COGNITIVE VERSUS EXPOSURE THERAPY FOR PROBLEM GAMBLING: A RANDOMISED CONTROLLED TRIAL

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LIST OF ACRONYMS

AISS	Arnett Inventory of Sensation Seeking
ATE	Average treatment effect
ATET	Average treatment effect on treated
BLUP	Best linear unbiased predictors
CBT	Cognitive-behavioural therapy
CONSORT	Consolidated Standards of Reporting Trials
CPGI	Canadian Problem Gambling Index
CT	Cognitive therapy
DSM	Diagnostic and Statistical Manual of Mental Disorders
EGM	Electronic gaming machine
E-M	Expectation-maximization algorithm
ET	Exposure therapy
GRCS	Gambling Related Cognitions Scale
GUS	Gambling Urge Scale
IPW	Inverse probability weighting
ITT	Intent-to-treat
MAR	Missing at random
MCAR	Missing completely at random
ML	Maximum likelihood estimation
MNAR	Missing not at random
NHMRC	National Health & Medical Research Council
PMM	Pattern mixture model
POM	Potential outcome mean
RCT	Randomised controlled trial
REML	Restricted maximum likelihood estimation
SGTS	Statewide Gambling Therapy Service
SOGS	South Oaks Gambling Screen
SUD	Substance Use Disorder
VGS	Victorian Gambling Screen

DECLARATION STATEMENT

I certify that this thesis does not incorporate, without acknowledgement, any material previously submitted for a degree or diploma in any university and to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Signature_____ Date_____/_____/_____

David Peter Smith

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To the memory of Timothy Donald Smith, friend and brother.

OVERVIEW OF PAPERS

The following papers are based on the work described in this thesis:

Smith, D. P., Dunn, K. I., Harvey, P. W., Battersby, M. W., & Pols, R. G. (2013). Assessing Randomised Clinical Trials of Cognitive and Exposure Therapies for Gambling Disorders: A Systematic Review. *Behaviour Change, 30*(3), 139-158.

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SUMMARY

In South Australia, problem gambling is mainly a result of the widespread availability of electronic gaming machines (EGM) in venues across the state. To help lessen this problem, the Statewide Gambling Therapy Service (SGTS) offers free cognitive-behavioural therapy (CBT) and mental health care for help-seeking problem gamblers. A barrier to improving treatment delivery that clinicians faced was a lack of clear guidelines on the best gambling-specific CBT approaches.

This situation prompted this research to investigate the relative efficacy of pure cognitive therapy (CT) and behavioural (exposure-based) therapy (ET). Exposure therapy targets gambling related psychobiological states (e.g. the "urge" to gamble) and CT focuses on restructuring erroneous gambling related cognitions. A systematic literature review was first conducted to synthesise the current state of research on CT and ET approaches to problem gambling. The review suggested that trials with a lower risk bias were needed and therefore justified a further trial.

The main study was a trial to compare CT and ET across a 12-week intervention period and 6-month follow-up period. It was a single-site two-group randomised, parallel design, with adult EGM problem gamblers presenting to SGTS. Primary outcome was rated by participants using the Victorian Gambling Screen (VGS) with validated cut score 21+ (score range: 0 – 60) indicative of problem gambling. All the treatment sessions were audio recorded and 20% were randomly selected and checked for therapy fidelity.

Of the 87 participants who were randomised and started intervention (CT=44; ET=43), 51 completed intervention (CT=30; ET=21). Both groups experienced comparable reductions (improvement) in VGS scores at 12-weeks (CT versus ET 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). Similar improvements in both interventions were also found for secondary measures. One of the main limitations of this study was loss of power due to an under representative sample size. However, compatible with the observed data, upper and lower confidence limits for estimated mean VGS differences suggested more similarities than differences between therapy groups from a clinical perspective.

To explore treatment specific and non-specific effects for therapy, qualitative interviews were conducted with a sub-sample of participants. This examination revealed that all interviewees gained benefit from their respective therapies and their comments did not appear to favour one therapy over another. Both treatment specific and treatment non-specific effects were well supported as playing a therapeutic role to recovery. It was not clear as to what effect, if any, could explain most of the variability in therapeutic change.

Taken together, the results showed that CT and ET were feasible and effective treatments for problem gamblers who presented to a community-based gambling therapy service in South Australia. A significant concern was the high therapy drop-out rate that was consistent with other previous trials involving psychological treatments for problem gambling. A large-scale trial is needed to compare CT and ET alone to a combined exposure-cognitive approach that can flexibly account for inter-individual

variation in ‘urge-cognition’ experiences. A combined approach may enhance treatment retention and reduce drop-out rates.

CHAPTER 1: INTRODUCTION

1.1 GAMBLING

Gambling involves the risking of something of value on an uncertain outcome in the hope of gaining a benefit. It cuts across culture and reaches back to at least the 35th century BCE where sheep knuckle-bones were used for dice games (Bernstein, 1996). Modern forms of gambling include casino games, electronic gaming ('pokies'), horse racing, dog racing, bingo and Keno. Gambling has been ostentatiously legalised and commercialised since the 1960s by governments in pursuit of additional income (McMillen, 2005). In 2009 the legal gambling market totalled $335 billion globally ("Online gambling: "You bet"," 2010). It has been suggested that the gambling industry yields benefits to the wider community in terms of, for example, employment, tourism, and gambling tax revenues received by affiliated jurisdictions (Collins & Lapsley, 2003). Potential health-related benefits have also been linked to gambling revenue, such as, the association between opening or expanding of American-Indian owned casinos and a decrease in the likelihood of childhood obesity (Jones-Smith, Dow, & Chichlowska, 2014). On the flip side, and similar to other forms of entertainment such as alcohol, harms associated with gambling are a serious public health concern across the world.

1.2 PROBLEM GAMBLING

Problematic gambling that is persistent and recurrent may adversely affect individual psychosocial, health, and mental functioning and jeopardise family and vocational pursuits (American Psychiatric Association, 2013). Population prevalence rates for problem gambling average around 2% and it occurs more frequently in younger

populations (Becona, 1996; Bondolfi, Osiek, & Ferrero, 2000; Delfabbro, 2008; Shaffer & Hall, 2001; Wardle et al., 2007; Wong & Ernest, 2003).

In recent years, the term "problem gambling" has been used to define harm related to gambling with a broader definition than DSM-IV (Diagnostic Statistical Manual of Mental Disorders, 4th Edition) "pathological gambling" (American Psychiatric Association, 2000). This definition has been the basis of the development of screening instruments such as the Canadian Problem Gambling Index (CPGI) (Ferris & Wynne, 2001) and the Victorian Gambling Screen (VGS) (Ben-Tovim, Esterman, Tolchard, & Battersby, 2001). In DSM-5 the term "Gambling Disorder" has replaced pathological gambling and by definition it captures the continuum of problem gambling (American Psychiatric Association, 2013). The commonalities between problem gambling and substance use disorder (SUD) in neurocognitive and physiological pathways (Paris, Franco, Sodano, Frye, & Wulfert, 2009; Tamminga & Nestler, 2006) resulted in Gambling Disorder being recognised as an addiction in DSM-5 (American Psychiatric Association, 2013). The following section describes some of the more dominant explanations to the causes and pathogenesis of problem gambling.

1.2.1 Demographic factors

Surveys conducted in general populations have identified numerous demographic risk factors associated with problem gambling (Petry, 2005). A recurrent finding across the world has been the negative correlation between age of onset of gambling and progression to problem gambling behaviour. That is, the younger a person is at initiation of gambling behaviour the greater the likelihood for developing a gambling disorder. The findings from a meta-analysis involving prevalence studies conducted

in the United States and Canada indicated that young people were more prone to clinical and sub-clinical disordered gambling within lifetime and past year time frames (Shaffer & Hall, 2001). In terms of specific sub-populations, the lifetime prevalence rates of the most severe category of disordered gambling for adults was 1.92 %, adolescents 3.38 %, college students 5.56 % and adults in prison or in treatment for psychiatric or substance use disorders 15.44 % (Shaffer & Hall, 2001). Problem gamblers in the general population also tend to be of lower socio-economic status and experience higher rates of divorce than non-problem gamblers have also been linked to problem gambling in the general population (Petry, 2005).

In treatment-seeking samples the typical profile of a problem gambler has been described as:

> "…middle aged, married, and employed, with a relatively low level of education and Caucasian ethnicity" (Petry, 2005)(p82)

Volbergs' (1994) large- scale survey conducted in the United States indicated that the demographic features for both general population and treatment-seeking problem gamblers were consistent across all states involved in the study. However, there were significant differences between the two samples of problem gamblers:

> "…those scoring as probable pathological gamblers in the general population are more likely to be women and minorities, as well as less likely to have graduated from high school than pathological gamblers entering treatment in every state. Additionally, they are less likely to be married than those entering treatment in every state except California. It is worth noting that none of the probable pathological gamblers in the general population had ever sought treatment for a gambling problem" (Volberg, 1994) (p290).

The disparity between men and women who entered treatment at the time of Volberg's (1994) survey was proposed to be analogous to trends in alcohol use

disorder where women were more unlikely to seek help due to stigmatisation (Volberg, 1994).

2.2 Comorbidity

Comorbid disorders are highly prevalent in both population-representative problem gamblers and treatment-seeking problem gamblers. The more common co-morbid disorders include depression, anxiety and substance abuse disorders. A recent meta-analysis was conducted to investigate the prevalence rates of comorbid disorders in population-representative samples (Lorains, Cowlishaw, & Thomas, 2011). The 11 studies selected were comprised of samples drawn from the population using randomized sampling methods. The individual studies were published between 1998 and 2010 and 6 were conducted in the United States, 2 in Switzerland and Canada and one in Korea. All studies used bona fide instruments for the clinical assessment of comorbid disorders. For example, the Canadian study used the Composite International Diagnostic Interview (CIDI) based on DSM-IV criteria to evaluate the relationship between problem gambling and mental and physical health correlates among Canadian women (Afifi, Cox, Martens, Sareen, & Enns, 2010). Key findings showed that the highest prevalence rate was for "…nicotine dependence (60.1%), followed by substance use disorder (57.5%), any type of mood disorder (37.9%) and any type of anxiety disorder (37.4%)" (Lorains et al., 2011) (p490).

For treatment-seeking problem gamblers, rates of co-morbid conditions have also been shown to be high and commensurate with problem gamblers in the general community (Lorains et al., 2011). For example, Petry's (2005) review revealed that the proportion of treatment-seekers with lifetime diagnoses of alcohol or other

substance use disorders was 25% to 65% greater than that in the general population (Petry, 2005). Furthermore,

> Treatment-seeking gamblers with a history of substance use disorders tend to have more severe gambling problems, psychiatric symptoms, and other psychosocial difficulties than gamblers without substance use problems (Petry, 2005) (p91).

Similarly, depression and anxiety commonly co-occur in treatment-seeking problem gamblers. McCormick et al. (1984) investigated the temporal association between problem gambling and clinical depression in treatment-seekers and showed that depression was most likely a consequence of gambling related problems rather than a cause (McCormick, Russo, Ramirez, & Taber, 1984).

In a study involving problem gamblers who presented to an outpatient treatment centre, structured clinical interviews were used to assess for psychiatric co-morbidity. Compared to controls, problem gamblers had high lifetime rates of psychopathology including affective disorders and anxiety disorders (Specker, Carlson, Edmonson, Johnson, & Marcotte, 1996). In addition, females had higher rates of anxiety conditions. Consistent with an addictions model, it has been proposed that gamblers with an anxiety disorder tend to engage in gambling activities to reduce arousal states, while individuals with depression seek to heighten arousal states (Blaszczynski, Steel, & McConaghy, 1997). High levels of impulsivity traits have also been shown to co-occur with problem gambling severity. This subgroup of problem gamblers may also exhibit other conditions including mood disorders and substance dependency (Blaszczynski et al., 1997).

Personality disorders have also been shown to co-exist with problem gambling. Ibanez et al. (2001) recruited 69 problem gamblers who presented to a specialized outpatient treatment program and screened them for comorbid disorders. Based on structured interviews, self-report questionnaires and psychological scales the most frequent diagnoses were personality disorders (42 %), alcohol abuse (33 %) and adjustment disorders (17 %). Moreover, participants who had at least one co-morbid condition also experienced more severe gambling- specific symptoms (Ibanez et al., 2001).

1.2.3 Cognitive and psychobiological correlates

The cognitive approach to explaining problem gambling 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') (Ladouceur et al., 2001; Raylu & Oei, 2004a) 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 (American Psychiatric Association, 2010).

In one study that employed the 'think aloud' technique, two separate experiments were conducted. In experiment 1 the participants played a slot machine followed by roulette in experiment 2. In both activities the participants confirmed a preponderance of erroneous gambling related cognitions (Gadboury & Ladouceur, 1989). Based on these findings the gambling related cognitions scale (GRCS) was developed as a screening tool (Raylu & Oei, 2004a). The scale is comprised of 5 factors that reflect the multidimensionality of gambling cognitions: interpretative control/bias (e.g.

"Relating my winnings to my skill and ability makes me continue gambling"), illusion of control (e.g. "Praying helps me win"), predictive control (e.g. Losses when gambling, are bound to be followed by a series of wins"), gambling-related expectancies (e.g. "Gambling makes me happier") and a perceived inability to stop gambling (e.g. "I can't function without gambling") (Raylu & Oei, 2004a).

The psychobiological approach to explaining problem gambling has focused on brain functioning using comparative studies between cases (problem gamblers) and controls (non-problem gamblers). Neurochemical studies have shown that there are links between neurotransmitters (e.g. dopamine) and psychophysiological arousal (e.g. urge or craving states) in problem gamblers when they are exposed to gambling cues and that these effects are mediated within the brain 'reward system' in neuropsychological and neuroimaging studies (Clark, 2010).

Urge states play an important role in gambling pathology (Raylu & Oei, 2004b) and may increase during periods of psychological disturbances, such as depression and stress (American Psychiatric Association, 2000). The physiological state of gambling urge can arise from internal triggers (e.g. depression) and external triggers (e.g. gambling cues) that activate arousal and gambling-related cognitions (Sharpe, 2002). Imaging studies have established links between intensities of self-reported gambling urges and changes in brain activity including retrieval and processing of emotion and impulse regulation (Balodis, Lacadie, & Potenza, 2012; Potenza et al., 2003) and involve the same neural substrates as urge or craving in substance use disorders.

1.2.4 Genetics

A small number of studies have previously been conducted in attempt to identify any genetic links with problem gambling behaviour. From a familial perspective, Black and colleagues (2006) recruited case probands who met DSM criteria for problem gambling and control probands (non-problem gamblers) and interviewed participants regarding their first degree relative's (FDRs). They found that FDRs of problem gamblers had significantly higher lifetime prevalence rates of gambling disorders and greater co-aggregation with substance abuse (Black, Monahan, Temkit, & Shaw, 2006).

To explore the common genetic vulnerability to alcohol dependence and problem gambling in men, Slutske and colleagues analysed data from the Vietnam Era Twin Registry (VET) (Slutske et al., 2000). Specifically, the dataset was comprised of male to male twin pairs who were born between 1937 and 1954 and also served in the military during the Vietnam War era (1965 to 1975). Of the 3372 twin pairs of known zygosity, 1874 were monozygotic pairs and 1498 were dizygotic pairs. The main finding was that the risk for alcohol dependence accounted for a significant but moderate proportion of the genetic and environmental risk for problem gambling.

In another study using VET data it was found that familial contributions to problem gambling was between 35% and 54% for five DSM-III-R symptoms (Lin et al., 1998). The symptoms were identified through interview questions such as "have you often gone back to the place where you lost money to try to win it back?", "have you often gambled, bet, played the lottery too much or for a longer time than you intended to?" and "did risking the amounts that excited you at first begin to bore you later on so that

you had to increase the amount in order to continue to find it interesting?" The strengths of Lin's et al. (1998) study and Slutske's et al. (2000) study were the large sample sizes and robust data collection methods. Also, the flexible study inclusion criteria meant that findings were generalizable to a wider population and captured a continuum of problem gambling behaviours and co-morbid psychiatric conditions. However, no studies to date are able to claim causal links between genetics and gambling behaviours (Hodgins, Stea, & Grant, 2011).

1.2.5 Environmental factors

Opportunities to gamble are increasingly ubiquitous such as mobile casino games (e.g. "pokies"), sports betting apps supported by tablet computers and smartphones and community based EGMs. Gaming machines have been proposed as the 'crack-cocaine' of gambling due to their addictive properties (Dowling, Smith, & Thomas, 2005). They are designed using principles of classical and operant conditioning based on the finding that the most powerful reward schedule for animals and humans is intermittent and variable ratio reinforcement where a specific behaviour will be reinforced if the reward occurs unpredictably and the amount of the reward is variable (small to a big win) (Battersby, Oakes, Tolchard, Forbes, & Pols, 2008). The structural characteristics (e.g. form of gambling) and situational characteristics (e.g. location of the gambling venues) of gambling activities play an important role in the maintenance of problem gambling pathways (Griffiths, 1999).

Familial factors may also play an important role in the aetiology of problem gambling. Oei and Raylu (2004) investigated for any potential associations between parental attributes and offspring gambling behaviour. The study involved 189 child

offspring who were first year psychology students at an Australian university and their parent/s: 170 fathers and 187 mothers. The findings showed evidence for a relationship between the parents's gambling related cognitions and behaviours and offspring gambling behaviours and cognitions. Furthermore, the offspring to parent pathways were stronger for the father's compared to mother's (Oei & Raylu, 2004). Another study compared the characteristics of 517 adult problem gamblers with and without a problem gambling parent. It was found that the two groups were comparable on most measures relating to clinical characteristics, gambling severity, gambling related problems and psychiatric comorbidity. However, problem gamblers with at least one problem gambler parent were more likely to have a father with alcohol use disorder as well as financial and legal issues (Schreiber, Odlaug, Won Kim, & Grant, 2009).

1.2.6 Integrative model

The previous section described a set of potential causes of problem gambling where each one was considered in isolation of others. However, the reality of problem gambling (as for many other psychiatric conditions) is that it involves the dynamic interplay of a range of complex factors. In an attempt to account for the multiple biological, psychological and ecological variables involved in gambling pathology, Blaszczynski and Nower (2002) developed the Pathways model of problem gambling (Blaszczynski & Nower, 2002). It is comprised of 3 distinct paths (a) behaviourally conditioned problem gamblers (Pathway 1), (b) behaviourally conditioned and emotionally vulnerable problem gamblers (Pathway 2), and (c) problem gamblers who are behaviourally conditioned and have antisocial/impulsivity traits (Pathway 3).

Common to all 3 pathways is that:

> "Principles of learning theory and cognitive processes are instrumental in fostering a loss of control for all pathological gamblers" (Blaszczynski & Nower, 2002) (p492).

The Pathway 1 problem gambler is characterized by the absence of any pre-morbid psychopathology:

> "These gamblers fluctuate between the realms of regular/heavy and excessive gambling because of the effects of conditioning, distorted cognitions surrounding probability of winning, and/or a series of bad judgements or poor decision-making rather than because of impaired control" (Blaszczynski & Nower, 2002) (p494).

In addition to being behaviourally conditioned, Pathway 2 problem gamblers also present with premorbid psychopathology (e.g. Major Depression, Generalised Anxiety Disorder). These individuals may be motivated to gamble in attempt to escape psychological imbalances or disturbance. Finally, Pathway 3 problem gamblers have similar characteristics to those of Pathway 2 problem gamblers but also exhibit features of impulsivity and antisocial personality disorder (Blaszczynski & Nower, 2002).

Previous empirical studies have established a connection between sub-groups of problem gamblers (e.g. emotionally vulnerable, antisocial personality) and severity of gambling disorder. Ledgerwood & Petry(2006) administered a range of psychometric instruments to 149 treatment-seeking problem gamblers that included measures of escapist motivation, dissociation, narcissism/ attention seeking and severity of gambling symptoms (Ledgerwood & Petry, 2006). The results showed the data to be consistent for Pathways 2 problem gamblers (behaviourally conditioned and emotionally vulnerable) and Pathways 3 problem gamblers (behaviourally

conditioned and antisocial/impulsivity traits) (Blaszczynski & Nower, 2002). However, no Pathways 1 problem gamblers (behaviourally conditioned) were identified. It was suggested that this sub-group of problem gamblers experience less severe symptomatology relative to the other two sub-groups and tend to be non-treatment-seekers (Ledgerwood & Petry, 2006). Similarly, another study found a strong association between severity of problem gambling and impulsivity, depression, anxiety and erroneous beliefs which further supported that problem gamblers form a heterogeneous population (Turner, Jain, Spence, & Zangeneh, 2008).

1.3 GAMBLING HELP

The aetiological nature of problem gambling is multidimensional and consequently presents a major challenge to the development and implementation of gambling treatment programs across the public health system. Because problem gamblers form a heterogeneous population there has been a diversity of treatments tested in clinical trials. The more common treatments have included CBT and brief motivational interventions- either individually or combined (integrative therapy), Gamblers Anonymous (GA) and psychopharmacological interventions (Hodgins et al., 2011). A description of each of these approaches is provided in the following section.

1.3.1 Cognitive-behavioural therapy

The gambling treatments best researched in the literature have been elements of CBT. Therefore, variations in CBT currently furnish the best source of evidence based therapy for problem gambling (Cowlishaw et al., 2012; Gooding & Tarrier, 2009). The 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 (Problem Gambling Research and Treatment Centre (PGRTC), 2011).

The theoretical underpinnings of CBT include cognitive and psychobiological mechanisms and are two dominant approaches to explaining gambling disorders (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). Cognitive restructuring plays an important role in CT and has been shown to be clinically efficacious in treating a range of mental health conditions (Beck & Dozois, 2011).

Treatments that target gambling related psychobiological states (e.g. urge to gamble) are predominantly behavioural (exposure-based) (Battersby et al., 2008; Tolchard, Thomas, & Battersby, 2006). Exposure therapy is grounded in both operant and classical conditioning paradigms and cue-exposure with extinction processes (e.g. elimination of gambling urge) has been proposed as more beneficial than other types of behavioural therapy (e.g. aversive therapy) in treating gambling addiction (Brown, 1987). Exposure therapy has been shown to be clinically effective in treating psychological conditions such as anxiety disorder (Ougrin, 2011).

The most recent Cochrane review (2012) of gambling-specific psychological therapies showed that variants of CBT were, overall, clinically superior when compared to standard treatments or wait-list groups (Cowlishaw et al., 2012). Of the 12 studies included for meta-analysis, 3 were principally focused on CT (Ladouceur et al., 2003; Ladouceur et al., 2001; Sylvain, Ladouceur, & Boisvert, 1997). However, studies with

a focus on an exposure-based approach were excluded (McConaghy, Armstrong, Blaszczynski, & Allcock, 1983, 1988; McConaghy, Blaszczynski, & Frankova, 1991) due to a lack of a control group. Cognitive techniques were also a cornerstone of most combined CBT programs alongside behavioural approaches such as distraction, avoidance or exposure tasks.

1.3.2 Brief motivational interventions

Motivational interviewing (MI) is a general counselling approach that focusses on tapping into the person's intrinsic motivation to change their problem gambling behaviour. Amongst its early origins, MI was used to treat problem drinking where motivation was conceptualised as more of an interpersonal process over an intrapersonal characteristic (Miller, 1983). According to Hettema and colleagues (2005), MI aims to enhance a person's readiness to change by exploring and resolving ambivalence (Hettema, Steele, & Miller, 2005). Whilst MI has shown to be a clinically effective intervention in treating addictive behaviours, the underlying mechanisms of change are not well understood (Hettema et al., 2005).

Motivational interviewing has previously been modified for the treatment of problem gambling and subsequently tested in a numerous randomised controlled trials (Hodgins, 2009; Hodgins, Currie, & el-Guebaly, 2001; Hodgins, Currie, el-Guebaly, & Peden, 2004). For example, Hodgins and colleagues conducted a trial involving 314 problem gamblers who were recruited via media announcements (Hodgins, 2009). The participants either wanted to reduce their gambling behaviour or achieve abstinence. The key active ingredient of trial interventions was a single-session motivational interview conducted by a therapist by telephone. It was intended that the

therapist showed empathy, helped develop the participant's awareness of the disparity between their present gambling and future goals, avoid conflict, roll with resistance and support self-efficacy. Overall, the results supported the therapeutic benefits of MI from change in outcome measures of gambling behaviour (days of gambling per month) and self-efficacy across time (Hodgins, 2009).

In the most recent meta-analysis of psychological therapies for disordered gambling to date, 4 of the 14 eligible studies included motivational interviewing therapy as a study arm (Cowlishaw et al., 2012). The participants were mostly at the less severe end of the problem gambling spectrum in comparison to other study samples. Treatment effects from pooled estimates were (on average) in the moderate range for the outcomes 'reduced financial loss' and 'frequency of gambling' up to 12 month follow-up post-treatment. However, compared to control conditions, there was limited evidence to support MI efficacy in reducing gambling-specific symptoms (e.g. preoccupation with gambling and withdrawal) based on standardised measures. Overall, the findings for MI are preliminary due to the small number of studies conducted to date.

1.3.3 Integrative therapy

Previous studies have tested combinations of CBT and brief intervention motivational enhancement therapy (MET) compared to control conditions. Similar to MI, MET targets any ambivalence a person may have about changing their addictive behaviour. A key strategy is to encourage individuals to identify both positive and negative consequences of their gambling activities (Petry, Weinstock, Ledgerwood, & Morasco, 2008). The Cochrane review of psychological therapies for gambling

disorder published in 2012 identified two studies by the same authors that were eligible for inclusion in the meta-analysis (Cowlishaw et al., 2012; Petry et al., 2008; Petry, Weinstock, Morasco, & Ledgerwood, 2009). Because of this small number of studies, the pooled estimates lacked precision and conclusions were limited.

The first study was reported in 2008 and comprised of 4 arms: assessment only control, 10 minutes of brief advice, one session of MET and one session of MET plus 3 sessions of CBT (Petry et al., 2008). The brief advice intervention consisted of the research therapist describing a one page handout on problem gambling including risk factors as well as a number of strategies to avoid developing problems. The participants were recruited mainly from substance abuse treatment clinics and medical clinics where services were provided to the less privileged. Compared to assessment only group, the findings indicated that brief advice was better in the short term (baseline to 6 weeks) on outcomes Addiction Severity Index (ASI) and money gambled. For short to mid- term follow-up (6 weeks to 9 months), MET group and CBT plus MET group did better for ASI scores.

The second study was reported in 2009 and was of a similar design to the previous one conducted by the authors (Petry et al., 2009). The major difference was that the population of interest in the later study was college students. In short, the main findings showed all intervention groups made a significant recovery when compared to assessment only group whilst there was no significant difference between groups. A significant limitation of these studies involving integrated therapies is that the generalizability of findings was restricted to samples of non-treatment seekers who were at the less severe end of problem gambling symptoms.

1.3.4 Gamblers Anonymous

Gamblers Anonymous is a parallel organisation to Alcoholics Anonymous (AA) where peer-counselling is employed to help members stop gambling. The GA website welcome message is as follows:

> Gamblers Anonymous is a fellowship of men and women who share their experience, strength and hope with each other that they may solve their common problem and help others to recover from a gambling problem. The only requirement for membership is a desire to stop gambling. Our primary purpose is to stop our gambling and to help other compulsive gamblers do the same (Gamblers Anonymous, 2009).

At an international level, GA has been established in over 55 countries. The 12 step program is mostly based on spiritual principles and claimed to be "…rooted in sound medical therapy"(Gamblers Anonymous, 2009)

A few studies involving GA have been reported in the gambling treatment literature. In Petry and colleagues (2006) randomised controlled trial, the "real-world" control condition of GA referral was used to evaluate the efficacy of cognitive-behavioural therapy (Petry et al., 2006). The specific study arms were: referral to Gamblers Anonymous (GA), GA referral plus a cognitive– behavioural (CB) workbook, or GA referral plus 8 sessions of individual CB therapy. The CB workbook and CB therapy groups were superior to GA in terms of statistical significance but all groups experienced some degree of clinically meaningful change. For example, the difference between baseline South Oaks Gambling Screen (SOGS) scores and 12 month follow-up were of medium effect size for GA (Cohen's d = 0.58, 95% CI: 0.22 – 0.93) and large effect size for CB (Cohen's d = 0.90, 95% CI: 0.58 – 1.22). However, the effect estimate for GA showed more uncertainty than CB as reflected by the wide confidence interval.

One of the shortcomings of using referral to GA as a control group in previous outcome studies has been poor attendance (Hodgins et al., 2011). In Petry's study, referral of participants occurred in a one-time session without further follow-up or facilitation of contact with GA members (Petry et al., 2006). Another study found similar findings in which a brief 6-session format of imaginal desensitisation plus motivational interviewing was more efficacious than GA as control condition (Grant et al., 2009). However, individuals assigned to GA attended meetings infrequently. Also, the lack of certain non-specific therapy effects for GA (e.g. manualised intervention, therapist's empathy) has meant that the contextualisation of findings for active treatments are limited in terms of causal mechanisms. More studies are required to better understand the therapeutic role of GA.

1.3.5 Psychopharmacological treatment

Numerous classes of psychopharmacological treatments for problem gambling have been studied to date. These include opioid antagonsists, glutamergic agents, antidepressants and mood stabilisers (Hodgins et al., 2011). Opioid antagonsists may suppress the production of endogenous opiates by mediating mesolimbic dopaminergic pathways. Drugs such as Naltrexone have been successful in the treatment of drug dependence such as alcohol use disorder (Volpicelli, Alterman, Hayashida, & O'Brien, 1992). In gambling addiction, opioid antagonism has shown to simultaneously reduce gambling related urges and gambling behaviours (Grant, Kim, & Hartman, 2008). The glutamergic agent N-Acetyl Cysteine has also been found to be therapeutically effective in the treatment of gambling symptoms including gambling related urge and cognitions (Grant, Kim, & Odlaug, 2007). It works as a

mediator of reward-seeking behaviour by reducing the synaptic release of glutamate in the nucleus accumbens.

Anti-depressants such as paroxetine and fluvoxamine have also been investigated in the treatment of problem gambling (Blanco, Petkova, Ibáñez, & Saiz-Ruiz, 2002; Grant et al., 2003). The putative mechanism of action is that the reuptake of serotonin is inhibited which may in turn decrease levels of compulsiveness and impulsivity. It has been suggested that problem gamblers may be characterised by anomalous serotonergic functioning (Blanco, Ibáñez, Sáiz-Ruiz, Blanco-Jerez, & Nunes, 2000). Finally, mood stabilisers have also shown preliminary evidence for being effective treatments (Pallesen et al., 2007). In a head to head trial involving the mood stabilisers lithium and valproate, it was found that both drugs were comparable in terms of improvement in gambling related symptoms (Pallanti, Quercioli, Sood, & Hollander, 2002).

The most recent systematic review and meta-analysis of psychopharmacological treatments for problem gambling was conducted in 2006. It showed that the 3 major classes of drugs (opioid antagonists, anti-depressants and mood stabilisers) had comparable benefits (Pallesen et al., 2007). However, in terms of absolute effects, the medications did not appear to produce effect sizes of similar magnitude to that of psychological therapies (Pallesen, Mitsem, Kvale, Johnsen, & Molde, 2005; Pallesen et al., 2007). A more recent update of the gambling literature has indicated that the emerging evidence-base for gambling-specific medications is promising particularly for opioid antagonists (Hodgins et al., 2011). However, large scale randomised

controlled trials are needed to provide more robust data in relation to the differential effects of drugs and how they compare to other treatment types such as CBT.

1.4 GAMBLING HELP IN SOUTH AUSTRALIA

In South Australia (total population 1.6 million) problem gambling is mainly a result of the widespread availability of 12,688 EGMs in venues in nearly all towns and cities across the state (Government of South Australia:Consumer and Business Services, 2012). To help mitigate it, numerous community-based gambling help services are freely available. These include self-help peer support groups based on similar principles to Alcoholics Anonymous; a gambling helpline that provides 24-hour telephone counseling and support, crisis management and referral to face to face counseling services; and a support service for people affected by problem gambling who have been drawn into, or are at risk of entering the criminal justice system in South Australia.

A key treatment provider in South Australia is the SGTS where free CBT and mental health care is offered to help-seeking problem gamblers. The treatment program offers both one-on-one therapy and group therapy. An inpatient program at Flinders Medical Centre is also available (Morefield et al., 2013). In the financial year of 2008/2009 nearly three thousand occasions of face to face contact with 524 individual problem gamblers were provided by therapists (Statewide Gambling Therapy Service, 2009). Over 87% reported that EGMs were the main type of gambling that were causing problems. A central focus of the CBT program is to target the urge to gamble which is often out of control in problem gamblers by using exposure therapy.

At SGTS there is an emerging evidence base to support the clinical benefits of exposure therapy. For example, Smith and colleagues conducted a prospective cohort study involving 127 problem gamblers across 12 months and found that therapy-adherers reported greater improvements in gambling related outcomes than therapy non-adherers (Smith et al., 2010). This preliminary investigation enabled SGTS clinicians and researchers to have a better understanding of the nature and complexity of people attending SGTS and the association between therapy attendance and treatment outcomes. In a separate study it was shown that clients who received ET also experienced improvements in affective instability. However, those at the more severe end of depression were more prone to a relapse during treatment and at follow-up (Smith et al., 2011).

To investigate predictors of relapse in problem gambling, the SGTS team conducted a prospective cohort study with 158 treatment and support seeking problem gamblers from a range of gambling help services in South Australia. The findings showed that gambling related urge was consistently associated with relapse (Smith et al., 2015). Moreover, it was also found that when comparing the classification properties of the gambling urge scale (GUS) (Raylu & Oei, 2004b) to the gambling related cognitions scale (GRCS) (Raylu & Oei, 2004a) there was no difference between 23-item GRCS total score, a composite of several kinds of erroneous beliefs, and six-item GUS (Smith, Pols, Battersby, & Harvey, 2013). This suggested gambling urges were highly prevalent in problem gamblers as cravings are in SUD (American Psychiatric Association, 2013).

The significant role of urge also has implications for understanding the aetiology of problem gambling using behavioural models of conditioning where the variable interval schedule of reinforcement provided by EGMs and other forms of gambling explain the development and maintenance of urge (Battersby et al., 2008). Furthermore, it has been proposed that cognitions are a subclass of behaviours and exist within a human behaviour causal stream rather than as an independent entity (Latimer & Sweet, 1984). This is an important issue which requires further study as both cognitive and behavioural strategies have both been employed in the successful treatment of problem gambling (Gooding & Tarrier, 2009).

1.5 RESEARCH QUESTION AND OUTLINE

Previous research conducted at SGTS has indicated that exposure therapy is a useful treatment for problem gambling. However, it was not known if it worked better or worse or equally well as pure cognitive therapy. This information would improve the evidence base for two of the core CBT techniques, pure CT and behavioural (exposure-based) therapy (ET) in problem gambling and would also be the first step in conducting further trials to ultimately test whether either approach alone or combined had superior outcomes.

The primary research question addressed in this thesis was:

Among treatment-seeking problem gamblers does one of two core components of CBT - ET or CT – if administered alone, contribute more to short-term recovery from problem gambling than the other one administered alone?

The central focus of this thesis is on the effectiveness of CT and ET treatments for problem gambling. Therefore, its goal is to uncover new facts from an evidence based medicine (EBM) perspective. There is an urgent need for the generation of high quality evidence on gambling treatments so that clinicians and counsellors in everyday community health practices can choose treatments with greater confidence.

The main study was a single-site, two-group randomised, parallel trial. Participants were followed for up to six months after completing their course of therapy. This thesis outlines the study which was conducted in three phases:

Phase 1. Systematic literature review- to justify a new trial;
Phase 2. Randomised controlled trial- to investigate the interventions; and
Phase 3. Qualitative interviews- to support and extend trial findings.

Chapter 2 provides the findings from a systematic review of randomised controlled trials involving cognitive and exposure therapies. The third chapter describes the trial design and methods used to investigate the question. Chapter 4 details the statistical strategy used to analyse trial data. The trial results are presented in Chapter 5.The findings from qualitative interviews are described in context of quantitative findings as well as the literature in Chapter 6. A discussion of both quantitative and qualitative findings is presented in Chapter 7 as well as conclusions based on the study.

CHAPTER 2: SYSTEMATIC LITERATURE REVIEW

2.1 BACKGROUND

A systematic review was undertaken at the beginning of this study to attain a thorough understanding of the gambling evidence base surrounding cognitive and exposure therapies for problem gambling.

In general, evidence based treatments are ostensibly predicated on 'gold standard' randomised clinical trials (RCTs) (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996), for example, gambling-specific cognitive-behavioural therapies (Cowlishaw et al., 2012). However, a common problem in the reporting of RCT findings is a lack of transparency (Moher et al., 2010). In response to this and in order to improve the reporting of randomised trials and enable readers to critically appraise the validity of findings, an international group of experts developed the CONsolidated Standards Of Reporting Trials (CONSORT) (Begg et al., 1996). Since inception in 1996, the checklist has been shown to be associated with significant improvement in reporting of RCTs (Plint et al., 2006) and has evolved with revisions in 2001 (Moher, Schulz, & Altman, 2001) and 2010 (Moher et al., 2010). CONSORT has been extended for appraisal of cluster randomized trials (Campbell, Elbourne, & Altman, 2004), non-inferiority and equivalence randomized trials (Piaggio, Elbourne, Altman, Pocock, & Evans, 2006), non-pharmacological treatments (Boutron, Moher, Altman, Schulz, & Ravaud, 2008) and is endorsed by "many journals, influential editorial groups, such as the World Association of Medical Journals, and translated into several languages" (CONSORT, 2010). The objective of this review was to evaluate existing evidence from randomized clinical trials on the following research question. Among problem

gamblers (population) how accurate and valid was the evidence base on cognitive therapy alone and exposure-based therapies alone in terms of the CONSORT checklist for randomized trials of non-pharmacologic treatment (Boutron et al., 2008). It was also hypothesized that an improvement in the reporting of RCTs concerning these therapies was associated with the introduction of CONSORT in1996.

2.2 METHODS

2.2.1 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 (Medical Subject Headings) terms were generated to identify studies of cognitive and/or behavioural treatments for gambling disorders. Keywords used for the search were the union of gambling disorders/problem gambling/pathological gambling intersected with the union of cognitive therapy/ behaviour therapy/cognitive behaviour therapy and related terms. Appendix A provides search terms for PsycINFO; the same keywords were used for MEDLINE and MeSH terms were adapted for this database. Limitations were imposed restricting the searches to studies written in the English language and those involving a systematic review, meta-analysis, quantitative study, or treatment outcome/randomized clinical trial. An additional manual search was conducted of reference lists within full-text articles that were assessed for eligibility, systematic reviews and meta-analyses identified in the database search. The Guideline for Screening, Assessment, and Treatment in Problem Gambling approved by NHMRC for clinical practice guidelines was also downloaded (Melbourne Monash Problem Gambling Research and Treatment Centre) and further

manual searches of the associated references were conducted. Finally, 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).

2.2.2 Study selection

The titles and abstracts of the studies identified through the aforementioned searches were first assessed. Eligibility criteria for initial study inclusion were based on the Cochrane Handbook for Systematic Reviews (Higgins & Green, 2011) 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 (Hodgins et al., 2011); 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 texts of selected reports were then retrieved and examined for compliance with eligibility criteria for inclusion in the final review. The criteria were specific to the administration of ET or 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. ET was operationalized as a treatment that substantially involved problem gamblers being exposed to gambling-related stimuli, using either imaginal or in vivo procedures, with the aim of reducing or extinguishing psycho-physiological responses such as urge or craving to gamble (Battersby et al., 2008). CT was operationalized as any treatment that was predominantly comprised of a systematically structured intervention designed to alter participants' erroneous thoughts and belief structures specific to gambling, with the aim of facilitating the development of a more functional set of gambling-related cognitions (Ladouceur et al., 2001). Any disagreements about the eligibility of a study were resolved by discussion with thesis supervisors. Details of studies that passed initial screening and then subsequently excluded were recorded.

2.2.3 Study evaluation

The CONSORT guidelines for randomized trials of non-pharmacologic treatment (Boutron et al., 2008) were used in conjunction with more recent CONSORT guidelines for reporting parallel group randomised trials (Moher et al., 2010) in order to critically assess the accuracy and validity of results reported within each study. Where relevant, CONSORT extensions for other classes of trial design (non-inferiority, equivalence, factorial, cluster, and crossover trials) were also used concomitantly. The CONSORT for non-pharmacological treatments was developed as a guide for scientific reports of interventions such as surgery, rehabilitation, and psychological therapies. The checklist comprises 23 items to assist in the identification of key pieces of information ideally embedded in the title, abstract, introduction, methods, results, and discussion and essential to the evaluation of the

internal and external validity of reported findings. CONSORT statements for parallel group randomised trials as well as extensions are available at their web site (CONSORT, 2010). For each study included in this review, individual CONSORT items were rated as either 'absent', 'present with some limitations', or 'present'.

2.2.4 Data analysis

Statistical analyses were conducted using Stata 12.0 (StataCorp, 2011). Frequencies of ratings for CONSORT items (absent, present with some limitations, and present) were calculated for each article along with an average rating for all articles. Fisher's exact tests were conducted on cross-classification frequencies to identify any significant associations between ratings and CONSORT sections (title and abstract, background, methods, results, and discussion), year of publication and therapy type. A significance level of 5% was used.

2.3 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 was comprised of a treatment with both cognitive restructuring and behavioural components (problem-solving training and social-skills training) (Sylvain et al., 1997). 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. Reasons for study exclusion are provided in Appendix B.

The 7 included studies are summarised in Table 1. Three were conducted in Australia using imaginal desensitisation (ET) and published between 1983 and

1991(McConaghy et al., 1983, 1988; McConaghy et al., 1991) , one in Spain (1996) comprising individual and combined cognitive restructuring and in vivo exposure with response prevention (Echeburua, Baez, & Fernandez-Montalvo, 1996) and three in Canada with a main focus on cognitive restructuring between 1997 and 2003 (Ladouceur et al., 2003; Ladouceur et al., 2001; Sylvain et al., 1997). The mode of delivery for all ET interventions was individual format and three of these were conducted in an inpatient psychiatric facility (McConaghy et al., 1983, 1988; McConaghy et al., 1991). Cognitive treatments were delivered in outpatient settings for both individual (Ladouceur et al., 2001; Sylvain et al., 1997) and group (Echeburua et al., 1996; Ladouceur et al., 2003) 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 (Echeburua et al., 1996; Ladouceur et al., 2003; Ladouceur et al., 2001; Sylvain et al., 1997) as was one of the ET interventions (Echeburua et al., 1996). The remaining ET interventions (McConaghy et al., 1983, 1988; McConaghy et al., 1991) were conducted on the strength of self- reported problem gambling. 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 (Echeburua et al., 1996; Ladouceur et al., 2001; Sylvain et al., 1997), horse and dog racing in two studies (McConaghy et al., 1983, 1988) and no information was provided in two studies (Ladouceur et al., 2003; McConaghy et al., 1991).

Figure 1. Selection of studies.

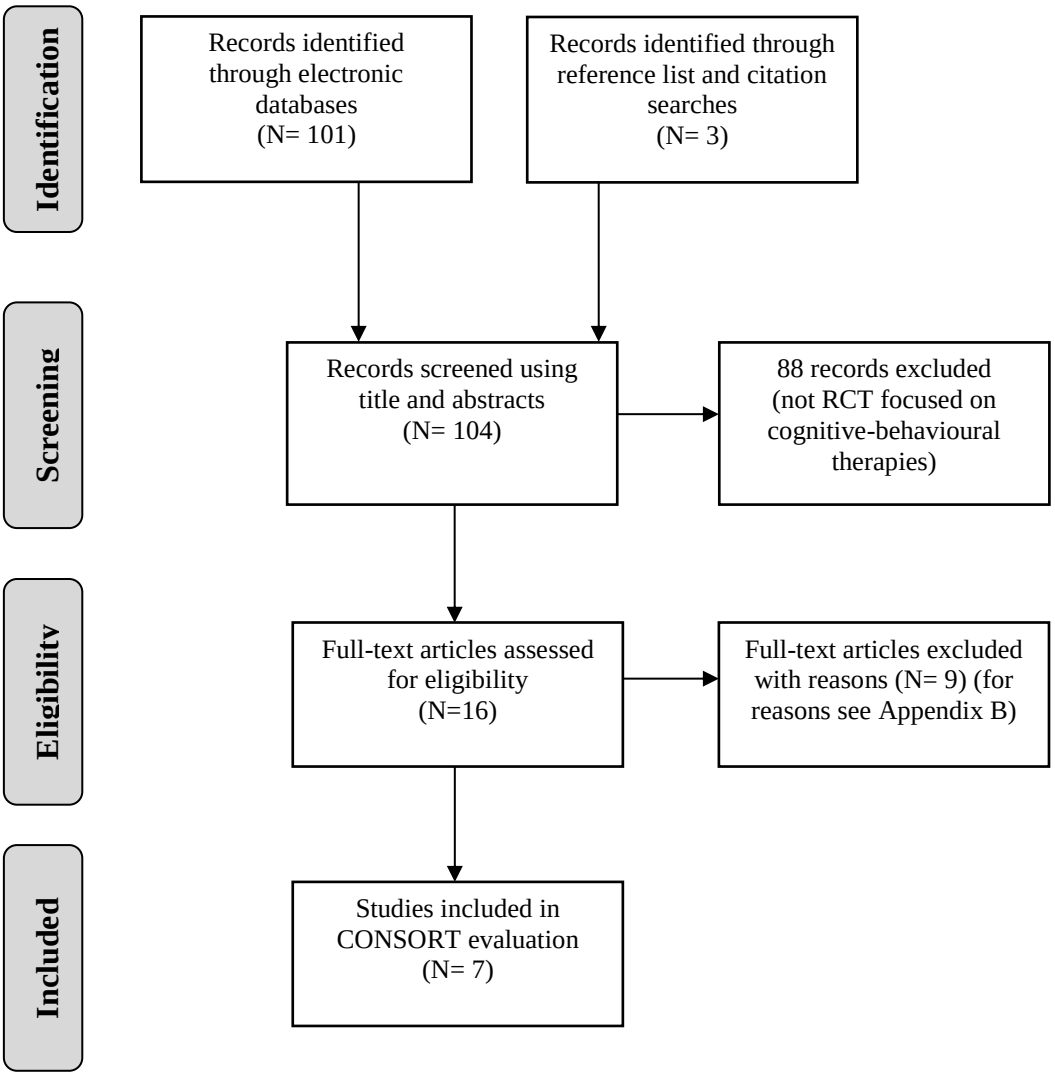


Table 1. Summary of included studies.

