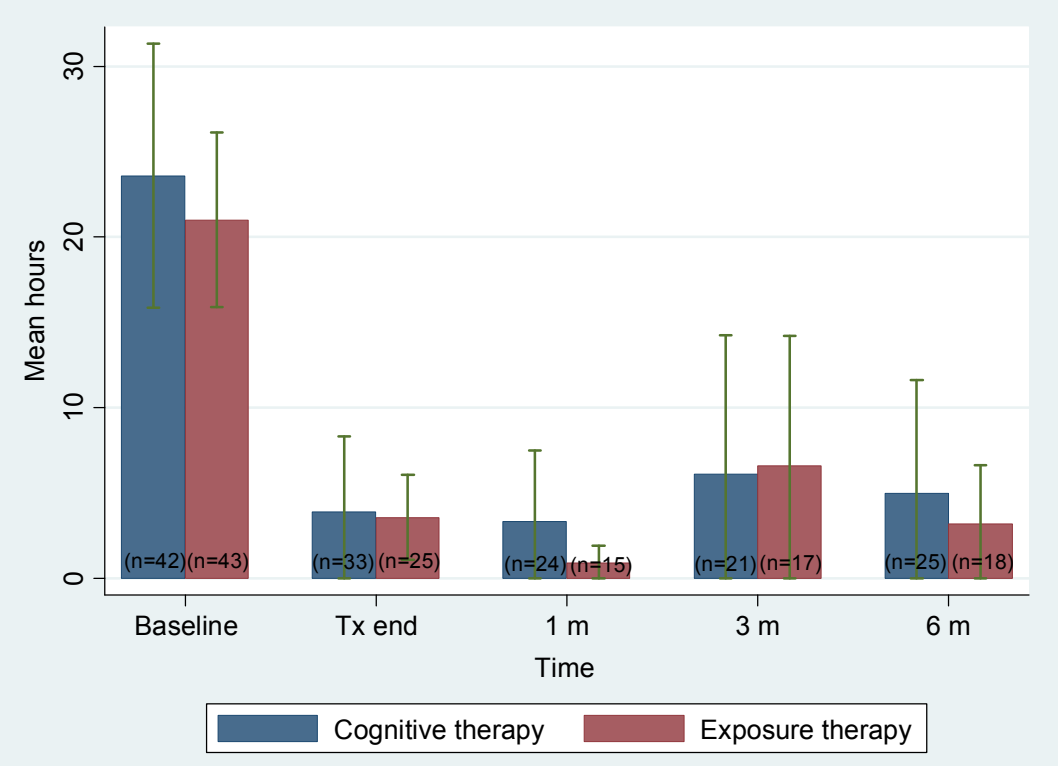
Figure 13. Observed self-efficacy scores by time and treatment group.



Higher scores indicate a greater level of confidence to control gambling behaviours.

Observed mean number of hours spent on gambling activities in previous month by treatment group and time is shown in Figure 14. Due to a sizeable right skewness of raw scores, hours was transformed using natural logarithm ($\log_e$(hours)) to provide a more normal distribution and the inverse of model estimates (exp(hours)) was then calculated for interpretation. The average number of observations per individual was 1.7 (Range, 1 - 4) and a total of 142 observations. A likelihood-ratio test comparing the mixed model with ordinary linear regression was significant for these data (χ^2 = 30.15, df = 3, $P < 0.001$). There was no significant difference between the two groups in rate of change in scores over time ($P = 0.322$). There was a statistically significant reduction (improvement) in hours gambled within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, for a one week increase in time, hours gambled decreased by 0.95 (95% CI: 0.92 – 0.98) in CT participants and 0.94 (95% CI: 0.92 – 0.96) in ET participants. The estimated random intercept standard deviation for hours was 1.82 (95% CI: 1.50 – 2.42). The mean decrease in scores per week varied with a standard deviation of 1.01 per week (95% CI: 1.00 – 1.04).

Figure 14. Observed mean hours of gaming machine use in previous month by time and treatment group.



There was no significant difference between the two groups in rate of change in DSM diagnoses over time ($P = 0.122$). There was a statistically significant reduction (improvement) in DSM diagnoses within treatment groups when controlling for baseline ($P < 0.001$). On average, for a one week increase in time, the odds of pathological gambling over the odds of non-pathological gambling decreased (improved) by a factor of 0.77 (95% CI: 0.68 to 0.87) in CT group and 0.62 (95% CI:0.49 to 0.79) in ET group. Observed number of pathological gamblers in the ET group at baseline was 43 (100%), 2 out of 22 (9.1%) at treatment-end and none out of 16 (0%) at 6 month follow-up. Observed number of pathological gamblers in the CT group at baseline was 40 out of 44 (90.9%), none out of 25 (0%) at treatment-end and 1 out of 22 (4.5%) at 6 month follow-up.

Figure 15 shows the cumulative log odds of amount spent in previous month on gaming machines from baseline to 6 month follow-up. The missing value for the log odds of being in categories above $0 at baseline for the CT group is due to the corresponding proportion being equal to 1. A similar trend for gambling frequency in previous month is shown in Figure 16 where two categories are considered: (i) log odds of the proportion of participants that gambled at least on one occasion in the previous month, and (ii) log odds of the proportion of participants who gambled more than weekly in the previous month. Results from random-intercept proportional odds models are shown in Table 14. The odds ratio of more money spent per week is 0.79 (95% CI from 0.74 to 0.83) for the CT group. The odds ratio for ET is estimated as 0.79 x 1.01 = 0.80 (95% CI from 0.76 to 0.84). There was no significant difference between treatment groups over time ($p = 0.350$).The odds ratio of more frequent gambling per week is estimated as 0.77 (95% CI from 0.72 to 0.82) for the CT group. The corresponding odds ratio for ET is estimated as 0.77 x 1.01 = 0.78 (95% CI from

0.74 to 0.83). There was no significant difference between treatment groups over time ($P = 0.448$).

Figure 15.Cumulative sample logits versus time.

