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Smith DP, Battersby MW, Harvey PW, Pols RG and Ladouceur R (2015) Cognitive versus exposure therapy for problem gambling: Randomised controlled trial. Behaviour Research and Therapy 69(0): 100-110, doi http://dx.doi.org/10.1016/j.brat.2015.04.008,

Title

Cognitive versus exposure therapy for problem gambling: randomised controlled trial

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Declaration of interest
This work was funded by the Victorian Department of Justice, Office of Gaming & Racing (tender 061/09), and management of the grant was transferred to the Victorian Responsible Gambling Foundation in July 2012. The SGTS is funded by the Office of Problem Gambling, Department of Families and Social Inclusion, Government of South Australia. The authors have no other conflicts of interest to declare.

Abstract

Background Problem gambling-specific cognitive therapy (CT) and behavioural (exposure-based) therapy (ET) are two core cognitive-behavioural techniques to treating the disorder, but no studies have directly compared them using a randomised trial.

Aims To evaluate differential efficacy of CT and ET for adult problem gamblers at a South Australian gambling therapy service.

Methods Two-group randomised, parallel design. Primary outcome was rated by participants using the Victorian Gambling Screen (VGS) at baseline, treatment-end, 1, 3, and 6 month follow-up.

Findings Of eighty-seven participants who were randomised and started intervention (CT=44; ET=43), 51 (59%) completed intervention (CT=30; ET=21). Both groups experienced comparable reductions (improvement) in VGS scores at 12 weeks (mean difference -0.18, 95% CI: -4.48 to 4.11) and 6 month follow-up (mean difference 1.47, 95% CI: -4.46 to 7.39).

Conclusions Cognitive and exposure therapies are both viable and effective treatments for problem gambling. Large-scale trials are needed to compare them individually and combined to enhance retention rates and reduce drop-out.

Keywords: Problem gambling, cognitive therapy, exposure therapy, randomised controlled trial.

Introduction

Maladaptive gambling behaviour is harmful to individuals, families, and communities with consequences including financial ruin, broken marriages, problems with the law, depression, anxiety and suicide. There is an urgent need to identify and develop effective treatments for problem gambling that are consistent with the inclusion of Gambling Disorder as an addiction in DSM-5 (American Psychiatric Association, 2013). The current evidence-base for gambling treatments suggests that psychological interventions, mainly variations of cognitive behavioural therapy (CBT), are the most promising (Cowlishaw et al., 2012).

The theoretical underpinnings of CBT include cognitive and psychobiological processes which are the basis of two dominant approaches to explaining decision-making during gambling (Clark, 2010). Cognitive therapy (CT) for problem gambling focuses on teaching the concept of randomness, increasing awareness of inaccurate perceptions and restructuring erroneous gambling beliefs (Ladouceur et al., 2001). Treatments that target gambling related psychobiological states (e.g. the "urge" to gamble) are predominantly behavioural (exposure-based) (Battersby, Oakes, Tolchard, Forbes, & Pols, 2008; Oakes, Battersby, Pols, & Cromarty, 2008; Tolchard, Thomas, & Battersby, 2006). Of the few randomised trials that have investigated behavioural (exposure-based) techniques for disordered gambling over the past 30 years none have attempted to isolate and compare their efficacy with pure cognitive therapy (Grant et al., 2009; McConaghy, Armstrong, Blaszczynski, & Allcock, 1983; McConaghy, Blaszczynski, & Frankova, 1991). It is important to dismantle combined CBT approaches to determine if each core component can be delivered independently and if one is more efficacious than the other. This has major clinical and policy implications if single modalities can be as efficacious and delivered in less time than combined approaches.

Therefore, in this randomised controlled trial, the research question we addressed was: Among treatment seeking problem gamblers can exposure therapy alone improve gambling related outcomes across intervention period and 6-month follow-up compared with cognitive therapy alone? The broader aims of the study were to establish whether exposure and cognitive therapy for problem gambling could be isolated, manualised and administered in a reliable and consistent manner across therapists whilst maintaining fidelity. As a phase II study, it would provide the basis for a phase III randomised trial comparing cognitive, exposure and combined cognitive and exposure therapy to assess the relative benefits of the individual and combined elements of CBT and determine underlying mechanisms of change.

Methods

Study design and participants

A detailed description of the study protocol has been published elsewhere (Smith, Battersby, Harvey, Pols, & Ladouceur, 2013). Comparing outcomes of cognitive and exposure therapy for problem gamblers was conducted using a two-group randomised, parallel design, with outcomes assessed up to 9 months after randomisation for treatment seeking problem gamblers. The study site was the Statewide Gambling Therapy Service (SGTS) in South Australia. The service offers free mental health and cognitive-behavioural treatment for help-seeking problem gamblers in key geographical areas. We recruited 99 participants from consecutive new outpatients attending SGTS Flinders site in South Australia between April, 2011 and April, 2012, and completed outcome data collection January, 2013.

To assess study eligibility, an independent clinician conducted semi-structured interviews by telephone with treatment seeking problem gamblers who contacted SGTS during the recruitment

period. The interview comprised of an assessment of demographic data, recent gambling activities, and administration of the well-validated South Oaks Gambling Screen (SOGS) as a screening questionnaire (Lesieur & Blume, 1987). The SOGS is a 20 item questionnaire based on DSM criteria for pathological gambling using a binary response method. It has previously been used in a population-based cross-sectional study of South Australian adults when administered by telephone (Gill, Dal Grande, & Taylor, 2006). A score of 5 or more is indicative of probable pathological gambling. In gambling treatment samples the scale has good reliability, exhibits high correlations with DSM-IV diagnostic criteria, and good to excellent classification accuracy (Stinchfield, 2002).

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; gambled in the past month using EGM's without any psychological treatment for problem gambling in the previous 12 months; willing to: participate in the study; to read and respond to self-rated questionnaires written in English; be randomised to one of two psychological treatments; provide follow-up data; have treatment sessions audio recorded; as well as scoring 5 or greater on the SOGS; and not suicidal, exhibiting acute psychosis or mania or experiencing significant mental distress such that the problem gambler would not be able to participate fully in the treatment offered or research procedures. Patients were not excluded if they exhibited co-morbid anxiety disorders, depression, personality disorders or drug and alcohol abuse.