Study	Population, setting, design	Inclusion criteria	Primary gambling type	Conditions	Outcomes
McConaghy et al. (1983)(McConaghy et al., 1983)	Age, mean (range), years: 35 (20 - 63) % female: 20 Population: Compulsive gamblers requesting behavioural therapy. Country: Australia Design: Two group, randomized 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) (McConaghy et al., 1988)	Age, mean (range), years: 35 (18 - 58) % female: 5 Population: Persons who were seeking treatment for problem gambling. Country: Australia Design: Two group, randomized 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) (McConaghy et al., 1991)	Age, mean, years: 42.5 % female: 9.2 Population: Persons who were seeking treatment for problem gambling. Country: Australia Design: Two group, randomized 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)(Echeburua et al., 1996)	Age, mean(SD), years: 35 (11) % female: 55.6 Population: Pathological gamblers who sought treatment for gambling at a mental health centre. Country: Spain Design: Four group, randomized 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 based on DSM-III-R criteria. • 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)(Sylvain et al., 1997)	Age range, mean (SD), years: treatment group: 37.6 (10.3) control group: 42.6 (12.1) % female: 0 Population: Pathological gamblers recruited via media announcements or referred by health professionals. Country: Canada Design: Two group, randomized trial. Time points: Baseline, end of treatment, 6 and 12 month follow-up.	Primary diagnosis of pathological gambling based on DSM-III-R criteria. 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)(Ladouceur et al., 2001)	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, randomized 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 randomization.	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)(Ladouceur et al., 2003)	[a]Age, mean (SD), years: treatment group: 42.56 (10.48) 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, randomized trial. Time points: Baseline, end of treatment. Six, 12 and 24 month follow-up for treatment group.	Primary diagnosis of pathological gambling. No evidence of current or past schizophrenia, bipolar disorder or organic mental disorder. Willing to undergo randomization.	NA	Therapy type: Cognitive Mode of therapy: Group Session no: 10 weekly sessions. Session duration: 120 minutes	• DSM-IV • Self-efficacy 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.

2.4 VALIDITY OF EVIDENCE

Table 2 shows the final ratings for each study across all 23 CONSORT items. The evaluations are provided in Appendix C. The frequency of items rated as 'absent' per study ranged from 6 to 7 (26.09% -30.43%), with an average of 6.86 (29.83%) rated as 'absent'. The frequency of items rated as 'present with some limitations' per study ranged from 11 to 14 (47.83% - 60.87%), with an average of 13.14 (57.13%) rated as 'present with some limitations'. The frequency of items rated as 'present' ranged from 2 to 5 (8.70% - 21.74%), with an average of 3 (13.04%) rated as 'present'.

Table 3 presents the results of comparisons between rating categories and CONSORT section using cross-classification analysis and indicated there was a significant association ($P < 0.001$). Across all studies, 70.83% of items rated as 'absent' were in the methods section. A consistent issue was that the terms "randomly assigned" (Echeburua et al., 1996; Ladouceur et al., 2003; Ladouceur et al., 2001; Sylvain et al., 1997) or "randomly allocated" (McConaghy et al., 1983, 1988; McConaghy et al., 1991) were used in the methods section of each study without elaboration about how the random allocation sequence was generated, how allocation was concealed, or how the treatment allocation was implemented. There was no significant association between frequency of rating categories and year of publication ($p = 0.999$) (Table 4) or treatment type ($p = 0.981$).

Table 2. Evaluation of included treatment studies using 23-item CONSORT checklist for non-pharmacologic interventions.

	Title/abstract	**Background**	**Methods** Participants	Interventions	Objectives	Outcomes	Sample size	Randomisation-sequence generation	Allocation concealment	Implementation	Blinding (masking)	Statistical methods	**Results** Participant flow	Implementation of intervention	Recruitment	Baseline data	Numbers analysed	Outcomes and estimation	Ancillary analyses	Adverse events	**Discussion** Interpretation	Generalizability	Overall evidence
McConaghy et al. (1983)	?	?	?	?	?	?	−	−	−	−	?	?	?	+	−	?	+	?	?	−	?	?	?
McConaghy et al. (1988)	?	+	?	?	+	?	−	−	−	−	?	?	?	?	−	?	+	?	−	−	?	?	?
McConaghy et al. (1991)	?	?	+	?	?	?	−	−	−	−	−	?	?	?	?	?	+	?	−	−	?	?	?
Echeburua et al. (1996)	?	+	+	?	?	?	−	−	−	−	−	?	?	?	+	?	?	?	?	−	?	?	?
Sylvain et al. (1997)	?	?	?	+	+	?	−	−	−	−	−	?	?	?	−	?	?	?	?	−	?	?	?
Ladouceur et al. (2001)	?	+	+	+	+	?	−	−	−	−	−	?	?	+	−	?	?	?	?	−	?	?	?
Ladouceur et al. (2003)	?	?	?	+	+	?	−	−	−	−	−	?	?	?	−	?	+	?	?	−	?	?	?

+ Present ? Present with some limitations − Absent

Table 3. The distribution of ratings and CONSORT sections.

	CONSORT section					
Rating	Title/abstract	Introduction	Methods	Results	Discussion	Total (n = 161)
Absent	0 (0)	0 (0)	34 (70.83)	7 (14.58)	7 (14.58)	48
Present with some limitations	7 (7.61)	4 (4.35)	25 (27.17)	35 (38.04)	21 (22.83)	92
Present	0 (0)	3 (14.29)	11 (52.38)	7 (33.33)	0 (0)	21

Values are *n* (%).
$P < 0.001$, Fishers exact.

Table 4. The distribution of ratings and year of publication.

	Year of publication							
Rating	1983 (ET)	1988 (ET)	1991 (ET)	1996 (ET/CT)	1997 (CT)	2001 (CT)	2003 (CT)	Total (n = 161)
Absent	7 (14.58)	7 (14.58)	7 (14.58)	6 (12.50)	7 (14.58)	7 (14.58)	7 (14.58)	48
Present with some limitations	14 (15.22)	13 (14.13)	13 (14.13)	14 (15.22)	14 (15.22)	11 (11.96)	13 (14.13)	92
Present	2 (9.52)	3 (14.29)	3 (14.29)	3 (14.29)	2 (9.52)	5 (23.81)	3 (14.29)	21

Abbreviations: ET, exposure therapy; CT, cognitive therapy.
Values are *n* (%).
$p = 0.999$, Fishers exact.

2.5 DISCUSSION

In this systematic review of randomised controlled trials involving cognitive therapy and exposure-based therapy for gambling disorders 7 studies were identified for appraisal of reported evidence using CONSORT. The studies were published between 1983 and 2003 and conducted across Australia, Canada, and Spain. There was a preponderance of males across

samples and mean age ranged from 35 to 45 years. On average, approximately 31% of the 23 CONSORT items were rated as 'absent' across studies and more than 52% rated as 'present with some limitations'.

Similar to the findings of a broader systematic review of psychological therapies (Cowlishaw et al., 2012), a number of methodological shortcomings were also 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.

Sample sizes were generally small and although three of the studies (Echeburua et al., 1996; McConaghy et al., 1983, 1988) 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 generalizability of trial findings (Boutron et al., 2008).

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 and should be considered descriptive rather than suggestive of causal inferences.

Only one study reported any blinding status to minimise the possibility of biased influences (McConaghy et al., 1983). Although it is impossible to blind therapists or participants to CBT interventions, CONSORT states that unblinded data analysts may introduce bias through the selection of statistical techniques to generate more favourable estimates of treatment effects. However, with a growing number of trial protocols becoming available in the research literature (West, 2012) the reader will be able to assess if data analyses were carried out according to a pre-specified statistical plan (Miller & Stewart, 2011).

Ideally, clinicians should be able to research and evaluate the relevance and efficacy of any given treatment in terms of its historical context within the intervention literature. However, in the current review, only one study reported dates for recruitment and follow-up (Echeburua et al., 1996), limiting the reader's capacity in this area.

Cognitive-behavioural therapies for a range of disorders, particularly anxiety disorders and depression, have continuously developed over the past 50 years or so. Behavioural therapy emerged as the 'first wave' in the 1950s followed by a second wave of cognitive therapy in the 1970s. A subsequent merger of CT and BT occurred in the late 1980s to early 1990s to become the generic CBT (Öst, 2008). Since the mid-1990s a third wave has evolved with a range of approaches, such as acceptance and commitment therapy (ACT), cognitive behavioural analysis system of psychotherapy (CBASP) and functional analytic psychotherapy (FAP). While some of these approaches are becoming more and more widely used in clinical interventions, there is currently a relatively low level of evidence providing empirical support (Öst, 2008). Based on the studies examined in this review there is potential for gambling treatments to be accepted and applied as 'gold standard' ahead of the supporting data.

Research has indicated that there may be harmful effects for some patients following psychological treatments. For example, in the treatment of Chronic Fatigue Syndrome (CFS) patient organisations reported that CBT worsened symptoms and consequently motivated a safety and effectiveness trial (P. White et al., 2011). A previous survey of Cochrane reviews showed that most studies involving drug interventions reported adverse events whereas further improvement was generally required for non-pharmacological interventions (Hopewell, Wolfenden, & Clarke, 2008). Commensurate with this, none of the studies included in the current review reported on adverse events, rendering it difficult to consider the risk associated with these treatments in a meaningful way (Moher et al., 2010). Similarly, reporting of adverse events in the treatment of conditions that are commonly co-morbid with gambling disorders (such as major depression) is often limited (Jakobsen, Hansen, Simonsen, Simonsen, & Gluud, 2012). This is an important consideration as treatments specific to gambling disorders have potential for negative effects. For example, patients engaged in imaginal and in vivo exposure tasks are more vulnerable to harmful gambling behaviour due to increased urge levels (Sharpe & Tarrier, 1992) and appropriate management strategies need to be employed.

The findings of this literature review did not support the hypothesis that there would be an improvement in the reporting of RCTs concerning CT and ET in association with the introduction of CONSORT in 1996. The reviewed studies were published between five and twenty-five years before the CONSORT extension for non-pharmacologic treatments became available. However, three studies were published following the first CONSORT for parallel randomised trials in 1996 (Begg et al., 1996). Another recent systematic review also found that reporting of study findings for behavioural interventions for problem gamblers had not

significantly improved over time (Fink et al., 2012) although none of the Australian studies involving imaginal desensitisation were included (McConaghy et al., 1983, 1988; McConaghy et al., 1991). Conversely, reporting transparency has been shown to have improved significantly for a range of clinical conditions (e.g. rheumatic diseases, ophthalmology, and obstetrical anaesthesia) where reporting according to CONSORT guidelines has also been adopted (Plint et al., 2006).

This systematic review had a number of limitations. Search terms in MEDLINE and psycINFO were limited to English language. There may be other publications reporting randomised trials in non-English language sources that could potentially influence the conclusions of this trial. Also, it is possible that some studies were missed due to deviations in article indexing as a result of incomplete reporting, for example, the lack of identification as a randomised trial in the title and abstract. This was accounted for, at least partly, by not including the criterion of randomised trials in the initial screening. Further, there may have been limitations in search terms used in the databases and these may not have fully covered the terminology for cognitive and behavioural (exposure-based) therapies. However, the author had over 6 years' experience in the field of gambling intervention research and is confident that a comprehensive search was achieved.

Only 7 reports were identified for evaluation in this review and this represents a small proportion of the gambling intervention literature. This is not surprising considering the relatively nascent stage of research into gambling treatments (Hodgins et al., 2011) and the principal focus on two key therapeutic approaches. The most recent reviews of psychological treatments in general have evaluated randomised designs (n=12) (Cowlishaw et al., 2012) and both randomised and nonrandomised designs (n=26) (Fink et al., 2012) for gambling

disorders. Finally, the author did not contact authors of the studies in order to clarify any missing or incomplete details. It is unlikely that clinicians, policy makers or patients would do this; and a principal conclusion, for pragmatic purpose's, to be drawn from the critical literature review is that the evidence base it provides, taken at face value, is spotty at best.

2.5.1 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" (Problem Gambling Research and Treatment Centre (PGRTC), 2011), the data from meta-analyses offered to support this recommendation are uncertain due to methodological limitations as highlighted in this current review. These findings therefore justify a new trial in order that CT, ET, and CBT approaches may continue to be improved.

CHAPTER 3: METHODS

3.1 ETHICAL CONSIDERATIONS

This study was motivated by the uncertainty about the clinical superiority of CT over ET in the treatment of problem gambling. Based on this uncertainty, ethical equipoise applied and participants were not disadvantaged from assignment to either treatment group. A state of equipoise was also expected to be maintained throughout the trial due to its single-site design which otherwise may have been disrupted from conflicting treatment paradigms in a multi-site study (Peduzzi et al., 2010). Furthermore, collective equipoise within the research team was evident from individual doubts of certitude in relation to differential efficacy of CT and ET and respect for each other's expert opinion. (Piantadosi, 2005; Smith, Battersby, Harvey, Pols, & Ladouceur, 2013).

The findings from the systematic literature review in Chapter 2 provided a sound justification for this study protocol to help uncover "gold standard" facts to improve guidance for patients and clinicians in treatment choices. To achieve this, a direct comparison of CT and ET was considered to be a logical step because the absolute effects of these therapies had been previously established (e.g. CT or ET versus control group (Echeburua et al., 1996; Ladouceur et al., 2003; Ladouceur et al., 2001; McConaghy et al., 1983, 1988; McConaghy et al., 1991; Sylvain et al., 1997)). The study's main research question was also consistent with the Declaration of Helsinki principle that "…research involving human subjects must…be based on a thorough knowledge of the scientific literature" (World Medical Association, 2013).

A considerable weakness of previous investigations of gambling-specific CBT interventions has been a lack of novel analytic techniques to maximize potential of data collected from patients. Instead, the interpretation of findings was mostly predicated on hypothesis testing *p*-values that limited translatability to the clinical setting. To address this deficiency, the study protocol described in the remainder of this chapter and in Chapter 4 is targeted at contributing new information to the current evidence-base as well as to put forth an improved methodological framework for research in the gambling field. This is in accordance with the Declaration of Helsinki principle that "The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol" (World Medical Association, 2013).

In terms of the manualised structure of treatments in this study, the mechanisms of delivery and therapist related variable's, no meaningful differences were expected to exist when compared to the standard therapy program offered to clients at SGTS. For example, both formats were based on manualised techniques that were underpinned by gambling-specific theoretical mechanisms of change and delivered in a face-to face format by therapists with similar experience and professional qualifications. Therefore, it would have been difficult for an individual to have a clear preference for non-participation in the study based on the commonalities between all treatments on offer and so making it "morally acceptable" to enrol participants (Chambers, 2011).

Furthermore, the state of clinical equipoise in this trial meant that any risks associated with either CT alone or ET alone would be similar even if a treating therapist had preference for one type of therapy over another. For example, a participant who was randomly assigned to receive CT would not be exposed to any estimative risks (e.g. lack of therapeutic benefit) that

would be greater than the risks that would be faced by the same participant if he or she received ET on the basis of the therapist's beliefs (Lantos & Spertus, 2014)

The study received approval from the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee (see Appendix D), 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 (see Appendix E). 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.

3.2 TRIAL DESIGN

The research question addressed in this study was:

> Among treatment-seeking problem gamblers does one of two core components of CBT - ET or CT - if administered alone, contribute more to short-term recovery from problem gambling than the other one administered alone?

Secondary questions related to therapy-specific causal mechanisms and the research process, for example, rate of recruitment, therapy sessions required, duration of sessions, drop outs, data completion and level of treatment fidelity achieved by the therapists.

The study was a two-group randomised, parallel design, with treatment seeking problem gamblers presenting to the 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 (Battersby et al., 2008). It was the first randomised trial to compare these treatments in a population of problem gamblers.

3.3 PARTICIPANTS

Participants were recruited over a 12 month period that commenced April 2011. To assess study eligibility, an independent clinician (DS) conducted semi-structured interviews by telephone with treatment seeking problem gamblers who contacted 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) (see Appendix F) (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 gambler. 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 EGMs; 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 EGMs; 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.

3.4 INTERVENTIONS

The trial was comprised of two interventions, CT and ET, which are described in the following sections. A summary of treatment sessions is provided in Table 5.

CT. Cognitive therapy is focused on correcting misconceptions relating to gambling such as the basic notion of randomness. Key components of cognitive correction involve: (i) understanding the concept of randomness: the therapist explains 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 explains how the illusion of control contributes to the maintenance of gambling habits, and then corrects these erroneous beliefs; (iii) awareness of inaccurate perceptions: the problem gambler is

Table 5. 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.

informed that erroneous perceptions, mainly making links between independent events, predominate when gambling, and is taught to distinguish between adequate and inadequate verbalisations; and (iv) cognitive correction of erroneous perceptions: the therapist is to train the problem gambler to correct inadequate verbalisations and faulty beliefs (Ladouceur et al., 2003). Cognitive therapy has been empirically validated as an efficacious treatment of problem gambling (Petry, 2009). Previous studies have indicated that cognitive factors play a significant role in problem gambling pathways (Ladouceur, Sylvain, Letarte, Giroux, & Jacques, 1998).

ET. Exposure therapy is 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 (Battersby et al., 2008; Oakes, Battersby, Pols, & Cromarty, 2008). The initial procedure is 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 is 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 habituates to the urge in imagination, clients habituate to their urge to gamble using a variety of live tasks at gambling venues (in-vivo exposure) to challenge the triggers of their urges (Battersby et al., 2008).

Participants in each treatment group were to receive up to twelve 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 (Oakes et al., 2008; Tolchard et al., 2006). 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 the senior therapists presented by Robert Ladouceur, a widely published international clinician and researcher in the field of cognitive therapy for gambling disorders (Ladouceur et al., 2003; Ladouceur et al., 2001; Ladouceur et al., 1998). 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) (Ladouceur & Lachance, 2007).

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 would 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 exercise sets with rationales 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 the use of technical language was minimised.

Participants in both ET and CT groups were provided with a pre-treatment assessment to identify problem gambling and any co-occurring conditions. The interview was comprised of a gambling focused cognitive behavioural assessment including DSM-IV-TR criteria for identifying a gambling disorder. 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 covered relapse prevention strategies.

3.5 TRAINING AND THERAPIST FIDELITY

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 therapist fidelity 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). 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 6). 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.

Table 6. 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)*

3.6 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 (Arnett, 1994; Nower, 2004; Smith et al., 2010), 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 (Roth, 2003).

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 money spent on EGMs; *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 was 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 are provided in Appendix G. The measurement occasions are presented in Table 7.

3.6.1 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 to which gambling behaviour has impeded an individual's life. The screen comprises three sub-scales (enjoyment of gambling, harm to partner and harm to self) with a total of 21 items. 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 (Ben-Tovim et al., 2001). Reliability and validity of the VGS have been confirmed in a clinical population of problem gamblers (Tolchard & Battersby, 2010). 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 SOGS (r = 0.97), but extends the score range. The VGS has also shown similar properties in construct validity as the CPGI on a number of problem gambling correlates (e.g. 'self-rating of problem'; 'wanted help'; and 'suicidal tendencies') (McMillen & Wenzel, 2006). 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 (Smith et al., 2010).

3.6.2 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 (American Psychiatric Association, 2000).

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

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 (Raylu & Oei, 2004a).

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 and non-clinical or non-treatment seeking gamblers (Smith, Pols, et al., 2013). 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 (Raylu & Oei, 2004b).

Self-efficacy perception: To assess each 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 (Andrews & Slade, 2001; Slade, Grove, & Burgess, 2011). 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 - 50, 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 (Mundt, Marks, Shear, & Greist, 2002).

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 (Reinert & Allen, 2002).

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*).

3.6.3 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-month follow-up; and $25 at 6-month follow-up. Treatment drop-out was determined using the approach based on the therapist's judgement of participant progress up to the point of self-initiated termination (Smith et al., 2010).

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 (see Appendix H) (Edwards et al., 2002). 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 7. Measurements.

	Intervention period			Maintenance period		
Measurements	**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[a]	X		X	X	X	X
Hours[b]	X		X	X	X	X
Amount[c]	X		X	X	X	X
Treatment views						
Confidence about treatment		X[d]				
Treatment is logical		X[d]				
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.

[a]Days per month in which gambling takes place

[b]Time spent thinking about or engaged in the pursuit of gambling in previous month

[c]Expenditure in previous month

[d]Treatment session 2 only

3.7 SAMPLE SIZE CALCULATION

The primary research question tested in this study was: Among treatment-seeking problem gamblers is one of two core components of CBT - ET or CT – if administered alone, more effective in reducing gambling severity symptoms (harm to self-subscale of the VGS) over the 9-month study period (intervention and maintenance effects) than the other one administered alone?

In the sample size calculation there was an assumed 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 dropout rate experienced in the SGTS treatment programme (approximately 30%) the study 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 % (Gooding & Tarrier, 2009). 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.

3.8 RANDOM ASSIGNMENT

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 (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, and between 12 and 20 (Riley, Smith, & Oakes, 2011). An independent biostatistician then generated random sequences for each stratum using Stata version 11.1 software (StataCorp, 2013b) 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.

A near balance was expected to be achieved within each of the eight strata, however there was potential for an overall imbalance between the two treatment groups. In order to approximate the probability of any imbalances a priori the derivation of Hallstrom & Davis (1988) was used (Hallstrom & Davis, 1988). The overall variance of potential imbalance *D* for *K* strata and blocking factor *B* was calculated using:

$$\text{Var D} = \sum_{i=1}\binom{K}{i}(Bi+1)/6$$

For K = 8 strata and B = 3 block sizes of 2, 4, and 6 then:

$$\text{Var D} = 8[(2+1)/6 + (4+1)/6 + (6+1)/6] = 20$$

This gave a SD of $\sqrt{20}$ = 4.47. Therefore, the probability of an overall imbalance as large as 9 participants would of been 0.05 (two-sided) where Z = 1.96 (i.e. 1.96 x 4.47). Table 8

provides probability values for varying imbalance numbers and associated study power. For *t* treatments the imbalance (in each stratum) would be at most 1/*t* times the largest block size. In this case the maximum potential imbalance within each stratum would have been 3 participants and for all 8 stratum 24 participants. However, due to small probabilities and minimal effect on study power, the benefits from improving a balance in known and unknown confounders (e.g. external validity of findings) were considered to outweigh costs of potential imbalance.

Table 8. Probabilities and study power estimates for randomisation imbalance.

D	**Z**	***p*-value**[a]	**1-β**[b] **(*n1/n2*)**
5	1.0	0.317	0.897(47/52)
9	1.96	0.05	0.896(45/54)
11	2.57	0.01	0.895(44/55)
13	3.0	0.0026	0.893(43/56)
18	4.0	0.00006	0.891(41/59)

Abbreviations: D, potential imbalance of participant numbers; Z, standard score; β, type II error.
[a]Two-sided
[b]Power calculations based on parameters for study sample size calculation

3.9 MASKING

Statistical analyses were conducted according to pre-specified guidelines (provided in Chapter 4). 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 (Miller & Stewart, 2011). 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 were 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 is discussed in the following section.

3.10 QUALITATIVE INTERVIEWS

In recent years the use of qualitative investigations alongside RCTs have become more prominent in order to help enrich explanations of trial findings and translate theory to practice (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013). They also provide additional information to evaluate trial findings when problems common to RCTs arise such as, shortfalls in recruitment numbers and treatment uptake (Hawe, Shiell, Riley, & Gold, 2004).

Qualitative approaches are especially useful for evaluating complex interventions such as community development programs, health promotion interventions and psychological treatments (Campbell et al., 2000) such as CBT. Psychotherapies involve dynamic movements between therapy specific and non-specific variables that standard outcome measures may not capture (Oakley et al., 2006) especially in context of the when (temporal instants) and where (spatial locations) of experiences.

Specific to this study, CT and ET were considered to be complex interventions for a number of reasons (Craig et al., 2008). Firstly, there was a strong potential for interplay between therapy specific and therapy non-specific effects in both interventions. The intended specific effects (see Section 3.4) for each treatment involved the hypothesised mechanisms of change. The non-specific effects involved factors such as therapeutic environment and therapist related variables (Walker et al., 2006).

Secondly, a wide range of outcomes was selected for this study in accordance with recommendations for reporting outcomes in gambling treatment studies (Walker et al., 2006). The psychometric instruments covered domains of psychosocial functioning, processes of change variables and co-occurring mental health conditions. Thirdly, both CT and ET interventions were prescriptive in nature and therefore required active participation on the participants' behalf. The degree of association between participation and outcomes was expected to be highly variable due to individual characteristics such as personality traits (for example, impulsivity), co-occurring symptoms (e.g. depression and anxiety) and social and environmental factors.

Using a qualitative approach alongside the main trial was in line with the method of process evaluation (Oakley et al., 2006). It attempted to view the trial from the perspective of a sub-group of participants and analyse contributions from a variety of forces at work to the effectiveness, or otherwise, of CT and ET interventions. If a therapy was considered to be ineffective then an opportunity existed to uncover whether this was attributed to its components or delivery or both (Rychetnik, Frommer, Hawe, & Shiell, 2002). Furthermore, a process evaluation potentially enabled the assessment of therapy fidelity in addition to audio recordings and elucidate causal mechanisms (Oakley et al., 2006). However, the interviews

were not planned to evaluate differential treatment effects (the main research question of this study), thus discounting a 'mixed methods' label for the overall study design (Craig et al., 2008).

Whilst the CBT evidence base for gambling disorders has expanded in the past 10 years, no empirical data exists to date that delineates therapy-specific effects and non-specific effects for core techniques of this class of treatments. Furthermore, no qualitative investigation conducted in concurrence with an RCT has been reported in the gambling intervention literature. Therefore, the aim of the qualitative phase was to support and extend findings from the main randomised trial investigating CT and ET for problem gamblers.

To enhance transparency of reporting the findings from interviews, the COREQ (consolidated criteria for reporting qualitative research) guidelines were used (Tong, Sainsbury, & Craig, 2007). This checklist is comprised of 32 items that are grouped into three domains. Domain one consists of 8 items that focus on the reporting of detail in relation to the research team and reflexivity. For example, details relating to the author/s who conducted the interviews such as their experience and qualifications, occupation at the time of the study, relationship with the participants as well as the participant's knowledge of the interviewer including personal goals from the interviews. Domain two is comprised of 15 items that target the reporting of study design characteristics such as methodological orientation, participant selection, methods of approach and sample characteristics. The remaining 9 items in domain three are centred on the analysis and findings. For example, steps behind the development of key themes, participant quotations to support themes and identification of quotations.

3.11 SUMMARY

This study was designed to provide high quality data for therapeutic benefits of ET compared with CT in people seeking treatment for problem gambling using EGMs. The outcome data collected was to cover the domains of gambling behaviours, problems caused by gambling and mechanisms of change.

CHAPTER 4: STATISTICAL METHODS

4.1 BACKGROUND

The use of longitudinal or repeated measure designs to assess efficacy and effectiveness of problem gambling treatments has grown in recent years (e.g. (Carlbring, Jonsson, Josephson, & Forsberg, 2010; Carlbring & Smit, 2008; Dowling, 2006; Dowling, Smith, & Thomas, 2007; Petry et al., 2006; Petry et al., 2008). One of the principal motivators for this shift has been the advent of more powerful computing technology and statistical software that is readily accessible to researchers. The analysis of repeated measures on the same study participant across a period of time provides more in-depth information than traditional approaches such as end-point analysis (i.e. baseline and final observation). However, such datasets can present challenges in relation to analyses such as missing data, heterogeneity, unbalanced measurement occasions, and participant clustering.

Firstly, missing data are common in studies involving complex interventions. For example, treatment drop-out rates involving psychological therapies for gambling disorder can be as high as 50% (Melville, Casey, & Kavanagh, 2007). Reasons for drop-out within a study can vary between participants. Some may discontinue their assigned intervention due to therapy related variables. For example, a participant who experiences a recovery from problem gambling in the early phase of therapy may decide to discontinue their involvement with the study based on the belief that any further engagement would not provide an added benefit. Alternatively, the participant's personal goals from therapy may be discordant with those that are implicit to a specific therapy. Also, study drop-out may result from factors that are independent of therapy such as moving to another country or injury as a result of an accident.

Secondly, heterogeneity relates to the deviation of individual correlated responses from the average or population response. These unobservable relationships may result in loss of information if not appropriately accounted for in the statistical modelling process. For example, some individual trend lines may differ from the average due to higher levels of psychopathology at baseline followed by a prompt response to study intervention. Thirdly, individual patterns of response to measurement occasions typically vary due to differential availability of people, generating an unbalanced dataset. Finally, it is possible that measurements on different individuals are correlated when clustered in the same domain such as therapist or treatment centre.

Traditional statistical approaches for handling repeated measures include univariate repeated measures analysis of variance (rANOVA) and multivariate ANOVA (rMANOVA) or multivariate growth-curve analysis (Gueorguieva & Krystal, 2004). Both methods provide a more comprehensive description of treatment response over time by including all time points in the analysis. For rANOVA, a group by time interaction enables the comparison of rates of change in outcome between treatments by accounting for each trajectory's unique characteristics. For example, the shape of the response curve may differ between a control and active intervention where participants, on average, respond faster to treatment than control participants. In this case if both groups had similar estimates of outcome at final data collection then an end-point analysis (e.g. t-test) would fail to capture the intermediate information.

Potential limitations of rANOVA include the deletion of cases if outcome data is missing at any time point resulting in a loss of study power and the assumption of sphericity. This means that for each individual the degree of correlation between all possible pairs of time points is

similar. However, in many everyday health settings this assumption lacks plausibility as datasets are often unbalanced in terms of data collection occasions and the associations between adjacent time points may be more similar and become more dissimilar as time points move further apart. Although methods exist to minimise Type I error such as Greenhouse-Geisser (Gueorguieva & Krystal, 2004) these can be highly conservative and more prone to Type II error. The rMANOVA provides more information than rANOVA as it incorporates the variance-covariance relationship between variables and is used for two or more dependent variables. Despite this added strength over rANOVA it also has similar limitations including case-wise deletion when missing data are present.

Techniques that use all available data and maximise study power include generalised estimating equations (GEE) and generalised mixed-effects models. Whilst GEE is robust in terms of normality assumptions it is little more than a special kind of clustering of treatment estimates at the population level and not at the individual level. In other words, clustering controls for individual effects rather than delineating their contribution to a statistical model. On the other hand, mixed-effects models calculate estimates at the individual level. Other advantages of mixed models over more traditional methods are the modelling of different variance-covariance patterns at the individual level and the ability to model time as a continuous covariate where longitudinal datasets are unbalanced (Gueorguieva & Krystal, 2004). Components of a mixed model are fixed effects, typically time invariant (e.g. measurement occasion and therapy group), and random effects that are time-varying such as the upward or downward shift in individual response trajectories relative to a population average trend.

In the gambling intervention literature, reporting of statistical methods used for primary analyses in randomised controlled trials has been mixed. A number of studies have employed traditional statistical methods such as rANOVA and rMANOVA where the imputation method of last observation carried forward (LOCF) has been a common practice to calculate estimates based on an intent-to-treat principle (Dowling, 2006; Dowling et al., 2007; Grant et al., 2009; Marceaux & Melville, 2011; Melville, Davis, Matzenbacher, & Clayborne, 2004; Myrseth et al., 2011). Single imputation methods such as LOCF and replacing missing values with the mean of observed data have numerous pitfalls. These include missing the informative properties of missingness and not accounting for error in imputed values that can lead to anti-conservative estimates of standard errors.

It is the intention of this chapter to describe a statistical plan that will facilitate an in-depth interpretation of trial data that will support and extend findings from previous research. The central focus is on mixed-effects modelling and includes: specification of the mixed model, assessing suitability and the fit of these models, model building approaches and a handling missing data strategy. All statistical analyses were conducted using Stata 12.0 (StataCorp, 2011) and the user-written Stata program gllamm (generalised linear latent and mixed models) for ordinal outcomes (Skrondal & Rabe-Hesketh, 2003).

4.2 MIXED MODELS

In this study, a generalised mixed-effects model approach was used for the analysis of repeated measures of primary and secondary continuous and categorical outcomes. Mixed model estimation is differentially sensitive to both fixed and random effects. Fixed effects were intervention group (CT or ET), time in continuous form (intervention period and maintenance effects), and interaction between group and 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. Random effects 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. The following description of a linear mixed model (LMM) for continuous outcomes is based on the work of West and colleagues (2007) (West, Welch, & Galecki, 2007).

For participant *i* with observation at time *t* a standard fixed effects model for a continuous outcome can be specified as:

$$y_i = X_i\beta + \epsilon_i, \qquad i = 1, \ldots, n, \tag{1}$$

where $y_i = (y_{i1}, \ldots, y_{it_i})'$ is a t_i x 1 vector of t_i independent observations on the *i*th participant, β is a p x 1 vector of unknown estimates for fixed population parameters of p covariates (treatment group, time and interaction term for group by time), X_i is a t_i x p design matrix of observed predictors (group, time and interaction term) and $\epsilon_i = (\epsilon_{i1}, \ldots, \epsilon_{it_i})'$ is a t_i x 1 vector of independent errors.

The mixed-effects model comprising both fixed effects and random effects may be specified as:

$$y_i = X_i\beta + Z_i u_i + \epsilon_i, \tag{2}$$

The fixed-effect component $X_i\beta$ in (2) is the same as that for the standard linear model (1). The Z_i matrix is a t_i x q design matrix for the q predictor variables (random intercept and random slopes) where

$$Z_i = \begin{pmatrix} Z_{i1}^{(1)} & \cdots & Z_{i1}^{(q)} \\ \vdots & \ddots & \vdots \\ Z_{it_i}^{(1)} & \cdots & Z_{it_i}^{(q)} \end{pmatrix}$$

The vectors $\mu_i = (\mu_{1i}, \ldots, \mu_{qi})'$ are parameters of unobserved random effects or random variables that represent the "missing data" problem when using maximum likelihood estimation for mixed models and discussed in the next section. The participant-specific intercepts and slopes are not estimated, only summarized by their variances and covariance by the generalised residual vector μ_i. This characterises the deviation of individual-level trajectories of change relative to population parameters. The q random effects in the μ_i vector are assumed to follow a multivariate normal distribution (i.e. every linear combination of μ_i components has a univariate normal distribution) with mean vector 0 and a variance-covariance matrix denoted by *D*:

$$\mu_i \sim N(0, D)$$

The *D* matrix comprises the variances of each random effect that are the main elements along the diagonal and covariances between random effects are represented by the off-diagonal elements. It is a square matrix (q x q) and symmetric about the main diagonal and positive definite meaning that eigenvalues are real and positive numbers. The elements of *D* can be characterised by a smaller set of parameters that are stored in a vector represented by θ_D. A typical example of a *D* matrix structure used in the current study was for two random effects (q = 2) comprising of a random intercept (α) and random slope (β) associated with the *i*-th participant:

$$D = Var(\mu_i) = \begin{pmatrix} Var(\mu_{i\alpha}) & Cov(\mu_{i\alpha,}\mu_{i\beta}) \\ Cov(\mu_{i\alpha,}\mu_{i\beta}) & Var(\mu_{i\beta}) \end{pmatrix} \quad (3)$$

Finally, within-subject errors ϵ_i for repeated measures were assumed to be correlated and represented by t_i x 1 vectors. The t_i residuals for each participant were also assumed to follow a multivariate normal distribution with mean vector zero and a positive definite symmetric covariance matrix R_i:

$$\epsilon_i \sim N(0, R_i)$$

Furthermore, each participant's residuals ϵ_i were assumed to be independent of one another and of the vectors μ_i. The R_i matrix in the current study with outcome assessments at five time points (t = 0, 1, ... , 4) of baseline, post-treatment, and 1, 3, 6-month follow-up is represented as

$$R_i = Var(\epsilon_i) = \begin{pmatrix} Var(\epsilon_{i0}) & cov\,(\epsilon_{i0}, \epsilon_{i1}) & \cdots & cov\,(\epsilon_{i0}, \epsilon_{i4}) \\ cov\,(\epsilon_{i0}, \epsilon_{i1}) & Var(\epsilon_{i1}) & \cdots & cov\,(\epsilon_{i1}, \epsilon_{i4}) \\ \vdots & \vdots & \ddots & \vdots \\ cov\,(\epsilon_{i0}, \epsilon_{i4}) & cov\,(\epsilon_{i1}, \epsilon_{i4}) & \cdots & Var(\epsilon_{i4}) \end{pmatrix} \quad (4)$$

Similar to the *D* matrix (3), elements of R_i (4) can be characterised by a smaller set of parameters that are stored in a vector represented by θ_R. The parameters of vectors θ_D and θ_R are combined in the vector θ to estimate random effects. Various possible structural patterns exist for the matrices *D* and *R*. In this study, the primary hypothesis relating to differential treatment effects was focused on individual participant change over time. Therefore, a model comprised of both random intercepts and random slopes was required to answer study questions. The *D* matrix (3) was unrestricted with unique values for variance-covariance elements. Alternatively, a restricted model was also considered where covariances were equal to zero:

$$D = Var(\mu_i) = \begin{pmatrix} Var(\mu_{i\alpha}) & 0 \\ 0 & Var(\mu_{i\beta}) \end{pmatrix}$$

In Stata (12.0) there are numerous patterns available to model participant-specific residuals ϵ_i in the *R* matrix (4). The Toeplitz structures the correlations between two time points as constant for a time interval less than a pre-specified value and zero otherwise. An autoregressive structure means that equally spaced repeated measures have one correlation for the same time interval and higher values for closer time points. A compound symmetric or exchangeable pattern models all correlations as being equal between time points. In this study, all variances and covariances were distinctly estimated using an unstructured pattern for the initial model as it was assumed that random effects were correlated. Also, an unstructured pattern is more flexible for an unbalanced dataset of repeated measures.

To identify any relationship between random intercept (individual baseline score) and random slope (individual rate of change over time), patterns of residuals were investigated by comparing the unstructured model with a restricted model. Using variance-covariance patterns of independent structure (residuals assumed to have one unique variance parameter per random effect and all covariances zero) versus unstructured, the correlation between intercept and slope was tested using a likelihood-ratio test. The covariance matrix generally has q (q + 1) / 2 unique parameters and so in this study three random effects ($Var(\mu_{i\alpha})$, $Var(\mu_{i\beta})$, $Cov(\mu_{i\alpha,}\mu_{i\beta})$) were tested against the independent structure comprising the two variance components ($Var(\mu_{i\alpha})$, $Var(\mu_{i\beta})$) and covariance equal to zero.

The random effects model considered so far summarises individual deviations at an average level that assumes similar patterns in both CT and ET trajectories of change. To check this assumption, treatment group was introduced into the random component of the model to

assess for heteroskedastic effects or variance in sub-populations (Rabe-Hesketh & Skrondal, 2012). This was achieved by creating a dummy variable for group assignment (random intercept) and the interaction between intercept and time (random slope) to give a dual repeated-level specification for outcome measurement at time *t* on the *i*th participant. The overall random intercept in this model was separated into one specific to exposure participants and one specific to cognitive participants.

For study outcomes 'frequency of gambling' and 'amount spent on gambling' in the previous month, the ordered response variables were analysed using mixed-effects ordered logistic regression (StataCorp, 2011). For a set of cut-points k (e.g. amount spent on gambling: > \$0, > \$500, > \$1000), the cumulative probability of the response across time being in a category higher than k is:

$$\Pr(y_{it} > k|X_{it}, k, \mu_t) = H(X_{it}\beta + Z_{it}u_t - k_k) \quad (5)$$

where cut-points k are labelled $k_1, k_2, \ldots, k_{K-1}$, and K is the number of possible outcomes. $H(.)$ is the logistic cumulative distribution function that represents cumulative probability. Both fixed and random effects are analogous to the parameterization of equation (2).

The probability of observing *k* can be derived from (5) as

$$\begin{aligned}\Pr(y_{it} = k|\ K,\ \mu_t) &= \Pr(k_{k-1} < X_{it}\beta + Z_{it}u_t + \epsilon_{ij} \leq k_k) \\ &= \Pr(k_{k-1} - X_{it}\beta - Z_{it}u_t < \epsilon_{ij} \leq k_k - X_{it}\beta - Z_{it}u_t) \\ &= H(k_k - X_{it}\beta - Z_{it}u_t) - H(k_{k-1} - X_{it}\beta - Z_{it}u_t)\end{aligned}$$

where k_0 is taken as $-\infty$ and k_K is taken as $+\infty$.

The above model can also be conceptualised in terms of model (2) where observed ordinal outcomes y_i are inferred from latent or unobserved continuous outcomes y_i^*:

$$y_i^* = X_i\beta + Z_i u_i + \epsilon_i,$$

and

$$y_{it} = \begin{cases} 1 & \text{if} \quad y_{it}^* \leq k_1 \\ 2 & \text{if} \quad k_1 < y_{it}^* \leq k_2 \\ \vdots & \\ K & \text{if} \quad k_{K-1} < y_{it}^* \end{cases}$$

The errors ϵ_{ij} are distributed as logistic with mean 0 and variance $\pi^2/3$ and are independent of μ_i (StataCorp, 2013a).

For mixed models involving either continuous or ordinal outcomes the computation of treatment effect estimates was based on maximum likelihood estimation (ML) (Laird, Lange, & Stram, 1987) and is discussed in the next section.

4.2.1 Estimation in mixed models

To minimise potential for biased estimates of treatment effects, all observed data for both treatment completers and non-completers was used in the primary analysis. In order to achieve this in the linear mixed model, there are two commonly used methods to estimate fixed-effect parameters and the covariance parameters. The first approach is restricted maximum likelihood (REML) or residual maximum likelihood where the outcome distribution is free of fixed-effects. The second approach is maximum likelihood estimation (ML) where both fixed-effects and random-effects contribute to estimation of unknown model parameters (West et al., 2007). Estimates of variance and covariance parameters based on ML tend to be biased downwards in balanced-data problems because they do not incorporate degrees of freedom used to estimate fixed-effects. Restricted estimation does take into account loss of degrees of freedom, this being dependent on the number of regression coefficients. However, any differences between ML and REML estimates in unbalanced data

such as in this study are mostly negligible (Rabe-Hesketh & Skrondal, 2012). One advantage of ML is that nested mixed models can be statistically compared to help determine a model that provides a better fit of the data.

The following discussion on ML is focused on continuous outcomes as this was the main form used in the trial for primary and secondary measures. For ordinal outcomes, estimation follows a similar iterative process as described below but using different computing formulas (Rabe-Hesketh & Skrondal, 2012).