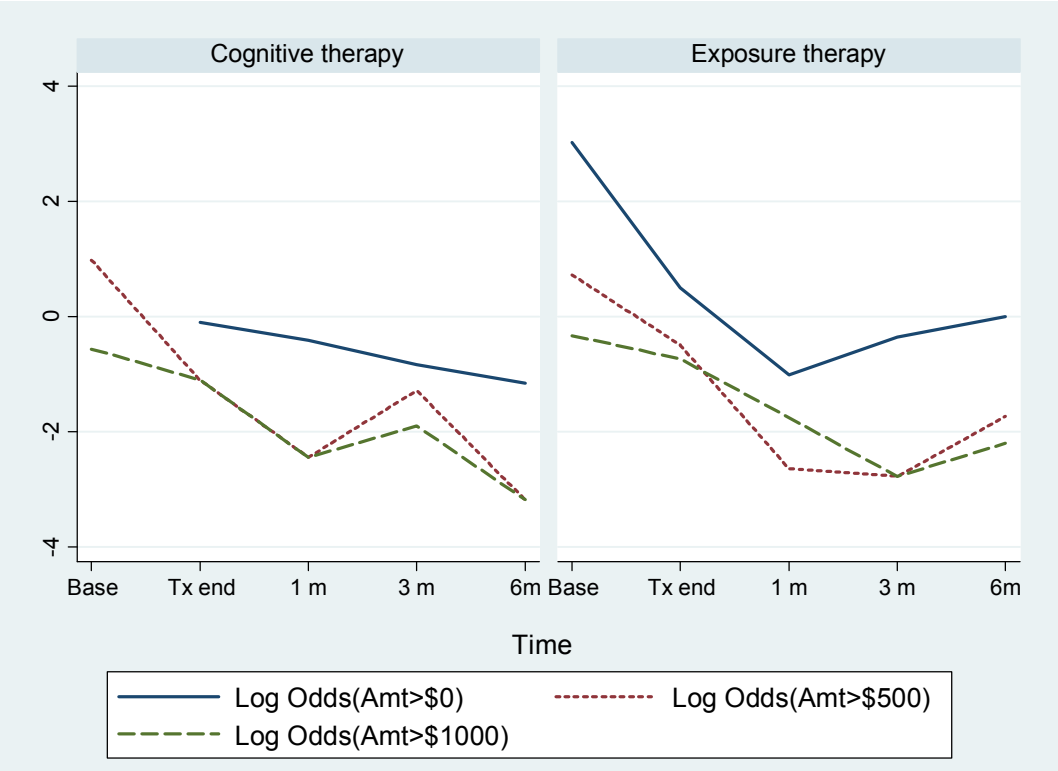


Figure 16.Cumulative sample logits versus time.

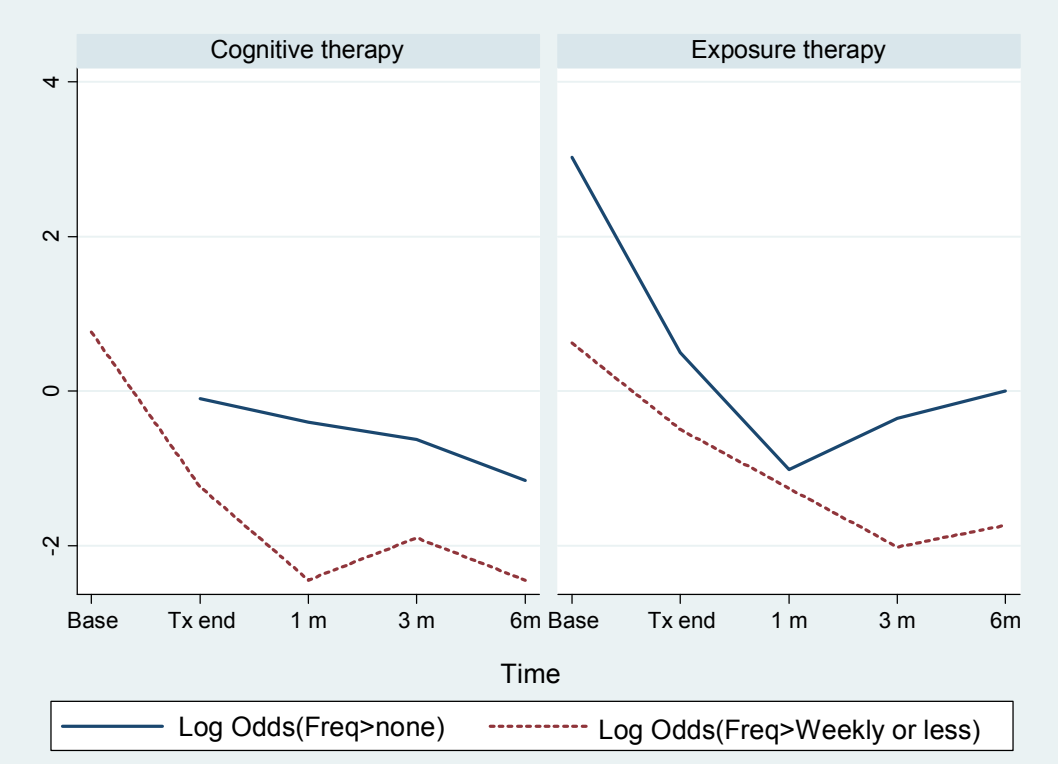


Table 14. Maximum likelihood estimates and 95% CIs for random-intercept proportional odds model of gambling behaviours.

	Gambling frequency			Amount spent		
	Estimate	95% CI	*P* - value	Estimate	95% CI	*P* -value
Fixed part: odds ratios						
Time (weeks)	0.77	0.72-0.82	< 0.001	0.79	0.74-0.83	< 0.001
Treatment[a]	1.04	0.41-2.65	0.935	1.03	0.45-2.37	0.943
Weeks X Treatment	1.01	0.98-1.05	0.448	1.01	0.98-1.04	0.349
Random part:						
Variance	1.40			1.15		

[a]Referent is cognitive therapy group

Test of mediation

Results from putative urge and cognitive mediators of the effects of ET (versus CT) on perceived self-efficacy in problem gambling are shown in Table15. The average number of responses per individual for outcome self-efficacy was 7.8 (Range: 1 – 23) and a total of 675 observations. For GRCS and GUS total score the average response per individual was 8.8 (Range: 1 – 29) and a total of 768 observations. There was no statistical evidence to support causal inferences relating to mediation effects. Firstly, the condition that treatment assignment was associated with outcome response was not met ($P = 0.853$). Secondly, treatment assignment was not associated with response to cognitive ($P > 0.05$) or urge mediators ($P = 0.716$). For the third condition, there was a significant between mediators and outcomes ($P < 0.001$) when adjusted for the interaction between treatment and time. However, it remains uncertain whether the associations are specific to mediation or the shared relationship between outcome and mediators and combined treatment group effects. Indirect effects based on the Sobel test were insignificant at $P < 0.05$. Figure17 shows results for path models examining hypothesised mediation effects of urge and interpretive bias.