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.

Randomisation

Eligible individuals were randomly assigned to one of two treatment groups with 1:1 allocation ratio before their pre-treatment assessment with a therapist. 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. Stratification variables were age, gender and SOGS scores for gambling severity. Based on previous SGTS data, age was stratified as 18 - 42 years, and 43 years or more (Smith et al., 2010). Recent population data for South Australia showed a median age of 39.5 years (Australian Bureau of Statistics, 2011). Gambling severity was stratified according to previous treatment- seeking problem gamblers SOGS scores of either 5 - 11 or 12 - 20 (Riley, Smith, & Oakes, 2011). A biostatistician independently generated random sequences for each stratum using Stata version 11.1 software 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.

Masking

In this trial, therapists knew what treatment they were administering and participants were provided with information that rationalised and described their assigned therapy protocol. It was intended that participants were masked to the study hypothesis in order to help limit the likelihood for self-report bias. Participant information sheets referred to treatments as "well known and commonly used psychological treatments". To avoid contamination of masking, SGTS administration staff members were instructed not to reveal specific treatment labels to any participants and therapists not to reveal the alternative treatment label.

Procedures

Table 1 shows a summary of therapy sessions and manuals are available from authors upon request. Participants in each group received, on average, twelve 60-minute individual treatment sessions conducted at weekly intervals. For this study, both CT and ET manuals were written as a session-by-session guide for therapists treating individuals with a gambling disorder where EGMs were the main form of gambling. Participants in both groups were given home exercises with rationale and instructions and a review of these was conducted at the beginning of each session. After eligibility screening by the research assistant and randomised allocation to the intervention, all participants were provided with a screening interview by the allocated CT or ET trial therapist at study commencement that comprised a gambling focused cognitive behavioural assessment including DSM-IV-TR criteria for identifying pathological gambling. All subsequent therapy sessions were audio recorded and 20% were randomly selected from early, mid, and late study phases and checked for therapy fidelity. For this, a 10 item checklist was developed based on the Cognitive Therapy Scale (CTS) which is an 11-item instrument with good reliability when used by experienced clinicians (Young & Beck, 1980). Treatment drop-out was determined using the approach based on therapists' judgement of participant progress up to the point of self-initiated termination (Melville, Casey, & Kavanagh, 2007). Specifically, participants were classified as drop-outs if they stopped attending therapy before completion of the therapy program- either without discussion with the therapist or when the therapist believed the participant was in need of further therapy.

Table 1 here

Cognitive therapy

The therapists at SGTS had previous experience in administering CT in groups with treatment being structured according to a manual that outlined procedures over 12 weekly sessions. The training and supervision of cognitive therapists for the individual format in this study was provided by RL

(Ladouceur et al., 2003; Ladouceur et al., 2001) and a registered clinical psychologist who had received extensive training in CBT protocols. The supervisors also conducted therapist fidelity checks for both CT and ET groups. Cognitive therapy was provided by two cognitive behavioural therapists with qualifications in clinical psychology and who had 4 and 6 years respectively of practice experience, including 2 years in treating individuals with gambling disorders.

Exposure therapy

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 (Battersby et al., 2008; Tolchard et al., 2006). Therapists who administered ET received supervision from MB (Battersby et al., 2008). Fidelity checks of audio recordings were also conducted by MB and RP (Battersby et al., 2008; Oakes et al., 2008). Exposure therapy was provided by two cognitive behavioural therapists with post-graduate qualifications in CBT; a registered mental health nurse and an honours psychology graduate with 10 years and 3 years respectively of clinical experience including 2 years in delivering CBT treatments to gambling clients of SGTS using the ET program.

Outcomes

We undertook assessments at baseline, post-treatment (12 weeks) and follow-up at 1, 3 and 6 month post-treatment. Follow-up questionnaires were mailed to both treatment completers and treatment drop-outs with a pre-paid self-addressed envelope. To improve response rates to mailed questionnaires, multiple contacts were implemented with phone calls and reminder letters. Also, all participants were offered honorarium gift vouchers to the value of $10 at completion of therapy; $20 at 3 months follow-up; and $25 at 6 months follow-up.

The participant-rated primary outcome measure was the Victorian Gambling Screen (VGS) harm to self- subscale (Likert scoring 0, 1, 2, 3, 4; range 0-60; score of 21+ identifies a person as a problem gambler) relating to the person's experiences in the previous 4 weeks. It is a valid and reliable instrument with concurrent validity with other measures of problem gambling including SOGS but extends the score range (Tolchard & Battersby, 2010). It also has shown similar properties in construct validity to the Canadian Problem Gambling Index (CPGI) on a number of problem gambling correlates (e.g. 'self-rating of problem'; 'wanted help'; and 'suicidal tendencies') (Jacobson, Dobson, Traux, et al., 1996). It was chosen as the primary outcome measure because it was developed and validated in Australia and it has a one month time frame for reporting, hence enabling measurement of change during and after treatment.

For secondary outcomes, measures relating to gambling behaviours using EGMs were: 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. We also assessed gambling related cognitions with the gambling related cognitions scale (GRCS) (Raylu & Oei, 2004a), gambling urges with the gambling urge scale (GUS) (Raylu & Oei, 2004b), psychological distress using Kessler 10 (K10) (Andrews & Slade, 2001), and overall disability with the work and social adjustment scale (WSAS) (Mundt, Marks, Shear, & Greist, 2002). These secondary outcomes were a subset of those specified in the protocol, selected as most relevant for this report. 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*).

Statistical analysis

In our sample size calculations, we assumed a correlation between follow-up measures of r = 0.7 (Frison & Pocock, 1992). Based on a type I error rate of 5% , power of 90%, two-tailed test, and a VGS standard deviation of 10.2 units (Smith et al., 2010), 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 drop-out 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.