Maximum likelihood estimation was implemented by examining the observed values of *n* scores (e.g. VGS) and then determining which estimates of unknown random parameters maximized the probability of obtaining the observed scores. The log-likelihood function for the complete dataset (y, θ) is:

$$L_F(\beta, \theta) = \sum_{i=1}^{n} \left[\log f_1\left(y_i | \mu_{i,}, \beta, \sigma_\epsilon^2\right) + \log f_2(\mu_i | \sum) \right] \quad (6)$$

where θ incorporates both $\theta_D(\sum)$ and $\theta_R(\sigma_\epsilon^2)$ as described in the previous section and $f_{(.)}(.)$ are density functions with multivariate normal distributions (StataCorp, 2013a). Estimation of unknown parameters used two approaches in the study: E-M (expectation-maximization) algorithm and N-R (Newton-Raphson) method. The E-M algorithm was first used due to its efficiency in establishing robust starting values to estimate the unobservable random parameters $\widehat{D}_0$ and $\hat{\sigma}_0^2\left(\hat{R}_0\right)$ from ordinary least squares (OLS) estimates of $\beta(\hat{\beta}_0)$ and $u_i(\hat{\mu}_i)$ as

$$\hat{\mu}_i = (Z_i^T Z_i)^{-1} Z_i^T \left(y_i - X_i \hat{\beta}_0\right),$$

and

$$\hat{\beta}_0 = \hat{\beta}_{OLS} = \left(\sum_{i=1}^{n} X_i^T X_i\right)^{-1} \sum_{i=1}^{n} X_i^T y_i$$

where *T* is the transpose of a matrix (rows and columns are reversed). The starting unobservable residuals are then calculated as

$$\hat{\sigma}_0^2 = \left(\sum_{i=1}^{n} y_i^T y_i - \hat{\mu}_i^T Z_i^T y_i\right) / (N - nq)$$

where *N* is the total number of observations, and random parameters as

$$\widehat{D}_0 = \left[\sum_{i=1}^{n} \hat{\mu}_i \hat{\mu}_i^T - \left(\sum_{i=1}^{n} \hat{\mu}_i\right)\left(\sum_{i=1}^{n} \hat{\mu}_i\right)^T / n\right] / (n-1) - \hat{\sigma}_0^2 \sum_{i=1}^{n} (Z_i^T Z_i)^{-1} / n$$

In this study, the E-M procedure was comprised of 20 iterations, the default in Stata, with each iteration involving two steps; the expectation step (E-step) and the maximization step (M-step). The E-step involved the augmentation of observed values with the expected values of the unobserved random effects and residuals to provide a "complete" data set for the current iteration (West et al., 2007). Using the computing formulas for implementing the E-M algorithm by Laird and colleagues (1987) (Laird et al., 1987), let $\omega(\omega = 0,1, \dots, \infty)$index the iterations, where $\omega = 0$ refers to the starting values and $\omega = \infty$ refers to convergence. The fixed-effect estimate or population parameter β is improved from unobserved random parameters in the following:

$$\beta^{(\omega)} = \left(\sum_{i=1}^{n} X_i^T W_i^{(\omega)} X_i\right)^{-1} \sum_{i=1}^{n} X_i^T W_i^{(\omega)} y_i$$

where

$$W_i^{(\omega)} = \left(\Sigma_i^{(\omega)}\right)^{-1} = 1 / \left(\sigma^{(\omega)^2} I + Z_i D^w Z_i^T\right)$$

and *I* is an identity or unit matrix that is a *n* x *n* square matrix with ones on the main diagonal and zeroes elsewhere. Also, estimates of unobserved random parameters at each iteration is defined as

$$\mu_i^{(\omega)} = D^{\omega} Z_i^T W_i^{(\omega)} r_i^{(\omega)},$$

where

$$r_i^{(\omega)} = y_i - X_i \beta^{(\omega)}$$

A complete data log-likelihood function was then generated (6) and maximized in the M-step, in other words, for the current iteration (ω) maximize (θ^{ω}) to produce $(\theta^{\omega+1})$ where θ incorporates both θ_D and $\sigma^2(\theta_R)$. The computing formulas for this step are:

$$\sigma^{(\omega+1)^2} = \left\{ \sum_{i=1}^{n} \left[\left(r_i^{\omega} - Z_i \mu_i^{(\omega)} \right)^T \left(r_i^{(w)} - Z_i \mu_i^{(\omega)} \right) + \sigma^{(\omega)^2} tr \left(I - \sigma^{(\omega)^2} W_i^{(\omega)} \right) \right] \right\} / N$$

where *tr* is the trace of an *n* x *n* square matrix and defined to be the sum of elements on the main diagonal that characterises the unobservable random parameters, and N is the total number of observations. The random parameters are calculated from

$$D^{(\omega+1)} = \sum_i^n \left[b_i^{(\omega)} b_i^{(\omega)T} + D^{(\omega)} \left(I - Z_i^T W_i^{(\omega)} Z_i D^{\omega} \right) \right] / n.$$

As E-M approaches convergence it becomes less efficient and fails to calculate standard errors for random effects. Therefore, the N-R method was then used to complete convergence and calculate standard errors (Rabe-Hesketh & Skrondal, 2012).

4.2.2 Assessing suitability and fit of the mixed model

4.2.2.1 Testing model consistency

So far it has been assumed that a mixed model provides a better fit of the data than an ordinary fixed-effects approach. To assess this assumption, the Hausman specification test formally compares the consistent fixed-effects regression estimator (within participant effects) versus the efficient generalized least squares (GLS) estimator (random-effects estimator) (Hausman, 1978) . The GLS is very similar to ML and therefore similar to REML. It is a weighted average of the between participant effects using participant-level means and within participant effects and is more efficient because it utilizes both components of information. For example, GLS is valid for comparing VGS scores from different participants, one in CT and one in ET (the *between* effect) and VGS scores from the same participant in either CT or ET (the *within* effect).

To date, the random intercept model is the highest level in which assumptions can be tested in order to determine if a mixed-effects approach is appropriate. The Hausman test checks if the random-effects estimates are a consistent estimator of the true parameters of the fixed-effects. The statistic $\hat{\theta}$ is a consistent estimator of the parameter θ if and only if for each $c > 0$

$$\lim_{n \to \infty} P(|\hat{\theta} - \theta| < c) = 1$$

In other words, for indefinite sampling ($n \to \infty$) a consistent estimator occurs when the sequence of estimates for random-effects converges in probability to the consistent estimator of fixed-effects so that the probability of the estimator being arbitrarily close to θ converges to one. The null hypothesis of the Hausman test is that random-effects are a consistent (and efficient) estimator of the true parameters. If there is strong statistical evidence to support a

systematic difference in the estimates, then the assumptions relating to GLS as consistent estimator can be doubted.

The Hausman statistic is distributed as $\chi^2$and is computed as

$$H = (\beta_c - \beta_e)'(V_c - V_e)^{-1}(\beta_c - \beta_e)$$

where

β_c is the coefficient vector from the consistent estimator

β_e is the coefficient vector from the efficient estimator

V_c is the covariance matrix of the consistent estimator

V_e is the covariance matrix of the efficient estimator (StataCorp, 2013a).

The within coefficient (β_c) is consistent under both null and alternative hypotheses and GLS (β_e) is inconsistent under the alternative hypothesis and efficient under the null hypothesis.

4.2.2.2 Goodness-of-fit assessment

To test hypotheses relating to fixed-effects (e.g. quadratic term for covariate time) and random-effects (e.g. random intercept and slope, variance-covariance patterns) between full and constrained models, likelihood ratio tests (LRTs) were performed. Mixed models were also compared to a one-level ordinary linear regression without random effects using LRTs.

If L_0 and L_1 are log-likelihood statistics (calculated from maximum likelihood estimation) for a full and constrained model respectively, then the LRT statistic is calculated using the equation

$$-2log\left(\frac{L_1}{L_0}\right) = -2\log(L_1) - (-2\log(L_0)) \sim \chi^2_{df}$$

If the LRT value is large enough to statistically favour the alternative hypothesis then the full model is considered to provide a better fit of the data (i.e. $|L_0| < |L_1|$).

4.2.2.3 Model diagnostics

In mixed models a distinct regression line for each individual is assigned for the random-effects, however individual-specific intercepts and slopes are not estimated but are summarised by the variance-covariance components. These can be predicted after estimation by obtaining best linear unbiased predictions (BLUPs) and estimated regression lines for each individual can then be plotted. The intercept is calculated using both fixed and random components:

$$\beta_0 + \mu_{\alpha i}$$

and similarly for the slope:

$$\beta_p + \mu_{\beta i}$$

Normal Q-Q plots (quantiles of random intercept or slope against quantiles of normal distribution) can be plotted to check the distributions of the predicted variables for any outliers. Alternatively, fitted values can be directly predicted that are comprised of fixed-portion linear predictions plus contributions based on predicted random effects and then plotted. Finally, standardised residuals (difference between observed and predicted values that take into account both fixed and random-effects multiplied by the inverse square root of the estimated error covariance matrix) can also be calculated to identify any poorly fitting data or outliers.

4.3 MODEL BUILDING STRATEGY

Following on from the linear notation of equation (2), the model building approach for each outcome started with a simple model and then gradually increased in complexity, each time using LR tests to compare log-likelihood estimations between models. The strategy for

primary outcome VGS scores and fixed-effects of time (weeks) and intervention (CT and ET) aimed to test the model features of

(i) overall quadratic change in scores across time

(ii) participant-specific random intercepts

(iii) participant-specific linear trends

and is summarised in the following steps:

1. Begin with treatment effect (i.e. a treatment interaction) to mean linear change rate in VGS scores and random intercept for participant-specific baseline scores

$$VGS_{it} = \beta_0 + \beta_1 time_{it} + \beta_2 treat_{it} + \beta_3 (treat_{ij}/time_{ij}) + \mu_{i0} + \epsilon_{ij}$$

2. Add quadratic effect to mean linear change in VGS scores

$$VGS_{it} = \beta_0 + \beta_1 time_{it} + \beta_2 time_{it}^2 + \beta_3 treat_{it} + \beta_4 (treat_{ij}/time_{ij}) + \mu_{i0} + \epsilon_{ij}$$

3. Add random coefficient for participant-specific linear trends

$$VGS_{it} = \beta_0 + \beta_1 time_{it} + \beta_2 time_{it}^2 + \beta_3 treat_{it} + \beta_4 (treat_{ij}/time_{ij}) + \mu_{i0} + \mu_{i1} time_{ij} + \epsilon_{ij}$$

4. Add treatment effect (ET and CT) to variance of linear change rates in VGS scores

$$VGS_{it} = \beta_0 + \beta_1 time_{it} + \beta_2 time_{it}^2 + \beta_3 treat_{it} + \beta_4 (treat_{ij}/time_{ij}) + \mu_{i0}^{ET} ET_{ij} + \mu_{i1}^{ET} (ET_{ij} \times time_{ij}) + \mu_{i0}^{CT} CT_{ij} + \mu_{i1}^{CT} (CT_{ij} \times time_{ij}) \epsilon_{ij}$$

4.4 MISSING DATA

4.4.1 Handling missing data

The trial adhered to the following recommended steps for handling missing data (White, Horton, Carpenter, & Pocock, 2011):

1. Follow-up of all randomised individuals was attempted, even if they withdrew from therapy. Strategies to improve follow-up rates included minimising the number of attendances required at SGTS by sending questionnaires by post and offering incentives.
2. A relatively large timeframe was also allowed for each follow-up assessment and so response intervals and frequency of questionnaire completion was expected to vary between individuals. Mixed models were then used to account for an unbalanced dataset and time was entered into models as a continuous covariate from the date of baseline measurement to date of each follow-up measurement.
3. The main analysis performed (mixed models) were valid under a plausible assumption about the missing data. Assumptions are discussed in the next section.
4. The analysis used all available data.
5. Sensitivity analyses were conducted to explore the impact of departures from the assumption about missingness that was made in the main analysis.

4.4.2 Mechanisms of missing data

Missing data may be attributed to mechanisms of missing completely at random (MCAR), missing at random (MAR) and missing not at random (MNAR). Missing completely at random occurs when the probability of data missing is independent of both observed and unobserved data. For example, a trial participant does not attend a follow-up assessment due to hospitalisation following a car accident or relocates to another city. In each case the event

is independent of gambling behaviour or associated variables. For these scenarios missing data are simple random samples of the observed data.

If the probability of missing data is dependent on observed values but independent of unobserved values then it is MAR (Carpenter & Kenward, 2008). The observed data provide all the information for the missingness mechanism. For example, a study participant experiences a rapid improvement in symptoms following commencement of psychological treatment for problem gambling and so decides to terminate treatment. Another example is where missing measurements of problem gambling severity are lower than measured severity only because younger people were more likely to drop-out from the study. Both MAR and MCAR are ignorable in terms of underlying assumptions of maximum likelihood estimation.

When the probability of missingness is dependent on both observed and unobserved values the mechanism is MNAR. For example, a participant may experience a relapse in problem gambling and decide not to attend a follow-up assessment due to a sense of failure. The cost of MCAR and MAR is reduced statistical power, however estimates of population parameters remain unbiased whilst those calculated under conditions of MNAR are biased (Graham, 2009).

Vetting patterns of missing data in repeated outcome measures may aid an intuitive assessment of underlying mechanisms. If data for a participant is missing from some time onward then the pattern is monotonic (e.g. study drop-out) and the interpretation is straight forward in terms of a MAR assumption (National Research Council, 2010). When missingness does not follow any obvious pattern (e.g. data given at one assessment, missing at the next assessment, but then given at a subsequent time) it is intermittent or non-monotone

missing-value pattern. This uncertainty in missingness potentially complicates an appraisal of underlying mechanisms. However, subject knowledge can aid in the determination of plausible assumptions. For example, knowing that some follow-up assessments were forgotten by research staff may, at least partially, explain arbitrary patterns of missing data.

4.4.3 Assessing departures from assumptions

Assumptions relating to mechanisms of MAR and MNAR are untestable but biases caused by data that are MNAR can be assessed using a sensitivity analysis (Sterne et al., 2009). Pattern-mixture models (PMM) is one type of sensitivity analysis to represent MNAR behaviour for a range of differences between unobserved outcome data and observed outcome data. If therapy effects were relatively constant over the specified range then the findings are considered to be clinically plausible (National Research Council, 2010). The PMM method used in this study was based on the approach by White and colleagues (White, Kalaitzaki, & Thompson, 2011) and their user written program "rctmiss" for Stata (MRC Biostatistics Unit, 2014).

In this study, assumptions about the missing data were made for primary outcome VGS scores in the range of zero to 6 points or up to approximately half a standard deviation (medium effect size) of baseline scores. For assumed departures from MAR, expressed as parameter delta, sensitivity analyses were conducted under 3 conditions. Firstly, delta varied over the specified range of VGS scores in CT group only and held at zero in ET group. Secondly, delta varied in ET group and was zero otherwise. Finally, delta was equal in both groups and varied over the specified range of VGS scores. Allowing different missingness mechanisms in each therapy group allowed the possibility that one therapy may have differed from the other (e.g. level of intensity), therefore departing further from MAR. More formally, the PMM technique can be summarised in the following steps.

(i) Assumed departures from MAR:

a. let δ= mean unobserved VGS – mean observed VGS

b. taking values δ_{CT}, δ_{ET} in groups CT, ET

(ii) Values estimated from observed data:

a. p_{CT}, p_{ET}= proportion of missing data in groups CT, ET

b. Δ_{obs} = therapy effect in observed VGS

c. Δ = true therapy effect

(iii) Then the true effect for each sensitivity analysis is calculated from:

a. $\Delta = \Delta_{obs} + \delta_{ET}\, p_{ET} - \delta_{CT}\, p_{CT}$

b. $se(\Delta) \approx se(\Delta_{obs})$

4.5 ANALYTIC FRAMEWORK

The primary analysis followed an intent-to-treat (ITT) approach to investigating differences in primary and secondary outcomes over time between CT and ET. The ITT principle preserves the benefits of randomisation where all individuals were included in the analysis, in the groups to which they were randomised to avoid potential effects from group crossover and study drop out (I. White, E. Kalaitzaki, et al., 2011). Inferences from ITT analysis are generalizable to therapy effectiveness in everyday clinical practice but may overestimate either CT or ET effects in the presence of disparate adherence to therapy protocol. Alternatively, to address the question of how well therapies worked under 'near perfect' conditions, a 'per protocol' analysis was conducted (Hernan & Hernandez-Diaz, 2012). This approach seeks to estimate the treatment effect if all participants completed their assigned treatment providing MAR is a reasonable assumption for treatment non-adherers.

Because the analytic framework for a per-protocol analysis transforms the randomised design to observational, the difference in sample means does not estimate the true average treatment effect, because outcome such as severity of gambling symptoms may have been dependent on factors such as gender and gender may have been correlated with treatment. To address extant observational data, treatment effects were considered in a counterfactual framework or potential outcomes framework. This meant that estimates were corrected for the missing-data problem arising from study participant's being observed in only one group. In other words, the estimates account for how the missing data depend on covariates that affect the potential outcomes.

The inverse probability weighting (IPW) technique was used to calculate relatively unbiased treatment estimates that were standardised to the target population of problem gamblers (both therapy adherers and non-adherers) who may have differed from the non-adherers alone (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 model of therapy status (ET = 1; CT = 0) on age, gender, baseline gambling severity (VGS), and participants self-reported perception of treatment logic and confidence following treatment rationale provided by the therapist in session two. From this model, probabilities (pr) were firstly calculated and then IP weights for ET were calculated by taking the inverse and weights for CT participants was the inverse of 1 – pr. 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.

Within this counterfactual framework, consistent estimates of the effect parameters were produced because each therapy is assumed to be independent of the potential outcomes after

conditioning on the covariates. Three treatment effect estimates were calculated. Firstly, the potential outcome mean (POM) for ET was the mean of both observed outcome scores and scores if CT participants had received ET treatment after correcting for potential confounding variables. Similarly, the POM for CT participants was calculated when considering potential outcomes if ET participants had received cognitive therapy. Secondly, average treatment effects (ATE) was the difference between POMs for ET and CT participants. Thirdly, the average treatment effect on treated (ATET) was the mean of the difference in outcomes between participants that received ET and if these same participants had received CT. Using a similar approach, ATET was also calculated for CT participants.

Due to the relatively small ratio of cases to variables used in the calculation of ATEs, robust standard errors (SEs) were calculated using a bootstrap method. This technique treats the observed dataset as the population of interest and obtains parameter estimates from a pre-specified number of samples with replacement. This means each observation selected is then put back in before the next random selection. The SE is then calculated using the following formula where $i = 1, 2, 3\ldots, k$ denotes the bootstrap sample, $\hat{\theta}_i$ is the value of the mean from the ith bootstrap sample and $\bar{\theta}$ the overall mean from k bootstrap samples.

$$\widehat{se} = \left\{ \frac{1}{k-1} \sum_{i=1}^{k} \left(\hat{\theta}_i - \bar{\theta}\right)^2 \right\}^{1/2}$$

One assumption for using estimators of average treatment effects is the overlap assumption where each participant has a positive probability or chance of seeing observations in both CT and ET groups at each combination of covariate values. Violation of this assumption means that estimated probability densities have little mass in the regions of overlap and most density around zero and one. Furthermore, because IP weights are the reciprocal of the probability,

when probabilities approach zero the weight becomes unstable. An example of violation of the overlap assumption is where age is a confounder (i.e. age effects outcome and age is correlated with therapy) and there are no observations in cognitive group for younger ages, and there are no observations in exposure group for older ages. For the multivariate model in the current study (i.e. confounding variables age, sex, baseline VGS and treatment confidence and logic) the predicted probability is a one-dimensional measure that captures the important information. To investigate any deviation from the overlap assumption, estimated densities of the probability of receiving CT and ET were plotted on a graph.

4.6 POST-HOC ANALYSES

4.6.1 End-point analysis

A secondary post-hoc analysis compared 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 using Fisher's exact test. Also, to facilitate a clinically meaningful interpretation of changes in gambling related problems as measured by K10 and WSAS, effect sizes (Cohen's *d*) were calculated for mean differences between baseline and follow-up (Matthey, 1998). An effect size of 0.2 was considered small, 0.5 as medium, and 0.8 as large.

4.6.2 Predictors of therapy drop-out and therapy attendance

To investigate the association between therapy drop-out, socio-demographics and baseline gambling related measures, binary logistic regression was used. In accordance with the 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. To categorise participants into three ordered groups at outcome two tertiles were used. Firstly, participants receiving 3 or less treatments were categorised as treatment drop-outs in accordance with the 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 the bootstrap method with 200 resamplings.

4.6.3 Mediation analysis

To determine mechanisms of therapeutic change based on each treatment's intended effects a mediation analysis was conducted using mixed-effects models for all observed data. 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 was attenuated upon the addition of the mediator to the model (Baron & Kenny, 1986). The second approach assessed indirect mediation effects using the Sobel test $Z = \alpha\beta / \sqrt{\alpha^2 \sigma_\beta^2 + \beta^2 \sigma_\alpha^2}$ 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 (MacKinnon, 2008).

4.7 SUMMARY

In this chapter, the generalised mixed-effect model was described as the method of choice to account for individual response patterns across time and their random variation from an overall population parameter. The mixed model is a parsimonious representation of individual change with numerous advantages over more traditional models such as repeated measures analysis of variance (rANOVA). This includes maximizing statistical power by using all available data based on the expectation-maximization algorithm to calculate maximum likelihood estimates.

An alternative approach to handling missing data is multiple imputation (MI). Multiple imputations represent multiple sets of plausible values thus accounting for the uncertainty about missing values in contrast to single imputation techniques (Sterne et al., 2009). However, MI is closely related to ML estimation and the latter is the choice method in trials where it is common for missing data in outcomes rather than independent variables (Carpenter & Kenward, 2008). Moreover, because it is important to include outcome values in imputation models, the specification of an imputation model is problematic where there are also missing outcome values. Previous studies have shown that it is not necessary to impute missing values using MI and then perform mixed model analysis in observational datasets (Twisk, de Boer, de Vente, & Heymans, 2013) and trial data (Peters et al., 2012) and that mixed models can be more efficient.

CHAPTER 5: TRIAL RESULTS

5.1 INTRODUCTION

This chapter presents findings from the analyses of trial data. Preliminary results are first described and are comprised of baseline demographic and clinical characteristics of study participants in cognitive and exposure groups and their flow through the trial. A participant flow diagram is presented as recommended by CONSORT guidelines to communicate details of participant adherence to the trial protocol and any deviations (Moher et al., 2010). A table of baseline characteristics is also provided to assess how similar the study groups were following randomisation. Furthermore, in accordance with the CONSORT statement for non-pharmacologic trials, information relating to CT and ET as they were implemented is presented (Boutron et al., 2008). This allowed for an assessment of any differences between how CT and ET were intended to be delivered and how they were actually delivered.

The information from preliminary findings is essential to enable an accurate appraisal of the external validity of the main results that follow. For each primary and secondary outcome, estimates of therapy effects are presented for each therapy group, together with the contrast between cognitive and exposure therapies. For continuous outcomes, effect sizes are mean differences and for categorical outcomes, odds ratios. The precision or uncertainty of estimates was evaluated using 95% confidence intervals in order to facilitate a clinically meaningful interpretation of findings. Based on the statistical strategy described in Chapter 4, detailed results are described for primary outcome VGS. The main results for secondary outcomes and mechanism of change variables are also presented.

In addition to the main results from the trial, findings from ancillary analyses are presented. Firstly, within group end-point analyses were conducted for primary outcome VGS and secondary outcomes K10 and WSAS at follow up. The distribution of scores on secondary measures at follow up was also examined using validated cut scores for diagnostic classification.

Secondly, an investigation of factors associated with therapy drop out was carried out. A range of candidate predictors were investigated from domains of socio-demographics, mental conditions and personality constructs in an attempt to support and extend the current evidence base on drop out in the gambling intervention literature (Melville et al., 2007). Thirdly, a related question to predictors of dropout addressed was predictors of therapy attendance. It may have been that a significant proportion of variance in therapy uptake and dosage was explained by the characteristics of sub-populations.

Finally, this study was predicated on questions relating to causal relationships between cognitive and exposure therapies and treatment outcomes. However, the main results presented in Chapter 6 provided only a "black-box" view of therapies, that is, the internal workings of CT and ET for problem gambling remained opaque. In an effort to address this issue, a mediation analysis was conducted to investigate the following: (i) the translational effects of the habituation and extinction of gambling urge on therapy techniques to outcome, and (ii) the translational effects of the acquisition of a more rational set of gambling related beliefs on therapy techniques to outcome. It was expected that ET would be more efficacious than CT for pathway (i) and vice-versa for pathway (ii).

5.2 PRELIMINARY RESULTS

5.2.1 Participant recruitment

Approximately 69% of participants were recruited from self-referrals to the Statewide Gambling Therapy Service (Table 9). A number of participants were also recruited via a range of media announcements about the study including community newspapers, television and radio. To further help with recruitment rates, a member of the research team (DS) visited senior gaming staff at 11 gaming venues across the southern region of Adelaide to inform them about the study and to distribute promotional material such as flyers and wallet cards (Appendix I). Similar materials were also disseminated to community centres and medical clinics.

Table 9. Participant recruitment.

Source	**Randomised but did not attend any therapy sessions (n =12)**	**Randomised and received allocated intervention (n = 87)**
Self-referred	9	68
Media announcements		
Radio	0	1
Television	2	9
Flyer		
Public hospital	1	1
Medical centre	0	1
Gaming venues	0	2
Newspaper advertisements	0	5

5.2.2 Participant flow

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, 2011 to 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 10). Of the 99 participants randomized, 12 did not receive allocated intervention and therefore did not complete a baseline assessment. One participant allocated to 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), 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 1-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.

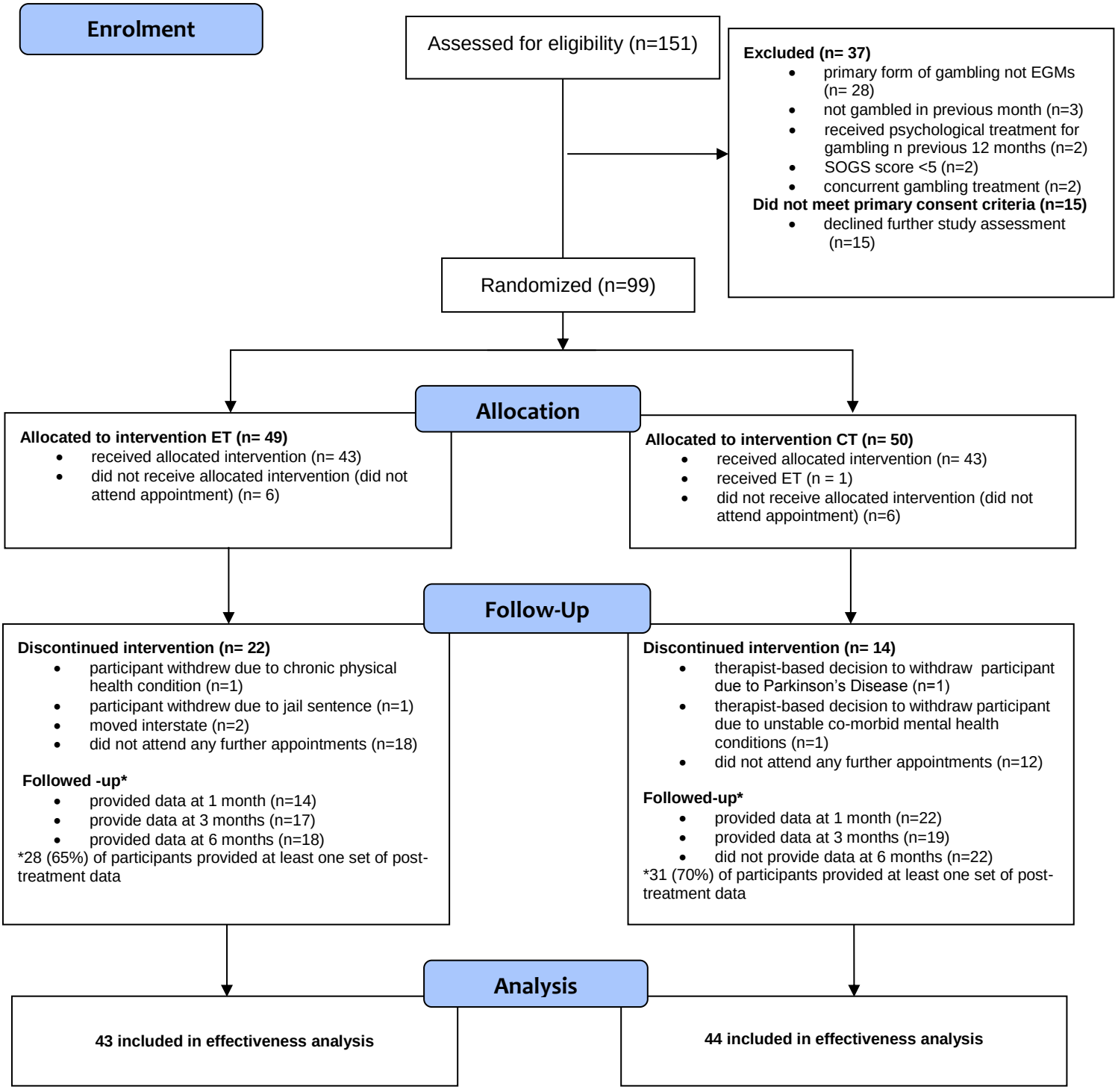
Table 10. Distribution of participants using stratified blocked randomisation.

	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.



5.2.3 Baseline data

Baseline characteristics for n=87 participants are presented in Table 11. 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 based on clinical assessment by a study therapist. Three participants who did not meet problem or pathological gambling criteria had DSM scores 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 significant 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 participant's 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 11. 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.

5.2.4 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 CT therapist received on-site supervision with a registered clinical psychologist who had 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 (RL) was conducted using a voice over Internet Protocol (VoIP) service. Therapists who administered ET received on-site supervision from MB who trained at the Institute of Psychiatry, London in behavioural treatments of anxiety disorders and severe neurotic conditions and was the Director of the Flinders Gambling Research Centre and SGTS (Battersby et al., 2008).

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) ($p = 0.316$).

Based on therapist judgement, 41% (36/87) of participants were classified as treatment drop-outs: 31.8 % (14) for CT, and 51.2 % (22) for 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) ($p = 0.893$).

Following an explanation of treatment rationale and protocol in session one, both exposure and cognitive participants rated high levels of 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 (Table 12). There were no statistically significant differences between the therapy groups. Participant ratings on the satisfaction scale (from 0 = *extremely unsatisfied* to 6 = *extremely satisfied*) at completion of final treatment were also high.

Table 12. 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)

5.2.4.1 Therapy fidelity

Exposure therapy sessions were evaluated by MB and RP, both senior consultant psychiatrists. CT sessions were evaluated by RL and MD, both senior registered clinical psychologists.

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 differ significantly between the two groups ($p = 0.142$). For inter-rater scores, no significant difference was also found ($p = 0.710$).

5.3 MAIN RESULTS

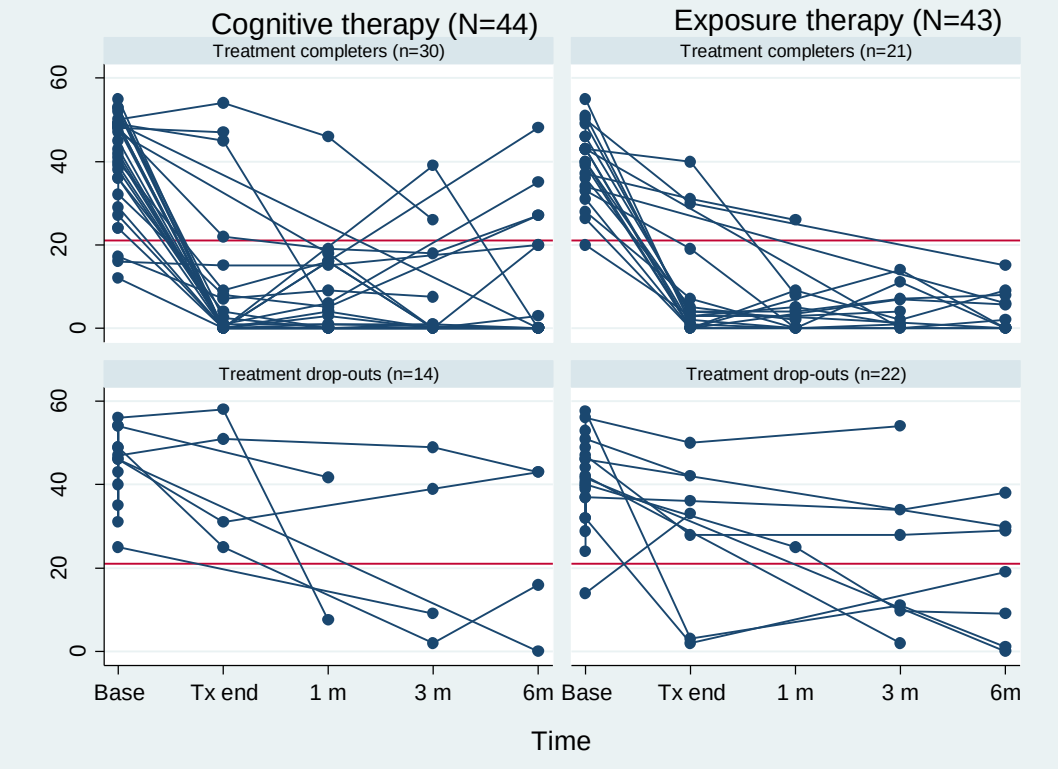
5.3.1 Primary outcome

The primary research question that was tested in this study was: Among treatment seeking problem gamblers was 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? The first step to estimating treatment effects at the individual-level was to explore patterns in VGS scores.

5.3.1.1 Observed data

A plot of observed trajectories for VGS scores by therapy group suggested that trends were mostly nonlinear for treatment completers (Figure 3). There was also considerable variation at the participant level in baseline scores and rates of responses. Observed mean scores by treatment group and time are shown in Figure 4. The reduction (improvement) in mean scores in both CT and ET groups showed a similar trend to the individual plots in Figure 4; an initial fast improvement from baseline (problem gambling) to final treatment (non-problem gambling) and then a levelling-off effect in follow-up.

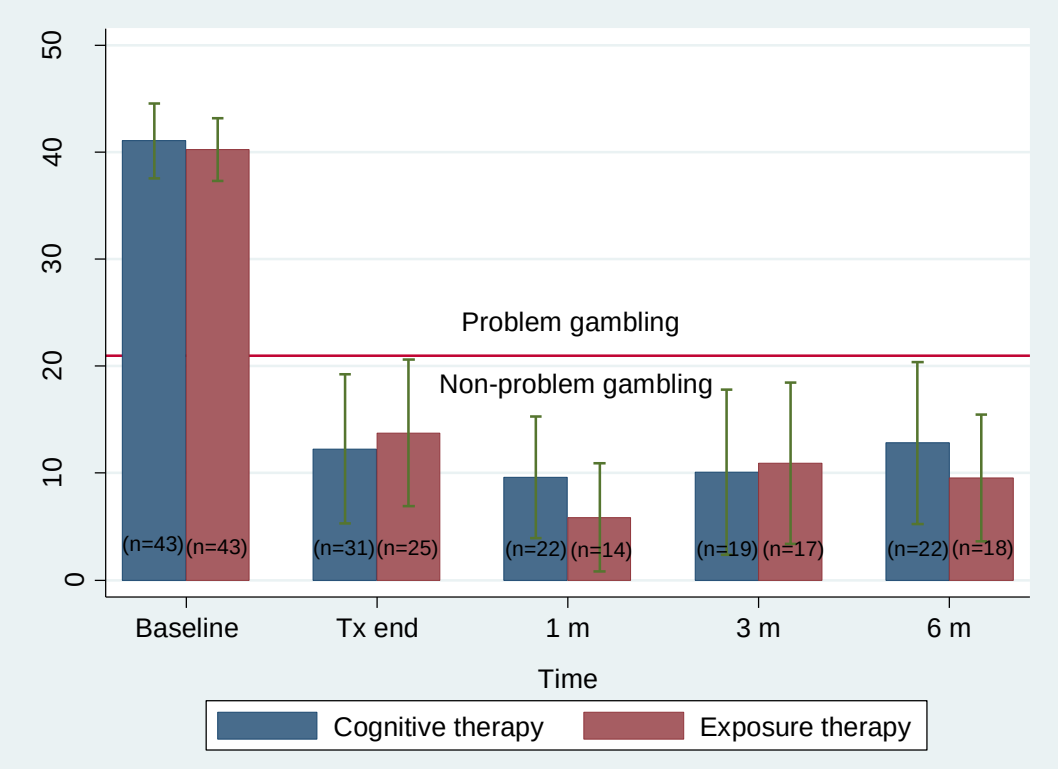
Figure 3. Individual response profiles for Victorian Gambling Screen (VGS) scores by treatment completion status, treatment group and time.[a]



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 4. 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 13 for CT participants and Table 14 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 MAR was a plausible assumption. This meant that the

probability of the missing data was independent of unobserved data but may have depended on observed data.

Table 13. Cognitive therapy: patterns of missing Victorian Gambling screen 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 14. Exposure therapy: patterns of missing Victorian Gambling Screen 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

5.3.2 Linear mixed model

Using all available data, results from between group comparisons for VGS using linear mixed modelling are shown in Table 15. 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 ($p = 0.477$).

Table 15. 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)		Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE)		Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE)		Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate (SE)		Estimated between-group difference (95% CI)[a]	*P*	Unadjusted estimate		Estimated 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.

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). A heteroskedastic random-effects model indicated that individuals within each intervention had similar variability in rates of change in VGS scores across time when compared to the main model ($p = 0.413$).

5.3.2.1 Testing model consistency

For the linear mixed model of VGS data, a Hausman test was performed to determine if the random-effects estimator was a consistent estimator of the true parameters of the fixed-effects model (Hausman, 1978). The fixed-effect coefficient is consistent under both null and alternative hypotheses and the random-effects estimator is inconsistent under the alternative hypothesis and efficient under the null hypothesis. The results showed no systematic difference between the coefficients ($\chi^2 = 4.93, df = 3, p = 0.177$). This indicated that the mixed model provided a consistent estimate of treatment effects as well as a more efficient estimate than the ordinary least squares regression model.

5.3.2.2 Assessing model fit

To assess how well the mixed model fitted VGS data, individual-specific intercepts and slopes were predicted after estimation by obtaining best linear unbiased predictions. A normal Q-Q plot for the random intercept BLUP values is shown in Figure 5. The linearity

of the points indicated that the model provided a good fit of the data that accounted for individual variation at study baseline. For predicted random slopes there was a degree of non-normality in BLUPs as shown in Figure 6 by the curvature of the normal Q-Q plot and possible outliers in the upper right quadrangle.

Figure 5. Best linear unbiased predictors (BLUPs) for random intercepts.

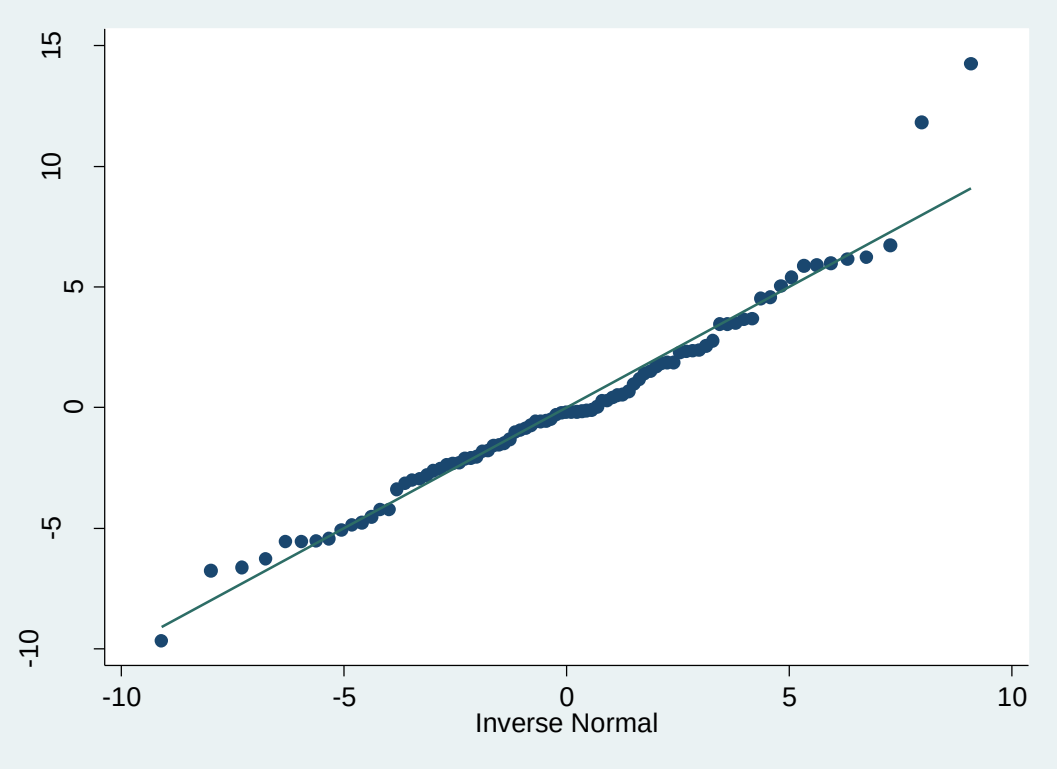
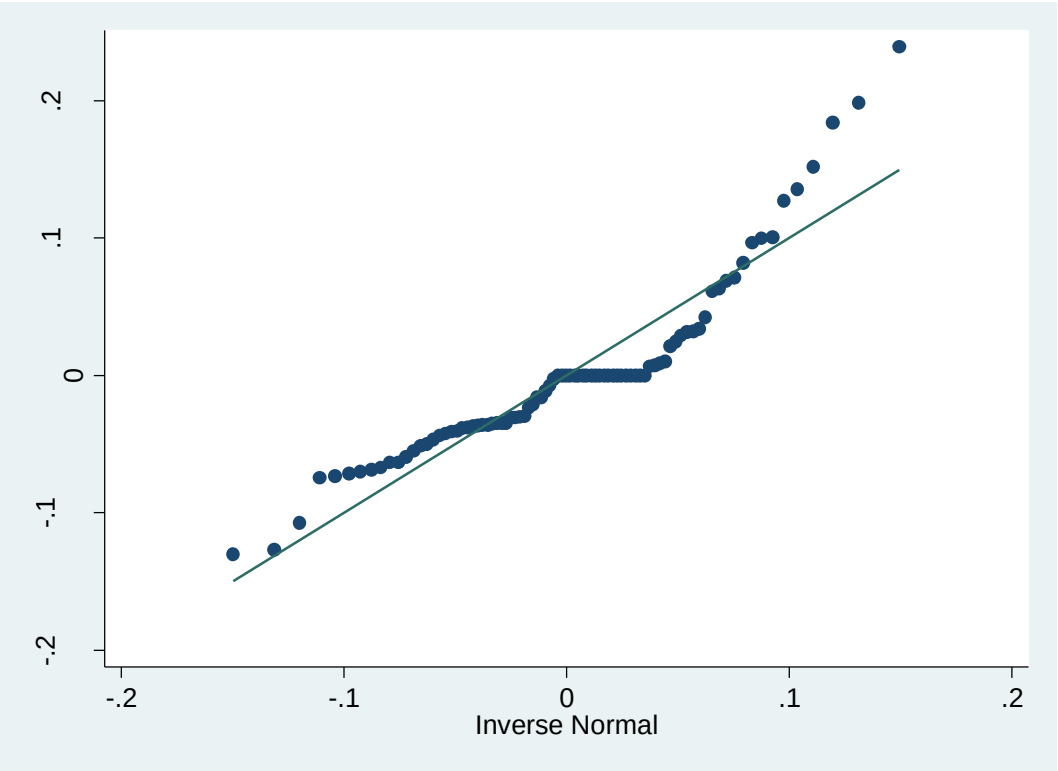


Figure 6. Best linear unbiased predictors for random slopes.



To assess fitted values that took into account both fixed and random-effects for each participant, standardised residuals were calculated. The distribution of standardized residuals from the mixed model of VGS outcome data is shown in Figure 7. There did not seem to be any poorly fitting data, but it was informative to identify individuals that had observations greater than two standard deviations (Table 16). Approximately 7% (6/87) of study participants had moderate to large residuals from high (worse symptoms) VGS scores post-baseline. Most of these observations (5/7) were from the cognitive group.

Figure 7. Standardized residuals for mixed model of Victorian Gambling Screen data.

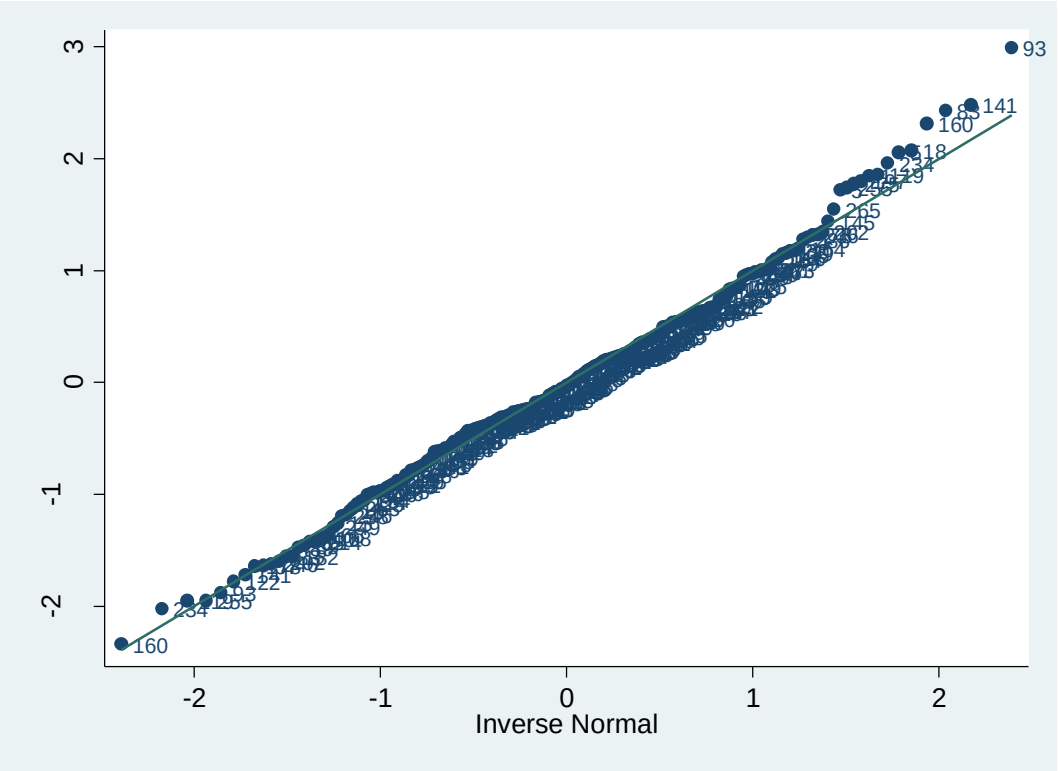
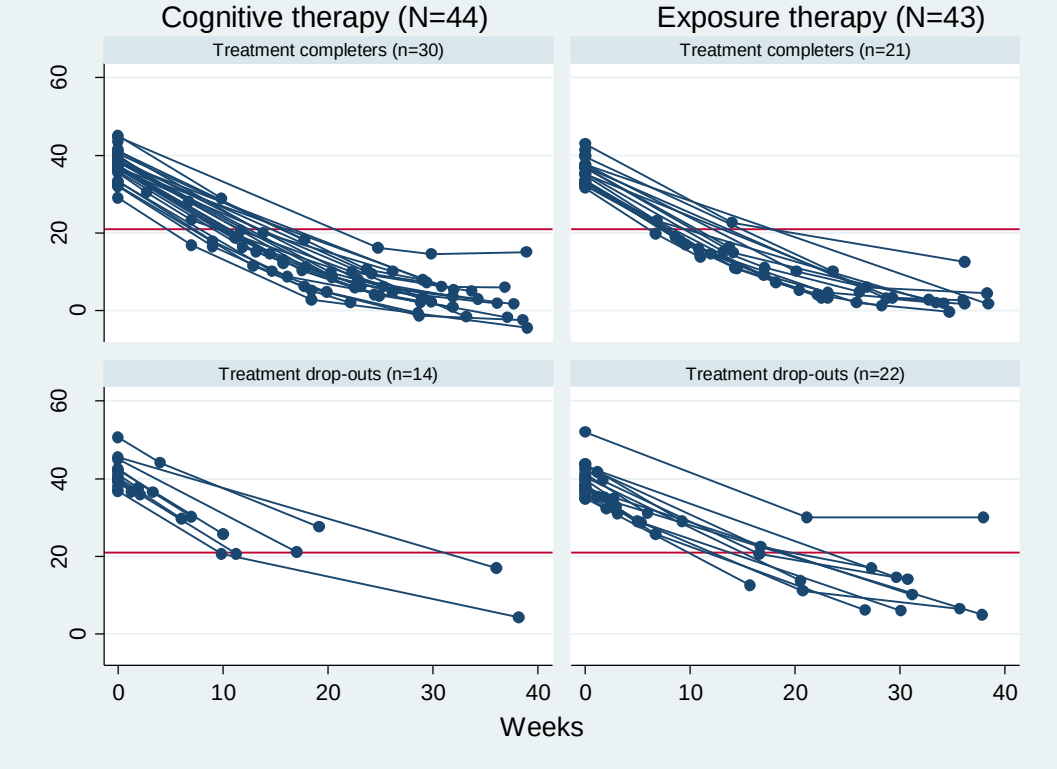


Table 16 . Individual residuals greater than two standard deviations.