Table 15. Associations between changes in urge to gamble and gambling related cognitions and improved self-efficacy[a]

	Δ Self-efficacy outcome				
	Direct effect[b]			Mediator effect[c]	
Variable	β	95% CI	*P*	*Z*	*P*
Δ Gamling urge	-0.09	-0.11, -0.62	<0.001	-0.40	0.689
Δ Gambling cognition					
Δ GE	-0.49	-0.68, -0.30	<0.001	-0.18	0.856
Δ IC	-0.52	-0.78, -0.25	<0.001	-0.03	0.979
Δ PC	-0.56	-0.79, -0.33	<0.001	-1.20	0.229
Δ IS	-0.74	-0.89, -0.58	<0.001	-1.08	0.282
Δ IB	-0.52	-0.71, -0.33	<0.001	-1.73	0.084

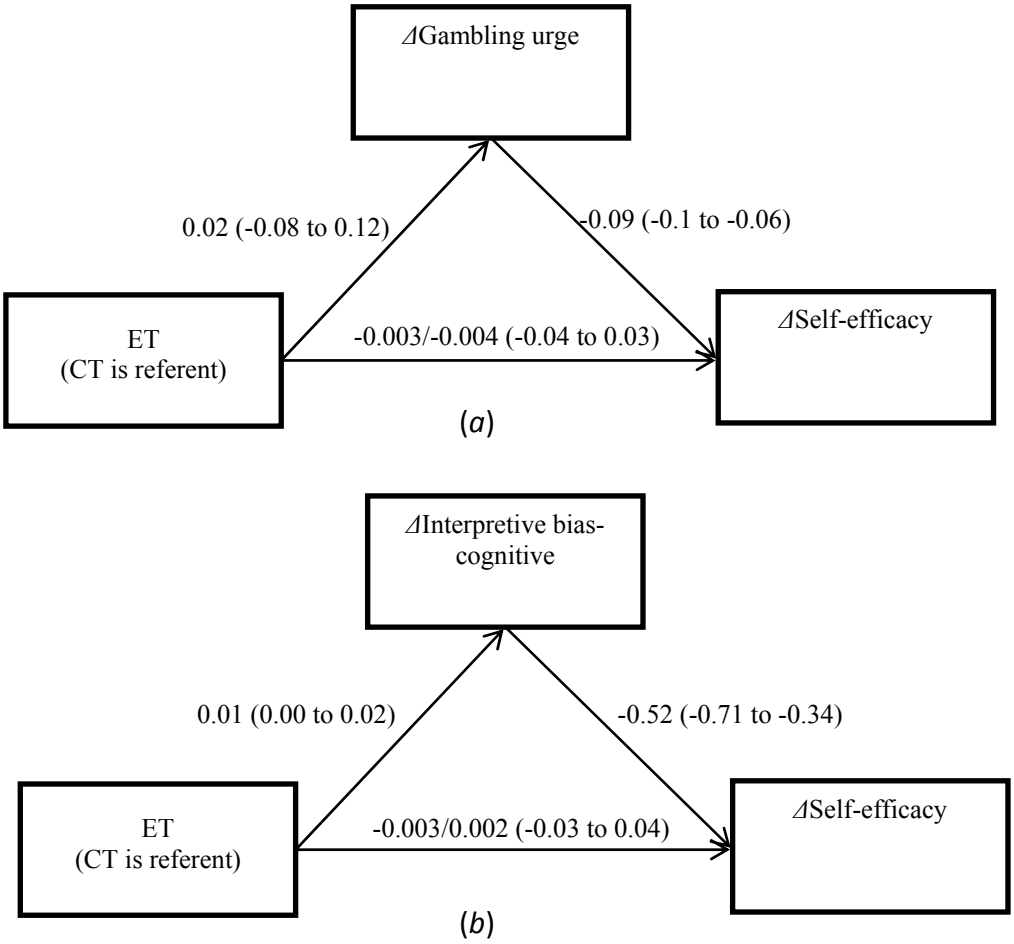
Abbreviations: GE, gambling expectancies; IC, illusion of control; PC, predictive control; IS, inability to stop gambling; IB, interpretive bias; CI, confidence interval.

[a]Results are based on mixed effects models with a single cognition or urge variable as the primary covariate, adjusting for treatment X time effect.

[b]Direct effect represents direct association between changes in cognition or urge and changes in self-efficacy.

[c]Mediator effects represent the translational effect of changes in cognition or urge on exposure therapy effects (versus cognitive therapy) on self-efficacy.

Figure 17. Hypothesised mediation paths



Urge to gamble (*a*) and cognitive- interpretive bias (*b*) putative mediators of the effects of exposure therapy (ET) on perceived self-efficacy in problem gambling. Regression coefficients (95% CI) on the right of the slash (/) represent direct effects of ET on self-efficacy after adjusting for the mediator.

9. QUALITATIVE EVALUATION AND PRELIMINARY FINDINGS

Methods

Participants
Following the treatment intervention period a sub-sample of participants were invited to take part in semi-structured interviews (87) to explore treatment specific and non-specific effects for cognitive and exposure therapies. Purposeful sampling was used to achieve equal numbers between cognitive and exposure groups and balanced on gender, therapist, distribution of treatment session numbers and time in treatment and follow-up. The initial interviewees were selected to ensure maximum variation in treatment adherence from each intervention to explore participant's experiences that ranged from treatment drop-out to treatment completion and follow-up.
Characteristics of the participants are presented in Table 16. Out of 8 interviewees, 6 had completed treatment (completers, COM) and 2 had not completed treatment (non-completers, NON).

Interviews
One-on-one interviews were planned to last for approximately one hour and conducted in person with participants. Initial interviews commenced with a 'grand tour' question "Tell me about your experiences with your gambling treatment?" Open ended questions were designed to guide interviews including "What made it easy or difficult with your gambling treatment?" and "How can treatments improve for problem gamblers?" An initial topic list was used to guide the first four interviews. The interviews were recorded using a digital voice recorder and transcribed verbatim. Each transcript was read by the study project officer and data was analysed using directed content analysis. The preliminary findings from transcripts of the first four interviews were presented for discussion to a group of researchers (n=2) and CBT therapists (n=6). The purpose of this session was to further develop the topic list and to guide selection of individuals for invitation to participate in future interviews.

Data Analysis
Using an iterative process between data collection and preliminary analyses, participants within each treatment modality were invited to participate in one-on-one interviews based on developing themes and adjusted questions. All recordings were transcribed to a Microsoft word document and then verified for consistency by the project officer and then uploaded to NVivo software for analysis. Each transcript was given equal attention and commenced with open coding as a first step to organising the data into meaningful units. The initial codes were then further conceptualised using thematic analysis to report participant's experiences with treatment (88, 89). More specifically, a deductive or 'theoretical' approach was used to identify themes in relation to treatment specific and non-specific effects. The data was organised and summarised based on what the participant said at the semantic level (88) and key preliminary findings are reported in the following section. Further interpretation of the data is to be conducted and will include the consideration of main trial results and other relevant literature. These findings will be reported in a future publication.