The primary analysis used all available data and followed an intent-to-treat principle to investigate any statistically significant differences in primary and secondary outcomes over time between cognitive and exposure therapy. Secondary analyses were conducted based on 'as treated' and 'per protocol' approaches within a counterfactual framework using inverse probability weighting (IPW) (Hernan & Hernandez-Diaz, 2012). The IPW uses the inverse of the probability of being in the observed treatment group. These probabilities were obtained by fitting a logistic regression model of therapy group (ET = 1; CT = 0) on age, gender and baseline gambling severity (VGS). From this model, probabilities (pr) were firstly calculated and then IP weights for ET were calculated by taking the inverse of 1 - pr, and weights for CT participants were similarly obtained. These weights were then used to calculate weighted means of the outcome measures for both ET and CT and contrasted to obtain an average treatment effect of ET versus CT at post-intervention and 6 month follow-up. Due to a relatively small sample size, robust standard errors were calculated from bootstrap samples. Where results did not differ between the three approaches, only results from the primary analysis and per protocol analysis are reported.

Generalised mixed-effects models were used in the analysis of repeated measures for primary and secondary continuous and categorical outcomes. Fixed effects (time- invariant variables) in models were intervention group (CT or ET), time in continuous form (intervention period and follow-up), and interaction between group and time. A quadratic term for time was also tested to allow for possible non-linear effects. A preliminary model assessed for a therapist effect across time and was to be included in the main analysis if statistically significant. Random effects in the model were at study participant level, and represented an upward or downward shift in the outcome measure from an average regression line and rate of change. An unstructured variance-covariance pattern was specified for the random effects. This meant that participant- specific baseline scores (intercepts) and rates of change across time (slopes) were assumed to be correlated. This assumption was tested by comparing the model with the unstructured pattern to a model with an independent structure (all correlations zero) using a likelihood-ratio test. Maximum likelihood estimation was used where both fixed effects and random effects contributed to the estimation of model parameters. A heteroskedastic random-effects model was also performed to assess if individuals within CT and ET had similar variability in rates of change in VGS scores across time when compared to the main model. Statistical analyses were conducted using Stata 12.0 (StataCorp, 2013) and the user-written program gllamm (generalised linear latent and mixed models) (Skrondal & Rabe-Hesketh, 2003).

A secondary post-hoc analysis compared VGS scores across time between therapy completers and non-completers using a mixed-effects model. Model specification included an interaction term between therapy completion status and time, and adjusted for stratification variables to account for the observational nature of this subset of data. The estimate of the difference in the adjusted means for completers versus drop-outs was then calculated at each time point as well as 95% confidence intervals.

Finally, the proportion of participants who had VGS scores in the non-problem gambling range (< 21) at 6 month follow-up or 3 months where 6 month data was missing were assessed using Fisher's exact test. In addition, a reliable change index (RCI) was calculated to determine how much therapeutic change occurred from baseline to follow-up using continuous VGS data. This was calculated using the formula $SE_{diff} = SD_b * \sqrt{2} * \sqrt{1 - r}$ where SE_{diff} was the standard error of difference, SD_b was baseline standard deviation and *r* was Cronbach's alpha coefficient for VGS at baseline (Jacobson & Truax, 1991). A risk difference statistic was then calculated to determine if there were any differences between proportions of individuals in each therapy group who experienced a reliable change.Effect size statistics were also produced for comparisons of mean observed scores(Cohen's *d*) (Cohen, 2013) and associations of nominal variables (Cramer's V or phi for 2 x 2 contingency table) (Cramér, 1946). The interpretation of Cohen's *d* may be guided by the conventional standard of 0.2 to 0.49 as small, 0.5 to 0.79 as medium and 0.8 or above as large. For Cramer's V, less than 0.19 is weak, 0.2 to 0.29 is moderate and 0.3 or above is large. For nonparametric between-group tests, the Mann-Whitney statistic was calculated as a measure of effect size (Conroy, 2012). For statistically significant values, the probability of an observation in one therapy group having a true value higher than an observation in the alternative group was then reported. To interpret this probability in terms of Cohen's *d* effect sizes, the statistic $r = {}^{z}/_{\sqrt{N}}$ was also calculated (Fritz, Morris, & Richler, 2012).

RESULTS

Participant recruitment and flow

The flow of participants through each stage of the study is shown in Figure 1. Participants were recruited from 151 consecutive referrals to SGTS. The most common reason for study exclusion was non-EGM use as the primary form of problem gambling. Of the 99 participants randomized, 12 did

not attend and commence the allocated intervention. One participant allocated to the CT group received ET due to inconsistent application of the study protocol. No significant differences were found between intervention starters and non-starters on stratification variables age (p = 0.395, d = 0.26, 95% CI: -0.34 – 0.87), SOGS scores (P = 0.170, d = 0.43, 95% CI: -0.18 – 1.03) or gender distribution (p = 0.970, Cramer's V = -0.004).

Figure 1 here

For all participants, median time of engagement in the study from baseline to final data collection point 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.

Baseline characteristics

Baseline characteristics for n=87 participants are presented in Table 2. When stratifying VGS at cut score 21 there were 81(94.2%) classified as problem gamblers. For DSM-IV-TR criteria there were 83(95.4%) diagnosed as pathological gamblers based on scores of 5 or more when assessed by a therapist at study commencement. 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, 25(28.7%) were in the sub-clinical range, 40(46%) with significant impairment, and 22(25.3%) in the moderate to severe range.

Table 2 here

Implementation of interventions

For treatments implemented, the case volume for CT therapist one was 28 participants and 15 for therapist two.. For ET, the case volume for therapist one was 27 participants and 17 for therapist two. For participants who started an intervention (n=87), the median number of CT sessions was 8.5 (IQR, 4 - 11.5) and 5 for ET sessions (IQR, 3 - 9) (p = 0.046). The effect size statistic for this difference was small (r = 0.21) and 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, d = 0.47, 95% CI: 0.29 – 0.64). 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). There was no significant difference in rate of therapy sessions attended per week between ET (Median = 0.58; IQR, 0.40 – 0.95) than CT (Median = 0.62; IQR, 0.47 – 0.77) (p = 0.814) where ET values were slightly lower but more variable than CT.

Based on therapists' judgement, 41% (36/87) of participant's were classified as treatment drop-outs: 31.8 % (14) for CT and 51.2 % (22) ET (p = 0.067, Cramer's V = -0.20). Of these, 66.7% (24/36) attended 1 to 3 sessions (CT, 8/14; ET, 16/22) (p = 0.334, Cramer's V = -0.16). 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 episode (weeks) between CT (Median = 16.6; IQR, 11.9 - 24.1) and ET (Median = 18.1; IQR, 12.0 - 28.7) (p = 0.893).