Study participant	**Group**	**Treatment adherence**	**Follow-up time**	**VGS**
234	ET	non-completer	baseline	14
18	ET	completer	treatment-end	40
5	ET	non-completer	3-months	54
93	CT	completer	treatment-end	45
160	CT	completer	treatment-end	54
160	CT	completer	3-months	26
141	CT	completer	3-months	39
83	CT	completer	6-months	48

Finally, estimated regression lines were directly predicted that were comprised of fixed-portion linear predictions plus contributions based on predicted random effects (Figure 8). The trajectories of VGS scores indicate that individuals who complete a course of therapy would be expected to experience a greater reduction in problem gambling symptoms than therapy drop-outs.

Figure 8. Predicted individual trajectories of Victorian Gambling Screen across time using estimates from both fixed and random-effects.



Lower scores indicate a reduction (improvement) in gambling symptom severity.

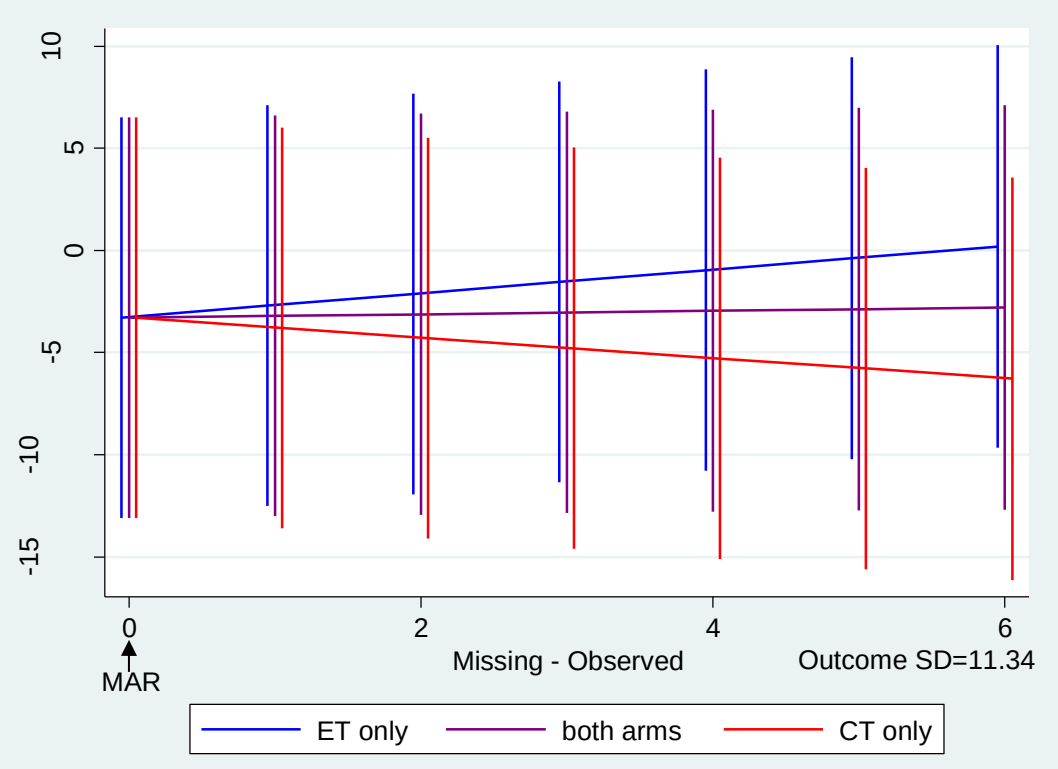
Note: [a] Horizontal line is VGS cut score of 21+ (indicative of problem gambler).

5.3.2.3 Sensitivity analyses

The main outcome analysis for VGS used maximum likelihood estimation based on the assumption that missing data were MAR. In order to assess for departures from 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 9 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 were not very sensitive to departures from MAR. For different missing data mechanisms between ET and CT groups the results were sensitive to departures from MAR with estimates ranging from – 6.28 to 0.20. Overall, sensitivity analyses suggested that trial findings were more biased if departures from MAR differed between the two groups. It is important to note that sensitivity analyses were limited to an end-point analysis and therefore did not capture additional information from repeated measures.

Figure 9. Sensitivity analysis for Victorian Gambling Screen data.



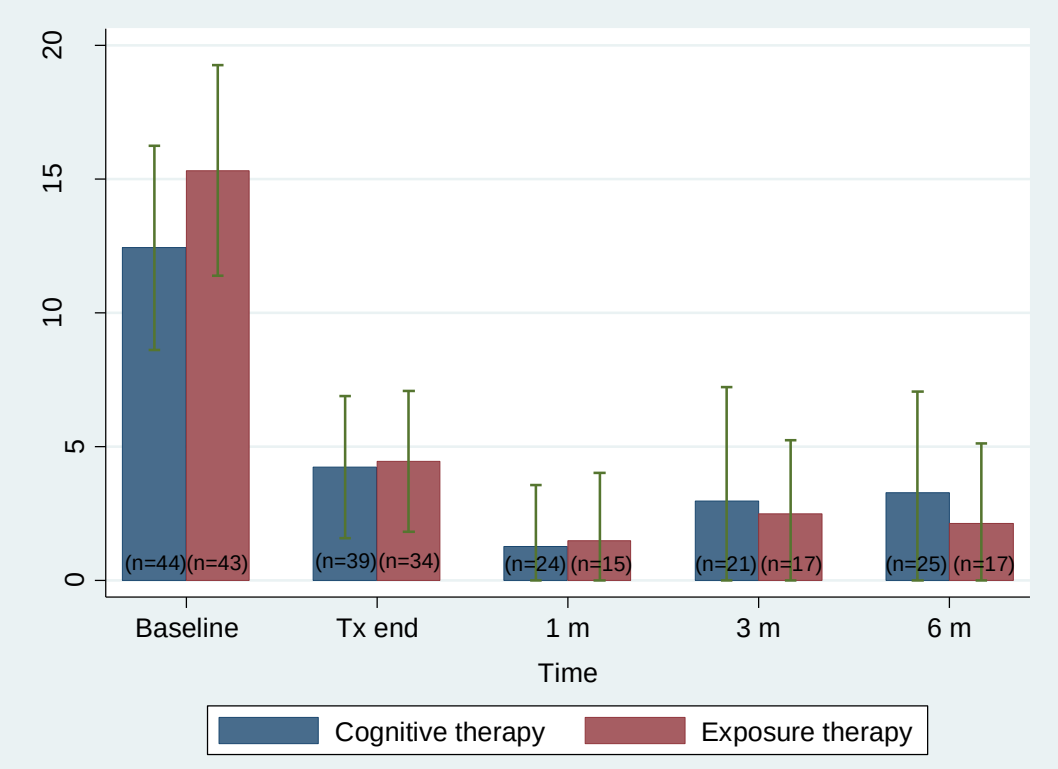
Abbreviations: ET, exposure therapy; CT, cognitive therapy; MAR, missing at random; SD, standard deviation.

5.3.3 Mechanisms of change outcomes

Results from between group comparisons for outcome measures related to mechanisms of change (GUS and GRCS) using linear mixed modelling are shown in Table 15. The observed mean scores for urge to gamble (GUS) by treatment group and time are shown in Figure 10. 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 were comprised of unstructured versus identity 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) ($P < 0.001$). This possibly indicated a regression to the mean effect.

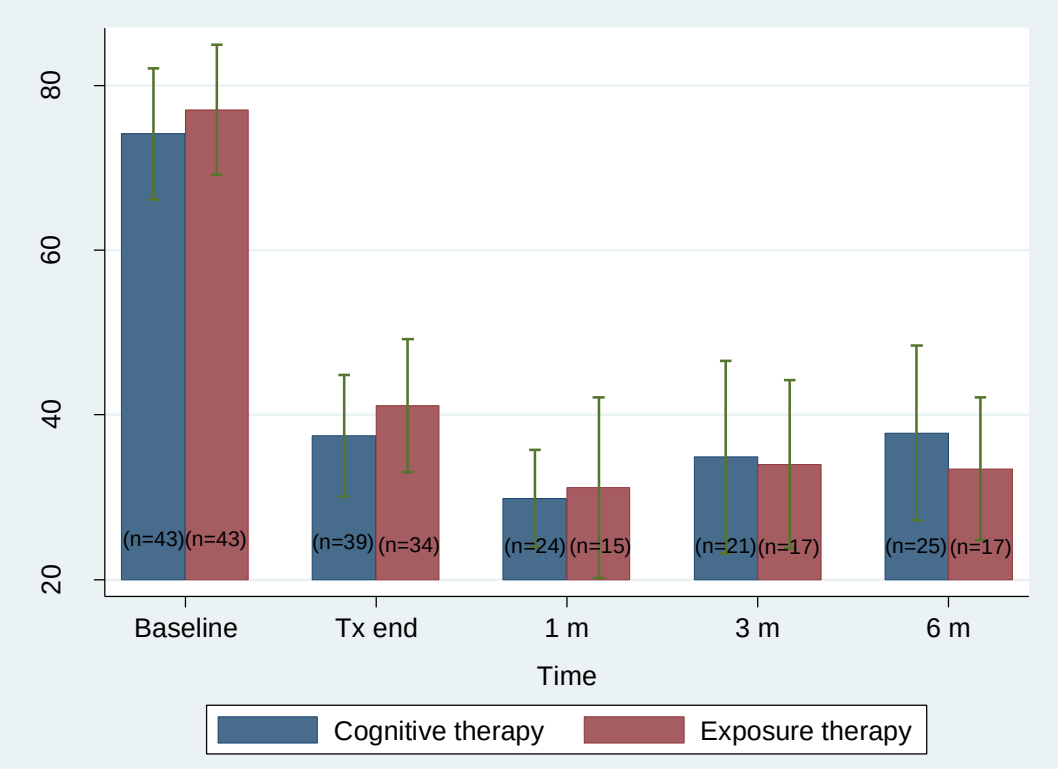
Figure 10. Observed Gambling Urge Scale (GUS) scores by time and treatment group.



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

Observed mean scores for gambling related cognitions (GRCS) by treatment group and time are shown in Figure 11. 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 identity 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 ($p = 0.029$).

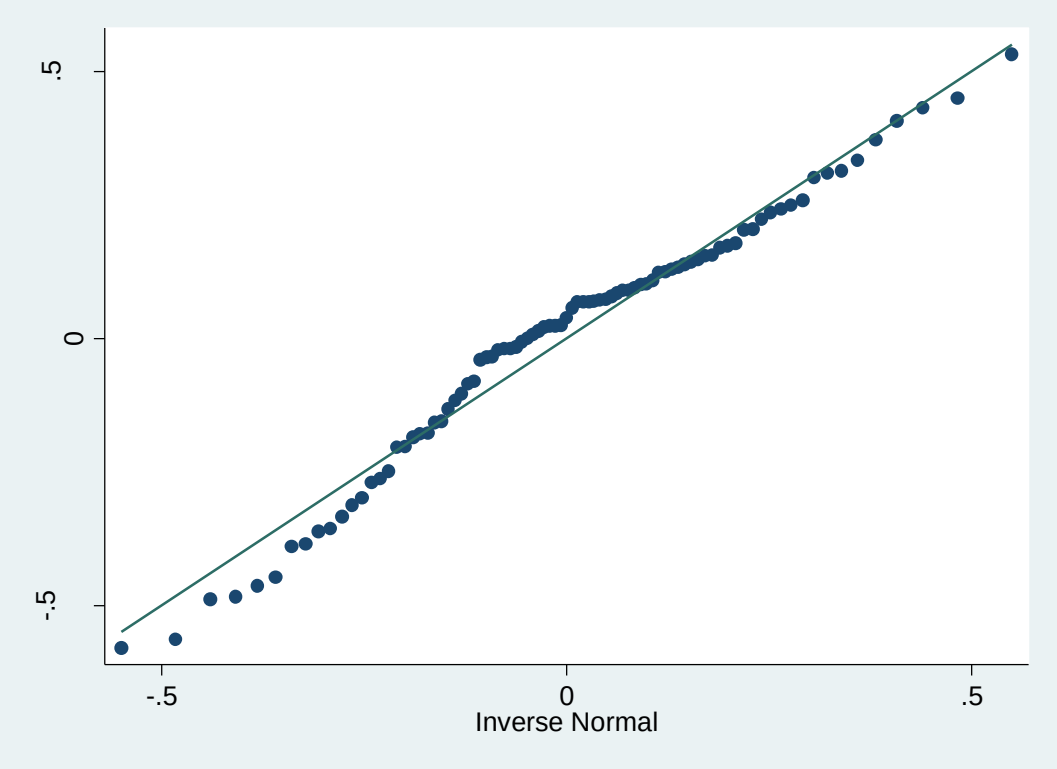
Figure 11. Observed Gambling Related Cognitions Scale (GRCS) scores by time and treatment group.



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

Predicted values for random intercepts and random slopes from the mixed model of GRCS data were more normally distributed than those for primary outcome VGS (Figure 12).

Figure 12. Best linear unbiased predictors for Gambling Related Cognitions Scale scores.



5.3.4 Secondary outcomes

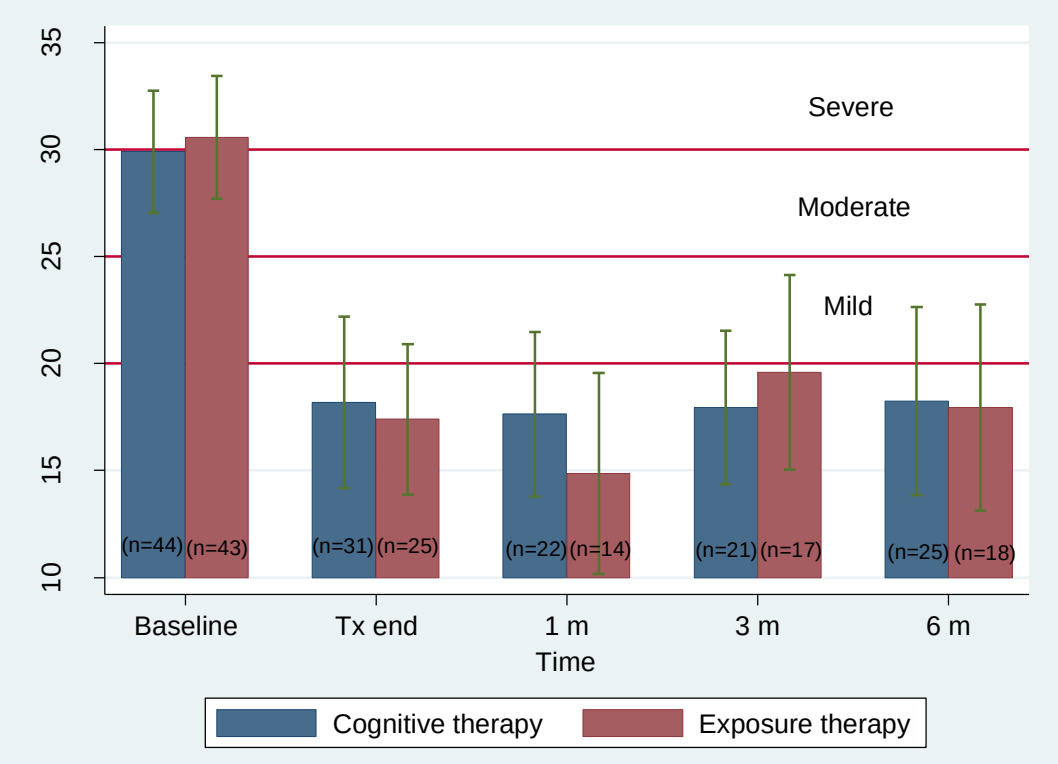
5.3.4.1 Linear mixed models

Results from between group comparisons for continuous secondary outcome measures (K10, WSAS, AUDIT, perceived self-efficacy, and hours gambled) using linear mixed modelling are shown in Table 13.

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 13). The average number of outcome assessments per individual for K10 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 13. Observed Kessler 10 (K10) scores by time and treatment group.[a]

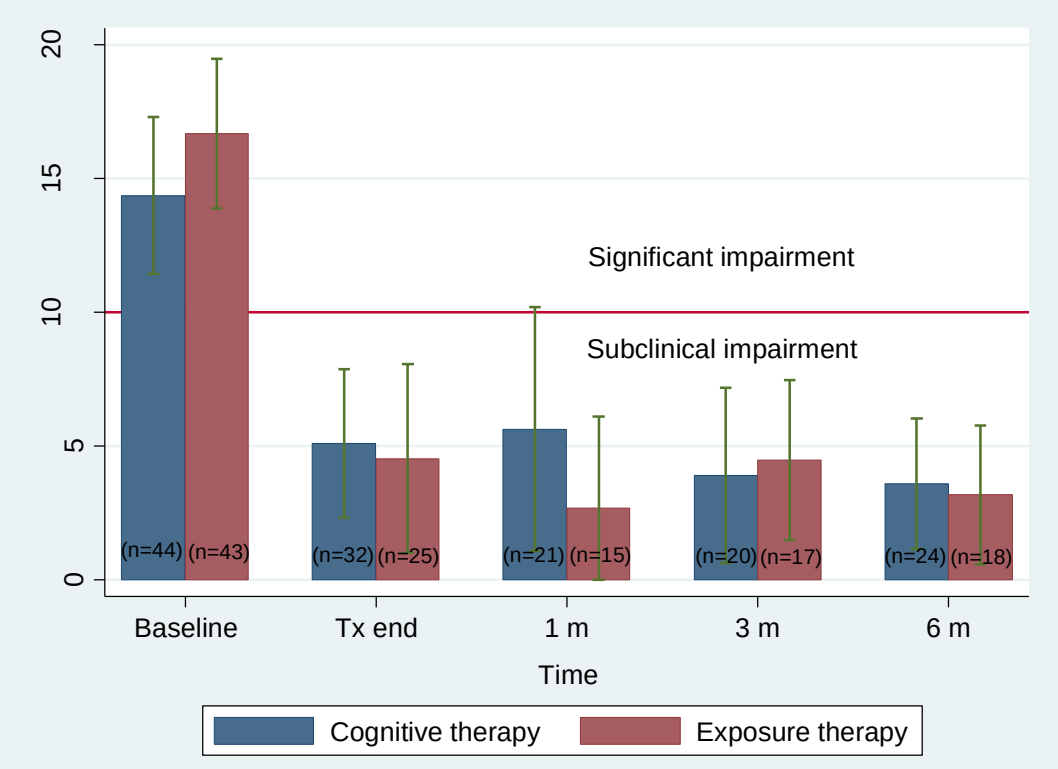


Lower scores indicate a reduction (improvement) in psychological distress.

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



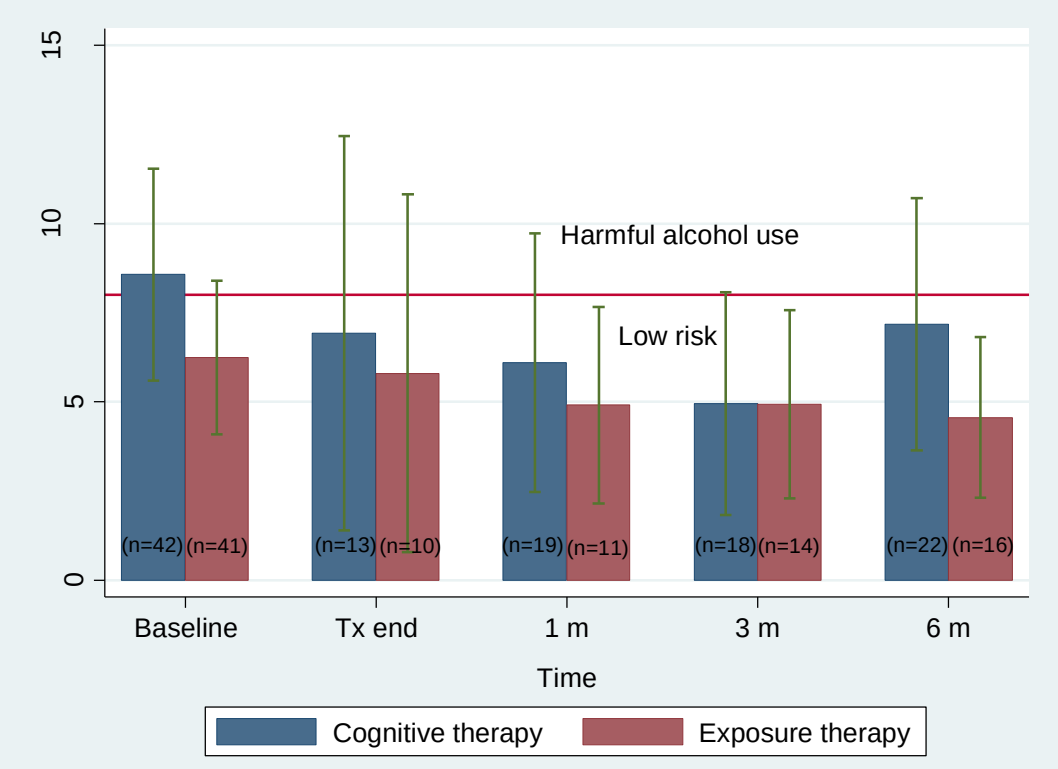
Lower scores indicate an improvement in social and work functional ability.

Note: [a] Horizontal lines are WSAS cut scores to interpret levels of functional ability/impairment.

As shown in Figure 15, 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 (χ^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 15. Observed Alcohol Use Disorders Identification test (AUDIT) scores by time and treatment group.[a]



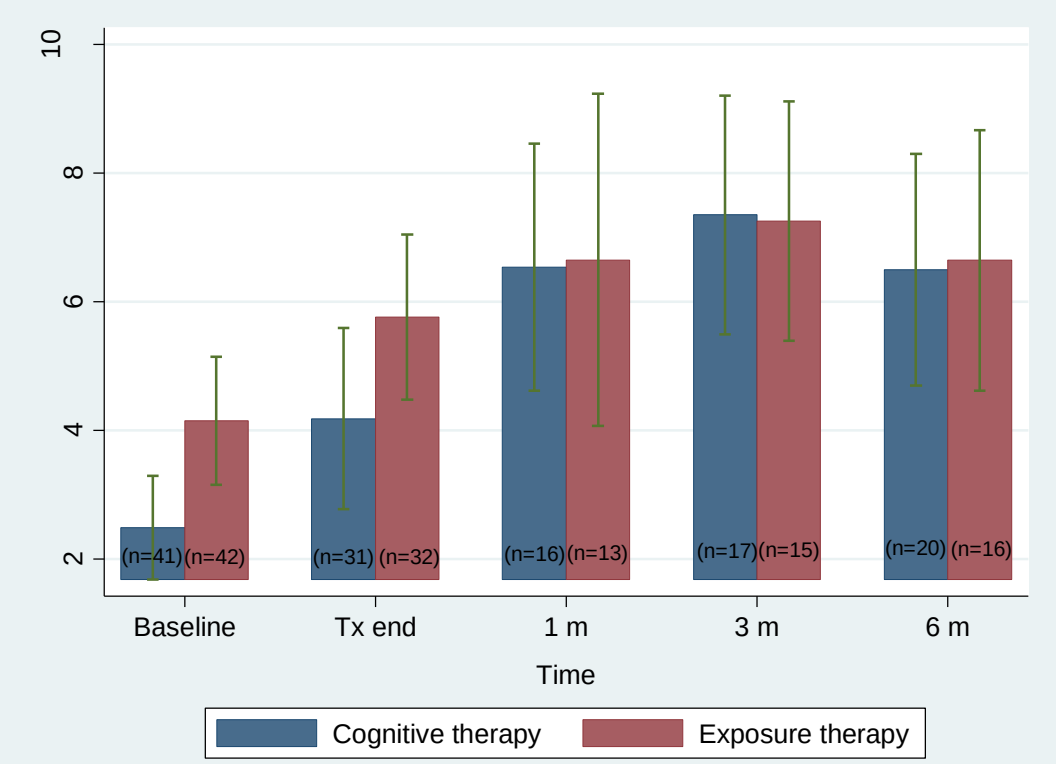
Lower scores indicate a reduced risk of harmful alcohol use.

Note: [a] Horizontal line is AUDIT cut score to indicate risk level from alcohol use.

For scores on the perceived self-efficacy measure there was a substantial increase (improvement) in observed mean values from baseline to one month follow-up and then a levelling-off effect (Figure 16). 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 (χ^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 16. Observed self-efficacy scores by time and treatment group.

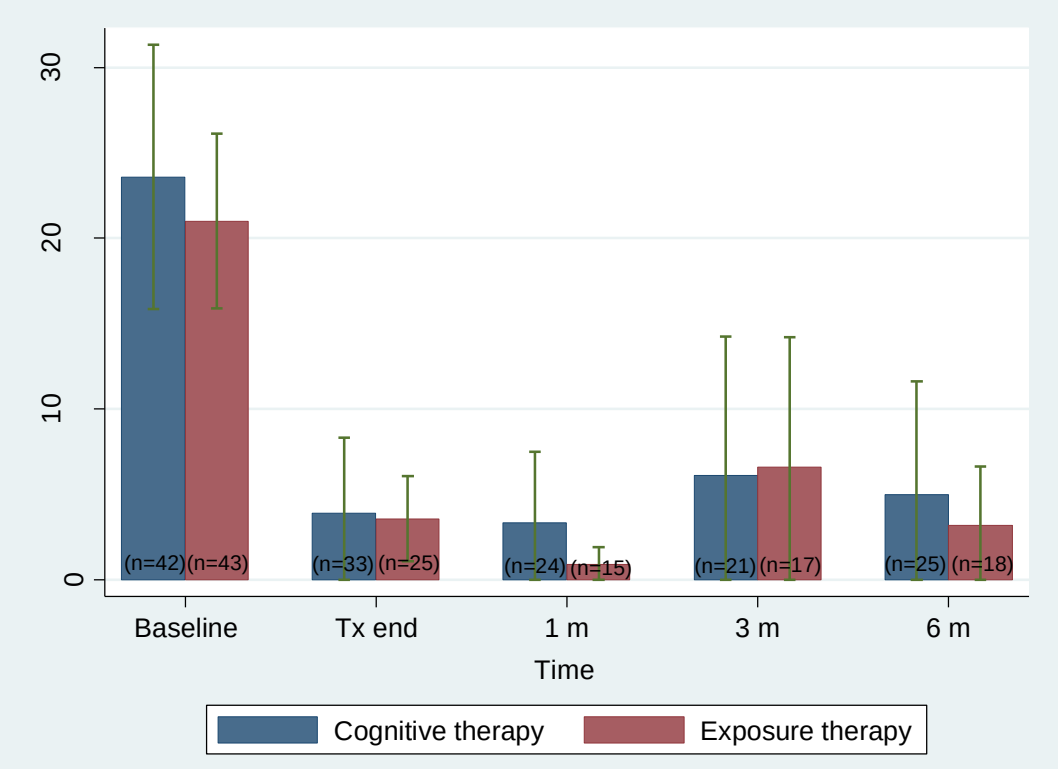


Higher scores indicate a greater level of confidence to control gambling behaviours.

Observed mean number of hours spent on gambling activities in previous month by treatment group and time is shown in Figure 17. Due to a sizeable right skewness of raw

scores, hours was transformed using natural logarithm $\{log_e(\text{hours})\}$ 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 ($\chi^2 = 30.15$, 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 17. Observed mean hours of gaming machine use in previous month by time and treatment group.



5.3.4.2 Generalised mixed models

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 18 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 19 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 17. 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 18. Money spent on gambling: cumulative sample logits versus time.

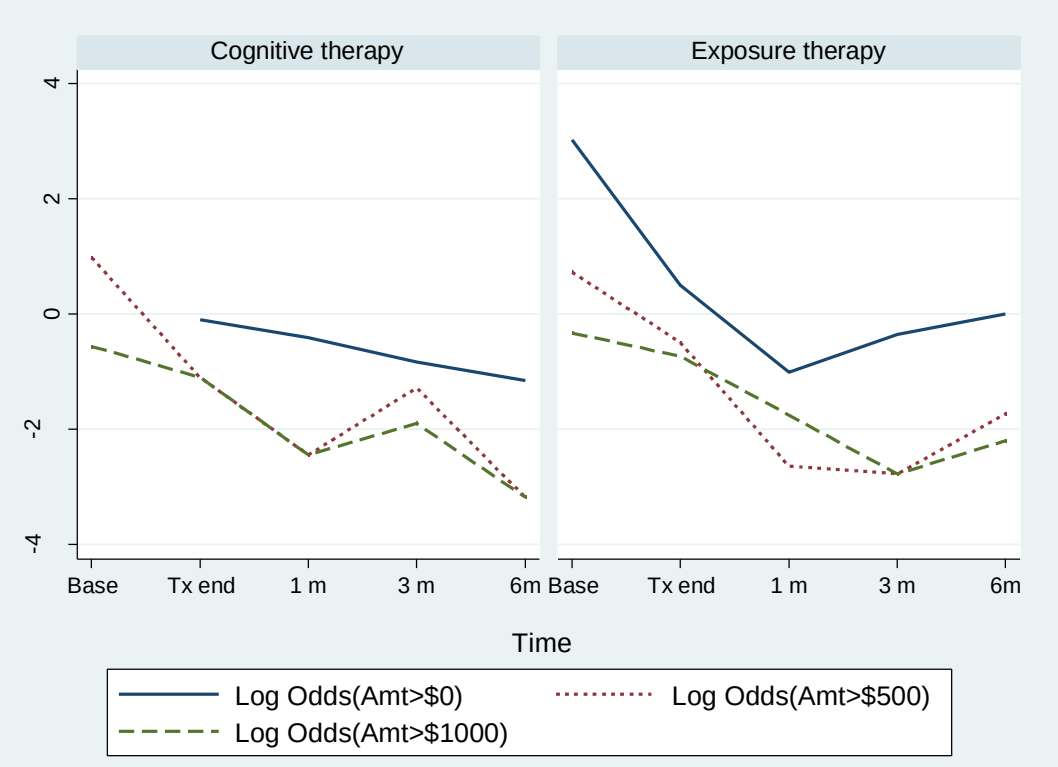


Figure 19. Frequency of gambling: cumulative sample logits versus time.

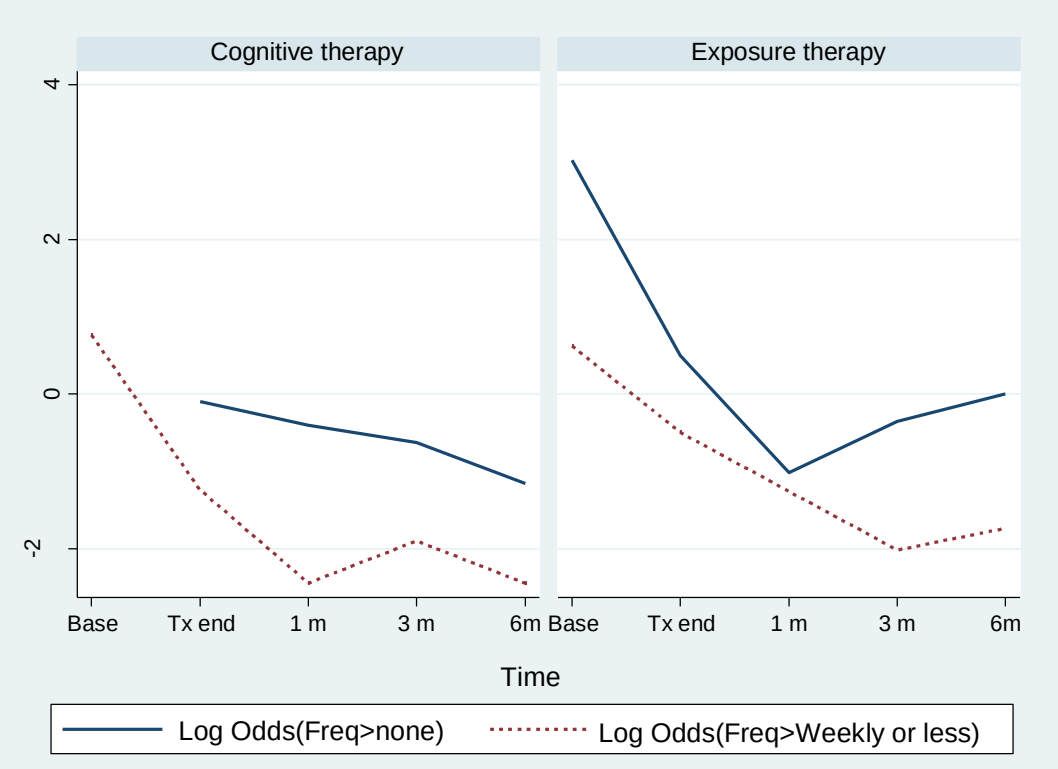


Table 17. Maximum likelihood estimates and 95% CIs for random-intercept proportional odds model of gambling behaviours.

	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

5.3.5 Per protocol analysis

For primary outcome measure VGS a per protocol analysis was conducted to estimate the treatment effect if all participants completed their assigned treatment. The IPW technique was used to calculate the probability of being in the observed treatment group. A logistic regression model was fitted to obtain probabilities that was specified as therapy status (ET = 1; CT = 0) on age, gender, baseline gambling severity (VGS), and participants self-reported perception of treatment logic and confidence following treatment rationale provided by the therapist in session two. Weighted mean VGS scores for ET and CT were then calculated from probabilities and contrasted to obtain an average treatment effect of ET versus CT.

Findings from the PP analysis are shown in Table 18. The POM for ET was the mean of both observed outcome scores and scores if CT participants had received ET treatment after correcting for potential confounding variables. The POM for CT participants at 12-weeks was 8.18 points (95% CI: 2.77 – 13.59) and was significantly smaller than the mean estimate calculated from all available data at the same time point (M=19.18; 95% CI: 15.77 – 22.59) (Table 15). The ATE or difference between POMs for ET and CT participants was insignificant (p = 0.916). The POM for ET can be calculated from Table 18 (8.18 – 0.41) to give 7.45 units (95% CI: 1.47 – 13.43). The ATET or the mean of the difference in outcomes between participants that received ET and if these same participants had received CT was insignificant (p = 0.983). Similarly, the ATET for CT participants was also insignificant (p = 0.833).

Table 18. Average treatment effect (ATE) and average treatment effect on treatment (ATET) estimates for Victorian Gambling Screen scores at treatment-end.

VGS	Estimate	Bootstrap SE	*P*- value	95% CI
ATE				
(ET vs CT)				
ET	-0.41	3.91	0.916	-8.08 – 7.26
POM				
CT	8.18	2.76	0.003	2.77 – 13.59
ATET				
(ET vs CT)				
ET	-0.10	4.56	0.983	-9.03 – 8.84
POM				
ET[a]	8.08	3.27	0.014	1.67 – 14.49

Abbreviations: ET, exposure therapy; CT, cognitive therapy; POM, potential outcome mean; SE, standard error; CI, confidence interval.

[a]Average score that would of occurred if ET participants received CT.

5.4 ANCILLARY RESULTS

5.4.1 Primary and secondary outcomes

A secondary post-hoc analysis compared 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 using Fisher's exact test. Also, to facilitate a clinically meaningful interpretation of changes in gambling related problems as measured by K10 and WSAS, effect sizes (Cohen's *d*) were calculated for mean differences between baseline and follow-up (Matthey, 1998). An effect size of 0.2 was considered small, 0.5 as medium, and 0.8 as large (Cohen, 1992).

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: $d = 2.52$). For K10 scores there was a clinically significant reduction (improvement) from baseline to follow-up with large effect size in CT ($d = 1.04$, $p < 0.001$) and ET ($d = 1.16$, $p < 0.001$). Using previous normative data (Andrews & Slade, 2001; Slade et al., 2011) the distribution of K10 scores at baseline for CT participants who also had 6-month follow-up data ($n = 31$) were 9 (29%) self-reporting minimal to mild levels of psychological distress, 8 (25.8%) as moderate and 14 (45.2%) in the severe range. At 6-month follow-up, CT scores were distributed as 26 (83.9%) in the minimal to mild range and 5(16.1%) in the moderate to severe range. For baseline ET, 8 (34.8%) participants reported minimal to mild levels, 5 (21.7%) as moderate, and 10 (43.5 %) in the severe range. At follow-up, 15 (65.2%) were at the minimal level, 4 (17.4%) in the moderate range and 4 (17.4%) in the severe range of psychological distress.

For participants who had 6-month follow-up WSAS scores ($n = 53$) there was a clinically significant improvement (reduction) from baseline with large effect size for CT ($d = 1.30$, $p < 0.001$) and ET ($d = 1.48$, $p < 0.001$). The distribution of WSAS scores for CT at baseline when using stratification levels for other DSM-IV disorders (American Psychiatric Association, 2000; Mundt et al., 2002) were 11(36.7%) in the sub-clinical range, 14(46.7%) with significant impairment, and 5(16.7%) in the moderate to severe range. At follow-up, scores were distributed as 27(90%) in the sub-clinical range and 3(10%) in the significant impairment to severe range. For ET at baseline, 6 (26.1%) were in the sub-clinical range, 11(47.8%) had significant impairment, and 6 (26.1%) in the

moderate to severe range. At follow-up, scores were distributed as 17 (73.9%) in the sub-clinical range and 6 (26.1%) had significant impairment in work and social functionality.

5.4.2 Predictors of therapy drop-out

To investigate the association between therapy drop-out, socio-demographics and baseline gambling related measures, binary logistic regression was used. In accordance with the 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. Both univariate and multivariate models were calculated. To account for potential bias of estimates in the final multivariate model, 95% confidence intervals and *P*- values were derived from the bootstrap method with 200 resamplings.

Results from regression analyses are provided in Table 19. 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 20). 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 this was insignificant in the multivariate model ($p = 0.661$).

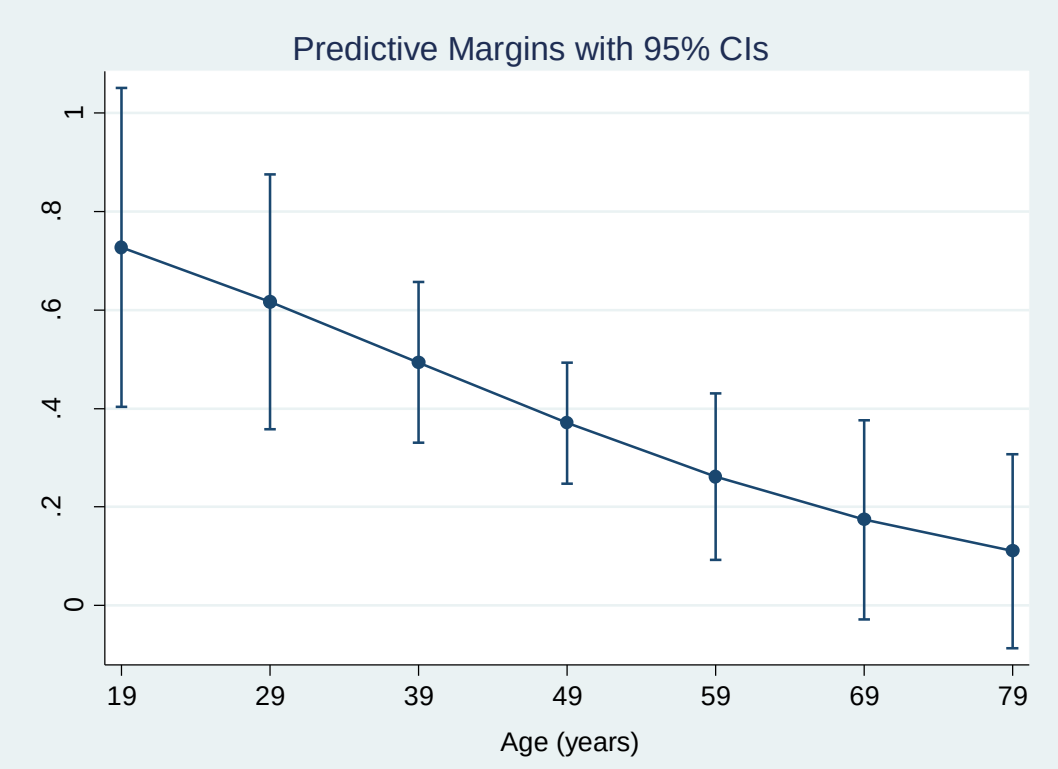
Table 19. Univariate and multivariate binary logistic regression models of factors associated with treatment drop-out.

	Univariate model			**Multivariate model**[a]		
					Normal-based	
Variable	OR	95% CI	*P*	OR	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.

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

Figure 20. Predictive probabilities of treatment drop-out by age.



5.4.3 Predictors of therapy attendance

In order to identify any association between number of therapy sessions attended by participants, socio-demographics and baseline gambling related measures, ordinal logistic regression analyses were conducted. To categorise participants into three ordered groups as the outcome or dependent variable, two tertiles were used. 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. To account for potential bias of estimates in the final multivariate model, 95% confidence intervals and *p*-values were derived from bootstrap method with 200 resamplings.

Results from ordinal logistic regression analyses to are provided in Table 20. The following ordered categories show the distribution of treatment sessions attended by participants: 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.

Table 20. Univariate and multivariate ordinal logistic regression models for factors associated with number of treatment sessions.

	Univariate model			Multivariate model[a]		
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.

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

5.4.4 Test of mediation

To determine mechanisms of therapeutic change based on each treatment's intended effects, a mediation analysis was conducted using mixed-effects models for all observed data. The mediation analysis was based on two approaches. The first approach followed the traditional steps that were proposed by Baron and Kenny for testing mediation (Baron

& Kenny, 1986). The second approach assessed indirect mediation effects using the Sobel test (MacKinnon, 2008).

Results from putative urge and cognitive mediators of the effects of ET (versus CT) on perceived self-efficacy in problem gambling are shown in Table 21. 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 difference between mediators and outcomes ($p < 0.001$) when adjusted for the interaction between treatment and time. It remained uncertain however, as to whether the associations were 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 $p < 0.05$. Figure 21 shows results for path models examining hypothesised mediation effects of urge and interpretive bias.