Findings

The preliminary findings are presented in two sections: (i) participants overall evaluation of the intervention (outcome); (ii) the thematic analysis capturing how participants experienced the intervention and its effects (process). There was considerable similarity in how participants experienced CT and ET for problem gambling. Four preliminary themes have been identified to date: (i) *Participants overall evaluation of the therapy* (ii) *How participants experienced the therapy and therapy related changes* (iii) *Experiences of the therapy specific effects for CT participants* and (iv) *Experiences of the therapy specific effects for ET participants*. The final two themes highlight the main differences between the CT and ET formats. The participants experiences with the treatment and context are illustrated with quotations, each quotation having a participant identifier indicating the therapy and compliance status (COM,NON).

Table 16. Characteristics of participants

Participant	Gender	Age	Marital status	Employment	Treatment group	Number of sessions	VGS[a]
CT01,COM	Female	47	Single	Self employed	CT	14	48
CT02,NON	Male	29	Single	Employed	CT	2	49
CT03,COM	Male	51	Single	Self-employed	CT	11	40
CT04,COM	Female	65	Married	Retired	CT	13	32
ET01,COM	Female	56	Separated	Employed	ET	11	55
ET02,NON	Female	50	Married	Employed	ET	3	47
ET03,COM	Male	51	Single	Disability support	ET	14	43
ET04,COM	Male	36	Single	Employed	ET	9	36

[a]VGS, Victorian Gambling Screen at baseline. Score of 21 or more is indicative of a problem gambler.

Participants overall evaluation of the therapy

All the interviewees who completed a CT or ET course reported that the overall experience was positive, the only variation being the degree of enthusiasm expressed.

> Like right now, six months ago I would be tied to a machine, desperate, definitely on a Friday night like now, and it was all consuming with mental obsession and now I'm actually available for life, you know, and friends and family. (CT01,COM)

> Now my financial situation is still bad, it's not great but at least I'm not going further and further down. I've had to take some drastic measures to sort of draw a line in the sand and move forward but that was only possible I think because with this treatment I was able to say no, I will stop. (ET01,COM)

Similarly, the two non-completers of therapy described aspects of their experience in a positive light such as one feeling a "lot more empowered" after each of the two

sessions he received (CT02,NON). The second non-completer described how she benefited from the initial sessions involving cash restriction planning but the exposure tasks were disconcordant with her personal goal of wanting to achieve a level of controlled gambling rather than abstinence .

> Because I was very worried if I gave up the pokies completely what else might take over and that's one of the things that was stopping me coming for the treatment as well, or help, you know, yeah, because I feel like I do have an addictive personality. (ET02,NON)

From a simplistic interpretation of the abovementioned extract it appears this person had good insight of her coping mechanisms to manage situations such as boredom with "housework… you just get itchy feet". Another interviewee described juxtaposition between gambling experiences following completion of therapy and benefits of therapy.

> So you lapse every now and again… I don't spend as much either, and I don't go in and feel better when I don't go in. Some days I drive past and I don't go in. When I don't go in I say, 'Oh, you go home and you can get some things done instead of pressing the button'. (CT04,COM)

How both ET and CT participant's experienced the intervention and therapy related changes

From the transcripts it was evident that the working alliance between therapist and participant played a facilitative role in therapy and may even be the *sine qua non* of effective intervention in some cases.

> …you know, how I got to where I was, talked through those processes. So that's an understanding as well, not that that's a pre-requisite to starting this (*therapy*) but it was good to - because it reaffirms, by me talking it through I'm also refreshing my mind of all the processes and bad habits I acquired and what were the stimuluses for making me gamble and situations, mindsets. (CT03, COM)

> Well it was just, it's good to talk to someone who, you know, totally different who's not a friend…but has had nothing to do with my outside, (*therapist's*) here to help me get over this…to me it was a care factor, it was someone who actually cared and just caring about the way she did her job. (ET03, COM)

However, at least for one individual, the alliance factor alone was not enough to continue with treatment.

> I feel like I've let her (*therapist*) down bailing out like that, because I just feel like, 'Oh she was so nice', but I really feel like it was not for me. I came to that realisation it wasn't for me all the way. (ET02, NON)

One participant described her diarising in context of a commitment to the therapist. This commitment was forged through a perception of a caring therapist and in return she is motivated to perform set exercises (CT01,COM). The practical nature of exercises is important as it provides a tangible medium to anchor the developing alliance in early phases of treatment.

Most participants highlighted the benefits of a sequentially structured therapy that specifically targeted gambling.

> Now, well then, the treatment itself, I thought that was - to me it just sort of worked well because it was very logical and I knew - and it was like a progressive - it was in stages, so like every week or two weeks, whatever we did, progressed on and slotted in, so I think it was well structured and it made sense to me. (CT03,COM)

> And just yeah, it just, getting to home and doing something 'cause look I've been to counsellors before earlier on but I didn't keep going…they weren't really dealing with the issue, whereas this, it was more dealing with the issue, it wasn't just come here, talk, rah-rah-rah, have you gambled this week, no, alright, okay bye. It was more in-depth. (ET04,COM)

> …when I was explained about the treatment, at first I thought how can this possibly work because I thought you had to go through so many psychiatric sessions…more the kind of talking about your history, what you did, why, when, was your mother bad, was your father bad, that's what I classically feel that kind of field. Whereas this was, this is your problem, let's attack your problem kind of thing. More direct I suppose to the problem itself. (ET01,COM)

The relationship between a prescribed therapy and the feeling of gaining control was evident in some transcripts. One participant described her experiences of treatment that empowered her to act independently and able to better deal with stressful situations. Her previous experiences with a group support program for problem gambling left her with the feeling that they took control (CT01,COM). Similarly, for another participant:

> …it was such a revelation of yes, I'm sitting here with this money in the bucket but I do not have the feelings I used to have when I used to be there and absolutely feel that rush and that, I want to play, I want to, you know. So that was good. It was a good feeling to sit there and feel that you are in control. (ET01,COM):

Experiences of the therapy specific effects for CT participants

A central focus of CT for problem gambling was on teaching the concept of randomness, increasing awareness of inaccurate perceptions and restructuring erroneous gambling beliefs. Categories of gambling related cognitions include illusion of control, predictive control and interpretative bias. It was evident from the transcripts that CT completers had experienced therapeutic change in gambling related cognitions. One participant described symptom change in terms of reframing gambling outcomes that would encourage continued gambling despite losses (interpretive bias).

> What this therapy did was show me in truth and in fact what gambling did to me, what it means, the fact that I will always lose really, ultimately I lose when I play, with the illusion of sometimes winning, even when I win I'd lose. (CT01,COM)

Increased cognitive awareness using the ABCD (situation, thoughts, behaviour, consequences) model and exercises to focus on the gambling thoughts or 'inner dialogue' was evident from another participant.