Therapy fidelity

All therapy sessions were audio recorded (n = 526). 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 therapist fidelity with assigned treatment manual. A total of 107 out of 526 (20 %) recordings were evaluated and comprised of 76 unique sessions (14.4%, 39 for CT, 37 for ET) and 31 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 fidelity score was 98.5% for CT (SD = 4.4%) and 99.5% for ET (SD = 2.8%). These scores did not significantly differ between the two groups where the mean difference was 1.1% (95% CI: 0.4% - 2.5%, $p = 0.142$). To assess inter-rater agreement, mean difference (bias statistic) and limits of agreement were calculated based on the formula for small sample sizes (bias ± 2*SD) (Krippendorff, 2012) where values closer to zero indicate stronger agreement. The mean difference between each pair of rater's observations was 2.1%. This result, in conjunction with an insignificant difference between mean scores ($p = 0.710$) indicated that rater's observations tended to agree. In future study samples, the difference in rater's osbervations would be expected to lie within the limits of agreement of -11.3% to 15.6% approximately 95% of the time.

Analysis of primary outcome

Participant views about treatment are shown in Table 3. For the primary outcome measure VGS, the pairwise correlation coefficients for follow-up measurement occasions were in the range 0.44 to 0.73 and mean value of 0.63. In terms of effect size, the mean correlation value was a close approximation

to an assumed value of 0.7 in the sample size calculation. Also, baseline SD values in both groups (Table 2) were close to the assumed value used for sample size calculations. However, there was considerable variation in follow-up SD values for CT (12.90 to 19.10) and ET (8.86 to 16.66). The observed individual trajectories of scores over time by therapy group (Figure 2) indicated that trends were generally nonlinear for treatment completers. Different trends are observed for CT and ET completers with more CT completers relapsing post treatment and more ET non-completers improving over time. For CT participants, VGS data were available for 79.5% (35/44) on at least one occasion post- baseline assessment and 70% (31/44) provided at least one set of post- treatment data. For ET participants, VGS data were available for 72.1% (31/43) on at least one occasion post-baseline assessment and 65% (28/43) provided at least one set of post-treatment data. 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 relative to study completion date.

Table 3 here

Figure 2 here

Using all available data (n = 87), results from between group comparisons for VGS using linear mixed-modelling are shown in Table 4 for baseline, end of treatment, 1, 3 and 6 month follow-up. The average number of outcome assessments per individual was 2.9 (Range, 1 - 5) and a total of 254 observations. In a preliminary analysis, there was no significant therapist effect across time ($\chi^2(3) = 1.58$, $p = 0.664$). For the main analysis, there was no significant difference between the two groups in rate of change in scores across all time points ($\beta_{(ET-CT)}$= 0.07, 95% CI: -0.12 - 0.26, $p = 0.477$). There was a significant reduction (improvement) in VGS scores within treatment groups during intervention and follow-up time periods ($P < 0.001$). On average, the VGS score decreased by 0.71

points per week (95% CI: 0.58 - 0.83) in CT participants and 0.89 points per week (95% CI: 0.74 - 1.03) in ET participants.

The estimated random intercept standard deviation for VGS was 6.3 points (95% CI: 4.29 - 9.38) and this considerable variation between individuals is indicated from baseline scores in Figure 2. There was no significant correlation between individual baseline VGS scores (intercepts) and rate of improvement over time (slope) from the comparison of models with an unstructured variance-covariance pattern of random effects versus independent structure (p = 0.149). A heteroskedastic random-effects model indicated that the variability in participant-specific deviations from the average change in VGS scores across time was the same for CT and ET groups ($\chi^2(2) = 1.77, p$ = 0.413).

A per protocol analysis was conducted to determine how well the therapies worked under 'near-perfect' conditions. The estimated mean VGS scores at 12 weeks for ET and CT was 8.18 points (95% CI: 2.77 – 13.59) and 7.77 points (95% CI: 1.93 – 13.61) respectively. There was no significant difference between therapy groups for this analysis ($\beta_{CT\ vs\ ET}$ = - 0.41, 95% CI: -8.08 – 7.26, p = 0.916). This analysis showed an additional improvement for treatment completers when compared to estimates obtained from the intent-to-treat analysis which comprised of data for both therapy completers and non-completers (Table 4). At 6 month follow-up the estimated mean VGS scores for ET and CT was 4.57 points (95% CI: 1.01 – 8.13) versus 10.38 points (95% CI: 4.09 – 16.66) (p = 0.165) respectively. These estimates were less precise because of missing data and bootstrap sampling to account for the small sample size. However, upper confidence limits for both groups were in the non-problem gambling range based on VGS cut score of 21 or less.

Table 4 here

Analysis of secondary outcomes

Results from between group comparisons for continuous secondary outcome measures are shown in Table 4. For gambling urges, there was no significant difference between the two groups in rate of change in scores over time ($\beta_{(ET-CT)}$= -0.05, 95% CI: -0.19 - 0.09, p = 0.463). There was a significant reduction (improvement) within treatment groups across time (p < 0.001). On average, the GUS score decreased by 0.24 points per week (95% CI: 0.15 – 0.34) in CT participants and 0.38 points (95% CI: 0.27 – 0.48) in ET participants. For gambling related cognitions there was no significant difference between groups ($\beta_{(ET-CT)}$= 0.04, 95% CI: -0.25 – 0.33, p = 0.806) but a significant reduction (improvement) in scores within treatment groups (p < 0.001). On average, the GRCS score decreased by 0.97 points per week (95% CI: 0.77 – 1.16) in CT participants and 1.25 points (95% CI: 1.02 – 1.47) in ET participants. For measures of depression and anxiety (K10) there was no significant difference between groups ($\beta_{(ET-CT)}$= -0.001, 95% CI: -0.12 – 0.11, p = 0.977) as well as for overall disability with work and social adjustment (WSAS) ($\beta_{(ET-CT)}$= -0.03, 95% CI: -0.13 – 0.08, p = 0.614) but significant reductions (improvement) in scores on each measure within groups (p < 0.001).