Table 21. 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

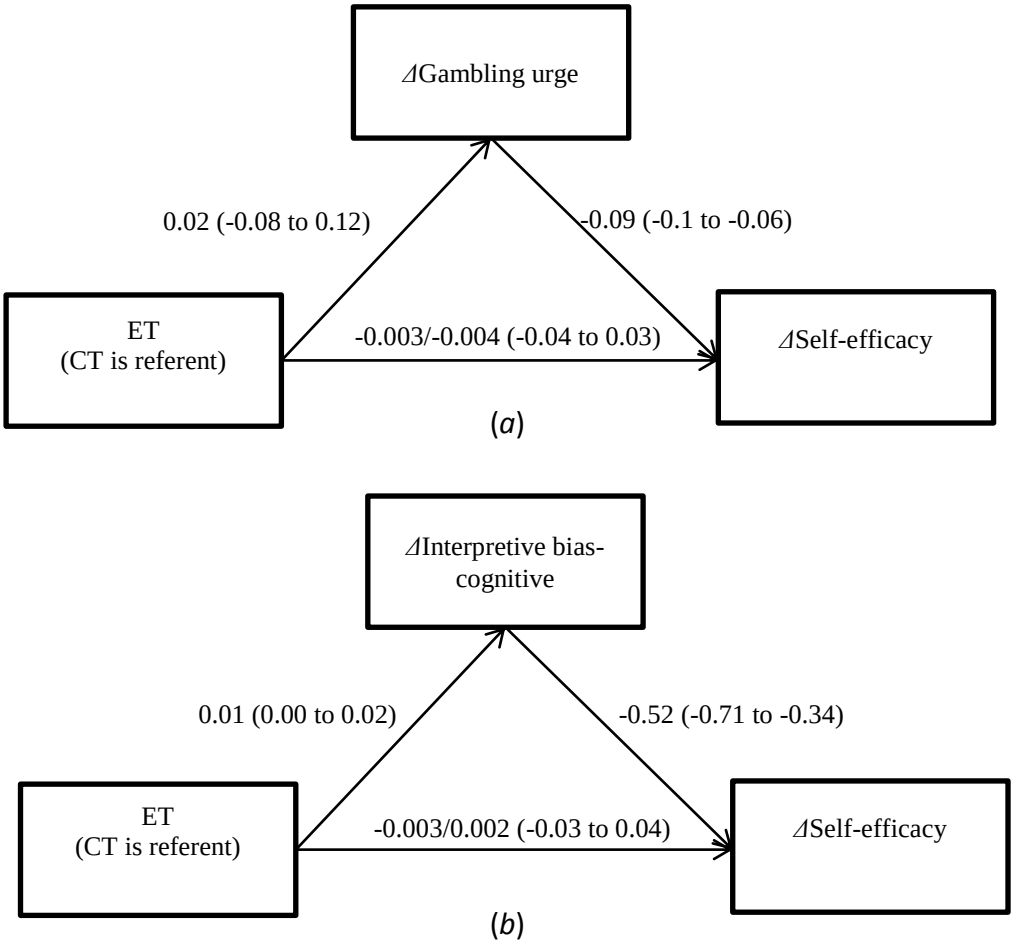
Abbreviations: GE, gambling expectancies; IC, illusion of control; PC, predictive control; IS, inability to stop gambling; IB, interpretive bias; CI, confidence interval.

[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 21. 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.

5.5 SUMMARY

From 151 consecutive referrals to the SGTS during the 12 month study recruitment period 65 % were allocated to either cognitive or exposure group and 58% started their allocated intervention. Based on this high recruitment rate, the sample was a robust representation of treatment-seeking problem gamblers who presented for treatment to the service. The

baseline data showed that both study groups were highly balanced on all demographic and clinical variables in spite of 6 exposure and 6 cognitive participants not attending a baseline assessment following randomization.

For the 87 participants who started intervention there was a statistically significant difference in the mean duration of CT and ET sessions (52 minutes vs 43 minutes) respectively. For treatment completers, there was no significant difference between median numbers of CT sessions of 9.5 versus 9 sessions for ET group. Similarly, there was no significant difference in duration of time in therapy between CT (Median = 17 weeks) and ET (Median = 18 weeks). The therapy drop-out rate was 41% whilst, on average, 68 % of participants provided follow-up data on at least one occasion post intervention. Study drop out was mostly a result of loss to follow-up. The co-operation rate for those participants who could be contacted to provide data was almost 100 % and there were no refusals. There were no reports of study discontinuation as a result of therapy related adverse events.

For primary outcome measure, the VGS, there was a significant decrease (improvement) in scores over time for both cognitive and exposure 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 suggested that both behavioural (exposure) and cognitive techniques had potential mediating effects within their own and the alternative therapeutic modality.

Additionally, there was a significant correlation between participant-specific intercepts and slopes for mediation variables urge and cognitions for both groups. This showed that individuals with higher levels of baseline severity experienced a faster initial improvement than those at a lower level of severity. In contrast, VGS trajectories were mostly similar across the study period despite considerable variability in baseline scores. Mediation pathways are further investigated in Chapter 7.

For measures of gambling related behaviours (e.g. money spent on gambling), DSM-IV diagnosis of pathological gambling, psychological distress, work and social functionality, and alcohol consumption there were also clinically meaningful improvements across time in both groups. The findings were concordant with improvements on primary outcome VGS and provided preliminary evidence for concurrent validity. That is, measures of mental health and social functioning appeared to be related to the validated measure of problem gambling behaviour VGS. This was further supported by the non-linear trajectories of change in secondary continuous outcomes across the study period. The findings for both primary and secondary outcome measures were consistent across ITT, per-protocol, and as-treated analyses. Also, post-estimation results showed that mixed-effects models provided consistent and robust estimates of therapy effects.

The use of mixed-effects models was justified for the outcome data. Firstly, there was significant variation between individual trajectories of change over time from an average trend. Secondly, the statistical models included all observed data; therefore all participants were included in an intent-to-treat analysis regardless of missing data. Lastly, the assumption relating to MAR for missing data appeared to be plausible for the observed dataset. This was particularly evident from sensitivity analyses that showed for a range of

putative departures from MAR, CT and ET were consistently more similar than different. The statistical models were also shown to be robust following post-estimation diagnostic tests.

The results from post-hoc secondary analyses were presented for primary outcome VGS and secondary outcomes relating to psychological disturbance (K10) and work and social functioning (WSAS). Approximately 80 % of cognitive and exposure participants were classified as non-problem gamblers at 6-month follow up based on VGS scores provided by both therapy completers and drop outs. These findings were supported by a mean change in VGS scores from baseline to follow up with large effect size. Similar improvements for K10 and WSAS were also found at follow up of clinical significance.

To investigate predictors of therapy drop out, univariate and multivariate logistic regression modelling was conducted. Univariate models showed that higher scores (worse symptoms) on K10 and WSAS were statistically significant predictors of drop out. However, effect sizes or odds ratios were small hence limiting any clinically meaningful interpretation. Younger age was also a significant predictor of therapy drop out in the unadjusted model. For the fully adjusted regression model, participant age retained an association with therapy drop out at the 10% significance level. In this model, the precision of estimates was mostly conservative due to the calculation of 95% confidence intervals from resampling. This was to account for a small sample size relative to the number of independent variables. No other predictor variables in the adjusted model showed a trend towards statistical significance.

For univariate analyses of therapy attendance the only statistically significant predictor was allocated therapy group. It was found that exposure participants were more likely to attend fewer therapy sessions than cognitive participants. As for the precision of estimates of therapy drop out, the confidence interval was conservative where the odds of an exposure participant attending fewer sessions may have been as high as 82% or as low as 9%. A similar trend was found for therapy group in the fully adjusted model at the 10% level.

Based on intent-to-treat analyses there was no evidence for a greater mediation role for gambling related cognitions in CT participants compared to ET. Similarly, the mediation role for gambling related urge was no better in ET compared to CT group. Therapeutic changes in cognitions and urge accompanied both CT and ET groups. These findings supported those of the main results where more similarities than differences were found between cognitive and exposure therapies. The dataset for these exploratory analyses comprised of approximately three times more observations than those of primary outcome measure VGS, thus providing more robust estimates of treatment effects. However, as sample size calculations were based on VGS, the interpretations of these findings are speculative in terms of study power. Furthermore, this study was designed as a superiority trial and not a non-inferiority trial or equivalence trial, and therefore it could not be concluded that the statistical evidence was in favour of any null hypothesis.

CHAPTER 6: QUALITATIVE INTERVIEWS

6.1 BACKGROUND

In Chapters 6 and 7 the results from the main trial and ancillary analyses were described. The findings indicated that there were more similarities between cognitive and exposure groups than differences in terms of therapeutic benefits. Furthermore, there was no evidence to support hypothesised mechanisms of change for each therapy relative to the alternative therapy. Perhaps seeking what the participants had to say about their experiences with therapy would provide a better understanding of therapy effects.

6.2 METHODS

6.2.1 Interviewer

The author (DS) conducted all interviews. He has a Masters degree in nursing and 12 years clinical experience as a mental health nurse. His PhD is focused on differential efficacy of CT and ET for problem gambling using a randomised trial and this accompanying qualitative inquiry. His first contact with trial participants was by telephone to conduct individual screening interviews to assess study eligibility. He then met eligible participants at their first study-site attendance to provide further explanation of the trial and obtain consent. Following this, no further contact with participants was initiated until treatment-end when a sub-sample was telephoned and invited to participate in a semi-structured interview. Participants were told that the reason for conducting interviews was to strengthen trial findings by listening to what they had to say. As DS was employed as the research officer for this funded project he did not discuss any aspects of his personal goals involving a PhD with participants. His research question for this qualitative component

was “What were the participants’ experiences and perceptions of therapy received in the trial?”

6.2.2 Participants

Following the treatment intervention period a sub-sample of participants were invited to take part in semi-structured interviews (Crabtree & DiCicco-Bloom, 2006) to explore treatment specific and non-specific effects for cognitive and exposure therapies. At the outset, DS contacted study therapists to identify potentially suitable participants based on a purposive sampling design. This approach was used to achieve equal numbers between cognitive and exposure groups and a balance on gender, treating therapists, distribution of treatment session numbers and time in treatment and follow-up. Additionally, initial interviewees were selected to ensure maximum variation in treatment adherence that ranged from treatment drop-out to treatment completion. A total of 9 individuals were contacted by telephone (DS) and invited to take part in a face-to-face interview at a time and location that was convenient to them. All agreed to be interviewed at this time, however one person was unable to commit to a date due to work obligations. On a follow-up phone call the person then declined to participate due to time constraints. Characteristics of interviewees are presented in Table 22. Of the 8 participants, 6 had completed treatment (completers, COM) and 2 had not completed treatment (non-completers, NON).

Table 22. Demographic and therapy characteristics of participants.

Participant	Gender	Age	Marital status	Employment	Group	No. of sessions
CT01,COM	Female	47	Single	Self employed	CT	14
CT02,NON	Male	29	Single	Employed	CT	2
CT03,COM	Male	51	Single	Self-employed	CT	11
CT04,COM	Female	65	Married	Retired	CT	13
ET01,COM	Female	56	Separated	Employed	ET	11
ET02,NON	Female	50	Married	Employed	ET	3
ET03,COM	Male	51	Single	Disability support	ET	14
ET04,COM	Male	36	Single	Employed	ET	9

6.2.3 Interviews

One-on-one interviews were planned to last for approximately one hour and conducted in person with participants between April 2012 and November 2012. Participants were offered a $50 gift voucher in acknowledgement of their contribution to the study. All interviews were held at the study-site (SGTS) based on participants requests. Interviews were conducted at a time nominated by the participant where in most cases this was to accommodate working hours. Interviews were recorded using a digital voice recorder and transcribed verbatim by an independent transcriber.

Each interview 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?” The interview was semi-structured where a topic list was used as a guide by the interviewer to ask questions and probe within topics that focused on treatment specific and non-specific effects (Appendix J). The participant

was not introduced to the topic list. The interviewer took a curious stance whilst the participant reflected on his or her therapy. This semi-structured approach to the interview enabled the researcher to focus on the areas of interest that were considered important to CBT but at the same time was flexible to allow collaborative discussion and any deviations from this guide that were important to the participant. The preliminary findings from transcripts of the first four interviews were presented for group discussion with 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.

6.2.4 Theoretical framework

Therapeutic benefits of CBT for problem gambling can arise from both therapy-specific and non-specific effects (Walker et al., 2006). In this study, these domains were pre-specified as categories for an initial directed content analysis using a deductive approach i.e. data analysis was researcher driven. Data were organised and summarised at the semantic level and themes were developed to capture participant experiences within categories and also commonalities. These were interpreted at a theoretical level in relation to findings of the main trial and previous literature. This approach to exploring participants' experiences was motivated by two underpinning properties of the trial design. Firstly, the trial was centred on testable hypotheses to investigate individual outcomes and processes of change or intended effects of each therapy (e.g. urge reduction and extinction from exposure therapy and acquisition of a more realistic set of beliefs from cognitive therapy). Secondly, non-specific effects in the trial could not be directly tested due to a lack of control condition. However, the assumption was made that therapies were

approximately similar in relation to structure (e.g. 12 weekly sessions) and implementation (e.g. therapist administered interventions). Therefore, qualitative interviews provided an opportunity to explore any deviation from this assumption about non-specific effects.

6.2.5 Data Analysis

Interview recordings were independently transcribed verbatim to a Microsoft word document and included reference to behaviours such as laughing and retained punctuated dialect. Transcripts were made available to DS between two to five days post-interview and then uploaded to NVivo software for data management. The analytic steps followed those recommended by Braun and Clarke (Braun & Clarke, 2006) using a directed content analysis (Hsieh & Shannon, 2005) that was informed by the framework for reporting outcomes in problem gambling treatment research (Walker et al., 2006). These steps are described in the following. (1) Transcripts were initially checked for accuracy and salient observations were documented that were abetted by a relatively unsullied memory of the interview. (2) Transcripts were then analysed independently where data that was seen as relevant at the semantic level was coded around one or both of the main categories in relation to therapy specific and non-specific effects (Walker et al., 2006). The context of extracts was also preserved at the semantic level by coding the surrounding data if applicable. (3) The broad range of codes within main categories were then sorted into sub-categories as a way of exploring the interrelationships between interviewees by comparing quotations to develop a more encompassing account of individual experiences. (4) Themes were developed from main categories and sub-categories based on the qualities of supporting data. (5) Interpretation of themes was then done in context of the main trial

findings and existing gambling intervention literature involving cognitive-behavioural therapies.

For each interviewee a reliable change index (RCI) was calculated to determine how much therapeutic change occurred from baseline to post-therapy. This allowed an opportunity to qualitatively assess the degree of concordance in therapeutic change between quantitative measures and participant's perception and experiences. The measures tested were gambling related cognitions scale (GRCS) (Raylu & Oei, 2004a) and gambling urge scale (GUS) (Raylu & Oei, 2004b) that were chosen for the trial to assess hypothesised mechanisms of change for CT and ET respectively. Reliable change 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 each measure at baseline (Jacobson & Truax, 1991). A reliable change was indicated when the difference between post-therapy and baseline ($x_2 - x_1$) were outside the range of $1.96 * SE_{diff}$ with 95% confidence. Alternatively, if the standardised difference between scores ($(x_2 - x_1)/SE_{diff}$) was greater than 1.96 then a reliable change was indicated with 95% confidence.

6.3 FINDINGS

The findings are presented in five main themes. In the first two themes both groups showed considerable similarity: (i) *participants overall evaluation of the intervention* (outcome) and (ii) *how participants' experienced the intervention and its effects* (process). The next two themes highlight the main differences between the CT and ET formats: (iii) *experiences of the therapy specific effects for CT participants* and (iv) *experiences of the therapy specific effects for ET participants*. The final theme was grounded on comparable

outcomes between the two groups in the main trial on therapy specific variables: (v) *relational interpretation of CT and ET specific effects*. 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).

6.3.1 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)

The above extracts support findings from the main trial in terms of improved social functioning and reduction in money spent on gambling activities. The CT participant operationalizes a temporal association between problem gambling and social impairment where she reports being free of EGMs and "available" for social engagement. Testament to this was her choice to be interviewed on a Friday evening where previously she would most likely be gambling at this time. For the ET participant, her primary evaluation of treatment was framed in a financial context. Her comments suggested ongoing financial stress but that she had gained enough control of her gambling to at least prevent further decline.

One non-completer of treatment described how she benefited from the initial sessions involving cash restriction planning but the exposure tasks were discordant 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 seems this person had good insight into her level of ability to cope in situations such as boredom with "housework… you just get itchy feet". She also described patterns of her pre-gambling behaviours that were commensurate with the concept of 'switching addictions':

> I came from smoking for 10 years, gave that up (then) I became addicted to going to the gym. (ET02,NON)

Another interviewee described juxtaposition between her gambling behaviours 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)

Another prominent narrative in participant accounts was a developed sense of control over gambling following therapy. One participant described her experiences of treatment that empowered her to act independently and enable her 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). Another person stated that after attending each of two therapy sessions he "definitely left them feeling a lot more empowered". He terminated therapy though because of working "a stupid amount of hours" that conflicted with operation times of the therapy centre (CT02,NON). 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)

6.3.2 How both ET and CT participants experienced the intervention and therapy related changes

From the transcripts it was evident that nearly all the participants' experience of therapist related variables played an important role in the recovery process and this may have been sine qua non of effective intervention in some cases.

> 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, (the therapist) 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)

> …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 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)

Another participant described her uptake of diarising in the context of therapist alliance. This was forged through a "…combination of trusting (the therapist) and she cared" and therefore "…I was willing to give that (diary) a shot". (CT01,COM) For one participant however, therapist empathy was not enough for her to continue with treatment.

> Yeah, she seemed very nice and very understanding and knew what she was doing, she'd done it before. It seemed a little bit regimental, a little bit like, 'This is what we do, look at this devil picture and this angel picture'…I came to that realisation it wasn't for me all the way... .(ET02, NON)

Most participants however, talked about the benefits of a 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)

6.3.3 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 otherwise would have maintained gambling behaviours 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 regarding 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. Participants 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)

Beyond therapy sessions participants were asked to keep a self-monitoring diary on a daily basis. This was to provide them with a prop to help describe to the therapist any situations which triggered desire to gamble and how each of these situations was managed. If gambling had occurred, it provided an opportunity for the therapist and participant to discuss specific gambling thoughts and how these influenced their behaviour. One participant found the self-monitoring diary to be "really therapeutic" despite initial disinclination based on the perception that it would be "indulgent and crap" (CT01,COM). She was motivated to push through her negative perception of diarising and subsequently acquired therapeutic benefits from using this tool. Conversely, another participant appeared less enthused to use the diary.

> 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)

6.3.4 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 or personal triggers or cues. The theoretical mechanism of behavioural therapy is de-conditioning of the urge using graded 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 all 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 most 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 aforementioned 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)

His scores of zero on the gambling urge scale (GUS) at baseline and post-treatment (Table 23) tend to contradict his overall experiences of urge.

> …those forms are just forms and they can be filled out any way you like...to try and get a true picture of how you feel and how your urges are, I do find it difficult to produce that in an office. (ET04,COM)

Table 23. Observed outcome scores for each participant and reliable change index (RCI).

Participants	Therapy sessions	GRCS			GUS		
		Baseline	Post-therapy	Reliable change[a]	Baseline	Post-therapy	Reliabile change[b]
CT01,COM	14	118	23	Improved	35	0	Improved
CT02,NON	2	61	50	No change	25	20	No change
CT03,COM	11	110	23	Improved	5	0	No change
CT04,COM	13	53	25	Improved	6	0	No change
ET01,COM	11	108	23	Improved	18	0	Improved
ET02,NON	3	97	55	Improved	7	1	No change
ET03,COM	11	106	23	Improved	10	0	Improved
ET04,COM	4	31	23	No change	0	0	No change

Abbreviations: VGS, Victorian Gambling Screen; GRCS, Gambling Related Cognitions Scale; GUS, Gambling Urge Scale; RCI, Reliable Change Index.
[a]RCI (95% Confidence); < -21.24 = clinically significant decrease (improvement) in scores; > 21.24 = clinically significant increase (worsening) in scores.
[b]RCI (95% Confidence); < - 7.55 = clinically significant decrease (improvement) in scores; > 7.55 = clinically significant increase (worsening) in scores.

The challenge to understanding treatment logic in early phases of exposure therapy was highlighted by two participants suggesting it to be a potential threat to successful treatment adherence.

> I was just reading all the stuff and really taking it in, really thinking okay, what is the logical side of this, why is it doing this and the more I looked into it and yeah, it was easy to explain each week as I did it… if the person isn't a thinking person who can think about what was going on, it's going to be very hard. (ET03,COM)

> 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)

6.3.5 "Questioning your desire": relational interpretation of CT and ET experiences

In the main trial it was expected that ET participants would experience a significantly greater reduction (improvement) in GUS (gambling urge scale) scores compared to CT participants and contrariwise for GRCS (gambling related cognitions scale). This was considered a plausible hypothesis in light of the two paradigms to explaining gambling disorders. However, it was evident from most participant transcripts that there was dynamic interplay between psychobiological states and perceptions of control that was suggestive of an urge-cognition continuum.

> Thoughts and everything is oh, you know, well I've got an urge I might go and win. It's more the winning factor, you know, you're going to go oh look, yeah I've got $100, I might make that into $1000. You've got the urge that you're going to make something out of it. (ET03,COM)

Findings from the trial showed similar improvements in urge and cognitions between study groups as measured by GUS and GRCS respectively. Nevertheless, at the interviewee level there was considerable variation in the reliability of these findings as indicated in Table 23. One participant who indicated a reliable improvement on both measures described a situation during therapy where she considered gambling again due to a sense of failure.

However, by utilising cognitive strategies she was able to overcome erroneous thoughts and not gamble despite an omnipresence of urge.

> I was driving towards a venue and I had it all set up, and because of the foundations that were laid with this outcome, 'What would happen to me when I gamble? What it means for me to gamble?' that overpowered that intense urge which I found remarkable, so I'd rather go home and white knuckle than go to a machine and that was another big turning point. (CT01,COM)

Another participant who also described benefits of recruiting cognitive strategies in face of emotional states reported a reliable change in GRCS scores but not GUS (Table 23). Her reference to urge-type experiences appeared to be less intense than abovementioned participant that perhaps was reflected by her low GUS score at baseline assessment.

> Well recognising they're gambling thoughts and understanding that the machines are not going to win and actually questioning your desire to go in there, you know, in your head - that was good. (CT04,COM)

Another participant described how his developed rational thinking foreshadowed desire to gamble in decision-making processes.

> 'Well, you know, because they were fighting for position in the brain, so the desire to gamble because of the association with the lights and the chance to win money, or just purely the entertainment as opposed - so that was fighting for a place, now it's taken - the statement in my head that, you know, don't gamble or whatever the voice is, that's now taken over. Right, so now that's come into the primary position in my brain. So the fact that the lights and the spinning wheels and the chance to win money are not appealing to me. So that took time to progress.'(CT03,COM)

Most ET participants indicated a beneficial shift in their cognitions that occurred in parallel to exposure tasks. One participant felt that the "simplistic attack" of ET on problem gambling was an essential ingredient to success. She reported a reliable change on GRCS (Table 23) and described changes in her thought processes that were concomitant with intended effects of exposure therapy.

> When the rational thought started taking over together with this (exposure therapy) it helped me sort of break if you know what I mean. I mean I was also surprised how quickly it worked for me. I don't know how everybody else is but it was quite quick. (ET01,COM)

Finally, another ET participant felt they had gained greater insight of their gambling behaviours from completing homework measures.

> …when you take the sheets to the pub or you take them home and you actually do that, I think that's probably one of the most beneficial things too because if you do that fair dinkum it actually gives you a chance to stop and think as well and also to know what you're doing, why you're doing it, so it also can help you stop getting in your car and going to the pub. (ET04,COM)

6.4 SUMMARY

By seeking to understand what problem gamblers had to say, this examination of cognitive and exposure therapies revealed that experiences both supported and extended key findings of the randomised trial. First, all interviewees gained benefits from therapy. They reported outcomes ranging from reductions in problem gambling to improved psychosocial wellbeing. Second, participant comments did not appear to favour one therapy over another. The transcripts suggested considerable commonalities between the two groups in terms of improved outcomes at short-term follow-up. Third, findings provided a more in-depth perspective of outcomes experienced that were meaningful at the individual level. Fourth, both treatment specific and non-specific effects were well supported as playing a therapeutic role to recovery. It was not clear as to what effect, if any, could explain most of the variance in therapeutic change. Finally, most ET participants indicated that imaginal exposure tasks in early phase of treatment could hinder therapy adherence due to a lack of connectivity with rationale. Together, these participant comments indicated both cognitive and exposure therapies were beneficial and also highlighted areas for further improvement.

CHAPTER 7: DISCUSSION

7.1 INTRODUCTION

This thesis was conducted in three phases. Phase 1 involved a systematic literature review to attain a comprehensive understanding of the evidence surrounding cognitive and exposure therapies for problem gambling. It was shown that the evidence base was limited and a new trial was justified. The discussion of literature review findings was presented in Chapter 2. Phase 2 of the study was comprised of a randomised controlled trial to investigate the differential efficacy of interventions. Phase 3 sought to understand what participants had to say about their experiences and perceptions of cognitive and exposure therapies using qualitative interviews. Findings from the trial and qualitative interviews are discussed in this chapter.

7.2 FINDINGS OF THE RANDOMISED CONTROLLED TRIAL

The testable hypothesis in this study related to the differential efficacy of two core cognitive-behavioural approaches:

The primary research question tested in this study was: Among treatment-seeking problem gamblers is one of two core components of CBT - ET or CT – if administered alone, more effective in reducing gambling severity symptoms (harm to self-subscale of the VGS) over the 9-month study period (intervention and maintenance effects) than the other one administered alone?

The trial was a single-site, two-group randomised, parallel design. Participants were followed for up to six months after completing their course of therapy.

7.2.1 Baseline characteristics of participants

When comparing characteristics of study participants to problem gamblers in the general population of South Australia there were more females in this study sample (50 % versus 43 %), fewer employed full-time or part-time (53 % versus 68 %) and fewer married or in a relationship (38 % versus 59 %) (Gill et al., 2006). Similar differences were also found when comparing study participants with those from Petry and colleagues trial (2006), arguably, one of the most comprehensive studies to date involving CBT for problem gamblers (Petry et al., 2006). In addition, baseline mean SOGS scores suggested that gambling pathology was more severe in the present sample (M = 11.7, SD = 2.7) when compared to those in Petry's trial (M = 8.4, SD = 3.9) (Petry et al., 2006).

This variation in participant characteristics may be explained by the different recruitment methods employed in each study. The participants in Petry's trial were recruited via media announcements and were more representative of problem gamblers in the general population on a range of gambling activities. Participants in the current study were mostly self-referrals to a community based gambling help service for problems with electronic gaming machine use. Furthermore, this sample was comprised of a greater proportion of individuals with baseline co-occurring affective and anxiety symptoms in the severe range than problem gamblers in the general population of South Australia (53 % versus 33 % respectively). Also, more individuals in this study were in the intermediate to high risk group of alcohol use (22 % versus 14 %) (Gill et al., 2006).

The high rates of co-morbidity found in this study were commensurate with previous investigations involving treatment-seeking problem gamblers (Petry, 2005). The prevalence of anxiety and depression was also much higher than that found in population-

representative samples of problem gamblers at a transnational level (Lorains et al., 2011). This study data extends the evidence base in that treatment-seeking problem gamblers in South Australia have higher levels of gambling related pathology compared to those in the general population (American Psychiatric Association, 2013).

The study participant characteristics were also highly balanced between CT and ET groups at baseline. This was achieved by using blocked randomisation within strata variables age, gender and SOGS scores. This approach was more conducive to attaining prognostic benefits of randomisation on both known and unknown confounders than simple randomisation due to the relatively small sample size. An alternative method may have been probabilistic minimisation (Moher et al., 2010). However, this method lacks the theoretical basis of pure randomness and therefore posed a greater risk of an imbalance. For example, in a trial to investigate brief psychological treatments for problem gamblers there were imbalances on numerous clinical and socio-demographic variables at baseline when minimisation was used (Hodgins, 2009).

7.2.2 Implementation of interventions

For therapies actually implemented, treatment completers in both study groups attended, on average, one session every 2 weeks for approximately 18 weeks. Individual exposure sessions were shorter in duration than cognitive sessions. This data highlighted the disparity between how therapy was intended to be delivered and how it was actually delivered. Nevertheless, therapy fidelity checks indicated that the techniques of cognitive and exposure therapies were reproducible gambling-specific interventions. Also, there was no evidence of co-intervention bias from techniques being introduced by a therapist from an alternative therapy.

7.2.3 Therapy drop-out

The therapy drop-out rate of 41% in this study was comparable to previous investigations involving psychological treatments for problem gambling. For example, a meta-analysis found that drop-out rates ranged from 14% to 50% with a median of 38% (Melville et al., 2007).

Over 66% of drop-outs attended 3 or fewer sessions. It was evident that some individuals experienced a degree of improvement although limited compared to therapy completers. Similar findings were found in a previous cohort study conducted at Statewide Gambling Therapy Service (SGTS) where drop-outs, on average, experienced a modest improvement in gambling symptoms compared to the more substantial improvement of treatment completers (Smith et al., 2010). However, drop-outs in both the present study and previous cohort study were participants who had engaged in at least one therapy session (initial screening) and therefore did not account for drop-outs prior to commencing treatment. This rendered the definition of 'drop-out' to being problematic as it has been shown that even single sessions can influence outcome significantly (Tolchard et al., 2006).

A further finding of the SGTS study was that problem gamblers who self-reported higher levels of sensation-seeking traits were also more likely to discontinue therapy after 3 or less sessions (Leblond, Ladouceur, & Blaszczynski, 2003; Smith et al., 2010). This finding motivated the inclusion of a baseline measurement of sensation-seeking in the current study to investigate predictors of drop-out in context of a randomised trial. However, no statistically significant association was found at the univariate or multivariate level. A possible explanation was that this study focused on EGM use whereas a range of gambling forms was examined in the SGTS study including horse and dog racing. This is supported

from other studies where higher levels of sensation-seeking traits were associated with gambling types involving skills (e.g. racetrack gambling) (Bonnaire, 2009) and betting on several gambling forms (Coventry & Brown, 1993).

7.2.4 Participant follow-up

In accordance with the ITT principle, best efforts were made to attain follow up assessments from all participants regardless of adherence to study protocol. Strategies to improve follow-up response rates included minimising the number of attendances required at SGTS by sending questionnaires by mail and offering gift vouchers as an incentive. A wide timeframe was also allowed for each follow-up assessment and resulted in considerable variability in follow-up times.

In spite of the attempts at follow-up, missing data was common, which may have been due to a number of plausible causes. Firstly, study questionnaires demanded considerable time and effort from participants to complete over 100 items on a range of experiences such as gambling behaviours, therapeutic change mechanisms, work and social functionality and alcohol use. In the face of competing interests such as daily activities involving work and family, participants may have placed less precedence on completing questionnaires.

Secondly, approximately 50 % of participants self-reported a gambling problem of at least 5 years. In light of inveterate patterns of problem gambling behaviour some may have felt less motivated to complete assessments due to a lack of expectation from research findings (Morton, Bandara, Robinson, & Carr, 2012). Thirdly, it has been suggested that volunteerism and social participation in health related research has declined in the 21st Century (Morton et al., 2012). The sine qua non was that participants were not paid for their contributions to this study and this may have reflected a methodological limitation. In

context of the aforementioned barriers to follow-up, the response rate was most likely a realistic representation of participant flow through an everyday community based gambling help service.

7.2.5 Main findings

The effectiveness of cognitive and exposure therapies or 'how well treatments worked in everyday practice' (Hernan & Hernandez-Diaz, 2012) were shown to be clinically beneficial across 9 month study period. There was no evidence to favour one therapy over another. This finding was based on an ITT analysis where estimates of therapy effects were conservative due to inclusion of participants who did not fully adhere to assigned treatment.

To address the question of how well therapies worked under 'near perfect' conditions, a per protocol analysis was conducted within a counterfactual framework to control for selection bias. This provided the opportunity to assess both average treatment effects for adherers as well as for non-adherers had they completed treatment as per protocol. The results showed that problem gamblers who adhered to therapy protocol experienced more superior benefits when compared to ITT estimates. There was no statistically significant difference between ET and CT in the per protocol analysis.

In all analyses, it was assumed that missing data was mostly ignorable as a considerable proportion continued to be missing from some time onwards. In other words, treatment drop-out was dependent on observed data but not dependent on unobserved data. For example, participants who achieved their therapeutic goals early in treatment may have then discontinued with the study based on a decision that any further involvement would not provide additional benefit.

Despite missing data for both therapy completers and drop-outs, patterns of change in primary and secondary outcome measures in this study were comparable to those found in previous gambling trials. For example, in a study that investigated the efficacy of group cognitive-behavioural therapy involving cognitive restructuring and imaginary exposure tasks, improvements were found on the NODS (National Opinion Research Center DSM Screen for Gambling Problems) (Gerstein et al., 1999) as well as BDI (Becks Depression Inventory) (Beck & Steer, 1987) and BAI (Becks Anxiety Inventory) (Beck, Epstein, Brown, & Steer, 1988). Petry and colleagues (2006) also found matching results when using SOGS as primary outcome and BSI scores (Brief Symptom Inventory), a 53 item instrument to assess psychiatric symptoms (Derogatis, 1993; Petry et al., 2006). Taken together, results from both present and previous studies appear concordant in terms of the effectiveness of cognitive-behavioural interventions.

For mechanisms of therapeutic change, both CT and ET groups showed concomitant reductions in scores on self-report 6-item GUS and 23-item GRCS from baseline to 6-month follow-up. Improvements of a similar magnitude have been found in previous studies for single item measures of urge in exposure-based therapy (imaginal desensitisation) (McConaghy et al., 1983, 1988), and both 'desire' to gamble and perception of control in cognitive therapy (Ladouceur et al., 2003; Ladouceur et al., 2001; Sylvain et al., 1997). Both study groups also showed a significant correlation between baseline scores and rates of change in GUS and GRCS scores. Perhaps those at the severe end of the problem gambling spectrum were more responsive to change mechanisms in the early phases of cognitive or exposure therapy. Conversely, for primary outcome measure VGS; the rate of change was similar across most severity levels despite considerable

variation in baseline scores. Furthermore, heteroskedastic mixed modelling of VGS data indicated that the variance of individual responses from an average response did not differ between the two groups.

Only a few previous gambling trials have utilised mixed-effects modelling in order to address issues such as missing data and correlation within individuals (Carlbring et al., 2010; Carlbring & Smit, 2008; Petry et al., 2006; Petry et al., 2008). However, the interpretation of models in these papers has mostly been constrained to population average parameters and failed to capture additional information at the individual level. Furthermore, the ability to appraise the appropriateness and robustness of statistical models has been limited due to a lack of transparency in reported findings.

7.3 STRENGTHS AND LIMITATIONS OF THE RANDOMISED TRIAL

The design of this trial was guided by ethical considerations in line with the community service commitment of 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 conditions (e.g. anxiety) and this enhanced the external validity of findings. Nevertheless, the study was conducted at a single site and therefore findings were limited in terms of inference to a wider population. On the other hand, the benefits of being a single-site study included more effective lines of communication and a more consistent application of research protocol.

One of the main limitations of this study was a potential loss of power due to an under representative sample size. The a priori sample size estimation was for a total of 130

participants based on VGS as primary outcome. The calculation assumed a Type II error rate of 10 % (i.e. 90 % power) and a small effect size for change in VGS scores from baseline to 6-month follow-up. Subsequently, a relatively large sample was required to detect a small difference between cognitive and exposure groups. However, there was a shortfall in numbers with 99 problem gamblers being recruited and 87 receiving an intervention. This situation possibly moderated study power and favoured a conservative conclusion that treatments were more similar than different. However, a counter-effect was the repeated-measure design of this study where each person was his or her own control. This meant that participant-to-participant variability was mostly explained by intervention effects and so enhanced study power (Guo, Logan, Glueck, & Muller, 2013). Nonetheless, it could not be declared that cognitive and exposure therapies were statistically equivalent under conditions of a superiority trial design and the analytic approach.

The upper and lower confidence limits for estimated mean VGS differences did suggest however, more similarities than differences between therapy groups from a clinical perspective. At 6-month follow-up, the 95% confidence interval for a range of possible population mean differences was compatible with a difference of up to 4 points in favour of exposure group or a difference of up to 7 points in favour of CT. The sample size calculation was based on a mean difference of 5 points and, coupled with the fact that estimated mean differences were more likely to be in the middle of confidence intervals (Gardner & Altman, 1986) the extreme differences were of limited clinical utility.

A limitation of the study design was the lack of a formal control group to account for non-specific or absolute treatment effects. Still, 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. A number of previous randomised trials have shown that variants of gambling-specific CBT are causally effective. For example, in a randomised trial conducted by Petry and colleagues, 231 participants received either individual CBT plus gamblers anonymous (GA) referral- a self-support group that uses a 12 step program of recovery; referral to GA plus CB treatment in workbook format; or referral to GA alone (Petry et al., 2006). A significant improvement in mean SOGS scores was found for CBT group from baseline (M = 8.7, SD = 3.9) to 2 month follow-up (M = 2.9, SD = 3.6) with large effect size whereas for GA alone the change was clinically less substantial (M = 7.9, SD = 3.8) versus M= 4.5, SD = 4.3).

In terms of absolute effects, cognitive therapy had been established as superior to wait-list control conditions in previous clinical trials (Cowlishaw et al., 2012; Gooding & Tarrier, 2009). For example, Sylvain et al. (1997) found that mean SOGS scores for cognitive participants (n = 14) significantly reduced (improved) from baseline to post-treatment (M = 12.6, SD = 2.3 versus M = 2.7, SD = 3.7) with a large effect size but not so in the wait-list group (M = 13.1, SD = 2.9 versus M = 13.9, SD = 3.9) (Sylvain et al., 1997). Similar results for SOG scores were found in another randomised trial involving mostly males where CT group (n = 59) experienced a significant recovery rate from problem gambling compared to wait-list participants (n = 29) (Ladouceur et al., 2001). Finally, in a randomised trial evaluating the efficacy of CT treatment in group format (n = 34) compared to wait-list (n = 24) an absolute effect was found on DSM-IV instrument for pathological gambling from baseline (M = 7.3, SD = 1.5 versus M = 8.0, SD = 1.38) to follow-up (M = 1.6, SD = 2.3 versus M = 6.0, SD = 3.1). In light of the aforementioned

findings, it was therefore scientifically plausible to directly compare cognitive therapy (standard intervention) to exposure therapy (experimental intervention) in this study.

A further limitation at the study design level was missing data as participants had agreed to complete follow-up assessments. However, it may have been that the design itself was a key explanatory variable to inconsistent response patterns in terms of the burden placed on participants. Alternatively, an added strength of the follow-up procedure was the inclusion of multiple time points under flexible conditions (e.g. longer time intervals for data collection) to increase the likelihood of capturing data. Subsequently, an unbalanced dataset resulted but potentially with a greater yield of observed data. From a statistically theoretical level there was no missing data problem because estimation was based on maximum likelihood estimation using the E-M algorithm.

Finally, another limitation was that 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. The measures used in this study were commensurate with recommended minimum features for reporting efficacy of treatment in problem gambling (Walker et al., 2006) and covered domains of gambling behaviour, problems caused by gambling, and mechanisms of change. Also, this study improved upon previous trials for cognitive and exposure therapies (Echeburua et al., 1996; Ladouceur et al., 2003; Ladouceur et al., 2001; McConaghy et al., 1983, 1988; McConaghy et al., 1991; Sylvain et al., 1997) 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 (Boutron et al., 2008; Moher et al., 2010).

7.4 FINDINGS OF THE QUALITATIVE INTERVIEWS

Trial participants in both cognitive and exposure groups experienced, on average, similar reductions (improvement) on the gambling related cognitions scale (GRCS) and gambling urge scale (GUS). In addition, ET interviewees described an acquisition of "rational thought" and CT interviewees had "taken over" gambling urges. It may have been that mediation pathways were intrinsically intertwined for both therapeutic approaches. This is based on the theory that erroneous cognitions are part of the brain reward system involving psychobiological states (e.g. gambling urge or craving) and uphold addictive gambling behaviour (Clark, 2010). In other words, an internal or external cue can trigger an urge which includes a cognition or simultaneously link to cognition. Alternatively, a cue can trigger a cognition which simultaneously produces an urge. A psychological therapy targeted at either urge or cognitions may disband this underlying neurocognitive circuitry and consequently reduce problem gambling.

Most interviewees in this study also emphasized the important role of non-specific therapy effects in helping to reducing problem gambling. Indeed, this appears to be the case for most psychological disorders and has continued to be debated in the literature. It has been postulated by some that therapeutic alliance accounts for most of the variance in therapy outcomes (Deegear & Lawson, 2003).This in turn explains the relatively consistent magnitude of therapeutic benefits across bona-fide psychotherapies, known metaphorically as the "Dodo bird verdict" (Rosenzweig, 1936). A meta-analysis involving more than 200 clinical trials found that all psychotherapies were approximately equivalent thus

supporting the Dodo bird conjecture (Wampold et al., 1997). In family therapy, Blow and colleagues suggested that patients were more likely to seek a specific therapist based on personal qualities rather than their treatment faithfulness (Blow, Sprenkle, & Davis, 2007).

However, at least half of the participants in this trial experienced significant reductions in problem gambling symptoms that were consistent with a robust dose of therapy as shown by fidelity checks and session attendance. Moreover, the random assignment of participants to a treatment then allocation to an available therapist meant any preference bias was minimised. Personal attributes aside, therapists were mainly a homogenous group in terms of experience. Perhaps this meant that empathy was delivered in approximately equal measures and provided the "…necessary precondition for being successfully supportive and therapeutic'' at least for therapy adherers (Kohut, 1982) (p397). For both interviewees that dropped-out of therapy, primary barriers appeared to be related to techniques of therapy rather than therapist related factors.

All exposure interviewees indicated that imaginal tasks in the early phase of treatment were a potential deterrent to therapy adherence due to a perceived inappositeness of eliciting a gambling urge in the "office". The few previous randomised trials that have focused on gambling-specific imaginal exposure tasks were conducted in an inpatient psychiatric facility where drop-out was next to null (McConaghy et al., 1983, 1988; McConaghy et al., 1991). In specific phobias, it was found that in vivo tasks outperformed other modes such as imaginal exposure and virtual reality (Wolitzky-Taylor, Horowitz, Powers, & Telch, 2008). Conversely, in post-traumatic stress disorder (PTSD) Hembree et al. (2003) suggested that drop-out occurring before initiation of tasks (regardless of whether in vivo or imaginal) may have resulted from the fact that therapists were less

focussed on patients "comfort" and concerns in the present context (Hembree et al., 2003). The authors proposed that efficacy of ET could be enhanced if skills training preceded tasks.

A few interviewees indicated that a motivator to engage in CT or ET was the structured, goal-oriented approaches specific to gambling that "attack your problem". For others, this specificity may have been too limiting in terms of co-occurring conditions such as anxiety and depression. Baseline characteristics of trial participants showed a high prevalence of psychological disturbance and in univariate analyses it was a significant predictor of drop-out. Perhaps those who were suffering from co-occurring conditions were too distracted or less willing to focus on therapy and therefore self-terminated treatment.

Another potential factor associated with drop-out was conflict between an individual's desired outcome (e.g. controlled gambling) and the intrinsic goal of therapy of abstinence. A sub-group of individuals may have been be prone to "switching addictions" (Hodgins & el-Guebaly, 2010) and therefore controlled gambling may have been a less harmful alternative. For example, a person who is susceptible to addictive behaviours and achieves abstinence from gambling may then engage in more harmful behaviours (e.g. substance use) to promptly reinstate a more accustomed neurocognitive status. The potential for such an 'adverse event' indicated the need for more flexible treatment planning with the problem gambler. Previous research has shown the benefits of combined cognitive correction and in vivo exposure for problem gambling where the primary goal has been controlled gambling (Ladouceur, 2005).

Interviewee comments also highlighted caveats in the measurement of treatment outcomes using quantitative instruments. In spite of all reporting positive outcomes, there was variation in levels of enthusiasm expressed that ranged from being "available for life" to getting "things done instead of pressing the button". Most previous trials involving cognitive and exposure therapies have focused on psychological constructs as outcome (Smith, Dunn, Harvey, Battersby, & Pols, 2013) whereas measures of quality of life or psychosocial functioning have been limited. In the main trial, a significant reduction (improvement) in WSAS (Mundt et al., 2002) scores across 9 month study period was shown. However, the WSAS was designed to be a simple instrument for measuring impairment and has not been validated in gambling disorder.

Also, most participants interviewed reported a reduction in EGM expenditure following therapy thus supporting trial results. Money spent on gambling has been recommended as a key measure for gambling treatment efficacy studies (Walker et al., 2006). However, it was indicated by some interviewees that the stress of financial problems as a consequence of gambling expenditure could play a more prominent role in determining longer term outcomes. A recent study that explored predictors of outcomes following CBT-based treatment for problem gamblers found that larger than average debts were associated with significantly poorer outcomes at one year follow-up (Guo et al., 2012).

7.5 STRENGTHS AND LIMITATIONS OF THE QUALITATIVE INTERVIEWEES

In relation to the gambling intervention literature, this is the first qualitative investigation to explore how individual problem gamblers experienced cognitive and exposure therapy when taking part in a randomised controlled trial. The strengths and limitations are those

of the main trial. The trial design was specific to a hypothesis about comparative efficacy of CT and ET. In contrast, the flexible inclusion criteria meant that participants were representative of a broader population of treatment seeking problem gamblers. Furthermore, there was reasonable diversity of therapist clinical qualifications that was typical of a community based psychotherapy service. This qualitative study enabled an exploration of participant's experiences and perceptions at greater depth for an otherwise focused question.

Nevertheless, the findings were limited to the eight participants who took part in interviews. Additionally, from a theoretical perspective, the analysis took a deductive stance where participant's comments were interpreted at the semantic level within pre-specified categories. Alternatively, an inductive approach may have developed theory regarding the use of CBT for problem gamblers.

7.6 IMPLICATIONS OF TRIAL RESULTS AND INTERVIEWS

In both cognitive and exposure groups, quantitative findings and interviewee comments indicated that mechanisms of therapeutic change occurred on an urge-cognition continuum concurrent with improvements in gambling-related problems. A combination of CT and ET techniques in a flexible format may facilitate an even wider spectrum of individual symptom profiles to be targeted and consequently improve therapy adherence. A combined approach, grounded on techniques explicit to gambling disorder, would be an evolutionary advancement to an otherwise nascent gambling-specific CBT evidence base structure.

Both CT and ET on their own and combined would benefit from a preparatory phase to help individuals better understand the therapy rationale. This would be particularly

relevant to imaginal exposure tasks as reflected by participant's comments in the qualitative interviews. Also, adjunct interventions in early stages of treatment, such as motivational interviewing (MI), may help to keep the problem gambler in therapy long enough to experience benefits from gambling-specific mechanisms of change (Carlbring et al., 2010).