> Yeah, the strategies, you know, like she was saying 'You have to be able to recognise what's a gambling thought and what's not a gambling thought'. Before, I used to drive

past the casino and I used to go, 'Oh I'll stop and play' and now I say to myself, 'Oh do you really want to go and play? Are you really thirsty?' So you actually question your ideas of why you want to go in there. So I do that a lot more. (CT04,COM)

For two participants, a developed insight of the independence of random events was attributed to an activity involving a jar of marbles (all one colour/size apart from one distinct marble) and drawing one at a time with replacement. Clients were asked to determine the probability of an event based on different scenarios e.g. what are your chances of drawing the red one? This was repeated on a number of occasions to ensure the client saw the pattern.

Oh I think - the bag of marbles with the black on it or whatever, or the red - getting the home truth about the difference between talent and skill and what chance is really about, and having your nose rubbed in that, that's a good starting point. (CT03,COM)

And it does - yeah that's how it works, and the thing is it doesn't mean that - you know, before you're playing the machine saying, 'Well it's got to come up, it's got to come up' in your mind - that's what you say to yourself. You know, 'I've put in $50 into this machine, it must give me some free games in a minute', but now I know it doesn't happen. (CT04, COM)

The CT participants were asked to keep a diary each week to provide them with a prop to help describe any situations that triggered desire to gamble and how each of these situations was managed. If the client reported that they had gambled, it provided an opportunity for the therapist and client to discuss specific gambling thoughts and how these influenced their behaviour. One participant who did not complete treatment found that keeping a diary was difficult.

Well I wasn't filling out the diary like I should have been. I'm exceptionally poor with time management at the best of times, yeah, and then actually finding the time, which wouldn't be hard because it's really only 10 minutes a day but actually prioritising it and getting myself organised, was definitely a major issue. (CT02,NON)

Experiences of the therapy specific effects for ET participants

Exposure therapy was based on the theory that problem gambling is the result of the development of a psychophysiological "urge" to gamble in response to environmental triggers or cues. The theoretical mechanism of behavioural therapy is de-conditioning of the urge using exposure to gambling cues, and response prevention (resisting gambling) which results in habituation of the urge within a session and ultimately extinguishing of the urge if the exposure task is repeated. In terms of symptom change, the identification and reduction of urge 'feelings' was central for interviewees that completed ET.

…yeah, it's a strange, yeah. Once you've got that urge being a gambler, it controls you more than anything else. You thought I was always going with it, whereas now the urge isn't there, I've just, I've lost interest, it's just nothing, it doesn't, hasn't got that magnet to it to pull me in anymore. (ET03,COM)

So once I started doing those exercises and identifying those feelings, it was – it's almost like if you've ever felt like making an example say with something else, you say I really, really love chocolate cake – let's say chocolate cake right – and you have a feeling oh I want… and you can almost taste that chocolate cake and you want it so bad you imagine it, you picture it and this and that and your body is telling you, you really

> want it. Then your body is going through some kind of other feelings other than just in your head if you know what I mean. You almost feel hungry, you almost… well that's the kind of thing that you know, that I identified going through the exercise in the treatment because it was bit by bit looking at the picture, listening to the sounds bringing you there and then almost that feeling that you are there and what you feel. I actually think that was more a help than anything else, the identification of those symptoms if you like. (ET01,COM)

One ET participant who attended the first two therapy sessions only found the cash restriction plan to be helpful.

> But now we've put a plan into place where it's going to work and it has been working which, going to that therapy did help with that side of things, whereas I'm giving him my ATM card the night before I get paid and then when I get paid he takes me down and we pay the bills I have to pay on my side. (ET02,NON)

During the second ET session, participants were introduced to imaginal exposure exercises where they were taught to evoke gambling related thoughts and sensations using a picture of their favourite EGM and gaming machine music. For the abovementioned person, the imaginal exposure task was the turning point for her in deciding not to return to treatment.

> Oh I've seen it a couple of times, it's in the drawer and I think, 'Oh yeah, that picture again', but yeah, it doesn't make me get the urge to go to the pokies and it doesn't get me bored of looking at it, it's just, 'Oh yeah, that's my favourite machine', because that's what she gave me a picture of, the favourite one that I play, she did it that way so that you get bored with looking at it so you won't play that one, yeah. But the only reason I play that particular one is because I know the games come up more often, it seems they do anyway, yeah. (ET02,NON)

One treatment completer identified the *in-vivo* or 'live' task as more logical than the imaginal exposure task. The live task involved the client going to different venues that were familiar gambling locations and doing exposure exercises such as sitting in front of a gaming machine and placing a few coins in the machine without gambling.

> Pretty hard to run it from the lounge room or the car but you'd find that the circumstances and the urges don't come from the office, they actually - and I'm here for the problem but they don't get replicated here. (ET04,COM)

Another participant who described benefits from both imaginal and *in-vivo* exercises offered the following insight about potential drop-out in the early stages of treatment where the person is first introduced to exposure tasks.

> That's one thing I can see and I don't know how you could fix that but I could see some people dropping off at a one, two session or whatever, not allowing themselves to fully understand and to get to that stage of identifying the feelings and all that kind of thing where it starts to actually make a difference. (ET01,COM)

She described her mind as being clearer as treatment progressed in terms of understanding the logic of treatment tasks.

Together these participant comments demonstrate the strengths of both approaches, and the hypothesised links between the aetiological and therapeutic models. Barriers to engagement in therapy were identified, as were the complex motivations for people

wanting to give up a gambling problem competing with their perceived benefits of maintaining this lifestyle and behaviour.

10. DISCUSSION

This randomised controlled trial recruited treatment seeking people with moderate to severe gambling problems and often complex co-morbidities. The study is the first internationally to successfully isolate cognitive from behavioural (imaginal and live graded exposure) treatment techniques in a randomised trial. For the primary outcome measure, the Victorian Gambling Screen (VGS), there was a significant decrease (improvement) in scores over time for both groups based on all available data ($P < 0.001$) with no significant difference between groups ($P = 0.477$). There was a clinically meaningful reduction (improvement) in gambling related cognitions over time in both treatments ($P < 0.001$), but no significant differences were found between groups ($P = 0.806$). Similarly, there was a significant reduction in gambling urge for each treatment group ($P < 0.001$), but no differential treatment effects between groups ($P = 0.463$). This suggests that both behavioural and cognitive techniques have potential mediating effects within their own and the alternative therapeutic modality. Secondary measures of gambling related behaviours, psychological distress, work and social functionality, and alcohol consumption improved substantially across time, but there was no statistically significant or clinically meaningful difference between groups. For both groups, there was also a clinically significant reduction in the rate of DSM-IV diagnoses of pathological gambling from baseline to treatment end and 6 month-follow-up.