For time spent gambling in previous month, hours was transformed using natural logarithm ($\log_e$(hours)) and the inverse of model estimates (exp(hours)) were then calculated for interpretation. There was no significant difference between the two groups in rate of change in hours over time ($\beta_{(ET-CT)}$= -0.01, 95% CI: -0.03 – 0.01, 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, hours gambled decreased by 0.97 per week (95% CI: 0.95 – 0.98) in CT participants and 0.95 (95% CI: 0.94 – 0.97) in ET participants.

Results for amount spent in previous month using a random-intercept proportional odds model showed the odds ratio of more money spent per week was 0.78 (95% CI: 0.73 to 0.84) for the CT group. The odds ratio for ET was estimated as 0.82 (95% CI: 0.75 to 0.89). There was no significant difference between treatment groups over time (OR = 1.01, 95% CI: 0.98 – 1.04, $p = 0.371$). The odds ratio of more frequent gambling per week was 0.77 (95% CI: 0.73 to 0.83) for the CT group and 0.78 (95% CI: 0.74 to 0.83) for ET group. There was no significant difference between treatment groups over time (OR = 1.01, 95% CI: 0.98 – 1.04, $p = 0.448$).

Secondary post-hoc analysis

Results from a mixed-effect model showed that therapy completers in both study groups experienced a significantly greater rate of reduction (improvement) in VGS scores across time compared to drop-outs ($p = 0.010$). Figure 3 shows a plot of the estimate of the difference in the adjusted means for completers versus drop-outs at each time point and 95% confidence intervals. Similar trends favouring therapy completers over drop-outs were found on secondary continuous outcome measures GUS ($p = 0.015$), GRCS ($p = 0.003$) and K10 ($p = 0.013$) but not WSAS ($p = 0.349$).

Using VGS cut score of 21 or less for all available data at 6 month follow-up, 82.6% (19/23) of ET participants were classified as non-problem gamblers compared to 79.3% (23/29) of CT participants. No significant difference was found between group proportions ($p = 0.405$). Both groups also showed a clinically meaningful reduction (improvement) in mean VGS scores ($p < 0.001$) from baseline to follow-up with large effect sizes (CT: $d = 2.10$, ET: $d = 2.53$). For RCIs calculated from VGS data, 91.3% (21/23) of ET participants showed a reliable therapeutic change at 6 month follow-up and 8.7% (2/23) showed no real change. For CT participants, 79.3% (23/29) showed a reliable change, 17.2% (5/29) no real change and 3.5% (1/29) got worse. There was no significant difference between group proportions of RCI outcomes ($p = 0.426$). The risk difference was also insignificant

when comparing outcomes ‘reliable change’ versus ‘no real change’ or ’got worse’ between groups (risk difference = 0.15, 95% CI: -0.04 – 0.34).

Figure 3 here

DISCUSSION

To our knowledge this study is the first to test a direct comparison between CT alone and ET alone in problem gambling with fidelity testing confirming that there are valid and reliable CT and ET techniques that can be taught and delivered in manualised form. Exposure therapy achieved similar clinical outcomes as CT alone and gambling-specific CBT programs typically comprise of CT as the core element (Cowlishaw et al., 2012). However, due to a shortfall in participant numbers, a true difference between therapy groups of 4.8 points on VGS may have remained undetected. The therapy drop-out rate of 41% was comparable to previous studies involving psychological treatment of problem gambling that have ranged from 14% to 50% and median of 38% (Melville et al., 2007). Over 66% of drop-outs attended 3 or fewer sessions with a significant proportion improving over the study period suggesting that further research is needed to better understand outcomes for this sub-group.

Due to similar between-group benefits on measures relating to gambling urge and cognitions we were unable to identify different causal mechanisms being responsible for translation of CT and ET to the expected outcome. Nonetheless, if both cognitive and exposure therapy can mitigate gambling urge and cognitions then a more pertinent question relates to the comparative utility of these treatments in everyday clinical practice. Behavioural techniques in general are considered more parsimonious in terms of delivery than cognitive approaches (Jacobson, Dobson, Truax, et al., 1996).

Based on all therapy starters in this study, the average number and duration of ET sessions were significantly less than CT sessions. There tended to be more therapy drop-outs in the ET group but more CT completers relapsed after initial improvement and more ET drop-outs, receiving only 1-3 sessions improved by 6 months (Figure 2). This suggests that while CT is more consumable by patients, fewer sessions of ET may achieve the same outcomes as more sessions of CT. Perhaps therapists could offer either ET or CT alone or a combination of both according to patient preference and success. This may lead to more parsimonious treatments and greater retention of patients in therapy by flexibly tailoring programs according to individual needs.

Beyond findings of this current study, data in relation to differential drop-out from gambling-specific cognitive and exposure therapies is mostly non-existent. In posttraumatic stress disorder (PTSD) and obsessive compulsive disorder (OCD) it has been found that cognitive and exposure therapies are equally tolerable (Hembree et al., 2003; Van Oppen et al., 1995). Notwithstanding therapy type, it has also been suggested that manualised treatments may increase drop-out rates due to systematic procedures being less focussed on patients' concerns in the here and now (Hembree et al., 2003). Although we did not collect data in relation to formal diagnoses of co-morbid disorders, it was found that over 70% of participants self-reported moderate to severe levels of psychological distress at baseline assessment using the K10 instrument. In a previous study involving a large cohort of treatment- seekers who attended SGTS, similar prevalence rates were found for 12-month affective disorder and anxiety disorder based on Australian normative data (Slade, Grove, & Burgess, 2011; Smith, Harvey, Humeniuk, Battersby, & Pols, 2014). Based on the potential for high prevalence rates of co-occurring conditions in the present study, the specificity of CT alone or ET alone may have been too prescriptive for some participants alongside other mental symptoms. Perhaps those who were suffering from co-occurring conditions were too distracted or less willing to focus on a structured therapy and therefore self-terminated treatment.

The 6 month follow-up data indicated that the majority of treatment gains made by completers of CT and ET were clinically meaningful and psychometrically sound for primary outcome measure VGS. More specifically, RCIs indicated that the number of participants experiencing actual improvement in both groups was greater than the number of participants who experienced no change or got worse in problem gambling symptoms. In terms of predicted therapeutic change, both completers and non-completers showed an initial rapid improvement on the VGS. This may have been partly due to regression to the mean or random measurement error (Barnett, van der Pols, & Dobson, 2005).