Mobile device applications (mHealth apps) are another strategy to help keep people engaged in a therapy program. Mobile device applications have been shown to be effective in managing chronic diseases as well as promoting better adherence to treatments for psychological disorders (Powell, Landman, & Bates, 2014; Reger et al., 2013). The popularity of mHealth apps are rapidly increasing as they are inexpensive tools that offer an array of benefits, such as, allowing therapy sessions and homework to be scheduled directly in the app, recording completed homework exercises and populating the device calendar with client reminder notifications. Near real time data could also be collected to enhance the ecological validity of future treatment studies (McKay, Franklin, Patapis, & Lynch, 2006).

Devices such as mHealth apps may also improve data collection processes. However, missing data will undoubtedly continue to present a challenge in study designs involving multiple waves of assessments on the same individual. As part of a handling missing data strategy, auxiliary data should also be collected, for example, number of attempts to follow-up a study participant. The number of failed contact attempts could then be used in statistical models to produce unbiased estimates of treatment efficacy (I. White, E. Kalaitzaki, et al., 2011).

Reducing participant burden from voluminous self-report questionnaires could also lessen the problem of non-response. One method is the 3-Form design where outcomes are divided into a number of clusters, for example, Victorian Gambling Screen (VGS), co-morbid conditions (A), quality of life (B) and personality traits (C). All participants would then complete primary outcome VGS at each time point and outcomes A, B and C are rotated so that cluster one completes VGS, A and B, cluster two VGS, A and C, and cluster three VGS, B and C (Graham, 2009). All possible pairwise correlations between A, B, and C would then be estimable to strengthen inferences at the population level.

The role of self-report outcome measures also requires more detailed attention in gambling treatment studies. In this study, as well as previous trials, it was likely that a reasonable proportion of participants experienced a shift in their conceptualization and internal standards and values in relation to the constructs under measurement (e.g. harm related to problem gambling) (Sprangers & Schwartz, 1999). The potential for such a response shift can be considered in light of this study's findings and the pathways model of gambling addiction (Blaszczynski & Nower, 2002). The baseline scores showed a high prevalence rate of psychological disturbance (e.g. depression and anxiety) and all participants reported that EGMs were the primary form of gambling problem. This supported the proposition that problem gamblers who are depressed also tend to choose gambling activities that are "…socially isolating, repetitive, or monotonous to modulate this mood state" (McCormick, 1994; Rosenthal & Lesieur, 1992). This type of gambler also fitted the profile of a 'Pathway 2' gambler, that is, someone who had an emotional vulnerability to gambling behaviour such as pre-existing depression, anxiety and poor coping skills in addition to being behaviourally conditioned (Blaszczynski & Nower, 2002). These gamblers were

therefore more likely to experience a response shift after receiving a psychological intervention.

For example, if CT helped raise the persons awareness of erroneous cognitions relating to gambling expectancies (Raylu & Oei, 2004a) like ‘gambling makes me happier’ then measurement items relating to depression in a measure of psychological disturbance may have become more important. This may have obfuscated true change that was meant to be reflected from average scores of all measurement items. However, it would still signal a treatment effect but require interpretation from the perspective of change in the person’s conceptualisation of depression. A more in-depth understanding of psychometric analyses of self-report data would better explicate underlying mechanisms of therapeutic change.

Qualitative interviews would help to acquire a more complete picture of non-response to questionnaires as well as the relative importance of study outcomes. This type of data would also be useful to evaluate how therapies were experienced across different jurisdictions due to variability in contextual factors such as availability of resources and clinician experience and qualifications. It would assist in drawing more confident conclusions from meta-analyses that are often clouded due to the problem of study heterogeneity (Cowlishaw et al., 2012; Gooding & Tarrier, 2009).

Future intervention studies would also benefit from more in-depth statistical analyses to maximize the potential of data. This should include the investigation of heterogeneity between individuals at treatment level. It would assist in delineating between therapy specific and non-specific effects in trials involving control conditions as well as head to head trials. Using heteroskedastic mixed modelling would identify sub-groups who have

improved marginally, not at all, or whose conditions have even deteriorated. This information would be relevant to therapists, clients and managers of gambling help services.

7.7 RECOMMENDATIONS FOR FUTURE RESEARCH

In this study, a significant association was found between individual problem gamblers who received either cognitive or exposure therapy and a reduction in their gambling related symptoms. A chief concern was the sizable proportion of participants who prematurely stopped treatment based on therapist recommendations. This finding reinforced an urgent need to target high rates of treatment drop-out consistently reported in the gambling intervention literature. Therefore, advancement to this study would be a large scale randomised trial to investigate the effectiveness of a combined cognitive and exposure therapy (CBT) program that may be flexibly delivered at the individual level. The aim of this CBT approach would be to improve upon benefits of individual CT and ET by increasing treatment uptake and retention. The logic is robust behind the need for a component analysis of cognitive-behavioural treatment for gambling addiction. The science as yet has just not dug deep enough into each therapeutic area.

An alternative approach from a public health perspective may be a non-inferiority randomised trial to investigate differential efficacy of CBT programs. The rationale behind this approach is that generic cognitive-behavioural programs (e.g. cognitive therapy and problem solving training) have already been established as beneficial for problem gamblers (Cowlishaw et al., 2012). However, as behavioural techniques on their own (e.g. exposure therapy) are considered to be generally simpler and less costly both in therapist training and in clinical applications, a contemporary question may be in terms of non-

inferiority of ET versus CBT. A future trial could then test whether the "new" treatment (ET) is not inferior to standard CBT.

The non-inferiority design is increasingly being used for mental disorders (e.g.(Donker et al., 2013; Merry et al., 2012)) and in mainstream health research (Piaggio et al., 2006). Conventional superiority trial designs based on hypothesis tests are not adequate to deal with questions relating to equivalence or non-inferiority because low power or low precision favours a conclusion of equivalence. In other words, non-inferiority decisions under the typical hypothesis testing paradigm can be anti-conservative.

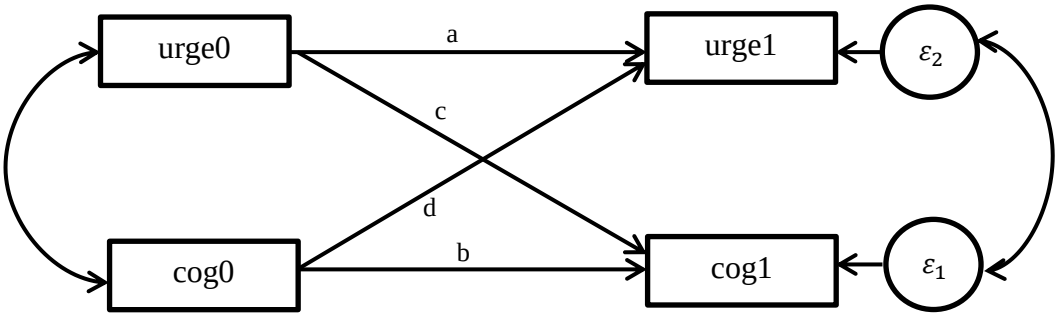
A critical decision in the design of a non-inferiority trial would be the quantitative definitions of what it means for ET and CBT to be non-inferior. For example, a small decrease in efficacy for gambling related outcomes may be well worth the benefits of a cheaper and more convenient therapy. The required sample size would depend strongly on the definition of non-inferiority and can become quite large if high precision is desired. For example, if the success rate for standard CBT delivered to problem gamblers is 80% based on independent DSM-5 diagnosis of disordered gambling and if it were considered that ET was equivalent with a success rate between 70% and 90% ($\delta = 0.10$), the null hypothesis would assume that the treatments are unequal. Then, using $\alpha = 0.10$ level test, we would have 90% power to reject non-equivalence with 275 patients assigned to each treatment group. In contrast, if equivalence is defined as $\delta = 0.15$, the required sample size would decrease to 122 per group.

Whilst superiority and non-inferiority designs each have distinct advantages they also comprise of mutual benefits including the ability to determine what therapies do and what

therapies do not work for whom. To address this question, it would necessitate the in-depth measurement of gambling related biopsychological states and cognitive processing in relation to temporal and spatial aspects of therapy delivery. A number of questions may then be addressed in terms of pathways to recovery that are different between individuals and therapy groups and which paths can be treated as equal.

For example, if we want to know the influence of gambling related urges on gambling related cognition scores and the influence of cognitions on urge for baseline and post-treatment data, a multiple-group cross-lagged panel design would be useful (Figure 22) (Acock, 2013). The formulation of specific pathways to investigate could best be informed from a qualitative standpoint. The synthesis of quantitative and qualitative data would then generate results regarding prognostic predictors, sub-groups of problem gamblers and therapy characteristics to guide stratified CBT approaches and treatment-seeker selection.

Figure 22. Cross-lagged panel design*



*Paths a and b are known as stability coefficients. They reflect how stable the corresponding concepts, gambling urge and gambling cognitions, are over time. The paths labelled c and d are of certain interest: they provide information about how much baseline urge (urge0) influences cognitions at post-treatment (cog1) and how much baseline cognitions (cog0) influences urge at post-treatment (urge1), respectively. An example of a question that may be addressed is: which paths are significantly different between CBT and ET and which paths can be treated as equal?

Prior to the investigation of a causal pathways model, it would be important to establish that self-report measures show psychometric stability across time. Therefore, it is recommended that future gambling treatment studies be comprised of an evaluation of longitudinal measurement invariance (ME/I) for self-report outcome measures (e.g. VGS, SOGS, CPGI) before calculating and reporting total mean scores (Vandenberg & Lance, 2000). No study to date has investigated longitudinal ME/I for a gambling treatment outcome measure.

The analytic steps recommended by Vandenberg and Lance (2000) (Vandenberg & Lance, 2000) to test for longitudinal ME/I could be used and operationalized in terms of response shift types reconceptualization, reprioritization and recalibration (Oort, 2005; Sprangers & Schwartz, 1999). This approach would also provide the opportunity to investigate how different types of problem gamblers respond to different treatments in context of the pathways model of gambling addiction (Blaszczynski & Nower, 2002).

Future treatment studies would also benefit from incorporating clinician's beliefs about the effectiveness of CBT. This could be achieved by using a subjective-Bayesian approach alongside traditional frequentist methods. Bayesian inference involves the calculation of a posterior distribution $p(\theta|y)$ that summarises information about outcome data after having obtained new data such as that generated in the current study. These effect estimates can be calculated from Bayes theorem:

$$p(\theta|y) = \frac{p(y|\theta)p(\theta)}{p(y)}$$

In this study, and most of the previous gambling treatment studies, effect estimates have been centred on the likelihood $p(y|\theta)$, the basis of ML estimation (Thompson, 2014). For primary outcome measure VGS, it was the probability of a set of observations given the value of the set of parameters obtained from mixed models. However, ML is reliant on implicit assumptions such as hypothetical random samples (Greenland, 2006). In reality though, mechanisms that generate random samples may be more non-random, for example, the researcher's personal judgements regarding study eligibility criteria (Greenland, 2006). A Bayesian analysis uses the ML estimates as well as $p(y)$, the probability of the data averaged over all possible values of θ where:

$$p(y) = \int p(y|\theta)p(\theta)d\theta \text{),}$$

and $p(\theta)$, the prior distribution is nominated by experts. For example, expert clinicians may be asked to respond to the following statements (modified from Chaloner and Rhame (2010) (Chaloner & Rhame, 2010):

(a) What is your estimate of the percent of participants randomised to CBT who will experience non-problem gambling at 6 month follow up (*X* %)?

(b) What is your estimate of the percent of participants randomised to ET who will experience non-problem gambling at 6 month follow up? (*Y* %)

(c) Write down the difference between the two estimated percentages. (*X* % - *Y* %)

(d) What is your estimate of the 95 percent probability interval of this difference? (95 % probability interval from – to –)

The specification of the above parameters would need special consideration due to the inherent subjectivity. There are numerous methods that have shown to be effective in eliciting such assumptions (Johnson, Tomlinson, Hawker, Granton, & Feldman, 2010).One approach would be to use a Delphi method. It is an iterative process that provides the opportunity for individual experts to change their opinions based on feedback of summary measures from preceding rounds (Mullen, 2003). Advantages of the Delphi method include its ability to structure and organise group communication. Using a Delphi method to establish prior estimates to incorporate experts knowledge into quantitative studies of gambling treatments could be used to maximum advantage given the range of expertise of gambling researchers and their flourishing networks across the world. This would lead to more comprehensive findings to provide for user-specific needs such as clinicians and policy-makers who often have varying interests from individual to population levels.

7.8 CONCLUSION

The main results of this thesis showed that participants who received exposure therapy for problem gambling using electronic gaming machines experienced comparable reductions (improvement) in gambling related pathology as cognitive participants across the 9 month study period.

It was the first RCT to successfully isolate problem gambling-specific cognitive from behavioural (imaginal and live graded exposure) therapy techniques. It established high quality treatment techniques and manuals, research protocol, and analytic workflow of participant data.

It was possible that there were more similarities than differences between cognitive and exposure groups due to a shortfall in participant numbers. However, mixed- modelling of individual trajectories across time under intent-to-treat and per protocol conditions provided robust estimates of therapy effects that were clinically meaningful.

There was a marked degree of premature drop-out from therapy throughout the study. This reinforced an urgent need to reduce high attrition rates commonly reported in the gambling intervention literature. It is recommended that future research should investigate combined formats of cognitive and exposure therapies to improve adherence to therapy protocols. A further limitation of this study was that the evidence was for short-term follow-up only. Whether these findings translate into long-term benefits needs further assessment.

A key strength of this study was that participant baseline characteristics and flow throughout the study was representative of treatment-seeking problem gamblers who attended a community-based gambling help service in South Australia. This was

highlighted by the fact that study participants had more severe gambling symptoms compared to problem gamblers in the general population.

The findings were also generalizable in terms of qualifications of therapists who delivered treatment as well as therapies that were actually delivered. This was confirmed by evaluations of therapist fidelity to treatment manuals that showed both cognitive and exposure techniques were valid and reliable. The main variation from intended implementation of therapies was that exposure sessions were briefer than cognitive sessions. Also, on average, therapy sessions were conducted once every two weeks for approximately 18 weeks in both groups instead of intended weekly sessions of 8 to 12 weeks.

In closing, this investigation was motivated by a barrier that clinicians faced at the Statewide Gambling Therapy Service to further improving treatment delivery and outcomes. It was founded on clinical equipoise where differential efficacy of cognitive restructuring versus urge reduction and extinction was mostly unknown. Subsequently, a new trial was justified to support and extend the CBT evidence base alongside the need for better transparency in reporting of findings from cognitive-behavioural research on problem gambling (Fink et al., 2012; Smith, Dunn, et al., 2013). This has been achieved.

From a theoretical perspective, it was evident from both quantitative findings and participants' comments that symptom reduction was experienced on an urge-cognition continuum notwithstanding excellent therapy fidelity. These findings provided support to the synthesis theory proposed by Clark (2010) that is predicated on anomalous gambling

related cognitions recruiting the brain reward system during decision-making in gambling disorder (Clark, 2010).

APPENDICES

APPENDIX A. SEARCH STRATEGY FOR PSYCINFO

1. gambl$.ab,ti. 2. (gambl$ adj3 addict$).ab,ti. 3. (gambl$ adj3 disorder$).ab,ti. 4. (pathолog$ adj3 gambl$).ab,ti. 5. (problem$ adj3 gambl$).ab,ti. 6. exp Pathological Gambling/ 7. cbt$.ab,ti. 8. cognitive behavio?r$ therap$.ab,ti. 9. cognitive behavio?r$.ab,ti. 10. (exposure$ adj3 graded).ab,ti. 11. (exposure$ adj3 imaginal$).ab,ti. 12. (exposure$ adj3 in vivo$).ab,ti. 13. (exposure$ adj3 therap$).ab,ti. 14. (exposure$ adj3 treatment$).ab,ti. 15. (implosive adj3 therap$).ab,ti. 16. (extinction$ adj3 response$).ab,ti. 17. (extinction$ adj3 rational$).ab,ti. 18. (extinction$ adj3 urge$).ab,ti. 19. (habituat$ adj3 rational$).ab,ti. 20. (imaginal$ adj3 desensiti?$).ab,ti. 21. (systematic adj3 desensiti?$).ab,ti. 22. (cogniti$ adj3 therap$).ab,ti. 23. (cogniti$ adj3 treat$).ab,ti. 24. (cogniti$ adj3 intervent$).ab,ti. 25. (cogniti$ adj3 technique$).ab,ti. 26. (cogniti$ adj3 restruct$).ab,ti. 27. exp Behavior Therapy/ or exp Cognitive Behavior Therapy/ or exp Cognitive Therapy/ 28. 1 or 2 or 3 or 4 or 5 or 6 29. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 30. 28 and 29 31. 31. limit 30 to (human and english language and ("0830 systematic review" or 1200 meta analysis or 1800 quantitative study or "2000 treatment outcome/randomized clinical trial"))

APPENDIX B. CHARACTERISTICS OF EXCLUDED STUDIES

Study	Reason for exclusion
Echeburua 2000 (Echeburua, Fernández-Montalvo, & Báez, 2000)	The study did not evaluate the efficacy of a cognitive or exposure based therapy using a randomised design.
Milton 2002 (Milton, Crino, Hunt, & Prosser, 2002)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.
Dowling 2006 (Dowling, 2006)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.
Petry 2006 (Petry et al., 2006)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.
Carlbring 2008 (Carlbring & Smit, 2008)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.
Myrseth 2009 (Myrseth, Litlerè, Støylen, & Pallesen, 2009)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.
Carlbring 2010 (Carlbring et al., 2010)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.
Echeburua 2011 (Echeburúa, Gómez, & Freixa, 2011)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.
Myrseth 2011 (Myrseth et al., 2011)	The primary study objectives and treatment components were not specific to a cognitive or exposure based approach.

APPENDIX C. CONSORT EVALUATIONS

Study ID: 01
Study author: Ladouceur et al
Study title: Cognitive treatment of pathological gambling
Year of publication: 2001
Journal: The Journal of Nervous and Mental Disease

Reviewer: DS
Date:

CONSORT item	Comment	Rating 2=Present 1=Present with some limitations 0=Absent
Title and abstract	Title- no mention of allocation i.e. randomisation. Abstract refers to "randomised". Experimental treatments and comparator were stated but not care providers, centres, or blinding status.	1
Introduction		
Background	Good scientific rationale for the study.	2
Methods		
Participants	Appropriate.	2
Interventions	Appropriate.	2
Objectives	Clearly stated.	2
Outcomes	Objectives are not adequately translated into outcomes. No clear differentiation between primary and secondary measures to underpin main research hypotheses. Measures were mostly self-rating. DSM conducted by an "experienced" psychologist. In terms of proposed minimum features of reporting the efficacy of gambling treatment outcome studies the measures are mainly limited to gambling behaviours. Given the study aims to test the efficacy of a core CBT treatment then	1

	a more precise measure to evaluate mechanisms of change should have been used. A better description of some measures would be helpful e.g. was there rank order for the two self-efficacy situations in order to differentiate in analyses such as missing in some cases. Also, were measures relating to frequency of gambling specific to primary form of gambling problem?	
Sample size	No sample size calculation provided.	0
Randomization-sequence generation	No description of randomisation procedures including any blocking or stratification for potential confounders.	0
Allocation concealment	Concealment of randomisation to investigators unknown.	0
Implementation	No.	0
Blinding (masking)	No reference to masking of assessors (e.g. DSM criteria) to group assignment at post-test or follow-up. Also same for data analyst.	0
Statistical methods	Details of statistical analyses are limited to model approach i.e. MANOVA without explanation of secondary analyses such as univariate approaches to test treatment effects using specific measures. No confidence intervals provided or other precision estimate e.g. SE. An appropriate hypothesis is not stated in the use of 'non-parametric' tests e.g. was the Wilcoxon test used to compare medians (and if so the assumptions need to be stated regarding distribution around the median i.e. symmetrical for both groups or if asymmetrical that they have similar shapes but different location). Alternatively, a hypothesis that seeks the probability that a member of one group will score higher than a member from another group. Overall, a statistician provided with the original dataset and stated analytic procedures would not be able to fully verify results.	1

Results		
Participant flow	Flow of participants through each stage described. Number of people assessed for eligibility not stated i.e. the number of people who phoned the centre and completed the SOGS and a socio-demographic questionnaire. Number of participants treated by each therapist not stated.	1
Implementation of intervention	Yes. This is one of the papers main strengths where treatment details have been thoroughly described enabling potential for replication.	2
Recruitment	No dates provided for recruitment and follow-up periods.	0
Baseline data	Means and SD appropriately reported for most continuous variables', however for those with asymmetrical distributions (e.g. hours gambled) a median and centile range (e.g. IQR) would be more useful. Baseline characteristics are in different sections i.e. demographics in methods and measures in results. A table with baseline information would be more useful. Data presented for a per protocol analysis rather than ITT i.e. 35/59. Was there any difference in characteristics between treatment adherers and dropouts?	1
Numbers analysed	Numbers analysed reported in section Clinically Significant Change as denominator. This seems to be an ancillary analysis whilst absolute numbers not provided for ANOVA's specific to each outcome variable. As above this is a per protocol analysis resulting in a loss of information. Data for six participants randomised to wait-list group are analysed for this condition and then cross-over (not in the true sense of experimental design where there is a balance in participant numbers receiving a pre-specified sequence of treatments) to the treatment group but not sure if they were treatment completers or dropouts.	1
Outcomes and estimation	Interpretation of estimates is limited in terms of research hypotheses due to multiplicity i.e. no distinct primary outcome measure and	1

	sample size calculation. Estimated effect sizes such as contrasts (mean differences) and it's precision (e.g. 95% CI's) not provided. Results are limited to P values. There is potential biasness in estimates from cross-over effects where expectancy bias in wait-list condition of n=6 carried over to treatment.	
Ancillary analyses	No clear distinction between primary and secondary analyses.	1
Adverse events	No reference to adverse events.	1
Discussion		
Interpretation	Limitations not adequately addressed such as potential bias due to randomisation procedure and per protocol analysis. Cross-over from wait-list to treatment may have disrupted prognostic balance expected from randomisation.	1
Generalizability	Results limited in generalizability on gender (83% male), gambling type, single site. Control for confounding variables unknown due to simple randomisation. Expectancy bias in wait list condition. Also comparison condition of wait-list is not reflective of usual practice in everyday clinical settings. Per-protocol analysis. No power calculations. Limited internal validity and therefore external validity is 'irrelevant'. In summary it is unknown from this study if a diverse range of pathological gamblers would benefit from cognitive treatment.	1
Overall evidence	A sweeping study conclusion given the limited evidence i.e. "…this controlled study shows the effectiveness of a cognitive treatment for pathological gamblers targeting the notion of randomness. Furthermore, results proved to be both statistically and clinically significant.	1

Study ID: 02
Study author: McConaghy et al
Study title: Controlled comparison of aversive therapy and imaginal desensitisation in compulsive gambling
Year of publication: 1983
Journal: British Journal of Psychiatry

Reviewer: DS
Date: 3/8/12

CONSORT item	Comment	Rating 2=Present 1=Present with some limitations 0=Absent
Title and abstract	No reference to randomisation in title. Abstract refers to randomisation and treatments delivered. No mention of therapists administering the treatment, location of study or blinding status where in fact blinding did occur during follow-up assessments. Abstract mainly presents findings and limited in aims and methods.	1
Introduction		
Background	A reasonable scientific rationale for comparing aversive and desensitisation treatments in general. However, the testing of these treatments in a population of problem gamblers appears to be an afterthought or secondary rather than a primary objective. This seems counter-intuitive where a mental condition is selected to suit mechanisms of treatment actions rather than the converse. Overall there is no clear justification for a randomised trial to compare these treatments in compulsive gamblers.	1
Methods		
Participants	"Twenty compulsive gamblers who requested behaviour therapy to reduce their urge to gamble…" Unclear as to how participants presented in the first place e.g. current inpatients, people seeking or referred to psychiatric inpatient treatment other than gambling, self-referred, media recruited. Not many laypersons would walk off the street requesting urge reduction therapy unless	1

	having some previous experience. This limits the ability to critique external validity of the findings. General treatment setting provided, however not the location for data collection at any time point. Also where specifically the interventions were administered in the hospital ward such as a private room. Reported eligibility criteria are limited e.g. no minimum age, other psychological states such as suicidality. No mention of those providing interventions (if this was the case or maybe self-administered). No description of psychiatric unit e.g. acute adult. Difficult to determine if results could be generalised to other treatment settings such as an outpatient community mental health service.	
Interventions	Details of each intervention provided. No mention of checking or enhancing care providers (if any) adherence to treatment protocols. Tailoring of aversive therapy (electric shock level) mentioned.	1
Objectives	The main hypothesis is clear i.e. aversive therapy versus imaginal desensitisation but lacks any specific translation to gambling disorders such as the primary hypothesised mechanism of change.	1
Outcomes	Primary and secondary measures are not pre-specified and therefore do not inform subsequent RCT's on what primary measures to use specific to these treatments. Provenance and properties of measures not reported. One author interviewed participant's at intervals between assessment time points to maintain contact and therefore enhance likelihood of data collection. Another author who was blinded to participant's treatment group conducted follow-up assessments.	1
Sample size	No sample size calculation provided or explanation of its absence.	0
Randomization-sequence generation	None reported.	0
Allocation concealment	None reported.	0

Implementation	None reported.	0
Blinding (masking)	Person who conducted follow-up assessments was blinded to group allocation. No mention of who delivered treatment or provided standby assistance if self-administered. No mention if psychiatric unit staff (carers of participants whilst in hospital) were blinded. Also blinding of non-study inpatients to study hypothesis would be important to reduce bias.	1
Statistical methods	Small sample size, no clustering. No statistical methods section. Brief description of statistical analysis given in results section such as t-test and Pearson r correlations. Primary (gambling urge & behaviours?) and secondary (anxiety?) analyses not clearly differentiated. No reference to effect size calculations or precision of estimates.	1
Results		
Participant flow	Number of people assessed for eligibility not reported. This would be useful to know in light of sample representativeness (external validity). Participant flow is straight forward and described at each stage including numbers that switched treatments and how these were analysed. No reference to number of care providers that were involved with the participant during the trial.	1
Implementation of intervention	No details relating to implementation other than "All patients completed the week's session of treatment in hospital…" More specific information is required to differentiate between intended intervention and received such as mean duration of each session within group and mean shock level self-administered.	1
Recruitment	No dates.	0
Baseline data		2

Numbers analysed		2
Outcomes and estimation	There is no reference to primary or secondary analyses in order to draw main conclusions regarding study hypotheses. The order in which results are presented suggest the primary analyses are Table 1 involving end point comparison of means for gambling urge and behaviours, secondary analyses are correlations for anxiety and personality factors. Table 1 provides number of participants experiencing each level of outcome measure for urge and behaviours and the results for a t-test can be replicated. However, no effect sizes such as Cohen's *d* or confidence intervals for mean change. Exact values for alpha not provided only $p<0.05$ for significance for correlations involving anxiety and personality measures.	1
Ancillary analyses	The paper does not report any pre-specified statistical analysis plan. At best the reader can only assume that Table 2 relates to secondary analyses.	1
Adverse events	Aspects of the study design should be reported in terms of any harms or unintended effects. For example the study setting where participants were inpatients of a psychiatric ward for the course of treatment and the nature of aversive therapy involving self-administered electric shocks.	0
Discussion		
Interpretation	Authors report "At one year a better response (in respect both of the strength of urge to gamble and of gambling behaviour) was reported by significantly more patients who received imaginal desensitisation…" However, tests of significance were based on mean differences not numbers of patients. No limitations addressed including small sample size, treatment setting and care providers. A discussion of findings relative to previous research is presented including potential benefits of imaginal desensitisation having less "threatening" properties to the self-esteem than aversive therapy. This warrants further discussion in context of adverse events	1

	and could have been addressed more thoroughly as an integral part of the study e.g. a measure of self-esteem administered at time points. Overall, the discussion is mainly rhetoric that supports the author's findings and minimal consideration given to the balance of strengths and limitations.	
Generalizability	Study design issues pose a significant threat to overall internal validity (a prerequisite for external validity) and therefore any conclusions drawn are limited to the sample.	0
Overall evidence	As above.	1

Study ID: 03
Study author: Ladouceur et al
Study title: Group therapy for pathological gamblers: a cognitive approach
Year of publication: 2003
Journal: Behaviour Research and Therapy

Reviewer: DS
Date:

CONSORT item	Comment	Rating 2=Present 1=Present with some limitations 0=Absent
Title and abstract	The word "randomised" not used in the title. Main eligibility criteria, outcome measures, treatment and comparator are provided. Study setting and trial design not specified e.g. parallel. The main hypothesis is framed in terms of treatment efficacy however no details are provided in terms of primary outcome measure. Random assignment to intervention is stated. No reference to blinding such as clinical assessments using criteria from Diagnostic Statistical Manual. Numbers randomised to each group provided but not numbers analysed at each follow-up. No primary outcome measure provided for results or effect sizes and precision of estimates other than DSM proportions at post-treatment. General interpretation of results not provided e.g. these results provide strong statistical evidence for cognitive correction techniques in reducing gambling symptoms with medium effect size.	1
Introduction		
Background	On the basis of a paucity of randomised trials that have investigated gambling treatments, the literature review justifies the current study.	2
Methods		
Participants	The method of recruitment is reported in general terms: "some contacted our treatment centre directly while others were referred by health professionals". However it is not clear if the direct contacts were in response to	1

	advertisements or self-initiated treatment seeking. This has implications for external validity of findings. Eligibility criteria are clearly stated as with location of the study. Study setting is not reported e.g. community health clinic or a university department.	
Interventions	Content and method of treatment administration clearly stated along with treatment integrity checking. Cognitive treatment manualised and available on request.	2
Objectives	Hypothesis statement could be more specific as gambling behaviours can mean a range of outcomes e.g. money spent on gambling, money lost, frequency and duration of gambling. This lack of clarity may arise from the fact that no primary outcome measure is specifically reported.	1
Outcomes	As above the primary outcome measure has not been pre-specified. Although results for DSM are presented in the abstract and the measure is listed as number one in methods section it cannot be assumed to be primary as there is some discordance with the hypothesis. The DSM is a diagnostic instrument whereas the stated hypothesis focuses on gambling behaviours. The Banff paper on reporting outcomes for gambling treatment studies cautions that a gambler may not meet DSM criteria for PG but still be gambling at problematic levels (Walker et al., 2006). This further discombobulates the main research hypothesis and limits the reader's ability to critically appraise key findings. For the outcome measure 'frequency of gambling' there is no specification of whether this is primary form of gambling problem or all gambling forms.	1
Sample size	No sample size calculations provided.	0
Randomization-sequence generation	No description of how randomisation sequence was generated and therefore the likelihood of bias in treatment assignment is unknown. The imbalance in group numbers for this trial may be a result of the randomisation method e.g. simple	0

	randomisation, blocked with large block sizes relative to sample size and/or stratified where too many strata were used for sample size.	
Allocation concealment	NA	0
Implementation	NA	0
Blinding (masking)	Although impossible to blind participants and therapists to treatment assignment the role of the clinician responsible for administering DSM after randomisation should be reported. For example, did an independent clinician blind to group conduct interviews or did study therapists who were the primary care provider for the participant. Also (as below) no statistical plan is provided *a priori* so it would be helpful to know whether the data analyst was blinded to treatment assignment in order to judge validity of the trial.	0
Statistical methods	Statistical methods are mainly described in the results section but do not specify primary and secondary analyses. Reference to the use of non-parametric procedures is provided in the methods section for frequency of gambling due to non-normal distribution. Why MANOVA was chosen is not clear for endpoint and repeated measures approach other than a broad-brush approach which can bias results due to multiplicity. Adjustment for multiple comparisons (Bonferroni) is reported.	1
Results		
Participant flow	The study reports 5 cognitive therapists who administered treatment, however the numbers treated by each therapist is not provided. No details provided of treatment non-adherers who were excluded from data analysis. The 'per protocol' approach attenuates any causal inference and conclusions drawn should be considered from the perspective of an observational study design. This arises from the loss of prognostic balance that is achieved	1

	from randomisation with all participants included.	
Implementation of intervention	Details of treatment integrity provided. No details of how the treatment was implemented such as summary statistics relating to the average duration and number of group sessions.	1
Recruitment	No dates reported for recruitment or follow-up.	0
Baseline data	Baseline data for demographics and clinical characteristics are reported for treatment adherers. No descriptive summaries provided for drop-outs which would be useful for assessing the external validity of results.	2
Numbers analysed	Analyses are 'per protocol' or 'on-treatment' and appropriate numbers are reported.	2
Outcomes and estimation	Results for pre and post tests are presented in conventional terms for continuous outcomes but no effect sizes and confidence intervals.	1
Ancillary analyses	Adjustment for multiple comparisons is reported for univariate analyses. No clear distinction between primary and secondary measures, and therefore what constitutes ancillary analyses for the data.	1
Adverse events	Not reported.	0
Discussion		
Interpretation	Results discussed in light of authors previous RCT involving cognitive therapy delivered on an individual basis. Limitation of wait list control group was acknowledged. Also potential bias in self-reporting acknowledged as authors suggest another person's point of view (e.g. partner) would have been useful. No discussion of therapist effects such as inequalities in experience. Characteristics of the treatment centre should also be considered in the interpretation of findings e.g. do referred patients expect to receive a structured psychological treatment when referred. These patients may do better due to a "readiness" for treatment.	1

Generalizability	Authors report that findings "shows the effectiveness of a cognitive treatment for pathological gamblers in a group format" may be misleading due to the per-protocol analysis of data. Also "This study shows clinically and statistically significant treatment effects in a randomized trial using a broadly based assessment of five gambling variables." However the findings are limited to an observational perspective due to the exclusion of 12 participants from treatment drop out. This exclusion may result in biased estimates as the prognostic effects of randomisation have been disrupted, therefore minimising the power to draw inferential conclusions based on cause and effect.	1
Overall evidence	Findings interpreted in context of the author's previous trial involving cognitive therapy.	2

References

1. Walker M, Toneatto T, Potenza MN, Petry N, Ladouceur R, Hodgins DC, et al. A framework for reporting outcomes in problem gambling treatment research: the Banff, Alberta Consensus. Addiction. 2006;101(4):504-11.

Study ID: 04
Study author: Echeburua et al
Study title: Comparative Effectiveness of Three Therapeutic Modalities in the Psychological Treatment of Pathological Gamblers: Long-term Outcome
Year of publication: 1996
Journal: Behavioural and Cognitive Psychotherapy

Reviewer: DS
Date: 4/10/12

CONSORT item	**Comment**	**Rating** 2=Present 1=Present with some limitations 0=Absent
Title and abstract	The word "randomised" not used in the title or the abstract. Study design is referred to as a multigroup experimental design with repeated measures which could mean participants were either randomised or not randomised to a treatment. Experimental treatments and comparator are stated in the abstract. No description of therapists delivering interventions, treatment centres or blinding is provided.	1
Introduction		
Background	Overall the authors present a good case for this study mainly due to the paucity of evidence for these treatments at the time (1996). The rationale for a homogenous group of slot machine pathological gamblers makes good sense. The influence of "addictive" properties of slot machines on cognitions and psychophysiological activity is also logical however a more explicit connection with treatment types would be helpful.	2
Methods		
Participants	Eligibility for study participation is clearly described along with a rationale for recruiting a homogenous cohort of problem gamblers. The centre where the study was conducted is provided and time period. Eligibility criteria for study centre not required as one site was involved. Method of recruitment was self-referral where individuals "sought treatment".	2

Interventions	A brief description of interventions is provided along with a reference to a diary of the sessions and homework tasks for cognitive and exposure therapies. It is assumed the diary provides a full account of each component including content and duration. This reviewer is not fluent in Spanish. In light of this it is not clear if the treatments are reproducible and the degree to which they have been standardised for example the flexibility in delivery of content, duration and sequence of specific techniques. No assessment of treatment adherence was reported.	1
Objectives	A "main" objective is described however it is not clear about specific research questions or hypotheses that have motivated this investigation such as expected differential treatment outcomes based on underpinning theory.	1
Outcomes	Primary and secondary measure not clearly pre-specified. However the authors state the main aim of the study is to assess dependency on slot machines in the introduction and measures using SOGS and gambling dependent variables are described in this context. As no sample size calculations are reported along with a primary measure it is unclear as to what outcomes will be used to draw final conclusions. Further details of Gambling Dependent Variables are required for the instrument to be reproduced. For example questions relating to frequency of gambling should be clearer to what timeframe averages were based on such as previous week or 4 weeks. Family members also completed measures of gambling dependent variables to assess degree of concordance.	1
Sample size	NA	0
Randomization-sequence generation	NA	0

Allocation concealment	NA	0
Implementation	NA	0
Blinding (masking)	NA	0
Statistical methods	A pre-specified statistical analysis plan is not provided in the Methods section. For results there is reference to statistical techniques used (e.g. ANOVA) although it is unclear how chi-square statistics were calculated for what appears to be the main research question i.e. number of successes and failures. For example the test statistic for the comparison between individual and combined treatment at 6 months was χ^2= 1.98. Treated as a 2x2 contingency table this reviewer calculated a Pearson χ^2=4.57. The limited information provided makes it difficult to check results.	1
Results		
Participant flow	The number of people assessed for eligibility is reported. Number of dropouts was reported and compared to treatment adherers. However, no reasons for classification as drop-out is provided e.g. attended <3 treatment sessions. For outcome variable "therapeutic success" (binary) the drop-outs were included in the analysis as "failures". The overall flow of participants through treatment and at follow-up time points of 6 and 12 months is difficult to follow. The numbers analysed at each time point are not explicitly stated for each intervention group. Although the study comprises of a relatively small sample a diagram would be helpful for the reader to track participant numbers at each stage.	1
Implementation of intervention	The 'expected' characteristics of the interventions are provided in a table such as duration and total hours. No reporting of descriptive statistics relating to actual	1

	implementation of interventions.	
Recruitment	February 1990 to May 1992.	2
Baseline data	Descriptive statistics are reported for all participants with respect to age, gender and socioeconomic status but not for each group. For gambling behaviours the mean is reported for each group but no measure of variability (SD). Information is reported about therapist administering treatment i.e. a clinical psychologist with 9 years of experience using CBT with psychological disorders.	1
Numbers analysed	It is difficult to follow numbers for results in Table 3 and could have been more clearly reported. The authors report a denominator of n=39 for those in the experimental condition but the success rate of 59% is based on no. of successes (n=28) over total number of participants in these groups (n=48).	1
Outcomes and estimation	Findings from binary outcome of success/failure are based on tests of association (chi-square) with p-values. This data would be better reported as relative effect sizes and confidence intervals in order to draw conclusions about actual treatment effects. Interpretation of findings are misleading e.g. "…at 12 months the individual treatment was also superior to the group treatment (χ^2=1.78, p<0.05). The observed means and standard deviations are reported for the between group analyses. No effect sizes reported in main tables. Treatment effects reported as F statistics and p-values.	1
Ancillary analyses	As noted for Outcomes item the primary and secondary measures and analyses are not pre-specified. The within-group analyses (Table 7) comprise of multiple t-tests and would normally be considered as secondary analyses and adjustment should have been made to account for effects of multiplicity.	0
Adverse events	NA	0

Discussion		
Interpretation	Study hypotheses were not clearly stated in terms of primary outcome measures and appropriate sample size calculations. Limitations are not explicitly discussed such as the threat of multiplicity from within group analyses involving multiple t-tests. The potential imbalance in therapist expertise is null as only one therapist delivered all treatments. The potential for confounding from single therapist should have been discussed.	1
Generalizability	Authors state that "*The validity of this study is derived from the equivalence of the groups in pre-treatment in all evaluative measures…*" Due to the lack of transparency in reporting of the randomisation procedure it is unclear if a true balance in known and unknown confounders was achieved. This is a threat to internal validity and therefore may limit the generalizability of findings to the study sample.	1
Overall evidence	Findings are discussed in light of evidence from the few other studies available at the time.	2

Study ID: 05
Study author: Sylvain C, Ladouceur R, Boisvert JM.
Study title: Cognitive and behavioral treatment of pathological gambling: a controlled study
Year of publication: 1997
Journal: Journal of Consulting and Clinical Psychology

Reviewer: DS
Date:

CONSORT item	Comment	Rating 2=Present 1=Present with some limitations 0=Absent
Title and abstract	No mention of "randomised" in the title. The trial design is not described in the abstract other than random assignment of participants. No clear description of eligibility criteria, objectives/hypothesis, how participants were randomised, numbers analysed, effect sizes for primary analyses and a general interpretation of results is provided. For the extension for non-pharmacologic interventions there is no description of therapists, treatment centres, or blinding status.	1
Introduction		
Background	Scientific rationale for cognitive restructuring is clear and ethical in context of the paucity of published trials involving gambling treatments at the time. Supporting evidence for problem solving training and social-skills training are limited however the authors explicitly state that cognitive components are the intended main mechanisms for therapeutic change. A study hypothesis is stated in terms of differential treatment effects although no primary outcome measure is specified.	2
Methods		
Participants	No description of trial design as for Item 3a of CONSORT 2010 e.g. two group, parallel, balanced randomisation (1:1) design. The only eligibility criteria formally stated is: "…participants had to answer "yes" to the following question: "Are you	1

	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." It is implied that participants needed to be assessed as pathological gambler based on DSM-III criteria.	
Interventions	Different components of treatment are described. Treatment manual available on request. Details provided for the evaluation of treatment adherence by study therapists.	2
Objectives	Although the "hypothesis" is stated in the introduction section (as recommended by CONSORT 2010 it is not amenable to statistical testing of a pre-specified primary outcome.	1
Outcomes	No primary outcome is specified. Outcome measures are adequately described with references to support each scales provenance and properties.	1
Sample size	NA	0
Randomization-sequence generation	No information provided other than the term "randomly assigned".	0
Allocation concealment	NA	0
Implementation	NA	0
Blinding (masking)	NA. For example half of the participants in each group were independently evaluated by a second experienced clinician to confirm the diagnosis of pathological gambling. There is no reference to whether this clinician was blinded to treatment allocation or not.	0
Statistical methods	No pre-specified statistical analysis plan is described in terms of the study estimand (e.g. intent-to-treat) and primary and secondary tests. The statistical methods are provided in the results section. No information to whether any testing for therapist X treatment effect was considered.	1

Results		
Participant flow	How many of the 58 individuals initially assessed for eligibility did not meet criteria based on questions relating to motivation levels? No report of how many participants each of the two therapists treated. Two participants who were assigned to wait-list condition then received active treatment. It is not clear on how the data for these participants was analysed such as intent-to-treat principle.	1
Implementation of intervention	The specified treatment *a priori* included problem solving training and social skills training to be implemented when necessary. The primary treatment was cognitive correction. Also "Treatment was conducted until patients developed an adequate perception of gambling and chance and ceased gambling". This being the case the treatment compositions that were actually implemented were not described. For example the number of sessions for each of the cognitive and behavioural components is important to discern whether the assumed mechanism of overall treatment effect is reasonable.	1
Recruitment	No dates provided.	0
Baseline data	Mean age of participants at study commencement is only demographic reported in Participants section. The gender (all men) is reported in the abstract but not along with age. No data on patients treated by each therapist. Clinical characteristics are presented in a table.	1
Numbers analysed	Two patients "could not wait longer (at study intake) and were immediately assigned to the treatment group". No further explanation is provided of how data for these participants were analysed such as ITT, PP, or AT. For example, numbers analysed at pretest /postest are not provided in Table 1 that reports findings for (assumedly) primary analyses. Numbers analysed are reported for clinically	1

	significant change and are the same as those at treatment commencement.	
Outcomes and estimation	Limited information provided about treatment effects in terms of estimates from MANOVA. For main results the F statistic along with P value is reported. No effect sizes are reported such as mean treatment differences along with a measure of precision for each estimate (e.g. 95% CI or SE). Analyses involving clinical change using a cut score on measures provide some effect size albeit secondary.	1
Ancillary analyses	The distinction between primary and secondary analyses is not entirely clear and no pre-specification of analyses is provided.	1
Adverse events	NA	0
Discussion		
Interpretation	No limitations described. For example the preponderance of males, no formal testing of hypothesised mechanisms of change (e.g. mediation analysis) and small sample size relative to the numbers assessed for eligibility.	1
Generalizability	40 participants were randomised at trial commencement. Subsequently 11 participants dropped out (8 in the treatment group, 3 in the control group) leaving 29 participants. This participant flow indicates that any treatment effects are based on observational data. Authors conclude "…this controlled study shows the effectiveness of a cognitive and behavioural treatment for pathological gamblers". However, the results are limited to a small sample of males where it is unknown if potential biasness due to confounders was adequately accounted for in the generation of the randomisation sequence and allocation concealment was implemented. There was no sample size calculation using a pre-specified outcome measure based on a primary hypothesis in order to power the study for robust inferences. Further, the discussion does not consider therapist characteristics required to effectively implement the treatment. The	1

	findings are limited to clinical psychologists with 4 to 5 years of experience. In many clinical settings this type of treatment is not be suited due to therapists/counsellors not having sufficient experience and qualifications.	
Overall evidence	Findings are briefly discussed in light of previous studies that have investigated cognitive correction techniques for PG. However, the overall evidence is not considered in context of critical appraisal (e.g. comparative efficacy in terms of effect sizes between studies and on what measures?).	1

Study ID: 06
Study author: McConaghy et al
Study title: Behavior Completion Versus Stimulus Control in Compulsive Gambling: Implications for Behavioral Assessment
Year of publication: 1988
Journal: Behavior Modification