To gain a better understanding of processes of therapeutic change for cognitive and exposure therapies, we conducted in-depth semi-structured interviews with 8 participants. Preliminary analyses identified themes concerning barriers and motivators experienced in both treatments. As with other psychotherapy research, the importance of therapist participant relationship was identified. Practical issues in the delivery of therapy and the importance of individual preferences in the uptake of specific therapy techniques was demonstrated. This has important implications for combining different components of CT and ET and a sequential structure that will maximise treatment uptake, adherence and therapeutic change in the short and long term.

The objectives of this pilot randomised controlled trial were to establish high quality recruitment methods, treatment techniques and manuals, research protocols, data collection methods and preliminary data in preparation for applications to national or international funding bodies for a phase III randomised controlled trial in the field of problem gambling practice and research. This has been achieved.

Strengths and limitations

The outcome data collected in this study covered the domains of gambling behaviours, problems caused by gambling, and mechanisms of change. The robust implementation of randomisation was demonstrated by the similarity in group characteristics on potential confounding variables at study screening and baseline demographic and clinical characteristics of treatment starters. The preliminary findings of qualitative interviews are the first to explore the individual's perspective of cognitive or exposure therapy in a randomised trial.

The design of this trial was guided by ethical considerations in line with the community service commitment of the Statewide Gambling Therapy Service. Therefore, a key strength of this study was that all treatment seeking problem gamblers meeting eligibility criteria received an active treatment. Also, due to the broad study inclusion criteria, a significant proportion of the sample had co-occurring gambling-related problems (e.g. psychological distress) and this enhanced the external validity of findings using an intent-to-treat design.

One of the main limitations of this study was loss of power due to an under representative sample size. Our *a priori* sample size estimation was 130. However, 99 problem gamblers were recruited and randomised and 87 received an intervention. This incomplete uptake of trial interventions meant that randomised groups potentially had more similar experiences than intended, and resulted in outcome differences to be smaller than if there was better uptake. This was compounded by missing data and may have resulted in Type II error where the null estimated differences were biased. Although the loss of power could not be reversed, we minimised the effects by using an appropriate analysis (linear mixed modelling) where all observed data were included in the analysis.

A further limitation of the study design was no control group to account for non-specific treatment effects. However, a reasonable assumption was made that non-specific effects would be approximately similar between study groups due to analogous therapy structures, therapist background and experience, and therapeutic environment. Also, outcome data were collected from self-report measures and therefore participants may have overestimated treatment effects. Because there was a high degree of uncertainty for differential treatment effects and blinding of participants to study hypothesis, the likelihood of bias in self-ratings was expected to be minimised. Finally, as this study was conducted at a single-site the findings are limited in terms of inference to a wider population. On the other hand, benefits of this single-site study have included more effective lines of communication and a more consistent application of research protocol as demonstrated by the high quality implementation of study methods such as randomisation, data collection, and therapist adherence to treatment protocol.

Research implications and clinical translation

This trial was funded, due to a limited gambling treatment evidence-base, to inform the design of a phase III trial to estimate the relative efficacy of core CBT components and a combination of these against a standard treatment such as general counselling. This is the first randomised 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 has provided high quality evidence to contribute to the development of more optimal combination of cognitive-behavioural therapies. A CBT manual has been trialled with current SGTS clients, with the aim of improving treatment adherence rates and treatment efficacy. The aim of the combined approach is not to synthesise the two approaches but to mutually enhance therapeutic impact. A combination of CT and behavioural (exposure-based) therapy (BT) is also hypothesised to be more conducive to treatment retention due to the higher degree of

treatment flexibility. The combined therapy is based on a parsimonious approach while aiming to provide the same therapist and patient contact time as the core components.

No previous randomised trials have compared the combination of cognitive and behavioural (exposure) therapies (BT) with purely cognitive and exposure therapy on their own in the field of problem gambling. Findings from this pilot trial will provide high quality data to inform the design of a study to answer questions such as: would participants receiving CT, BT, and CBT show a greater clinically meaningful reduction in problem gambling severity than those receiving treatment as usual? And, would participants receiving CBT show a greater improvement than those receiving BT and CT?

11. REFERENCES

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (4th Edition, Text Revision). 4th ed. Washington DC2000.
2. Potenza MN. Should addictive disorders include non-substance-related conditions? Addiction. 2006;101(s1):142-51.
3. Saunders JB, Cottler LB. The development of the Diagnostic and Statistical Manual of Mental Disorders version V substance use disorders section: establishing the research framework. Curr Opin Psychiatry. 2007;20:208-12.
4. Petry NM, Hodgins DC. An introduction to Addiction's new series on gambling. Addiction. 2012;107(6):1034-5.
5. 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.
6. Bondolfi G, Osiek C, Ferrero F. Prevalence estimates of pathological gambling in Switzerland. Acta Psychiatr Scand. 2000;101(6):473-5.
7. Delfabbro P. Australasian Gambling Review: Independent Gambling Authority of South Australia2009.
8. 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.
9. Wardle H, Sproston K, Orford J, Erens B, Griffiths MD, Constantine R, et al. The British Gambling Prevalence Survey. London: The Stationery Office 2007.
10. Wong ILK, Ernest MTS. Prevalence estimates of problem and pathological gambling in Hong Kong. The American Journal of Psychiatry. 2003;160(7):1353.
11. 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).
12. Hodgins DC, Stea JN, Grant JE. Gambling disorders. The Lancet. 2011;378(9806):1874-84.
13. 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.
14. Jackson A, Thomas S, Blaszczynski A. Best practice in problem gambling services. Melbourne: Gambling Research Panel2003.
15. 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.
16. Problem Gambling Research and Treatment Centre (PGRTC). Guideline for screening, assessment and treatment in problem gambling: Clayton:Monash University2011.
17. 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.
18. 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.
19. Raylu N, Oei T. The Gambling Related Cognitions Scale (GRCS): development, confirmatory factor validation and psychometric properties. Addiction. 2004;99(6):757-69.

