



EFFECTIVENESS OF PROBLEM GAMBLING BRIEF TELEPHONE INTERVENTIONS: A RANDOMISED CONTROLLED TRIAL

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EXECUTIVE SUMMARY

Background

Problem gambling and wider gambling-related harms constitute a significant health and social issue. A variety of policies and services have been developed with the intent of preventing and reducing problem gambling and related harms. In New Zealand this includes, among other measures, a national gambling helpline and face-to-face counselling services. It is not known how effective these services are, generally or for particular client groups. The evidence base is weak, locally and internationally, a consequence of both the relatively small number of studies conducted and the poor quality of most of them including clinically heterogeneous and statistically underpowered studies. The present statistically powered study used internationally accepted methods and outcome measures and was designed to assess the effectiveness of three brief telephone interventions relative to standard gambling helpline treatment and each other. Two of these brief interventions had been examined previously in North American efficacy trials involving volunteers recruited via the mass media. They are among only three forms of psychological intervention that can be considered, on the basis of research to date, to be 'possibly efficacious' in the treatment of problem gambling. However, it was not known how readily these brief interventions could be integrated into the day-to-day operations of an existing service or how effective they are when delivered by communitybased practitioners and evaluated by researchers independent of the person or team that developed them.

Since two of the interventions had been evaluated previously in efficacy trials that included wait-list controls, a further objective of the present study was to see how helpline standard care outcomes compared with those from these treatments. This would provide an indication of the extent to which current helpline practice reduces gambling problems beyond what would occur if the clients had wanted but not received helpline engagement until a later time. Given that the helpline does not have a waiting list it would not be ethical to include a control group of this type in evaluating the service.

A number of studies in the gambling and wider addictions field have found that even very brief interventions can be effective in reducing problems though the sustainability of the intervention effects remain unclear. For this reason, one of the interventions included in the present study involved just a single motivational interview, to enable comparison with standard treatment and the other interventions that, while brief, were somewhat more intensive.

A further objective of the present study was to identify subgroups of clients who do better with different types and intensities of intervention. This is important in terms of matching clients to interventions that are more effective for them and developing stepped-care models that are cost-effective in reaching larger numbers of problem gamblers, including the majority who do not currently access care. Very little is known about this important topic in relation to problem gambling, in large part because clinical trials to date have not included sufficient numbers of participants to examine subgroup differences in treatment response. The present study was designed to be sufficiently large to address this issue.

Methodology

The study was designed as a single-site Randomised Controlled Trial (RCT). The inclusion criteria were: minimum age of 18 years; perception of having a gambling problem; and

willingness to read a short workbook (to ensure reading ability), have calls recorded, provide follow-up data on gambling, and provide the name of collateral/s. Present or past involvement in treatment or mutual help groups for gambling or other mental health problems was documented and did not preclude participation. Callers were excluded from the trial if they were considered by the counsellor to be actively psychotic, or they required immediate crisis or police intervention because they posed a serious risk to themselves or others.

Four hundred and sixty-two first-time helpline callers who met eligibility criteria were randomly assigned to four groups on a 1:1:1:1 ratio using a computer-generated block randomisation procedure. The block size was 20, allocating participants to one of the four treatment groups. Random assignment continued until there was a minimum of 110 participants in each group. The trial had 70% power to significantly detect a one-day difference in mean days gambled between treatment groups (after accounting for time changes), a \$20/day difference in dollars gambled between treatment groups and a quit or improved gambling rate difference of 0.13.