Reviewer: D Smith
Date:

CONSORT item	**Comment**	**Rating** 2=Present 1=Present with some limitations 0=Absent
Title and abstract	No reference to randomisation in the title, however is mentioned in abstract. Interventions are referred to but no summary information other than behavioural based on organismic mechanisms of change. Treatment centre, therapists administering treatments, and blinding status such as person conducting assessments not stated.	1
Introduction		
Background	Scientific rationale is provided for the study based on previous studies and underpinning theory. The potential benefits of imaginal desensitisation are mentioned in context of the author's previous report (1983). Imaginal relaxation is justified in terms of the hypothesised mechanisms of therapeutic change.	2
Methods		
Participants	Referral mechanism is not described e.g. current inpatients, people seeking or referred to psychiatric inpatient treatment other than gambling, self-referred, media recruited. This limits the ability to critique external validity of findings e.g. outpatient community mental health service. Overview of treatment setting provided, however not the location for data collection at any	1

	time point. Also, it is unknown where specifically the interventions were administered in the hospital ward such as a private room. No details of those providing interventions (if this was the case or maybe self-administered). No description of psychiatric unit e.g. acute adult.	
Interventions	Details of each intervention provided. No reference to checking or enhancing therapist's adherence to treatment protocols.	1
Objectives	The primary objective is clear i.e. ID versus IR in terms of hypothesised mechanisms of change.	2
Outcomes	No clear differentiation between primary and secondary outcome measures and therefore does not inform subsequent RCT's on what primary measures to use with specificity to these treatments. Provenance and properties of measures not reported.	1
Sample size	NA	0
Randomization-sequence generation	NA	0
Allocation concealment	NA	0
Implementation	NA	0
Blinding (masking)	The author who conducted follow-up assessments was "unaware of the difference in the two treatment procedures. No description of who delivered treatment or provided standby assistance if self-administered. No mention if psychiatric unit staff (carers of participants whilst in hospital) were blinded. Also blinding of all inpatients to study hypothesis would be important to reduce bias. However, this may have been difficult due to close proximity of	1

	patients.	
Statistical methods	No statistical methods section. Reference only to statistical methods in results section such as t-test and Pearson r correlations. Primary (gambling urge & behaviours?) and secondary (anxiety?) analyses not clearly differentiated. No effect sizes and precision is provided.	1
Results		
Participant flow	Number of people assessed for eligibility not reported. This would be useful to know in light of sample representativeness (external validity). Participant flow is straight forward however. No reference to number of care providers that were involved with the participant during the trial.	1
Implementation of intervention	No details relating to implementation other than "All patients completed the week's session of treatment in hospital…" More information is required to differentiate between the intended intervention and what was received, such as mean duration of each session within group.	1
Recruitment	NA	0
Baseline data		2
Numbers analysed		2
Outcomes and estimation	No reference to primary or secondary analyses to draw main conclusions regarding study hypotheses. Presentation of the results suggest that primary analyses focus on Table 1.	1

Ancillary analyses	No pre-specified statistical analysis plan. The reader can only assume that Tables 3 & 4 relate to secondary analyses.	0
Adverse events	Aspects of the study design should be reported in terms of any harms or unintended effects. For example the study setting where participants were inpatients of a psychiatric ward for the duration (or longer?) of treatment.	0
Discussion		
Interpretation	No limitations addressed including small sample size, treatment setting and care providers. Overall, the discussion is mainly rhetoric that supports the author's findings and minimal consideration given to the balance of strengths and limitations.	1
Generalizability	An inference is made that the treatments can be administered by therapists with minimum training. However, no details of therapists are provided in this study such as professional qualifications, experience and training received for this study. The study design issues pose a significant threat to overall internal validity (a prerequisite for external validity) and therefore any conclusions drawn are limited to the sample.	1
Overall evidence	As above.	1

Study ID: 07
Study author: McConaghy et al
Study title: Comparison of imaginal desensitisation with other behavioural treatments of pathological gambling: A two- to nine-year follow-up.
Year of publication: 1991
Journal: British Journal of Psychiatry

Reviewer: DS
Date:

CONSORT item	**Comment**	**Rating** 2=Present 1=Present with some limitations 0=Absent
Title and abstract	No mention of random allocation in title. No reference to following in abstract: trial design (e.g. parallel); eligibility, settings, care providers; specific behavioural interventions for comparison group; hypothesis/objectives; clearly defined outcome, blinding status, estimated effect size and precision for primary analysis, and harms.	1
Introduction		
Background	No clinical rationale provided for treatments to justify their use or an ethical justification based on previous literature.	1
Methods		
Participants	Setting described. Eligibility criterion was participants considering their problem sufficiently serious to make a commitment to a 5-day inpatient stay. The only exclusion criterion was untreated active psychosis.	2
Interventions	Reference to previous study for aversive therapy. Enough detail provided for ID to be replicated. More details for *in vivo* exposure tasks needed e.g. is "customary" the participant's primary location of gambling problems; was it the participant's customary time of day to gamble? was the participant asked to focus on their subjective states during observations and make recordings? No treatment adherence checking e.g. the therapist introducing cognitive techniques during treatment.	1

Objectives	Objective of the study was to "compare" the outcome following ID with other procedures. Needs to be more specific in terms of primary outcome	1
Outcomes	References for standardised measures provided. Outcome relating to gambling behaviour mostly described although how participants rated their "subjective sense of impaired control" and "adverse financial consequences" is not clear. For example, self-reported yes/no responses or a Likert scale.	1
Sample size	NA	0
Randomization-sequence generation	NA	0
Allocation concealment	NA	0
Implementation	NA	0
Blinding (masking)	NA	0
Statistical methods	Methods used are presented in results section. Results can be verified.	2
Results		
Participant flow	Description of losses to follow-up and reasons are provided along with numbers analysed. No mention of number of care providers involved in each treatment.	1
Implementation of intervention	Unclear whether "All procedures…were administered in sessions of about 20 minutes…" refers to the intended implementation or the actual. It is not unreasonable to expect some variation in session duration and numbers of sessions between participants within treatments and between treatments.	1

Recruitment	Time frame is provided.	1
Baseline data		1
Numbers analysed		2
Outcomes and estimation		1
Ancillary analyses	Analyses focus on gambling behaviour as outcome and no consideration of other measures e.g. SCL-90	0
Adverse events	NA	0
Discussion		
Interpretation		1
Generalizability		1
Overall evidence		1

APPENDIX D. ETHICS APPROVAL

From: Randhawa, Harry (Health)
Sent: Friday, 17 September 2010 12:49
To: Smith, David (Health)
Subject: 342/10 - Ethical Approval

Importance: High

Dear David Smith

This is a formal correspondence from the Southern Adelaide Health Service / Flinders University Human Research Ethics Committee. This committee was renamed to reflect the regional nature of the committee and the fact that the committee is jointly hosted by the Flinders University. This committee used to be known as the Flinders Clinical Research Ethics Committee. Whilst this official title of the committee has changed the committee is still properly constituted under AHEC requirements with the registration number EC00188. This committee operates in accordance with the "National Statement on Ethical Conduct in Human Research (2007)." This department only uses email correspondence for all documents unless prior arrangements have been made with the manager. No hard copy correspondence will be issued.

Application Number: 342.10

Title: Evaluation of the benefits of psychological treatments for patients with gambling problems: a randomised controlled study.

Chief investigator: Prof Malcolm Battersby

The Issue: The Southern Adelaide Health Service / Flinders University Human Research Ethics Committee (SAFUHREC) have reviewed and approved the above application. Your project may now commence. The approval extends to the following documents:

- Committee Cover Letter dated 07th July 2010
- Participation Info and Consent Form dated 02nd July 2010
- Consent to Withdraw

Approval Period: 09th September 2010 to 09th September 2013

Please retain a copy of this approval for your records.

TERMS AND CONDITIONS OF ETHICAL APPROVAL

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007)

2. To immediately report to FCREC anything that may change the ethical or scientific integrity of the project.

3. To regularly review the FCREC website and comply with all submission requirements as they change from time to time.

4. Submit an annual report on each anniversary of the date of final approval and in the correct template from the FCREC website

5. Confidentiality of research participants MUST be maintained at all times.

6. A copy of the signed consent form must be given to the participant unless the project is an audit

7. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.

8. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.

9. The researchers agree to use electronic format for all correspondence with this department.

10. All requests for access to medical records at any SAHS site must be accompanied by this approval email.

Tanya Lyons
(Acting Ethics Manager)
Southern Adelaide Health Service/ Flinders University Human research Ethics Committee
Room 2A221 - Inside Human Resources
Flinders Medical Centre, Bedford Park SA 5042

Tel: 08 8204 6453
Fax: 08 8204 4586
Mobile: 0422 687 087
Email: research.ethics@health.sa.gov.au

Website: http://www.flinders.sa.gov.au/research/pages/ethics/

APPENDIX E. PARTICIPANT INFORMATION AND CONSENT-RANDOMISED TRIAL

FLINDERS UNIVERSITY
ADELAIDE • AUSTRALIA

Flinders Human Behaviour & Health Research Unit

Margaret Tobin Centre
GPO Box 2100
Adelaide SA 5001

Telephone: (08) 8404 2610
Facsimile: (08) 8404 2101

Email:
david.smith2@health.sa.gov.au

Participant Information Sheet

Prof M Battersby, Dr P Harvey, Dr R Pols, Mr D Smith

Project:

Evaluation of the benefits of psychological treatments for clients with gambling problems: a randomised controlled study.

We are inviting you to participate in this research project, but whether you wish to or not is entirely up to you. Whether you take part or not, the services which you receive from Statewide Gambling Therapy Service or any other service will not be affected in any way.

Dear Client

You have been asked to take part in a study to see if there is any difference between two well known and commonly used psychological treatments for problem gambling.

Before you agree to take part in the study, please read the information below.

Why is this study being carried out?

Research in the past has shown that a combination of psychological treatments can be effective in treating problem gambling. Flinders University through the Flinders Human Behaviour & Health Research Unit, and the Statewide Gambling Therapy Service is undertaking this research to better understand how psychological treatments on their own, rather than together may improve gambling related problems.

What does giving consent mean?

Giving consent means that you have signed a written consent form and read the information sheet. We are happy to answer any questions you may have. If you wish, you can discuss this with relatives, friends and your personal doctor.

What will you need to do?

If you take part in the study:

- You will need to commit to being involved in the study for a period of about nine months.
- You will be placed into one of two groups at random. Each treatment group will have the same general attributes of scientifically proven psychological treatments.
- We will ask you to fill out a few questionnaires about your gambling experiences and general mental health, including alcohol consumption, at times during and after treatment.
- An audio recording of each of your treatment sessions will be made so an independent expert clinician in psychological treatments for problem gambling can listen to these recordings and review the content of the treatment provided by the therapist. We will seek your consent to record the treatment sessions.

Will I be paid for doing this study?

You will not be paid to take part in this study. However, as acknowledgement of any inconveniences you may experience while participating in this study gift vouchers will be offered on the following occasions:

- $10 gift voucher when you have finished treatment
- $20 voucher on completion of questionnaires 3 months following treatment
- $25 voucher on completion of questionnaires 6 months following treatment
- $30 voucher on completion of your final questionnaires at approximately 12 months following treatment.

How will my privacy be protected?

The information we collect from you will not be seen or used by anyone except the research team. Your information will not be given to any other person without your permission. All personal information will be stored in the Statewide Gambling Therapy Service under lock and key. Data and audio recordings on computers will be password protected and any publications arising from the study will not contain any personal identifying information. Under privacy rules you are entitled to request a copy of your personal information at any time.

Is taking part in the study voluntary?

Yes. You don't have to participate in this study if you do not want to. If you choose to participate and then want to withdraw without giving a reason, that is OK – this will not affect your current or future treatment in any way.

If you have any further questions

This study has been approved by the Southern Adelaide Health Service / Flinders Universtity Human Research Ethics Committee. If you want to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Ethics Committee Manager, 8204 6453 or e-mail: research.ethics@health.sa.gov.au. If you feel that you would like to speak to someone regarding your immediate health concerns you can call any of the following numbers:

- Mental Health Service Emergency Crisis - 13 1465
- Gambling Helpline - 1800 060 757

- Emergency department Flinders Medical Centre (8204 5511) or your local hospital
- Your GP
- The Department of Psychiatry at Flinders Medical Centre - 8204 6110

Flinders University, South Australia

CONSENT TO PARTICIPATION IN RESEARCH

I, ...
(first or given names) *(last name)*

request and give consent to my involvement in the research project

Evaluation of the benefits of psychological treatments for patients with gambling problems: a randomised controlled study.

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by

.....
(first or given name) *(last name)*

and my consent is given voluntarily.

I acknowledge that the details of the following have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time; and the frequency with which they will be performed:

- I have had the opportunity to ask questions about the study and am satisfied with the answers and the explanations given to me.
- I know I will be asked to fill out a few questionnaires about my gambling related experiences at the beginning of treatment, and mid- treatment (4 weeks), and end of treatment (12 weeks) and then at three (3) months and six (6) months after treatment.
- I agree to my information and participation in each treatment session being audio recorded.
- I know I will be offered a gift voucher on the following occasions:
  - $10 gift voucher when I have finished treatment
  - $20 voucher when I have completed questionnaires 3 months following treatment
  - $25 voucher when I have completed questionnaires 6 months following treatment
  - $30 voucher when I have completed my final questionnaires about 12 months following treatment.

- I know I have the opportunity to discuss my involvement with another person and have had sufficient time to make the decision to take part in this study.
- I know that I may withdraw from this study at any time without affecting my usual care or treatment. If I refuse to participate, it will have no impact on the services which I receive.
- I understand that the results of this study may be published, but my identity will be kept confidential.
- I give consent for my therapist to advise the research team about which other gambling help services I may use and how often I used these services, for the period of the trial.
- I know that my answers will be completely confidential and no personal information, arising from study, which may identify me in any way, will be passed to any other Health service or department.
- I know that my answers will not in any way affect my treatment or access to any health services I am entitled to.
- The data will be stored in a secure data storage area for a period of fifteen years in accordance with Flinders University requirements.

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I declare that I am over the age of 18 years.

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

Signature of Research Participant : ..... Date:.....

I, ... have described to.....

the research project and nature and effects of procedures involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: .....

Status in Project:.....

Participant information and consent- interviews

FLINDERS UNIVERSITY
ADELAIDE • AUSTRALIA

Flinders Human Behaviour & Health Research Unit

Margaret Tobin Centre
GPO Box 2100
Adelaide SA 5001

Telephone: (08) 8404 2610
Facsimile: (08) 8404 2101

Email:
david.smith2@health.sa.gov.au

Participant Information Sheet

Prof M. Battersby, Assoc Prof P. Harvey, Dr R. Pols, Mr D. Smith

Project:

An exploration of psychological treatments for problem gambling: a clients perspective.

We are inviting you to participate in this research project, but whether you wish to or not is entirely up to you. Whether you take part or not, the services you receive from Statewide Gambling Therapy Service or any other service will not be affected in any way.

Dear Client

You have been asked to take part in this phase of the randomized clinical trial for gambling treatments to explore your perceptions on the psychological treatment you received for problem gambling.

Before you agree to take part in the study, please read the information below.

Why is this study being carried out?

Research in the past has shown that psychological treatments can be effective in treating problem gambling. Flinders University, through the Flinders Human Behaviour & Health Research Unit and the Statewide Gambling Therapy Service, is undertaking this research to better understand how psychological treatments may improve gambling related problems.

What does giving consent mean?

Giving consent means that you have read the project information sheet and signed a consent form agreeing to participate in the project interviews.. We are happy to answer any questions you may have. If you wish, you can discuss this process with relatives, friends and your personal doctor.

What will you need to do?

If you take part in the study:

- We will ask you to participate in a one-on-one interview with a Research Officer for approximately one hour and on one occasion only. The interview will be conducted at Flinders University or at a location that is best suited to your needs.
- An audio recording of the interview will be made so a researcher/s in the field of problem gambling can listen to these recordings and review the content. We will seek your consent to record the treatment sessions.

Will I be paid for doing this study?

You will not be paid to take part in this study. However, as acknowledgement of any inconvenience you may experience while participating in this study a $50 gift voucher will be offered.

How will my privacy be protected?

The information we collect from you will not be seen or used by anyone except the research team. Your information will not be given to any other person without your permission. All personal information will be stored in the Statewide Gambling Therapy Service / Flinders University under lock and key. Audio recordings stored on computers will be password protected and any publications arising from the study will not contain any personal identifying information. Under privacy rules you are entitled to request a copy of your personal information at any time.

Is taking part in this study phase voluntary?

Yes. You don't have to participate in this part of the study if you do not want to. If you choose to participate and then want to withdraw without giving a reason, that is OK – this will not affect your current or future treatment in any way.

If you have any further questions

This study has been reviewed by the Southern Adelaide Health Service / Flinders Universtity Human Research Ethics Committee. If you want to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant or should you wish to make a confidential complaint, you may contact the Ethics Committee Manager, 8204 4507 or e-mail: research.ethics@health.sa.gov.au. If you feel that you would like to speak to someone regarding your immediate health concerns you can call any of the following numbers:

- Mental Health Service Emergency Crisis - 13 14 65
- Gambling Helpline - 1800 060 757
- Emergency department Flinders Medical Centre (8204 5511) or your local hospital
- Your GP
- The Department of Psychiatry at Flinders Medical Centre - 8204 6110

CONSENT TO PARTICIPATION IN RESEARCH

I, ...
(first or given names) *(last name)*

request and give consent to my involvement in the research project

An exploration of psychological treatments for problem gambling: a clients perspective.

I acknowledge that the nature andpurpose of the research project, especially as far as they affect me, have been fully explained to my satisfaction by

.....
(first or given name) *(last name)*

and my consent is given voluntarily.

I acknowledge that the details of the following have been explained to me, including indications of risks, any discomfort involved, anticipation of length of time and the frequency with which they will be performed:

- I have had the opportunity to ask questions about the study and am satisfied with the answers and the explanations given to me.
- I agree to my information and participation in the interview being audio recorded.
- I know I will be offered a $50 gift voucher at the completion of the interview.
- I know I have the opportunity to discuss my involvement with another person and have had sufficient time to make the decision to take part in this study.
- I know that I may withdraw from this study at any time without affecting my usual care or treatment. If I refuse to participate, it will have no impact on the services which I receive.
- I understand that the results of this study may be published, but that my identity will be kept confidential.
- I know that my answers will be completely confidential and that no personal information, arising from study, that may identify me in any way, will be passed to any other Health service or department.

I know that my answers will not in any way affect my treatment or access to any health services I am entitled to receive.

- The data will be stored in a secure data storage area for a period of fifteen years in accordance with Flinders University requirements.

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I declare that I am over the age of 18 years.

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

Signature of Research Participant : ..... Date:.....

I, ... have described to.....

the research project and nature and effects of procedures involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature: ..... Date: .....

Status in Project:.....

APPENDIX F. STUDY SCREENING INSTRUMENT

RCT SCREENING

For Researcher Use Only

Statewide Gambling Therapy Service

Date: ____ ____ /____ ____ ____ / ____ ____ ____ ____

Interview Time: Start ____ ____ ____ ____ Finish____ ____ ____ ____

Client Name: ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

GHS No: ____ ____ ____ ____

Researcher Name: ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

Title and preamble:

Comparing benefits of psychological treatments for problem gambling: A randomized trial.

Hello (participants name)

We are inviting you to participate in a research project to see if there is any difference between two well known and commonly used psychological treatments for problem gambling, but whether you wish to or not is entirely up to you, the services which you receive from Statewide Gambling Therapy Service or any other service will not be affected in any way.

This study is being conducted here at Flinders Statewide Gambling Therapy Service and the chief investigators are Professor Malcolm Battersby, Associate Professor Peter Harvey, and Dr Rene Pols.

Why is this study being carried out?

Research in the past has shown that a combination of psychological treatments can be effective in treating problem gambling. Flinders University through the Flinders Human Behaviour & Health Research Unit, and the Statewide Gambling Therapy Service is undertaking this research to better understand how psychological treatments on their own, rather than together may improve gambling related problems.

		No *0*	***Yes*** *1*
1.	Have you read or heard about this study before contacting this service? If 'Yes' where from?.....	○	○
2.	Would you like to participate in this study? *If No, ask client what they would like to do, e.g., talk to SGTS staff to arrange an appointment not involving this study. If Yes, proceed with questions:*	○	○
3.	Are you 18 years of age or older?	○	○
4.	Are you seeking treatment for your problem gambling?	○	○
5.	What is the main form of gambling that you are seeking treatment for *(electronic gaming machines, horse racing, cards, online sports bets etc)?*		
6.	Are you presently involved in any other gambling treatment programmes?	○	○
7.	Have you received psychological treatment/s for gambling problems in the previous 12 months?	○	○

RCT SCREENING

For Researcher Use Only

Statewide Gambling Therapy Service

8. Are you willing to read and respond to self-rated questionnaires written in English?	○	○
9. Are you willing to be randomised to one of two psychological treatments?	○	○
10. Have you gambled in the past month using electronic gaming machines?	○	○
11. Are you willing to provide follow-up data?	○	○

ADMINISTER SOGS (ATTACHED)

12. Did the client score 5 or greater on the South Oaks Gambling Screen?	○	○

STUDY ELIGIBILITY

If items 2, 3, 4, 8, 9, 10, &11 above are 'Yes', the form of gambling stated in 5 is electronic gaming machines ('pokies'), and the client is not currently involved with another gambling treatment program (item 6 is 'No') then client is eligible for the study; proceed to 12 below. If client is not eligible, go to *REASONS FOR INELIGIBILITY.*

13. Contact Clinical Trials (Pharmacy) on Ext 66054 to have treatment group allocated.	○	○

TREATMENT GROUP:	○	Behavioural Therapy (or)	○	Cognitive Therapy

14. Inform SGTS administration about client's treatment allocation and provide with details for contacting client and arranging appointment	○	○

REASONS FOR INELIGIBILITY

If any of 1 – 10 are 'No', or if 4. is not electronic gaming machines, then select (one only) of the options below to indicate reason for study ineligibility:

○	Less than 18 years of age.
○	Person is not seeking treatment for problem gambling.
○	Primary form of gambling for which treatment sought is not electronic gaming machines.
○	Presently involved with another gambling treatment programme.
○	Person has completed or near completed psychological treatment/s for gambling problems in the previous 12 months?
○	Not willing to participate in the study.
○	Not willing/able to read and respond to self-rated questionnaires written in English.
○	Not willing to be randomised into one of two psychological treatments.
○	Has not gambled in the past month.
○	Not willing to provide follow-up data.
○	SOGS score <5
○	Other reason: .....

SOGS FOR RCT SCREENING

For Researcher Use Only

Statewide Gambling Therapy Service

Date: __ __ / __ __ __ / __ __ __ __

Client Name: _____

GHS No: __ __ __ __

Researcher Name: _____

For use with RCT SCREENING for Researcher Form

1. Please indicate which of the following types of gambling you have done in your lifetime.
For each type, mark one answer ('not at all', 'less than once a week', or 'once a week or more').

		Not at all 0	***Less than once a week*** 1	***Once a week or more*** 2
a.	Played cards for money	○	○	○
b.	Bet on horses, dogs or other animals (at TAB, track or with bookie)	○	○	○
c.	Bet on sport	○	○	○
d.	Played dice games, including craps, over and under, other dice games	○	○	○
e.	Went to casinos (legal or otherwise)	○	○	○
f.	Played the numbers or bet on lotteries	○	○	○
g.	Played bingo	○	○	○
h.	Played the stock and/or commodities market	○	○	○
i.	Played slot machines, poker machines, or other gambling machines	○	○	○
j.	Bowled, shot pool, played golf, or some other game of skill for money	○	○	○
k.	Played pull tabs, or 'paper' games other than lotteries	○	○	○
l.	Some form of gambling not listed above: _____	○	○	○

2. What is the largest amount of money you have ever gambled with on any one day? *Select one only:*

○	***Never gambled***	○	***$1 or less***	○	***More than $1, up to $10***	○	***More than $10, up to $100***
○	***More than $100, up to $1000***	○	***More than $1000, up to $10 000***	○	***More than $10 000***		

3. Indicate which of the following people in your life has (or had) a gambling problem:

○	***Father***	○	***Mother***	○	***Brother/sister***	○	***My spouse/partner***
○	***My child(ren)***	○	***Another relative***	○	***A friend/someone important to me***		

SOGS FOR RCT SCREENING

For Researcher Use Only

Statewide Gambling Therapy Service

4. When you gamble, how often do you go back another day to win back money you have lost?

○	***Never***	○	***Most of the times I lose***
○	***Some of the time (less than half of the time I lose)***	○	***Every time I lose***

5. Have you ever claimed to be winning money gambling, but you weren't really? In fact, you lost?

○	***Never***	○	***Yes, less than half the time I lost***	○	***Yes, most of the time***

6. Do you feel you have ever had a problem with gambling?

○	***No***	○	***Yes***	○	***Yes, in the past but not now***

	No *0*	***Yes*** *1*
7. Did you ever gamble more than you intended to?	○	○
8. Have people criticised your betting or told you that you had a problem, regardless of whether or not you thought it was true?	○	○
9. Have you ever felt guilty about the way you gamble, or what happens when you gamble?	○	○
10. Have you ever felt you would like to stop betting money on gambling but didn't think you could?	○	○
11. Have you ever hidden betting slips, lottery tickets, gambling money, IOUs or other signs of betting from your spouse, children or other important people in your life?	○	○
12. Have you ever argued with people you live with over how you handle money?	○	○
13. *(If you answered 'yes' to Qu 12)* Have money arguments ever centred on your gambling?	○	○
14. Have you ever borrowed from someone and not paid them back as a result of your gambling?	○	○
15. Have you ever lost time from work (or school) due to betting money or gambling?	○	○

16. If you have borrowed money to gamble or to pay gambling debts, who or where did you borrow from? (*tick 'yes' or 'no' for each)*

		0	1
a.	From household money	○	○
b.	From your spouse	○	○
c.	From other relatives or in-laws	○	○
d.	From banks, loan companies, or credit unions	○	○
e.	From credit cards	○	○
f.	From loan sharks	○	○
g.	You cashed in stocks, bonds or other securities	○	○
h.	You sold personal or family property	○	○
i.	You borrowed on your checking accounts (passed bad cheques)	○	○
j.	You have (had) a credit line with a bookie	○	○
k.	You have (had) a credit line with a casino	○	○

Scores on the SOGS are determined by scoring one point for each question that shows the "at risk" response indicated, and adding the total points.

Question	Score	'At risk' response
1.	X	Not counted
2.	X	Not counted
3.	X	Not counted
4.	_____	Most of the time I lose *or* Yes, most of the time
5.	_____	Yes, less than half the time *or* Yes, most of the time
6.	_____	Yes, in the past but not now *or* Yes
7.	_____	Yes
8.	_____	Yes
9.	_____	Yes
10.	_____	Yes
11.	_____	Yes
12.	X	Not counted
13.	_____	Yes
14.	_____	Yes
15.	_____	Yes
16a.	_____	Yes
16b.	_____	Yes
16c.	_____	Yes
16d.	_____	Yes
16e.	_____	Yes
16f.	_____	Yes
16g.	_____	Yes
16h.	_____	Yes
16.i	_____	Yes
16j.	X	Not counted
16k.	X	Not counted
TOTAL:		(max score = 20)

APPENDIX G. MEASURES

Statewide Gambling Therapy Service

DSM-IV Checklist for RCT

For Therapist / Researcher Use Only

CLIENT: _____

GHS ID: _____ RCT ID: _____

Start of treatment	*End of treatment*	*6 month Follow-up*
○	○	○

These details to be supplied by researcher

Date: ___ ___/___ ___ ___/___ ___ ___ ___

The diagnostic criteria relating to the extent of persistent and recurrent maladaptive gambling behaviour is measured using ten questions with response options *No* or *Yes*.

Persistent and recurrent maladaptive gambling behaviour is indicated by five (or more) of the following:

		No 0	*Yes* 1
1.	Is preoccupied with gambling (e.g., preoccupied by re-living past gambling experiences, handicapping or planning the next venture, or thinking of ways to get money with which to gamble).	○	○
2.	Needs to gamble with increasing amounts of money in order to achieve the desired excitement.	○	○
3.	Has repeated unsuccessful attempts to control, cut back, or stop gambling.	○	○
4.	Is restless or irritable when attempting to cut down or stop gambling.	○	○
5.	Gambles as a way of escaping from problems or of relieving a dysphoric mood (e.g., feelings of helplessness, guilt, anxiety or depression).	○	○
6.	After losing money gambling, often returns another day to get even ("chasing" one's losses).	○	○
7.	Lies to family members, therapist, or others to conceal the extent of involvement with gambling.	○	○
8.	Has committed illegal acts such as forgery, fraud, theft, or embezzlement to finance gambling.	○	○
9.	Has jeopardised or lost a significant relationship, job or educational or career opportunity because of gambling.	○	○
10.	Relies on others to provide money to relieve a desperate financial situation caused by gambling.	○	○

A total score is obtained from the sum of the 10 responses

TOTAL SCORE: _____

Victorian Gambling Screen (VGS)

Please answer the following questions – your answers will be about the last month:

	Never 0	*Rarely* 1	*Some-times* 2	*Often* 3	*Always* 4	*Can't say* 5	*N/A* 6
1. Nowadays, when you gamble, do you feel as if you are on a slippery slope and can't get back up again?	○	○	○	○	○	○	○
2. Has your need to gamble been too strong to control?	○	○	○	○	○	○	○
3. Has gambling been more important than anything else you might do?	○	○	○	○	○	○	○
4. Have you felt that after losing you must return as soon as possible to win back any losses?	○	○	○	○	○	○	○
5. Has the thought of gambling been constantly in your mind?	○	○	○	○	○	○	○
6. Have you lied to yourself about your gambling?	○	○	○	○	○	○	○
7. Have you gambled in order to escape from worry or trouble?	○	○	○	○	○	○	○
8. Have you felt bad or guilty about your gambling?	○	○	○	○	○	○	○
9. Have you thought you shouldn't gamble or should gamble less?	○	○	○	○	○	○	○
10. How often has anyone close to you complained about your gambling?	○	○	○	○	○	○	○
11. How often have you lied to others to conceal the extent of your involvement in gambling?	○	○	○	○	○	○	○
12. How often have you hidden betting slips, Lotto tickets, gambling money or other signs of gambling from your spouse, partner, children or other important people in your life?	○	○	○	○	○	○	○
13. How often have you spent more money on gambling than you can afford?	○	○	○	○	○	○	○
14. How often has your gambling made it harder to make money last from one payday to the next?	○	○	○	○	○	○	○
15. How often have you had to borrow money to gamble with?	○	○	○	○	○	○	○

Statewide Gambling Therapy Service

Gambling Related Cognitions Scale (GRCS)

Please read through each of the following statements and indicate (by ticking the box) the extent to which you agree with the value expressed in each statement:

	Strongly disagree 0	*Moderately disagree* 1	*Mildly disagree* 2	*Neither agree / disagree* 3	*Mildly agree* 4	*Moderately agree* 5	*Strongly agree* 6
1. Gambling makes me happier	○	○	○	○	○	○	○
2. I can't function without gambling	○	○	○	○	○	○	○
3. Praying helps me win	○	○	○	○	○	○	○
4. Losses when gambling, are bound to be followed by a series of wins	○	○	○	○	○	○	○
5. Relating my winnings to my skill and ability makes me continue gambling	○	○	○	○	○	○	○
6. Gambling makes things seem better	○	○	○	○	○	○	○
7. It is difficult to stop gambling as I am so out of control	○	○	○	○	○	○	○
8. Specific numbers and colours can help increase my chances of winning	○	○	○	○	○	○	○
9. A series of losses will provide me with a learning experience that will help me win later	○	○	○	○	○	○	○
10. Relating my losses to bad luck and bad circumstances makes me continue gambling	○	○	○	○	○	○	○
11. Gambling makes the future brighter	○	○	○	○	○	○	○
12. My desire to gamble is so overpowering	○	○	○	○	○	○	○
13. I collect specific objects that help increase my chances of winning	○	○	○	○	○	○	○
14. When I have a win once, I will definitely win again	○	○	○	○	○	○	○

(continues on next page)

Statewide Gambling Therapy Service

Gambling Related Cognitions Scale (GRCS)

	Strongly disagree 0	*Moderately disagree* 1	*Mildly disagree* 2	*Neither agree / disagree* 3	*Mildly agree* 4	*Moderately agree* 5	*Strongly agree* 6
15. Relating my losses to probability makes me continue gambling	○	○	○	○	○	○	○
16. Having a gamble helps reduce tension and stress	○	○	○	○	○	○	○
17. I'm not strong enough to stop gambling	○	○	○	○	○	○	○
18. I have specific rituals and behaviours that increase my chances of winning	○	○	○	○	○	○	○
19. There are times that I feel lucky and thus, gamble those times only	○	○	○	○	○	○	○
20. Remembering how much money I won last time makes me continue gambling	○	○	○	○	○	○	○
21. I will never be able to stop gambling	○	○	○	○	○	○	○
22. I have some control over predicting my gambling wins	○	○	○	○	○	○	○
23. If I keep changing my numbers I have less chance of winning than if I keep the same numbers every time	○	○	○	○	○	○	○

The Gambling Urge Scale

	Disagree 0	1	2	3	4	5	6	***Agree*** 7
1. All I want to do now is gamble	○	○	○	○	○	○	○	○
2. It would be difficult to turn down a gamble this minute	○	○	○	○	○	○	○	○
3. Having a gamble now would make things seem just perfect	○	○	○	○	○	○	○	○
4. I want to gamble so bad I can almost feel it	○	○	○	○	○	○	○	○
5. Nothing would be better than having a gamble right now	○	○	○	○	○	○	○	○
6. I crave a gamble right now	○	○	○	○	○	○	○	○

Statewide Gambling Therapy Service

Kessler 10 Scale (K10)

The following questions are about how you have been feeling over the past four weeks. Please tick the box that best describes how you have been feeling.

	None of the time 0	*A little of the time* 1	*Some of the time* 2	*Most of the time* 3	*All of the time* 4
1. In the past four weeks, about how often did you feel tired out for no good reason?	○	○	○	○	○
2. In the past four weeks, about how often did you feel nervous?	○	○	○	○	○

Skip question 3 if you answered "None of the time" to question 2

	None of the time 0	*A little of the time* 1	*Some of the time* 2	*Most of the time* 3	*All of the time* 4
3. In the past four weeks, about how often did you feel so nervous that nothing could calm you down?	○	○	○	○	○
4. In the past four weeks, about how often did you feel hopeless?	○	○	○	○	○
5. In the past four weeks, about how often did you feel restless and fidgety?	○	○	○	○	○

Skip question 6 if you answered "None of the time" to question 5

	None of the time 0	*A little of the time* 1	*Some of the time* 2	*Most of the time* 3	*All of the time* 4
6. In the past four weeks, about how often did you feel so restless that you could not sit still?	○	○	○	○	○
7. In the past four weeks, about how often did you feel depressed?	○	○	○	○	○
8. In the past four weeks, about how often did you feel that everything was an effort?	○	○	○	○	○
9. In the past four weeks, about how often did you feel so sad that nothing could cheer you up?	○	○	○	○	○
10. In the past four weeks, about how often did you feel worthless?	○	○	○	○	○

The Work and Social Adjustment Scale (WSAS)

Some people's problems affect their ability to do certain day-to-day tasks. How much does gambling impair your ability to do the following things?

	Not at all 0	1	*Slightly* 2	3	*Definitely* 4	5	*Markedly* 6	7	*Very severely* 8
1. Ability to work or study	○	○	○	○	○	○	○	○	○
2. Home management (e.g., cleaning, tidying, shopping, cooking, looking after home/children, paying bills)	○	○	○	○	○	○	○	○	○
3. Social leisure activities Things done with other people (e.g., parties, pubs, outings, visits, entertaining etc)	○	○	○	○	○	○	○	○	○
4. Private leisure activities Things done alone (e.g., reading, gardening, sewing, hobbies, walking)	○	○	○	○	○	○	○	○	○
5. Family & relationships Forming and maintaining close relationships with others including the people I live with.	○	○	○	○	○	○	○	○	○

Statewide Gambling Therapy Service

Alcohol Use Disorders Test (AUDIT)

Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest.

Tick the box that best describes your answer to each question.

	Never 0	*Monthly or less* 1	*2 – 4 times a month* 2	*2 – 3 times a week* 3	*4 or more times a week* 4
1. How often do you have a drink containing alcohol?	○ → Qu 9	○	○	○	○

	1 or 2 0	*3 or 4* 1	*5 or 6* 2	*7 to 9* 3	*10 or more* 4
2. How many standard drinks do you have on a typical day when you are drinking?	○	○	○	○	○

	Never 0	*Less than monthly* 1	*Monthly* 2	*Weekly* 3	*Daily or almost daily* 4
3. How often do you have 6 or more standard drinks in one session?	○	○	○	○	○
4. How often during the last year have you found that you were not able to stop drinking once you had started?	○	○	○	○	○
5. How often during the last year have you failed to do what was expected of you because of drinking?	○	○	○	○	○
6. How often during the last year did you need a first drink in the morning to get yourself going after a heavy drinking session?	○	○	○	○	○
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	○	○	○	○	○
8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?	○	○	○	○	○

	No 0	*Yes, but not in the last year* 1	*Yes, during the last year* 2
9. Have you or someone else been injured because of your drinking?	○	○	○
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	○	○	○

Arnett Inventory of Sensation Seeking (AISS)

For each item, please tick the box that best applies to you.	*Does not describe me at all* 0	*Does not describe me very well* 1	*Describes me somewhat* 2	*Describes me very well* 3
1. I can see how it would be interesting to marry someone from a foreign country.	○	○	○	○
2. When the water is very cold, I prefer not to swim even if it is a hot day.	○	○	○	○
3. If I have to wait in a long line, I'm usually patient about it.	○	○	○	○
4. When I listen to music, I like it to be loud.	○	○	○	○
5. When taking a trip, I think it is best to make as few plans as possible and just take it as it comes.	○	○	○	○
6. I stay away from movies that are said to be frightening or highly suspenseful.	○	○	○	○
7. I think it's fun and exciting to perform or speak before a group.	○	○	○	○
8. If I were to go to an amusement park, I would prefer to ride the rollercoaster or other fast rides.	○	○	○	○
9. I would like to travel to places that are strange and far away.	○	○	○	○
10. I would never like to gamble with money, even if I could afford it.	○	○	○	○
11. I would have enjoyed being one of the first explorers of an unknown land.	○	○	○	○
12. I like a movie where there are a lot of explosions and car chases.	○	○	○	○
13. I don't like extremely hot and spicy foods.	○	○	○	○
14. In general, I work better when I'm under pressure.	○	○	○	○
15. I often like to have the radio or TV on while I'm doing something else, such as reading or cleaning up.	○	○	○	○
16. It would be interesting to see a car accident happen.	○	○	○	○
17. I think it's best to order something familiar when eating in a restaurant.	○	○	○	○
18. I like the feeling of standing next to the edge of a high place and looking down.	○	○	○	○
19. If it were possible to visit another planet or the moon for free, I would be among the first in line to sign up.	○	○	○	○
20. I can see how it must be exciting to be in a battle during a war.	○	○	○	○

Statewide Gambling Therapy Service

Perceived Self-Efficacy Questionnaire (PSEQ)

Please describe your high-risk situations for gambling excessively (for example: "when I am bored and have nothing to do" or "when I just had an argument with my boss").

Then, indicate on a scale of 1 to 10 your level of confidence in controlling your gambling habits if you faced these situations at the present time.

Situation 1:

_____

_____

If you had to face this situation at the present time, to what extent would you have confidence in controlling your gambling habits?

Not at all		***A little***			***Moderately***			***A lot***		***Totally***
0	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
○	○	○	○	○	○	○	○	○	○	○

Situation 2:

_____

_____

If you had to face this situation at the present time, to what extent would you have confidence in controlling your gambling habits?

Not at all		***A little***			***Moderately***			***A lot***		***Totally***
0	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
○	○	○	○	○	○	○	○	○	○	○

Situation 3:

_____

_____

If you had to face this situation at the present time, to what extent would you have confidence in controlling your gambling habits?

Not at all		***A little***			***Moderately***			***A lot***		***Totally***
0	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
○	○	○	○	○	○	○	○	○	○	○

Statewide Gambling Therapy Service

Treatment impressions

How much logical sense does this treatment make in terms of helping you stop problem gambling?

Please circle the number that best describes your response:

Extremely illogical	*Moderately illogical*	*Slightly illogical*	*Neither logical or illogical*	*Slightly logical*	*Moderately logical*	*Extremely logical*
0	*1*	*2*	*3*	*4*	*5*	*6*

How confident are you that this treatment will help you stop problem gambling?

Please circle the number that best describes your response:

Extremely unconfident	*Moderately unconfident*	*Slightly unconfident*	*Neither confident or unconfident*	*Slightly confident*	*Moderately confident*	*Extremely confident*
0	*1*	*2*	*3*	*4*	*5*	*6*

Overall, how satisfied are you with the treatment for problem gambling you have received so far from Statewide?

Please circle the number that best describes your response:

Extremely unsatisfied	*Moderately unsatisfied*	*Slightly unsatisfied*	*Neither satisfied or unsatisfied*	*Slightly satisfied*	*Moderately satisfied*	*Extremely satisfied*
0	*1*	*2*	*3*	*4*	*5*	*6*

Gambling in the past month:

How much time (in hours) did you spend gambling on gaming machines during the last month?	hours
How much time (in hours) did you spend gambling on other gambling activities during the last month?	hours

	None 0	*Up to $100* 1	*$101 to $200* 2	*$200 to $500* 3	*$501 to $1000* 4	*$1001 to $1500* 5	*Over $1500* 6
How much money did you spend gambling on **gaming machines** in the last month?	○	○	○	○	○	○	○
How much money did you spend gambling on **other gambling activities** in the last month?	○	○	○	○	○	○	○

APPENDIX H. FOLLOW-UP LETTERS

Treatment completers

31 August 2013

Flinders University
Office

Flinders Human Behaviour
& Health Research Unit
(FHBHRU)
Margaret Tobin Centre
GPO Box 2100
Adelaide SA 5001

Telephone +61 8 8404 2610
Facsimile +61 8 8404 2101

www.flinders.edu.au/fhbhru

Dear ,

RE: Flinders gambling study

Thank you for participating in the gambling research study being held at Statewide Gambling Therapy Service and Flinders University.

As previously discussed this study involves the collection of follow-up data from you after finishing your treatment. To acknowledge your completion of questionnaires we would like to offer you shopping vouchers at the following time points:

$10 gift voucher when you have finished treatment
$20 voucher on completion of questionnaires 3 months following treatment
$25 voucher on completion of questionnaires 6 months following treatment
$30 voucher on completion of your final questionnaires at approximately 12 months following treatment.

Your responses are very important to the study. From the results, we hope to improve the treatments we provide to people.

If you have any questions or comments about the study, please call me on 8404 2610 or e-mail david.smith@flinders.edu.au

Regards,

David Smith
Research Officer

inspiring
achievement

Follow-up letter for treatment non-completers

31 August 2013

Flinders University
Office

Flinders Human Behaviour
& Health Research Unit
(FHBHRU)
Margaret Tobin Centre
GPO Box 2100
Adelaide SA 5001

Telephone +61 8 8404 2610
Facsimile +61 8 8404 2101

www.flinders.edu.au/fhbhru

Dear ,

RE: Flinders gambling study

Thank you for participating in the gambling research study being held at Statewide Gambling Therapy Service and Flinders University.

As previously discussed this study involves the collection of follow-up data even if you do not complete treatment. Please find enclosed study questionnaires for completion and a pre-paid envelope to return them. To acknowledge your completion of questionnaires we would like to offer you shopping vouchers at the following time points:

- $20 voucher on completion of questionnaires 3 months following your last treatment
- $25 voucher on completion of questionnaires 6 months following your last treatment
- $30 voucher on completion of your final questionnaires at approximately 12 months following your last treatment.

Your responses are very important to the study. From the results, we hope to improve the treatments we provide to people.

If you have any questions or comments about the study, please call me on 8404 2610 or e-mail david.smith@flinders.edu.au.

Regards,

David Smith
Research Officer

inspiring
achievement

APPENDIX I. RECRUITMENT ADVERTISING

Flyer

Chasing your losses again?

If your relationships or finances are beginning to suffer as a result of gambling maybe it is time to cut your losses and make a change.

If you would like help dealing with a gambling problem we can help.

Statewide Gambling Therapy Service and Flinders University are looking for participants for a study to investigate psychological treatments for problem gambling.

We offer free assessment, evidence-based treatment and follow-up counselling for all participants.

If you are interested in participating in this research or would like more information please call Statewide Gambling Therapy Service on 8204 6982 for an obligation free discussion.