Beyond study intervention period, improvements for treatment completers appeared to persist for up to 6 month follow-up. In previous gambling trials, similar patterns of change have been found on a range of symptoms including depression, urge and cognitions where treatments have involved a combination of cognitive-behavioural techniques (Carlbring, Jonsson, Josephson, & Forsberg, 2010), ET alone (McConaghy et al., 1983) and CT alone (Sylvain, Ladouceur, & Boisvert, 1997). Gambling-specific CT and ET teaches skills which the client are asked to use beyond therapy to unlearn or extinguish psycho-physiological gambling responses (Battersby et al., 2008). Comparable patterns of improvement in short to mid-term follow-up have also been shown in the treatment of anxiety disorders using CBT (Clark et al., 2006; Marks, Lovell, Noshirvani, Livanou, & Thrasher, 1998) where mechanisms of psychological and physiological (arousal) components in response to environmental triggers or cues are analogous to those in problem gambling (Battersby et al., 2008).

Strengths and limitations of the study

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. One of the main limitations of this study was loss

of power due to a deficit in the number of participants recruited and this may have resulted in a Type II error. Also, the relatively wide 95% confidence intervals reflected a degree of imprecision in estimates of differential treatment effects. For example, at 6 month follow-up, the 95% confidence interval was compatible with a difference of up to 4 points in favour of ET or a difference of up to 7 points in favour of CT given the study data. Funding constraints meant that we were unable to extend the recruitment period beyond 12 months.

Furthermore, attenuated study power resulted from a higher rate of therapy drop-out than expected and greater variability in VGS data at follow-up time points. In order to establish that CT and ET treatments are equivalent or non-inferior in a future trial, a much larger number of problem gamblers would need to be treated. For example, if there was truly no difference between CT and ET interventions, a total of 158 problem gamblers would need to be treated to be 90% sure that the limits of a two-sided 80% confidence interval excluded a difference in means of more than 7 points on VGS- the upper confidence limit for the treatment effect estimate at 6 month follow-up in this present study.

Whilst there was a therapy drop-out rate of 41%, follow-up of all randomised individuals was attempted. A strategy to improve post- treatment follow-up rates was to minimise the number of attendances required at the study site by sending questionnaires to participants by post. Subsequently, we obtained follow-up data from 79.5% (CT) and 72% (ET) of all participants on at least one occasion. This enabled a comparison between therapy completers and non-completers in how much improvement was achieved. Still, non-response to postal questionnaires may have produced biased estimates of therapy effects (Edwards et al., 2002). For example, participants who were classified as "drop-outs" may have in fact reached their personal goals early in treatment and consequently discontinued with the study based on a decision that any further involvement would not provide

additional benefits (Hembree et al., 2003). This may have led to more conservative estimates of treatment effects from an intent-to-treat perspective. Future studies should aim to address therapy drop-out by combining cognitive and exposure therapies in a flexible manner tailored to each participant and data collection rates using electronic data collection e.g., smart phone, text and web-based data collection systems, and key informant contacts to trace participants.

A further limitation of the study design was the lack of an active 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. Many studies have shown that various combinations of cognitive and behavioural therapies are superior to control conditions, including absolute effects; hence this study was designed to extend the evidence-base by directly testing cognitive and exposure therapies. Also, outcome data were collected from self-report measures and therefore participants may have overestimated treatment effects. Because there was a high degree of similarity between each therapy in terms of their structured approaches and masking of participants to study hypothesis, the influence of any bias in self-ratings was expected to be minimised. Finally, the range of measures used in this study were commensurate with recommended minimum features for reporting efficacy of treatment in problem gambling (Walker et al., 2006). Although there was potential for type I error due to multiple significance tests, it was improbable that any statistical adjustment would have influenced the main trial conclusions.

Implications for research

Further research in gambling disorder is required to test whether exposure alone is as efficacious as CT alone or combined as has been found for anxiety disorders (Marks et al., 1998). Future studies would also benefit from strategies to increase both therapy uptake and completion of follow-up data

to better determine relative efficacy of these treatments. Also, in addition to therapist fidelity, the measurement of participant alliance to therapy would augment the evidence relating to putative mechanisms of therapeutic change. This phase II study provides the clinical and statistical basis with effect sizes to determine sample size calculations for a definitive phase III randomised controlled dismantling trial comparing exposure, cognitive therapy and combined exposure and cognitive therapy with a control group. This will add to theory and clinical practice by testing the relative efficacy and retention of isolated against combined modalities and test underlying mechanisms of change potentially advancing knowledge of CBT for problem gambling to that achieved by the seminal dismantling studies of anxiety disorders and depression (Dimidjian et al., 2006; Jacobson, Dobson, Truax, et al., 1996; Marks et al., 1998).

In conclusion, we found that exposure therapy was no more effective than cognitive therapy at reducing problem gambling among treatment seeking adults. The findings suggest that both therapies were acceptable in the short-term for at least treatment completers but whether these translate into long-term benefits needs further assessment. The present study improved upon previous trials for cognitive and exposure therapies in gambling disorders by investigating a more extensive range of therapy outcomes and provided a greater level of transparency in reporting of findings such as determination of sample size, details of how participants were randomly assigned and details of therapies as they were implemented.