20. Gadboury A, Ladouceur R. Erroneous perceptions and gambling. Journal of Social Behavior & Personality. 1989;4 (4):411-20.
21. Cowlishaw S, Merkouris S, Dowling N, Anderson C, Jackson A, Thomas S. Psychological therapies for pathological and problem gambling. The Cochrane Library. 2012.
22. Beck AT, Dozois DJA. Cognitive Therapy: Current Status and Future Directions. Annu Rev Med. 2011;62(1):397-409.
23. 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.
24. 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.
25. Tolchard B, Thomas L, Battersby MW. Single-Session Exposure Therapy of Problem Gambling: A Single Case Experimental Design. Behaviour Change. 2006;23(2):148-55.
26. Brown RIF. Classical and Operant Paradigms in the Management of Gambling Addictions. Behavioural Psychotherapy. 1987;15(2):111-22.
27. Nemeroff CB, Bremner JD, Foa EB, Mayberg HS, North CS, Stein MB. Posttraumatic stress disorder: a state-of-the-science review. J Psychiatr Res. 2006.
28. Ougrin D. Efficacy of exposure versus cognitive therapy in anxiety disorders: systematic review and meta-analysis. BMC Psychiatry. 2011;11:200.
29. Carlbring P, Jonsson J, Josephson H, Forsberg L. Motivational interviewing versus cognitive behavioral group therapy in the treatment of problem and pathological gambling: A randomized controlled trial. Cogn Behav Ther. 2010;39(2):92.
30. Dowling N. Treatment of Female Pathological Gambling: The Efficacy of a Cognitive-Behavioural Approach. J Gambl Stud. 2006;22(4):355.
31. Raylu N, Oei TP. A cognitive behavioural therapy programme for problem gambling: Therapist manual. Behav Cogn Psychother. 2012;40:504-7.
32. Petry NM, Ammerman Y, Bohl J, Doersch A, Gay H, Kadden R, et al. Cognitive-behavioral therapy for pathological gamblers. J Consult Clin Psychol. 2006;74(3):555-67.
33. 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.
34. Sylvain C, Ladouceur R, Boisvert JM. Cognitive and behavioral treatment of pathological gambling: a controlled study. J Consult Clin Psychol. 1997;65(5):727-32.
35. McConaghy N, Armstrong MS, Blaszczynski A, Allcock C. Controlled comparison of aversive therapy and imaginal desensitization in compulsive gambling. Br J Psychiatry. 1983 Apr;142:366-72.
36. McConaghy N, Armstrong MS, Blaszczynski A, Allcock CC. Behavior completion versus stimulus control in compulsive gambling: Implications for behavioral assessment. Behav Modif. 1988 Jul;12(3):371-84.
37. McConaghy N, Blaszczynski A, Frankova A. Comparison of imaginal desensitisation with other behavioural treatments of pathological gambling: A two- to nine-year follow-up. Br J Psychiatry. 1991 Sep;159:390-3.

38. Jacobson NS, Dobson KS, Truax PA, Addis ME, Koerner K, Gollan JK, et al. A Component Analysis of Cognitive-Behavioral Treatment for Depression. J Consult Clin Psychol. 1996;64(2):295-304.
39. Sackett D, Rosenberg W, Gray J, Haynes R, Richardson S. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312(7023):71-2.
40. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. Br Med J. 2010;340:c869.
41. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the Quality of Reporting of Randomized Controlled Trials: The CONSORT Statement. Journal of the American Medical Association. 1996;276(8):637-9.
42. Plint A, Moher D, Morrison A, Schulz K, Altman D, Hill C, et al. Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. Med J Aust. 2006;185(5):263-7.
43. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. BMC Med Res Methodol. 2001;1(2).
44. Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. BMJ. 2004;328(7441):702-8.
45. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW, Group ftC. Reporting of Noninferiority and Equivalence Randomized Trials: An Extension of the CONSORT Statement. Journal of the American Medical Association. 2006;295(10).
46. 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.
47. Higgins J, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011] 2011. Available from: www.cochrane-handbook.org. .
48. Echeburua E, Baez C, Fernandez-Montalvo J. Comparative Effectiveness of ThreeTherapeutic Modalities in the Psychological Treatment of Pathological Gamblers: Long-term Outcome. Behav Cogn Psychother. 1996;24:51-72.
49. Melville KM, Casey LM, Kavanagh DJ. Psychological treatment dropout among pathological gamblers. Clin Psychol Rev. 2007;27(8):944-58.
50. Leung KS, Cottler LB. Treatment of pathological gambling. Curr Opin Psychiatry. 2009;22(1):69-74.
51. Shaffer HJ, Martin R. Disordered Gambling: Etiology, Trajectory, and Clinical Considerations. Annual Review of Clinical Psychology. 2011;7(1):483-510.
52. Toneatto T, Millar G. Assessing and treating problem gambling: empirical status and promising trends. Can J Psychiatry. 2004;49(8):517-25.
53. 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.
54. Stinchfield R. Reliability, validity, and classification accuracy of the South Oaks Gambling Screen (SOGS). Addict Behav. 2002;27(1):1-19.
55. 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.

56. Australian Bureau of Statistics. Population by Age and Sex, Regions of Australia. Available at: http://wwwabsgovau/ausstats/abs@nsf/Products/32350~2011~Main+Features~South+Australia?OpenDocument#PARALINK6 (accessed 28 March 2013). 2011.
57. 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.
58. StataCorp. Stata: Release 11. Statistical Software. College Station, TX: StataCorp LP; 2009.
59. Frison L, Pocock SJ. Repeated measures in clinical trials: analysis using mean summary statistics and its implications for design. Stat Med. 1992;11(13):1685-704.
60. Petry NM. Disordered Gambling and Its Treatment. Cognitive and Behavioral Practice. 2009;16(4):457-67.
61. Ladouceur R, Sylvain C, Letarte H, Giroux I, Jacques C. Cognitive treatment of pathological gamblers. Behav Res Ther. 1998;36(12):1111-9.
62. Tolchard B, Thomas L, Battersby M. Single-Session Exposure Therapy of Problem Gambling: A Single Case Experimental Design. Behaviour Change. 2006;23(2):148-55.
63. Ladouceur R, Lachance S. Overcoming Pathological Gambling: Therapist Guide: Oxford University Press; 2007.
64. Miller LE, Stewart ME. The blind leading the blind: Use and misuse of blinding in randomized controlled trials. Contemp Clin Trials. 2011;32(2):240-3.
65. Young J, Beck AT. Cognitive Therapy Scale: Rating manual. Unpublished manuscript, University of Pennsylvania, Philadelphia. 1980.
66. Arnett J. Sensation seeking: A new conceptualization and a new scale. Personality and Individual Differences. 1994;16:289-96.
67. Nower L. The Relationship of Impulsivity, Sensation Seeking, Coping, and Substance Use in Youth Gamblers. Psychol Addict Behav. 2004;18(1):49.
68. Roth M. Validation of the Arnett Inventory of Sensation Seeking (AISS): efficiency to predict the willingness towards occupational chance, and affection by social desirability. Personality and Individual Differences. 2003;35:1307-14.
69. Ben-Tovim D, Esterman A, Tolchard B, Battersby MW. The Victorian Gambling Screen: Project report. Melbourne: Victorian Research Panel2001.
70. Tolchard B, Battersby M. The Victorian Gambling Screen: reliability and validity in a clinical population J Gambl Stud. 2010;26:623-38.
71. McMillen J, Wenzel M. Measuring problem gambling: Assessment of three prevalence screens. International Gambling Studies. 2006;6(2):147-74.
72. Smith DP, Pols RG, Battersby MW, Harvey PW. The Gambling Urge Scale: Reliability and validity in a clinical population. Addiction research & theory. 2013;21(2):113-22.
73. Raylu N, Oei T. The Gambling Urge Scale: Development, confirmatory factor validation, and psychometric properties. Psychol Addict Behav. 2004;18(2):100-5.
74. Andrews G, Slade T. Interpreting scores on the Kessler psychological distress scale (K10). Aust N Z J Public Health. 2001;25:494-7.
75. Slade T, Grove R, Burgess P. Kessler Psychological Distress Scale: normative data from the 2007 Australian National Survey of Mental Health and Wellbeing. Aust N Z J Psychiatry. 2011;**45**:308–16.