Government of South Australia
SA Health

Statewide Gambling Therapy Service 8204 6982

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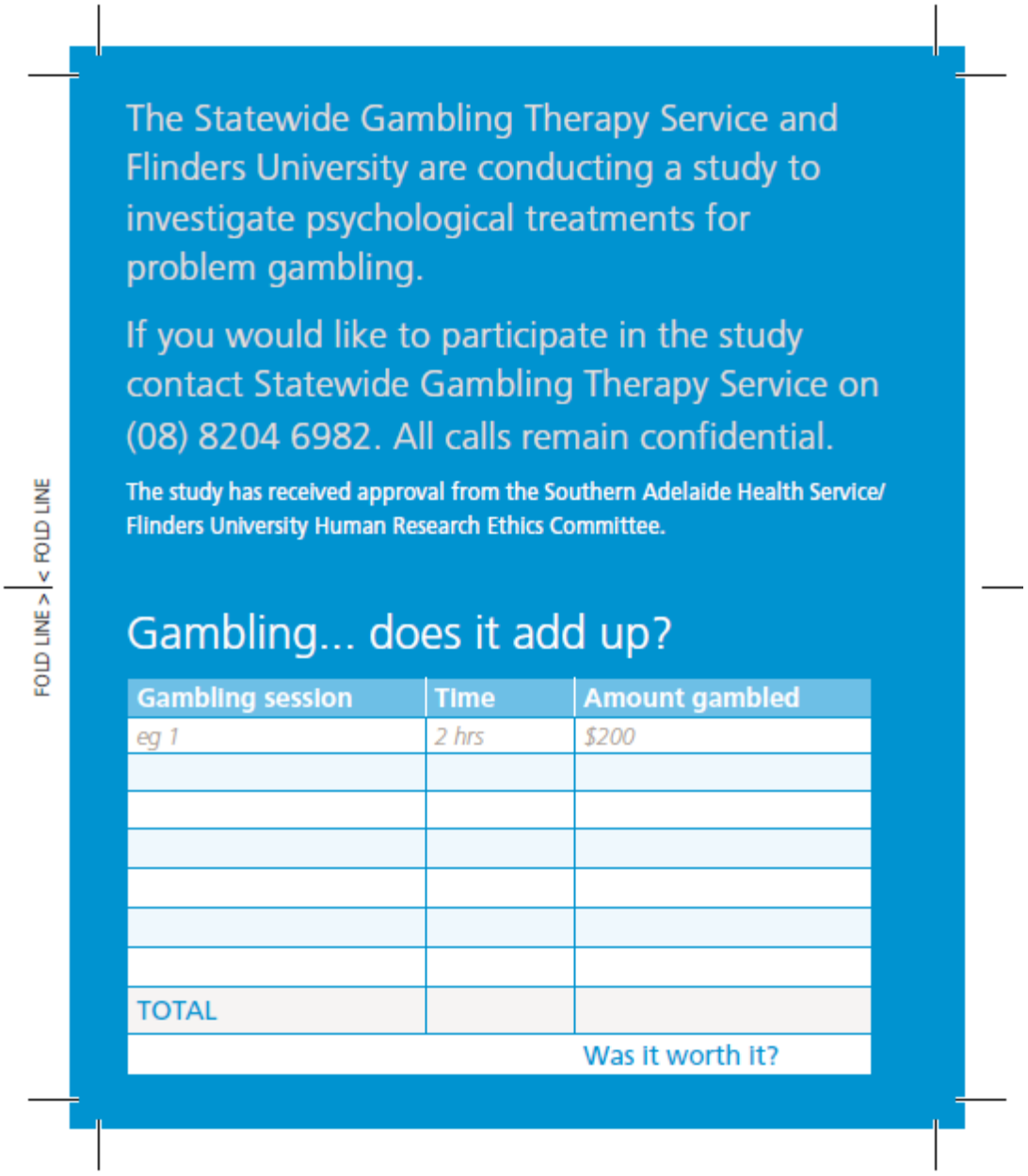
Statewide Gambling Therapy Service 8204 6982

Gambling wallet card

(Continued next page)



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The Statewide Gambling Therapy Service and Flinders University are conducting a study to investigate psychological treatments for problem gambling.

If you would like to participate in the study contact Statewide Gambling Therapy Service on (08) 8204 6982. All calls remain confidential.

The study has received approval from the Southern Adelaide Health Service/ Flinders University Human Research Ethics Committee.

Gambling... does it add up?

Gambling session	Time	Amount gambled
eg 1	*2 hrs*	*$200*
TOTAL		
		Was it worth it?

APPENDIX J. TOPIC LIST FOR QUALITATIVE INTERVIEWS

The questions in the interview were guided by the following topics.

(1) Motivators and barriers towards treatment and/or participation in the trial.

(2) The CT/ET treatment content, preference, adherence, experience and location.

(3) Experienced changes in symptoms and factors related to this change.

(4) Needs and advices to improve CT/ET.

(5) Other gambling treatments considered or received in the past.

(6) The (need for) involvement of the social environment in the symptoms and treatment.

(7) The experience of research activities.

REFERENCES

Acock, A. (2013). *Discovering structural equation modeling using Stata*. College Station, Texas: Stata Press

Afifi, T. O., Cox, B. J., Martens, P. J., Sareen, J., & Enns, M. W. (2010). The relationship between problem gambling and mental and physical health correlates among a nationally representative sample of Canadian women. *Canadian Journal of Public Health/Revue Canadienne de Sante'e Publique*, 171-175.

American Psychiatric Association. (2000). *Diagnostic and Statistical Manual of Mental Disorders (4th Edition, Text Revision)* (4th ed.). Washington DC.

American Psychiatric Association. (2010). DSM-5 development: pathological gambling. from http://www.dsm5.org/ProposedRevisions/Pages/proposedrevision.aspx?rid=210# (accessed Nov 6, 2011).

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental health disorders: DSM-5* (5th ed.). Washington, DC: American Psychiatric Publishing.

Andrews, G., & Slade, T. (2001). Interpreting scores on the Kessler psychological distress scale (K10). *Australian and New Zealand Journal of Public Health, 25*, 494-497.

Arnett, J. (1994). Sensation seeking: A new conceptualization and a new scale. *Personality and Individual Differences, 16*, 289-296.

Australian Bureau of Statistics. (2011). Population by Age and Sex, Regions of Australia. *Available at: http://www.abs.gov.au/ausstats/abs@.nsf/Products/3235.0~2011~Main+Features~South+Australia?OpenDocument#PARALINK6 (accessed 28 March 2013).*

Balodis, I., Lacadie, C., & Potenza, M. (2012). A preliminary study of the neural correlates of the intensities of self-reported gambling urges and emotions in men with pathological gambling. *Journal of Gambling Studies, 28*(3), 493-513.

Baron, R. M., & Kenny, D. (1986). The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology, 51*(6), 1173-1182.

Battersby, M., Oakes, J., Tolchard, B., Forbes, A., & Pols, R. (2008). Cognitive behavioural treatment for problem gamblers. In M. Zangeneh, A. Blaszczynski & N. E. Turner (Eds.), *In the pursuit of winning* (pp. 179-197). New York: Springer.

Beck, A. T., & Dozois, D. J. A. (2011). Cognitive Therapy: Current Status and Future Directions. *Annual Review of Medicine, 62*(1), 397-409.

Beck, A. T., Epstein, N., Brown, G., & Steer, R. A. (1988). An inventory for measuring clinical anxiety: psychometric properties. *Journal of Consulting and Clinical Psychology, 56*(6), 893.

Beck, A. T., & Steer, R. A. (1987). *BDI, Beck depression inventory: manual*: Psychological Corporation San Antonio, TX.

Becona, E. (1996). Prevalence surveys of problem and pathological gambling in Europe: The cases of Germany, Holland and Spain. *Journal of Gambling Studies, 12*(2), 179-192.

Begg, C., Cho, M., Eastwood, S., Horton, R., Moher, D., Olkin, I., . . . Stroup, D. F. (1996). Improving the Quality of Reporting of Randomized Controlled Trials: The CONSORT Statement. *Journal of the American Medical Association, 276*(8), 637-639.

Ben-Tovim, D., Esterman, A., Tolchard, B., & Battersby, M. W. (2001). The Victorian Gambling Screen: Project report. Melbourne: Victorian Research Panel.

Bernstein, P. (1996). *Against the Gods: the remarkable story of risk*. New York: John Wiley & Sons.

Black, D. W., Monahan, P. O., Temkit, M., & Shaw, M. (2006). A family study of pathological gambling. *Psychiatry Research, 141*, 295-303.

Blanco, C., Ibáñez, A., Sáiz-Ruiz, J., Blanco-Jerez, C., & Nunes, E. V. (2000). Epidemiology, pathophysiology and treatment of pathological gambling. *CNS drugs, 13*(6), 397-407.

Blanco, C., Petkova, E., Ibáñez, A., & Saiz-Ruiz, J. (2002). A pilot placebo-controlled study of fluvoxamine for pathological gambling. *Annals of Clinical Psychiatry, 14*(1), 9-15.

Blaszczynski, A., & Nower, L. (2002). A pathways model of problem and pathological gambling. *Addiction, 97*(5), 487-499.

Blaszczynski, A., Steel, Z., & McConaghy, N. (1997). Impulsivity in pathological gambling: The antisocial impulsivist. *Addiction, 92*(1), 75.

Blow, A. J., Sprenkle, D. H., & Davis, S. D. (2007). Is who delivers the treatment more important than the treatment itself? The role of the therapist in common factors. *Journal of Marital and Family Therapy, 33*(3), 298-317.

Bondolfi, G., Osiek, C., & Ferrero, F. (2000). Prevalence estimates of pathological gambling in Switzerland. *Acta Psychiatrica Scandinavica, 101*(6), 473-475.

Bonnaire, C. (2009). Subtypes of French Pathological Gamblers: Comparison of Sensation Seeking, Alexithymia and Depression Scores. *Journal of Gambling Studies, 25*(4), 455.

Boutron, I., Moher, D., Altman, D., Schulz, K., & Ravaud, P. (2008). Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration. *Annals of Internal Medicine, 148*(4), 295-309.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*, 77-101.

Brown, R. I. F. (1987). Classical and Operant Paradigms in the Management of Gambling Addictions. *Behavioural Psychotherapy, 15*(2), 111-122.

Campbell, M., Fitzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., & Tyrer, P. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ: British Medical Journal, 321*(7262), 694.

Campbell, M. K., Elbourne, D. R., & Altman, D. G. (2004). CONSORT statement: extension to cluster randomised trials. *BMJ (Clinical Research Ed.), 328*(7441), 702-708.

Carlbring, P., Jonsson, J., Josephson, H., & Forsberg, L. (2010). Motivational interviewing versus cognitive behavioral group therapy in the treatment of problem and pathological gambling: A randomized controlled trial. *Cognitive Behaviour Therapy, 39*(2), 92.

Carlbring, P., & Smit, F. (2008). Randomized trial of internet-delivered self-help with telephone support for pathological gamblers. *Journal of Consulting and Clinical Psychology, 76*(6), 1090-1094.

Carpenter, J. R., & Kenward, M. G. (2008). Missing data in clinical trials—a practical guide. *National Institute for Health Research, Publication RM03/JH17/MK: Birmingham*.

Chaloner, K., & Rhame, F. S. (2010). Quantifying and documenting prior beliefs in clinical trials. *Statistics in Medicine, 20*(4), 581-600.

Chambers, D. W. (2011). Confusions in the equipoise concept and the alternative of fully informed overlapping rational decisions. *Medicine, health care and philosophy, 14*(2), 133.

Clark, L. (2010). Decision-making during gambling: an integration of cognitive and psychobiological approaches. *Philosophical Transactions of the Royal Society B: Biological Sciences, 365*(1538), 319-330.

Cohen, J. (1992). A power primer. *Psychological Bulletin, 112*(1), 155.

Collins, D., & Lapsley, H. (2003). The social costs and benefits of gambling: An introduction to the economic issues. *Journal of Gambling Studies, 19*(2), 123-148.

CONSORT. (2010). Transparent reporting of trials. Retrieved 21 November 2011, from http://www.consort-statement.org/

Coventry, K., & Brown, R. F. (1993). Sensation seeking, gambling and gambling addictions. *Addiction, 88*(4), 541-554.

Cowlishaw, S., Merkouris, S., Dowling, N., Anderson, C., Jackson, A., & Thomas, S. (2012). Psychological therapies for pathological and problem gambling *Cochrane Database of Systematic Reviews*, Issue 11. Art. No.: CD008937. DOI:008910.001002/14651858.CD14008937.pub14651852.

Crabtree, B., & DiCicco-Bloom, B. (2006). The qualitative research interview. *Medical Education, 40*, 314-321.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ (Clinical Research Ed.), 337*.

Deegear, J., & Lawson, D. M. (2003). The utility of empirically supported treatments. *Professional Psychology: Research and Practice, 34*(3), 271.

Delfabbro, P. (2008). Australasian Gambling Review (Fourth ed.): Independent Gambling Authority of South Australia.

Derogatis, L. R. (1993). *Brief Symptom Inventory*. Baltimore: Clinical Psychometric Research.

Donker, T., Bennett, K., Bennett, A., Mackinnon, A., van Straten, A., Cuijpers, P., . . . Griffiths, K. M. (2013). Internet-Delivered Interpersonal Psychotherapy Versus Internet-Delivered Cognitive Behavioral Therapy for Adults With Depressive Symptoms: Randomized Controlled Noninferiority Trial. *Journal of Medical Internet Research, 15*(5).

Dowling, N. (2006). Treatment of Female Pathological Gambling: The Efficacy of a Cognitive-Behavioural Approach. *Journal of Gambling Studies, 22*(4), 355.

Dowling, N., Smith, D., & Thomas, T. (2005). Electronic gaming machines: are they the 'crack-cocaine'of gambling? *Addiction, 100*(1), 33-45.

Dowling, N., Smith, D., & Thomas, T. (2007). A comparison of individual and group cognitive-behavioural treatment for female pathological gambling. *Behaviour Research and Therapy, 45*(9), 2192-2202.

Echeburua, E., Baez, C., & Fernandez-Montalvo, J. (1996). Comparative Effectiveness of ThreeTherapeutic Modalities in the Psychological Treatment of Pathological Gamblers: Long-term Outcome. *Behavioural and Cognitive Psychotherapy, 24*, 51-72.

Echeburua, E., Fernández-Montalvo, J., & Báez, C. (2000). Relapse prevention in the treatment of slot-machine pathological gambling: Long-term outcome. *Behavior Therapy, 31*(2), 351-364.

Echeburúa, E., Gómez, M., & Freixa, M. (2011). Cognitive-behavioural treatment of pathological gambling in individuals with chronic schizophrenia: A pilot study. *Behaviour Research and Therapy, 49*(11), 808-814.

Edwards, P., Roberts, I., Clarke, M., DiGuiseppi, C., Pratap, S., Wentz, R., & Kwan, I. (2002). Increasing response rates to postal questionnaires: systematic review. *British Medical Journal, 324*(7347), 1183-1147.

Ferris, J., & Wynne, H. (2001). The Canadian Problem Gambling Index: Final Report: Canadian Centre on Substance Abuse.

Fink, A., Parhami, I., Rosenthal, R. J., Campos, M. D., Siani, A., & Fong, T. W. (2012). How transparent is behavioral intervention research on pathological gambling and

other gambling-related disorders? A systematic literature review. *Addiction, 107*(11), 1915-1928.

Frison, L., & Pocock, S. J. (1992). Repeated measures in clinical trials: analysis using mean summary statistics and its implications for design. *Statistics in Medicine, 11*(13), 1685-1704.

Gadboury, A., & Ladouceur, R. (1989). Erroneous perceptions and gambling. *Journal of Social Behavior & Personality, 4*(4), 411-420.

Gamblers Anonymous. (2009). Retrieved 26 January, 2015, from http://www.gansw.org.au/

Gardner, M. J., & Altman, D. G. (1986). Confidence intervals rather than P values: estimation rather than hypothesis testing. *British Medical Journal, 292*(15), 746-750.

Gerstein, D., Murphy, S., Toce, M., Hoffman, J., Palmer, A., Johnson, R., . . . Sinclair, S. (1999). Gambling impact and behavior study: Report to the National Gambling Impact Study Commission. Chicago: National Opinion Research Center, University of Chicago.

Gill, T., Dal Grande, E., & Taylor, A. (2006). Factors associated with gamblers: A population-based cross-sectional study of South Australian adults. *Journal of Gambling Studies, 22*(2), 143-164.

Gooding, P., & Tarrier, N. (2009). A systematic review and meta-analysis of cognitive-behavioural interventions to reduce problem gambling: Hedging our bets? *Behaviour Research and Therapy, 47*(7), 592-607.

Government of South Australia:Consumer and Business Services. (2012). Gaming Machines Act 1992, Annual Report 2011-2012

Graham, J. W. (2009). Missing data analysis: Making it work in the real world. *Annual Review of Psychology, 60*, 549–576.

Grant, A., Treweek, S., Dreischulte, T., Foy, R., & Guthrie, B. (2013). Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials, 14*(1), 15.

Grant, J., Donahue, C., Odlaug, B., Kim, S., Miller, M., & Petry, N. (2009). Imaginal desensitisation plus motivational interviewing for pathological gambling: Randomised controlled trial. *British Journal of Psychiatry, 195*(3), 266-267.

Grant, J., Kim, S., & Hartman, B. (2008). A double-blind, placebo-controlled study of the opiate antagonist naltrexone in the treatment of pathological gambling urges. *Journal of Clinical Psychiatry*.

Grant, J., Kim, S., & Odlaug, B. (2007). N-acetyl cysteine, a glutamate-modulating agent, in the treatment of pathological gambling: a pilot study. *Biological psychiatry, 62*(6), 652-657.

Grant, J., Kim, S., Potenza, M., Blanco, C., Ibanez, A., Stevens, L., . . . Zaninelli, R. (2003). Paroxetine treatment of pathological gambling: a multi-centre randomized controlled trial. *International Clinical Psychopharmacology, 18*(4), 243-249.

Greenland, S. (2006). Bayesian perspectives for epidemiological research: I. Foundations and basic methods. *International Journal of Epidemiology, 35*(3), 765-775.

Griffiths, M. (1999). Gambling technologies: Prospects for problem gambling. *Journal of Gambling Studies, 15*(3), 265-283.

Gueorguieva, R., & Krystal, J. H. (2004). Move Over ANOVA: Progress in Analyzing Repeated-Measures Data and Its Reflection in Papers Published in the Archives of General Psychiatry. *Archives of General Psychiatry, 61*(3), 310-317.

Guo, S., Manning, V., Thane, K. K. W., Ng, A., Abdin, E., & Wong, K. E. (2012). Predictors of Treatment Outcome Among Asian Pathological Gamblers (PGs): Clinical, Behavioural, Demographic, and Treatment Process Factors. *Journal of Gambling Studies, 30*.(1), 89-103.

Guo, Y., Logan, H. L., Glueck, D. H., & Muller, K. E. (2013). Selecting a sample size for studies with repeated measures. *BMC Medical Research Methodology, 13*(1), 100.

Hallstrom, A., & Davis, K. (1988). Imbalance in treatment assignments in stratified blocked randomization. *Controlled Clinical Trials, 9*(4), 375.

Hausman, J. A. (1978). Specification tests in econometrics. *Econometrica, 46*, 1251-1271.

Hawe, P., Shiell, A., Riley, T., & Gold, L. (2004). Methods for exploring implementation variation and local context within a cluster randomised community intervention trial. *Journal of Epidemiology and Community Health, 58*(9), 788-793.

Hembree, E. A., Foa, E. B., Dorfan, N. M., Street, G. P., Kowalski, J., & Tu, X. (2003). Do patients drop out prematurely from exposure therapy for PTSD? *Journal of Traumatic Stress, 16*(6), 555-562.

Hernan, M. A., & Hernandez-Diaz, S. (2012). Beyond the intention-to-treat in comparative effectiveness research. *Clinical Trials, 9*(1), 48-55. doi: 10.1177/1740774511420743

Hettema, J., Steele, J., & Miller, W. R. (2005). Motivational interviewing. *Annu. Rev. Clin. Psychol., 1*, 91-111.

Higgins, J., & Green, S. (2011). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]* Retrieved from www.cochrane-handbook.org.

Hodgins, D. (2009). Randomized trial of brief motivational treatments for pathological gamblers: More is not necessarily better. *Journal of Consulting and Clinical Psychology, 77*(5), 950.

Hodgins, D., Currie, S., & el-Guebaly, N. (2001). Motivational enhancement and self-help treatments for problem gambling. *Journal of Consulting and Clinical Psychology, 69*, 50 - 57.

Hodgins, D., Currie, S., el-Guebaly, N., & Peden, N. (2004). Brief motivational treatment for problem gambling: a 24-month follow-up. *Psychology of Addictive Behaviors, 18*, 293 - 296.

Hodgins, D., & el-Guebaly, N. (2010). The Influence of Substance Dependence and Mood Disorders on Outcome from Pathological Gambling: Five-Year Follow-Up. *Journal of Gambling Studies, 26*(1), 117-127. doi: 10.1007/s10899-009-9137-9

Hodgins, D., Stea, J., & Grant, J. (2011). Gambling disorders. *The Lancet, 378*(9806), 1874-1884. doi: 10.1016/s0140-6736(10)62185-x

Hopewell, S., Wolfenden, L., & Clarke, M. (2008). Reporting of adverse events in systematic reviews can be improved: survey results. *Journal of Clinical Epidemiology, 61*(6), 597.

Hsieh, H.-F., & Shannon, S. E. (2005). Three Approaches to Qualitative Content Analysis. *Qualitative Health Research, 15*(9), 1277-1288. doi: 10.1177/1049732305276687

Ibanez, A., Blanco, C., Donahue, E., Lesieur, H. R., Perez de Castro, I., Fernandez-Piqueras, J., & Saiz-Ruiz, J. (2001). Psychiatric Comorbidity in Pathological Gamblers Seeking Treatment. *American Journal of Psychiatry, 158*(10), 1733-1735. doi: 10.1176/appi.ajp.158.10.1733

Jacobson, N., & Truax, P. (1991). Clinical Significance: A Statistical Approach to Defining Meaningful Change in Psychotherapy Research. *Journal of Consulting & Clinical Psychology, 59*(1), 12-19.

Jakobsen, J. C., Hansen, J. L., Simonsen, S., Simonsen, E., & Gluud, C. (2012). Effects of cognitive therapy versus interpersonal psychotherapy in patients with major depressive disorder: a systematic review of randomized clinical trials with meta-analyses and trial sequential analyses. *Psychological Medicine, 1*(1), 1-15.

Johnson, S. R., Tomlinson, G. A., Hawker, G. A., Granton, J. T., & Feldman, B. M. (2010). Methods to elicit beliefs for Bayesian priors: a systematic review. *Journal of Clinical Epidemiology, 63*(4), 355-369.

Jones-Smith, J. C., Dow, W. H., & Chichlowska, K. (2014). Association between casino opening or expansion and risk of childhood overweight and obesity. *JAMA, 311*(9), 929-936. doi: 10.1001/jama.2014.604

Kohut, H. (1982). Introspection, empathy, and the semi-circle of mental health. *The International Journal of Psychoanalysis, 63*, 395-407.

Ladouceur, R. (2005). Controlled Gambling for Pathological Gamblers. *Journal of Gambling Studies, 21*(1), 49-57.

Ladouceur, R., & Lachance, S. (2007). *Overcoming Pathological Gambling: Therapist Guide*: Oxford University Press.

Ladouceur, R., Sylvain, C., Boutin, C., Lachance, S., Doucet, C., & Leblond, J. (2003). Group therapy for pathological gamblers: a cognitive approach. *Behaviour Research and Therapy, 41*(5), 587.

Ladouceur, R., Sylvain, C., Boutin, C., Lachance, S., Doucet, C., Leblond, J., & Jacques, C. (2001). Cognitive treatment of pathological gambling. *Journal of Nervous and Mental Disease, 189*, 774-780.

Ladouceur, R., Sylvain, C., Letarte, H., Giroux, I., & Jacques, C. (1998). Cognitive treatment of pathological gamblers. *Behaviour Research and Therapy, 36*(12), 1111-1119.

Laird, N., Lange, N., & Stram, D. (1987). Maximum likelihood computations with repeated measures: Application of the EM algorithm. *Journal of the American Statistical Association, 82*(397), 97-105.

Lantos, J. D., & Spertus, J. A. (2014). The Concept of Risk in Comparative-Effectiveness Research. *New England Journal of Medicine*. doi: 10.1056/NEJMhle1413301

Latimer, P. R., & Sweet, A. A. (1984). Cognitive versus behavioral procedures in cognitive-behavior therapy: A critical review of the evidence. *Journal of Behavior Therapy and Experimental Psychiatry, 15*(1), 9-22. doi: 10.1016/0005-7916(84)90116-2

Leblond, J., Ladouceur, R., & Blaszczynski, A. (2003). Which pathological gamblers will complete treatment? *British Journal of Clinical Psychology, 42*(2), 205-209.

Ledgerwood, D., & Petry, N. (2006). Psychological experience of gambling and subtypes of pathological gamblers. *Psychiatry Research, 144*(1), 17-27.

Lesieur, H. R., & Blume, S. B. (1987). The South Oaks Gambling Screen (SOGS): a new instrument for the identification of pathological gamblers. *Am J Psychiatry, 144*(9), 1184-1188.

Lin, S. A., Lyons, M. J., Scherrer, J. F., Griffith, K., True, W. R., Goldberg, J., & Tsuang, M. T. (1998). Familial influences on gambling behavior: an analysis of 3359 twin pairs. *Addiction, 93*(9), 1375-1384.

Lorains, F. K., Cowlishaw, S., & Thomas, S. A. (2011). Prevalence of comorbid disorders in problem and pathological gambling: systematic review and meta-analysis of population surveys. *Addiction, 106*(3), 490-498.

MacKinnon, D. (2008). *Introduction to statistical mediation analysis*. New York: Erlbaum/Psychology Press.

Marceaux, J. C., & Melville, C. L. (2011). Twelve-step facilitated versus mapping-enhanced cognitive-behavioral therapy for pathological gambling: A controlled study. *Journal of Gambling Studies, 27*(1), 171-190.

Matthey, S. (1998). p <.05 - But is it clinically significant? Practical examples for clinicians. *Behaviour Change, 15*(2), 140-146.

McConaghy, N., Armstrong, M., Blaszczynski, A., & Allcock, C. (1983). Controlled comparison of aversive therapy and imaginal desensitization in compulsive gambling. *British Journal of Psychiatry, 142*, 366-372.

McConaghy, N., Armstrong, M., Blaszczynski, A., & Allcock, C. (1988). Behavior Completion Versus Stimulus Control in Compulsive Gambling: Implications for

Behavioral Assessment. *Behavior Modification, 12*(3), 371-384. doi: 10.1177/01454455880123004

McConaghy, N., Blaszczynski, A., & Frankova, A. (1991). Comparison of imaginal desensitisation with other behavioural treatments of pathological gambling: A two- to nine-year follow-up. *British Journal of Psychiatry, 159*, 390-393.

McCormick, R. A. (1994). The importance of coping skill enhancement in the treatment of the pathological gambler. *Journal of Gambling Studies, 10*(1), 77-86.

McCormick, R. A., Russo, A. M., Ramirez, L. F., & Taber, J. I. (1984). Affective disorders among pathological gamblers seeking treatment. *The American Journal of Psychiatry, 141*(2), 215-218.

McKay, J. R., Franklin, T. R., Patapis, N., & Lynch, K. G. (2006). Conceptual, methodological, and analytical issues in the study of relapse. *Clinical Psychology Review, 26*(2), 109-127.

McMillen, J. (2005). *Gambling cultures: Studies in history and interpretation*: Routledge.

McMillen, J., & Wenzel, M. (2006). Measuring problem gambling: Assessment of three prevalence screens. *International Gambling Studies, 6*(2), 147-174.

Melbourne Monash Problem Gambling Research and Treatment Centre. (17 July 2013). Melbourne Monash Problem Gambling Research and Treatment Centre. Retrieved 21 November 2011, from http://www.med.monash.edu.au/assets/docs/sphc/pgrtc/guideline/problem-gambling-guidelines-web.pdf

Melville, C. L., Davis, C. S., Matzenbacher, D. L., & Clayborne, J. (2004). Node-link-mapping-enhanced group treatment for pathological gambling. *Addictive Behaviors, 29*(1), 73-87.

Melville, K. M., Casey, L. M., & Kavanagh, D. J. (2007). Psychological treatment dropout among pathological gamblers. *Clinical Psychology Review, 27*(8), 944-958.

Merry, S. N., Stasiak, K., Shepherd, M., Frampton, C., Fleming, T., & Lucassen, M. F. (2012). The effectiveness of SPARX, a computerised self help intervention for adolescents seeking help for depression: randomised controlled non-inferiority trial. *BMJ: British Medical Journal, 344*.

Miller, L., & Stewart, M. (2011). The blind leading the blind: Use and misuse of blinding in randomized controlled trials. *Contemporary Clinical Trials, 32*(2), 240-243.

Miller, W. (1983). Motivational interviewing with problem drinkers. *Behavioural Psychotherapy, 11*(02), 147-172.

Milton, S., Crino, R., Hunt, C., & Prosser, E. (2002). The effect of compliance-improving interventions on the cognitive-behavioral treatment of problem gambling. *Journal of Gambling Studies, 18*(2), 207-229.

Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gøtzsche, P. C., Devereaux, P. J., . . . Altman, D. G. (2010). CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *British Medical Journal, 340*, c869.

Moher, D., Schulz, K. F., & Altman, D. G. (2001). The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *BMC Medical Research Methodology, 1*(2).

Morefield, K., Walker, C., Smith, D., Harvey, P., Dunn, K., & Battersby, M. (2013). An Inpatient Treatment Program for People with Gambling Problems: Synopsis and Early Outcomes. *International journal of mental health and addiction*, 1-13.

Morton, S., Bandara, D. K., Robinson, E. M., & Carr, P. E. A. (2012). In the 21st Century, what is an acceptable response rate? *Australian and New Zealand Journal of Public Health, 36*(2), 106-108.

MRC Biostatistics Unit. (2014). Retrieved 30 November 2010, from http://www.mrc-bsu.cam.ac.uk/

Mullen, P. M. (2003). Delphi: Myths and reality. *Journal of Health Organization and Management, 17*(1), 37-52.

Mundt, J. C., Marks, I. M., Shear, M. K., & Greist, J. M. (2002). The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *British Journal of Psychiatry, 180*(5), 461-464.

Myrseth, H., Litlerè, I., Støylen, I. J., & Pallesen, S. (2009). A controlled study of the effect of cognitive-behavioural group therapy for pathological gamblers. *Nordic Journal of Psychiatry, 63*(1), 22-31.

Myrseth, H., Molde, H., Stoylen, I., Johnsen, B., Holsten, F., & Pallesen, S. (2011). A pilot study of CBT versus escitalopram combined with CBT in the treatment of pathological gamblers. *International Gambling Studies, 11*(1), 121-141.

National Research Council. (2010). 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

Nower, L. (2004). The Relationship of Impulsivity, Sensation Seeking, Coping, and Substance Use in Youth Gamblers. *Psychology of Addictive Behaviors, 18*(1), 49.

Oakes, J., Battersby, M., Pols, R., & Cromarty, P. (2008). Exposure therapy for problem gambling via videoconferencing: a case report. *Journal of Gambling Studies., 24*(1), 107-119.

Oakley, A., Strange, V., Bonell, C., Allen, E., Stephenson, J., & RIPPLE Study Team. (2006). Process evaluation in randomised controlled trials of complex interventions. *British Medical Journal, 332*(7538), 413-416.

Oei, T. P., & Raylu, N. (2004). Familial influence on offspring gambling: a cognitive mechanism for transmission of gambling behavior in families. *Psychological Medicine, 34*(07), 1279-1288.

Online gambling: "You bet". (2010). *The Economist*.

Oort, F. J. (2005). Using structural equation modeling to detect response shifts and true change. *Quality of Life Research, 14*(3), 587-598.

Öst, L.-G. (2008). Efficacy of the third wave of behavioral therapies: A systematic review and meta-analysis. *Behaviour Research and Therapy, 46*(3), 296-321.

Ougrin, D. (2011). Efficacy of exposure versus cognitive therapy in anxiety disorders: systematic review and meta-analysis. *BMC Psychiatry, 11*(1).

Pallanti, S., Quercioli, L., Sood, E., & Hollander, E. (2002). Lithium and valproate treatment of pathological gambling: a randomized single-blind study. *The Journal of clinical psychiatry, 63*(7), 559-564.

Pallesen, S., Mitsem, M., Kvale, G., Johnsen, B.-H., & Molde, H. (2005). Outcome of psychological treatments of pathological gambling: a review and meta-analysis. *Addiction, 100*(10), 1412-1422.

Pallesen, S., Molde, H., Arnestad, H. M., Laberg, J. C., Skutle, A., Iversen, E., . . . Holsten, F. (2007). Outcome of pharmacological treatments of pathological gambling: a review and meta-analysis. *Journal of clinical psychopharmacology, 27*(4), 357-364.

Paris, J. J., Franco, C., Sodano, R., Frye, C. A., & Wulfert, E. (2009). Gambling pathology is associated with dampened cortisol response among men and women. *Physiology & Behavior, 99*, 230-233.

Peduzzi, P., Kyriakides, T., O'Connor, T. Z., Guarino, P., Warren, S. R., & Huang, G. D. (2010). Methodological issues in comparative effectiveness research: clinical trials. *The American journal of medicine, 123*(12), e8.

Peters, S. A., Bots, M. L., Ruijter, H. M. d., Palmer, M. K., Grobbee, D. E., Crouse, J. R., . . . Moons, K. G. (2012). Multiple imputation of missing repeated outcome measurements did not add to linear mixed-effects models. *Journal of Clinical Epidemiology, 65* (6), 686-695.

Petry, N. (2005). *Pathological Gambling: Etiology, comorbidity and treatments*. Washington, DC: American Psychological Association.

Petry, N. (2009). Disordered Gambling and Its Treatment. *Cognitive and Behavioral Practice, 16*(4), 457-467.

Petry, N., Ammerman, Y., Bohl, J., Doersch, A., Gay, H., Kadden, R., & Molina, C. (2006). Cognitive-behavioral therapy for pathological gamblers. *Journal of Consulting and Clinical Psychology, 74*(3), 555-567.

Petry, N., Weinstock, J., Ledgerwood, D., & Morasco, B. (2008). A randomized trial of brief interventions for problem and pathological gamblers. *Journal of Consulting and Clinical Psychology, 76*(2), 318-328.

Petry, N., Weinstock, J., Morasco, B. J., & Ledgerwood, D. M. (2009). Brief motivational interventions for college student problem gamblers. *Addiction, 104*(9), 1569-1578.

Piaggio, G., Elbourne, D. R., Altman, D. G., Pocock, S. J., & Evans, S. J. (2006). Reporting of noninferiority and equivalence randomized trials. *JAMA: the journal of the American Medical Association, 295*(10), 1152-1160.

Piantadosi, S. (2005). *Clinical trials: a methodologic perspective*. New Jersey: John Wiley & Sons.

Plint, A., Moher, D., Morrison, A., Schulz, K., Altman, D., Hill, C., & Gaboury, I. (2006). Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. *Medical Journal of Australia, 185*(5), 263-267.

Potenza, M., Steinberg, M., Skudlarski, P., Fulbright, R., Lacadie, C., Wilber, M., . . . Wexler, B. (2003). Gambling urges in pathological gambling: a functional magnetic resonance imaging study. *Archives of General Psychiatry, 60*(8), 828.

Powell, A. C., Landman, A. B., & Bates, D. W. (2014). In search of a few good apps. *JAMA, 311*(18), 1851-1852.

Problem Gambling Research and Treatment Centre (PGRTC). (2011). Guideline for screening, assessment and treatment in problem gambling: Clayton:Monash University.

Rabe-Hesketh, S., & Skrondal, A. (2012). *Multilevel and longitudinal modelling using Stata* (Third ed.). College Station, Texas: Stata press.

Raylu, N., & Oei, T. (2004a). The Gambling Related Cognitions Scale (GRCS): development, confirmatory factor validation and psychometric properties. *Addiction, 99*(6), 757-769.

Raylu, N., & Oei, T. (2004b). The Gambling Urge Scale: Development, confirmatory factor validation, and psychometric properties. *Psychology of Addictive Behaviors, 18*(2), 100-105.

Reger, G. M., Hoffman, J., Riggs, D., Rothbaum, B. O., Ruzek, J., Holloway, K. M., & Kuhn, E. (2013). The "PE coach" smartphone application: An innovative approach to improving implementation, fidelity, and homework adherence during prolonged exposure. *Psychological Services, 10*(3), 342.

Reinert, D., & Allen, J. (2002). The Alcohol Use Disorders Identification Test (AUDIT): A review of recent research. *Alcoholism: Clinical and Experimental Research, 26*(2), 272-279.

Riley, B., Smith, D., & Oakes, J. (2011). Exposure therapy for pathological gambling in rural communities: a program model and early outcomes. *Australian Journal of Rural Health, 19*(3), 142-146.

Rosenthal, R. J., & Lesieur, H. R. (1992). Self-Reported Withdrawal Symptoms and Pathological Gambling. *The American Journal on Addictions, 1*(2), 150-154.

Rosenzweig, S. (1936). Some implicit common factors in diverse methods of psychotherapy. *American Journal of Orthopsychiatry, 6*(3), 412-415.

Roth, M. (2003). 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, 35*, 1307-1314.

Rychetnik, L., Frommer, M., Hawe, P., & Shiell, A. (2002). Criteria for evaluating evidence on public health interventions. *Journal of Epidemiology and Community Health, 56*(2), 119-127.

Sackett, D., Rosenberg, W., Gray, J., Haynes, R., & Richardson, S. (1996). Evidence based medicine: what it is and what it isn't. *BMJ (Clinical Research Ed.), 312*(7023), 71-72.

Schreiber, L., Odlaug, B. L., Won Kim, S., & Grant, J. E. (2009). Characteristics of pathological gamblers with a problem gambling parent. *The American Journal on Addictions, 18*(6), 462-469.

Shaffer, H. J., & Hall, M. N. (2001). Updating and refining prevalence estimates of disordered gambling behaviour in the United States and Canada. *Canadian Journal of Public Health, 92*(3), 168-172.

Sharpe, L. (2002). A reformulated cognitive–behavioral model of problem gambling: A biopsychosocial perspective. *Clinical Psychology Review, 22*(1), 1-25.

Sharpe, L., & Tarrier, N. (1992). A cognitive-behavioral treatment approach for problem gambling. *Journal of Cognitive Psychotherapy, 6*(3), 193-203.

Skrondal, A., & Rabe-Hesketh, S. (2003). Multilevel logistic regression for polytomous data and rankings. *Psychometrika, 68*(2), 267-287.

Slade, T., Grove, R., & Burgess, P. (2011). Kessler Psychological Distress Scale: normative data from the 2007 Australian National Survey of Mental Health and Wellbeing. *Australian and New Zealand Journal of Psychiatry, 45*, 308–316.

Slutske, W. S., Eisen, S., True, W. R., Lyons, M. J., Goldberg, J., & Tsuang, M. (2000). Common genetic vulnerability for pathological gambling and alcohol dependence in men. *Archives of General Psychiatry, 57*(7), 666-673.

Smith, D., Battersby, M., Harvey, P., Pols, R., Baigent, M., & Oakes, J. (2011). The influence of depression and other co-occurring conditions on treatment outcomes for problem gamblers: a cohort study. *The Medical Journal of Australia, 195* (3), S56-S59.

Smith, D., Battersby, M., Harvey, P., Pols, R., & Ladouceur, R. (2013). Two-group randomised, parallel trial of cognitive and exposure therapies for problem gambling: a research protocol. *BMJ Open, 3*(6).

Smith, D., Battersby, M., Pols, R., Harvey, P., Oakes, J., & Baigent, M. (2015). Predictors of Relapse in Problem Gambling: A Prospective Cohort Study. *Journal of Gambling Studies, 31*, 299-313. doi: 10.1007/s10899-013-9408-3

Smith, D., Dunn, K., Harvey, P., Battersby, M., & Pols, R. (2013). Assessing Randomised Clinical Trials of Cognitive and Exposure Therapies for Gambling Disorders: A Systematic Review. *Behaviour Change, 30*(03), 139-158.

Smith, D., Harvey, P., Battersby, M., Pols, R., Oakes, J., & Baigent, M. (2010). Treatment outcomes and predictors of drop out for problem gamblers in South Australia: a cohort study. *Australian and New Zealand Journal of Psychiatry, 44*, 911-920.

Smith, D., Pols, R., Battersby, M., & Harvey, P. (2013). The Gambling Urge Scale: Reliability and validity in a clinical population. *Addiction research & theory, 21*(2), 113-122.

Specker, S. M., Carlson, G. A., Edmonson, K. M., Johnson, P. E., & Marcotte, M. (1996). Psychopathology in pathological gamblers seeking treatment. *Journal of Gambling Studies, 12*(1), 67-81.

Sprangers, M. A., & Schwartz, C. E. (1999). Integrating response shift into health-related quality of life research: a theoretical model. *Social Science and Medicine, 48*(11), 1507-1515.

StataCorp. (2011). Stata: Release 12. Statistical Software. College Station, TX: StataCorp LP.

StataCorp. (2013a). Stata 13 Base Reference Manual. College Station, TX: Stata Press.

StataCorp. (2013b). Stata: Release 13. Statistical Software. College Station, TX: StataCorp LP.

Statewide Gambling Therapy Service. (2009). Annual Report 2008/2009 Adelaide, SA.

Sterne, J. A. C., White, I. R., Carlin, J. B., Spratt, M., Royston, P., Kenward, M. G., . . . Carpenter, J. R. (2009). Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ (Clinical Research Ed.), 338*(jun29_1), b2393-.

Stinchfield, R. (2002). Reliability, validity, and classification accuracy of the South Oaks Gambling Screen (SOGS). *Addictive Behaviors, 27*(1), 1-19.

Sylvain, C., Ladouceur, R., & Boisvert, J. M. (1997). Cognitive and behavioral treatment of pathological gambling: a controlled study. *Journal of Consulting & Clinical Psychology, 65*(5), 727-732.

Tamminga, C. A., & Nestler, E. J. (2006). Pathological gambling: focusing on the addiction, not the activity. *The American Journal of Psychiatry, 163*(2), 180.

Thompson, J. (2014). *Bayesian analysis with Stata*. College Station, Texas: Stata Press.

Tolchard, B., & Battersby, M. (2010). The Victorian Gambling Screen: reliability and validity in a clinical population *Journal of Gambling Studies, 26*, 623-638.

Tolchard, B., Thomas, L., & Battersby, M. (2006). Single-Session Exposure Therapy of Problem Gambling: A Single Case Experimental Design. *Behaviour Change, 23*(2), 148-155.

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care, 19*(6), 349-357.

Turner, N. E., Jain, U., Spence, W., & Zangeneh, M. (2008). Pathways to Pathological Gambling: Component Analysis of Variables Related to Pathological Gambling. *International Gambling Studies, 8*(3), 281-298. doi: 10.1080/14459790802405905

Twisk, J., de Boer, M., de Vente, W., & Heymans, M. (2013). Multiple imputation of missing values was not necessary before performing a longitudinal mixed-model analysis. *Journal of Clinical Epidemiology*.

Vandenberg, R. J., & Lance, C. E. (2000). A review and synthesis of the measurement invariance literature: Suggestions, practices, and recommendations for organizational research. *Organizational research methods, 3*(1), 4-70.

Volberg, R. A. (1994). The prevalence and demographics of pathological gamblers: implications for public health. *American Journal of Public Health, 84*(2), 237-241.

Volpicelli, J., Alterman, A., Hayashida, M., & O'Brien, C. (1992). Naltrexone in the treatment of alcohol dependence. *Archives of General Psychiatry, 49*(11), 876-880.

Walker, M., Toneatto, T., Potenza, M. N., Petry, N., Ladouceur, R., Hodgins, D. C., . . . Blaszczynski, A. (2006). A framework for reporting outcomes in problem gambling treatment research: the Banff, Alberta Consensus. *Addiction, 101*(4), 504-511.

Wampold, B. E., Mondin, G. W., Moody, M., Stich, F., Benson, K., & Ahn, H.-n. (1997). A meta-analysis of outcome studies comparing bona fide psychotherapies: Empiricially," all must have prizes". *Psychological Bulletin, 122*(3), 203.

Wardle, H., Sproston, K., Orford, J., Erens, B., Griffiths, M. D., Constantine, R., & Pigott, S. (2007). *The British Gambling Prevalence Survey*. London: The Stationery Office.

West, B., Welch, K., & Galecki, A. (2007). *Linear mixed models: A practical guide using statistical software*. Boca Raton: Chapman & Hall/CRC.

West, R. (2012). Trial protocols. *Addiction, 107*(9), 1544.

White, I., Horton, N., Carpenter, J., & Pocock, S. (2011). Strategy for intention to treat analysis in randomised trials with missing outcome data. *British Medical Journal (Clinical Research Edition), 342*.

White, I., Kalaitzaki, E., & Thompson, S. G. (2011). Allowing for missing outcome data and incomplete uptake of randomised interventions, with application to an Internet-based alcohol trial. *Statistics in Medicine, 30*(27), 3192-3207.

White, P., Goldsmith, K. A., Johnson, A. L., Potts, L., Walwyn, R., DeCesare, J. C., . . . Sharpe, M. (2011). Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *The Lancet, 377*(9768), 823-836.

Wolitzky-Taylor, K. B., Horowitz, J. D., Powers, M. B., & Telch, M. J. (2008). Psychological approaches in the treatment of specific phobias: A meta-analysis. *Clinical Psychology Review, 28*(6), 1021-1037.

Wong, I. L. K., & Ernest, M. T. S. (2003). Prevalence estimates of problem and pathological gambling in Hong Kong. *The American Journal of Psychiatry, 160*(7), 1353.

World Medical Association. (2013). Declaration of Helsinki, ethical principles for medical research involving human subjects. *64th WMA General Assembly, Fortaleza, Brazil*.

Young, J., & Beck, A. T. (1980). Cognitive Therapy Scale: Rating manual. *Unpublished manuscript, University of Pennsylvania, Philadelphia.*