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Table 1. Intervention schedule

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

Figure 1. Participant flow

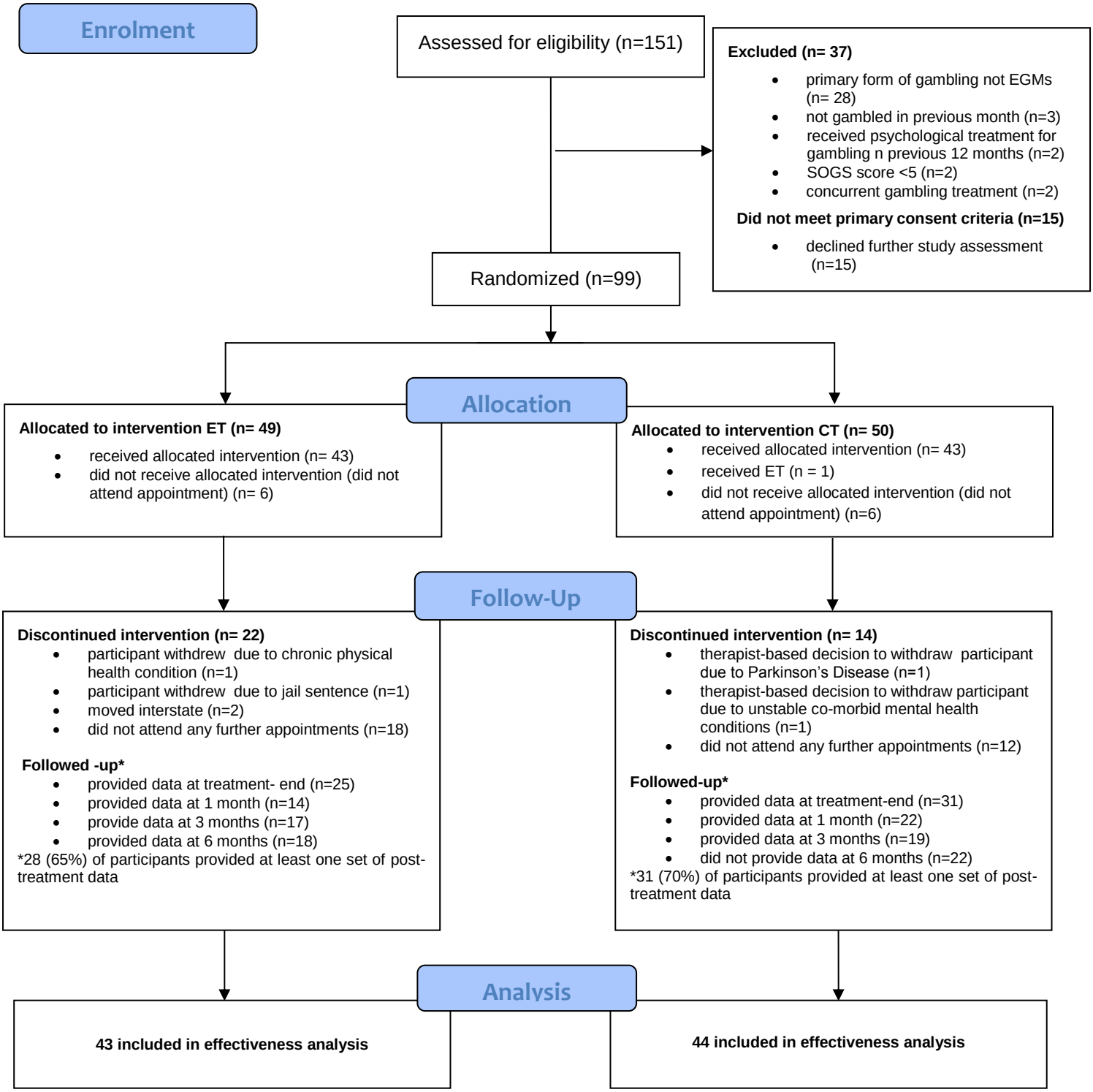


Table 2. Baseline socio-demographics and clinical characteristics

	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)
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)
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.

Data are mean (SD), or n (%) unless otherwise indicated.

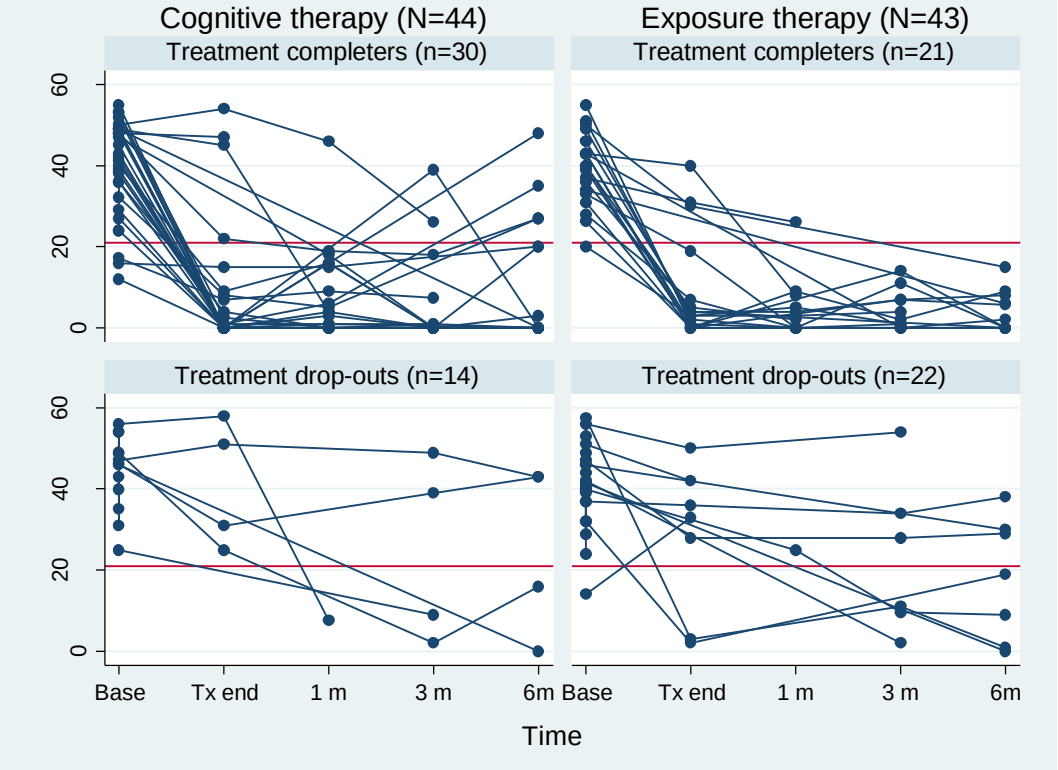
[a]Based on gaming machine use in previous month.