76. 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.
77. Reinert D, Allen J. The Alcohol Use Disorders Identification Test (AUDIT): A review of recent research. Alcoholism: Clinical and Experimental Research. 2002;26(2):272-9.
78. Edwards P, Roberts I, Clarke M, DiGuiseppi C, Pratap S, Wentz R, et al. Increasing response rates to postal questionnaires: systematic review. Br Med J. 2002 May 18, 2002;324(7347):1183-47.
79. StataCorp. Stata: Release 12. Statistical Software. College Station, TX: StataCorp LP; 2011.
80. Skrondal A, Rabe-Hesketh S. Multilevel logistic regression for polytomous data and rankings. Psychometrika. 2003;68(2):267-87.
81. White IR, Kalaitzaki E, Thompson SG. Allowing for missing outcome data and incomplete uptake of randomised interventions, with application to an internet-based alcohol trial. Stat Med. 2011;30(27):3192-207.
82. 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.
83. Gueorguieva R, Krystal JH. Move Over ANOVA: Progress in Analyzing Repeated-Measures Data and Its Reflection in Papers Published in the Archives of General Psychiatry. Arch Gen Psychiatry. 2004;61(3):310-7.
84. 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.
85. MacKinnon D. Introduction to statistical mediation analysis. New York: Erlbaum/Psychology Press; 2008.
86. White IR, Horton NJ, Carpenter J, Pocock SJ. Strategy for intention to treat analysis in randomised trials with missing outcome data. Br Med J (Clin Res Ed). 2011;342.
87. Crabtree B, DiCicco-Bloom B. The qualitative research interview. Med Educ. 2006;40:314-21.
88. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3:77-101.
89. Hsieh H-F, Shannon SE. Three Approaches to Qualitative Content Analysis. Qual Health Res. 2005 November 1, 2005;15(9):1277-88.

12. APPENDIX I: ACTIVITIES AND TIMELINE FOR THE RESEARCH GRANT

August 2010 to March 2011

Activities	Aug 2010	Sept	Oct	Nov	Dec	Jan 2011	Feb	Mar
Date of commencement on RCT contract 30th September 2010								
Signing off and therefore commencement of funding		30th Sept						
Stage 1: Developmental phase								
Project reference group – meetings.								
Literature search and review of cognitive behavioural treatments in problem gambling								
Obtain ethics approval for RCT		**Approval Period: 09th September 2010 to 09th September 2013**						
Cognitive Therapist				Advertise position	Interviews & recruit	Finalise with HR	Commence contract	
Robert Ladouceur visit - Cognitive therapist training and manual modification for individual therapy							Feb 14th-18th	
Progress report					Due Wed 22nd			Due Wed 30th
Detailed project plan and written evidence of ethics approval to Department of Justice					Due wed 22nd			

April 2011 to November 2011

Activities	April 2011	May	June	July	Aug	Sep	Oct	Nov 2011
Recruitment and intervention for RCT	Starts Fri April 1st →							Recruitment & intervention continues
Follow-up assessments: Mid- treatment = 4 weeks End of treatment = 8 to 12 weeks	Mid-treatment	Mid and end of treatment	Mid and end of treatment	Mid and end of treatment	Mid & end of treatment & 3m	Mid & end of treatment & 3m	Mid & end of treatment & 3m	Mid & end of treatment & 3, 6m
Follow-up of incomplete assessments								
Participant $50 vouchers								
Progress report			Due Thurs 30th			Due Fri 30th		
Project Reference Group – meetings.								

December 2011 to July 2012

Activities	December 2011	Jan 2012	Feb	Mar	April	May	June	July 2012
Recruitment and intervention for RCT	Recruitment & intervention continues			Recruitment finishes Fri. 30th Intervention continues	→	→	Completion of intervention Fri 29th	
Follow-up assessments	Mid and end of treatment & 3 , 6 months	Mid and end of treatment & 3 , 6 months	Mid and end of treatment & 3 , 6 months	Mid and end of treatment & 3 , 6 months	Mid and end of treatment & 3 , 6 months	End of treatment & 3 , 6, 12 months	End of treatment & 3 , 6, 12 months	3, 6 & 12 months.
Follow-up of unreturned questionnaires								
12 m f/up thank you letters to study participants								
Participant $50 vouchers								
Progress report	Due Fri 30th			Due Fri 30th			Due Fri 29th	
Project Reference Group – meetings.								

August 2012 to March 2013

Activities	August 2012	Sept	Oct	Nov	Dec	Jan 2013	Feb	Mar 2013
Follow-up assessments	3, 6 & 12 months.	3, 6 & 12 months.	6 & 12 months.	6 & 12 months.	6 months & 12 months* + final f\up for 8-10 months** Final follow-up mail out **Fri 21st**			
Follow-up of unreturned questionnaires						Last day for return of final questionnaire **Fri 11th**		
12 m f/up thank you letters to study participants								
Progress report		Due Fri 28th						
Commence data collation/analysis & report writing						Commence →		Complete
Submit draft report and journal article for Department to review, provide comments and receive back from us								Fri 29th March
Project Reference Group –meetings.								

* Participants recruited before Nov 30th 2011 i.e. follow-up approx. ≥ 11 months
** Participants recruited after Nov 30th 2011 and before February 28th 2012 i.e. 8 months ≤ final follow-up < 11 months

April 2013 to Dec 2013

Activities	April 2013	May	June	July	Aug	Sep	Oct	Nov/Dec 2013
Acceptance of final report and journal article by the Victorian Responsible Gambling Foundation			Fri 28th June					
Acquittal of project								30th Dec
Project Reference Group – meetings.								