Table 3. 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)

Figure 2. Observed trajectories for cognitive and exposure therapies



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

Table 4. Change in outcomes between exposure therapy (ET) and cognitive therapy (CT)

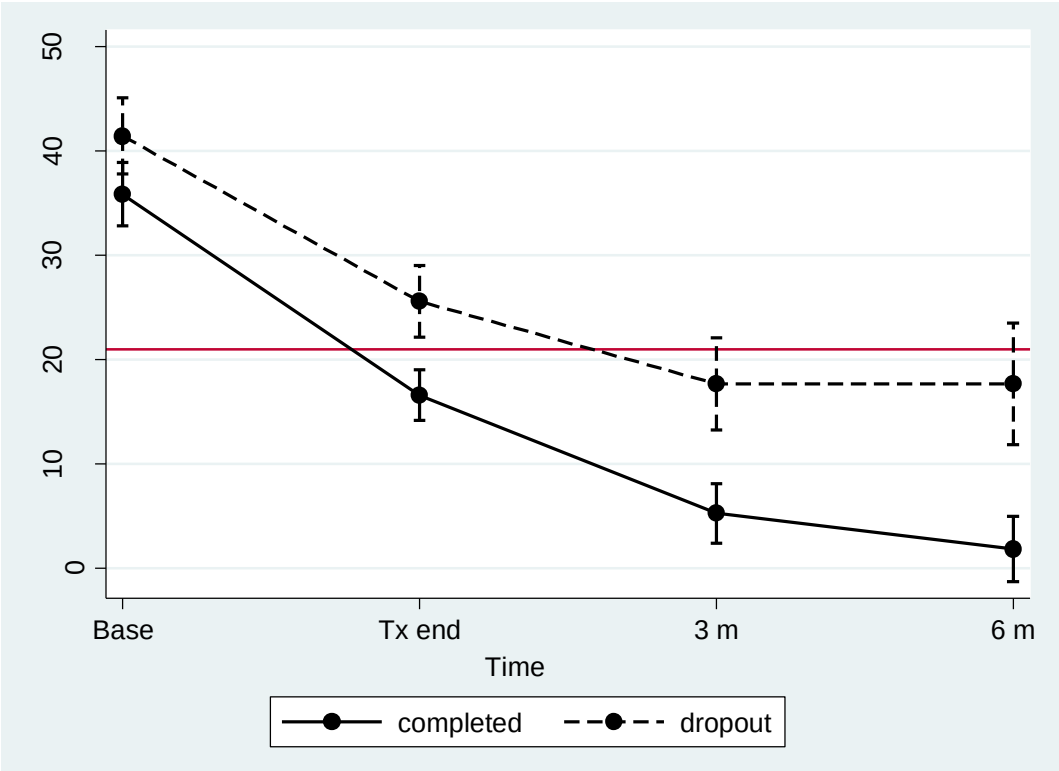
	Intervention							Follow-up										
	Baseline				12 weeks			1 month				3 months				6 months		
	Unadjusted estimate (SE)		Adjusted estimate: between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE)		Adjusted estimate: between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE)		Adjusted estimate: between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE)		Adjusted Estimate: between-group difference (95% CI)[a]	*P*	Unadjusted estimate		Adjusted estimate: between-group difference (95% CI)[a]	*P*
Outcome	CT	ET			CT	ET			CT	ET			CT	ET			CT	ET		
VGS	38.96 (2.02)	37.59 (1.96)	-1.01 (-6.08 - 4.05)	0.696	19.18 (1.74)	20.10 (1.91)	-0.18 (-4.48 - 4.11)	0.933	14.14 (1.86)	15.86 (2.06)	0.09 (-4.19 - 4.37)	0.967	7.73 (2.06)	9.76 (2.22)	0.64 (-4.00 - 5.28)	0.787	4.60 (2.10)	6.56 (2.13)	1.47 (-4.46 - 7.39)	0.627
GUS	11.65 (1.58)	14.08 (1.29)	1.97 (-2.43-6.37)	0.380	5.99 (1.30)	6.57 (1.21)	1.35 (-1.99-4.70)	0.428	4.58 (1.29)	4.73 (1.32)	1.15 (-1.97-4.26)	0.471	2.50 (1.28)	2.06 (1.45)	0.73 (-2.18-3.65)	0.946	1.18 (1.33)	0.55 (1.40)	0.12 (-3.24-3.47)	0.676
GRCS	70.62 (3.56)	73.49 (3.69)	3.38 (-6.37-13.13)	0.496	44.66 (3.00)	49.30 (3.51)	3.82 (-4.53-12.17)	0.370	38.47 (3.03)	43.49 (3.64)	3.96 (-4.20-12.13)	0.341	29.79 (3.13)	35.23 (3.78)	4.25 (-4.02-12.53)	0.336	26.01 (3.27)	31.28 (3.78)	4.69 (-4.87-14.25)	0.601
K10	28.68 (1.42)	29.28 (1.43)	0.67 (-3.19-4.53)	0.735	21.47 (1.31)	22.56 (1.44)	0.65 (-2.84-4.13)	0.716	19.74 (1.37)	20.90 (1.50)	0.64 (-2.83-4.11)	0.718	17.31 (1.46)	18.46 (1.58)	0.63 (-3.00-4.25)	0.735	16.20 (1.45)	16.98 (1.55)	0.61 (-3.61-4.82)	0.778
WSAS	13.58 (1.19)	15.60 (1.26)	1.74 (-1.87-5.34)	0.345	7.64 (1.08)	8.66 (1.25)	1.42 (-1.53-4.38)	0.346	6.18 (1.13)	6.97 (1.32)	1.32 (-1.51-4.14)	0.361	4.04 (1.22)	4.51 (1.40)	1.11 (-1.63-3.84)	0.428	2.77 (1.22)	3.15 (1.36)	0.79 (-2.25-3.83)	0.610
Hours[b]	2.67 (0.16)	2.77 (0.13)	0.09 (-0.27-0.47)	0.625	2.19 (0.20)	2.12 (0.18)	-0.02 (-0.42-0.38)	0.919	2.06 (0.22)	1.94 (0.20)	-0.06 (-0.49-0.38)	0.792	1.85 (0.25)	1.64 (0.21)	-0.13 (-0.67-0.40)	0.620	1.67 (0.27)	1.33 (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.

[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 3. Adjusted predictions of treatment completion status for combined cognitive and exposure groups with 95% confidence intervals



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