The treatments were: (1) Helpline standard care $(TAU)^1$, (2) Single motivational interview (MI), (3) Single motivational interview plus cognitive-behavioural self-help workbook (MI+W) and, (4) Single motivational interview plus workbook plus four follow-up motivational telephone interviews (MI+W+B). Callers could choose their own treatment goal (quit some or all forms of gambling, or control their gambling). The primary outcome measures were self-reports of days gambled, money lost gambling and treatment goal success. Secondary outcome measures included problem gambling severity, control over gambling, gambling impacts, psychiatric comorbidity, general psychological distress and quality of life. Initial assessments were conducted by helpline counsellors prior to participants receiving a randomly allocated intervention. Further information² was collected by research staff, blind to treatment allocation, within seven days after the telephone intervention and the primary and secondary outcome measures were generally repeated at three, six and 12 months post-intervention. Collateral information³, from one or more persons nominated by callers, was obtained at three and 12 months. Intention To Treat and Per Protocol analyses were used.

The primary hypotheses are:

- 1. All four groups will evidence significant reduction in gambling
- 2. The Motivational Interview (MI) group will show similar improvement to Helpline standard care (TAU)
- 3. The Motivational Interview plus Workbook group (MI+W) and the Motivational Interview plus Workbook plus Booster group (MI+W+B) will show greater improvement than the MI and TAU groups
- 4. The MI+W+B group will show greater improvement than the other three groups at the 12-month follow-up.

The trial was registered with the Australian New Zealand Clinical Trials Registry (registration number ACTRN12609000560291). The study was approved by the Multi-region Ethics Committee (reference number MEC/09/04/043, 3 June 2009).

¹ Brief screening, problem identification and referral to face-to-face problem gambling counselling services or other services and websites and/or suggestions for self-care. Motivational interviewing aspects were excluded.

² More detailed gambling/problem gambling history, the mood module of the Primary Care Evaluation of Mental Disorders, and the New Zealand Index of Socio-economic Deprivation for Individuals.

³ Collaterals were asked about the participant's involvement with gambling over the last month, and the confidence they had in the accuracy of their reports.

Results

All Helpline counsellors involved in the trial were successfully trained to reliably and consistently deliver motivational interviews, the standard helpline intervention and follow-up booster sessions. Following training, the new counselling approach and other trial procedures became integrated into the operations of the helpline service. The great majority of the 462 callers recruited into the trial (N = 451) received the applicable, randomised intervention, although only a minority of MI+W+B participants received all four booster sessions (N = 39, 34%). Overall trial retention was 81%, 74% and 64% at three-, six- and 12-months respectively, with participant retention varying slightly across the four interventions. Interview duration did not differ across the intervention groups and there was no significant differential loss to follow-up between the study groups or overall.

With respect to treatment outcome, participants in all four intervention groups evidenced statistically and clinically significant, sustained improvement on the three primary measures self-reports of days gambled, money lost gambling and treatment goal success). This applied when performance was time-averaged across the duration of the trial and when assessed at 12 months. Substantial improvement was also found for problem gambling severity and other measures including self-ratings of control over gambling, gambling impacts on work, social life, family and home and health, psychological distress, major and minor depression and quality of life. Little or no change was evident with respect to alcohol misuse and tobacco use.

As hypothesised, there were no significant outcome differences between the MI and TAU interventions. Contrary to expectation, participants in the more intensive MI+W and MI+W+B interventions did not have better outcomes on the primary outcome measures than those who received MI and TAU. Although there were no significant primary outcome differences between participants in each of the treatment groups overall, differences were found for a number of subgroups. Usually these differences were evident for only one or a In most cases MI+W+B participants had significantly better few outcome measures. outcomes than their counterparts receiving MI alone. MI participants with lower levels of belief in their success in achieving their treatment goal did worse on one outcome measure than those in TAU. In this case those in the more intensive MI+W+B condition had better outcomes than their MI counterparts. Participants who, at the baseline assessment, had more serious gambling problems or whose goal was to control/reduce their gambling rather than quit gambling had better outcomes in the MI+W+B group than in the TAU and MI groups. Similarly, participants in the MI+W+B group with higher levels of psychological disorder and lower alcohol misuse levels had better outcomes in relation to money lost gambling and/or having quit or improved control over gambling, compared with their counterparts in the MI group. The only finding related to ethnicity was that Maori in the MI+W+B group showed greater improvement in money lost gambling (i.e. lost less money on average) at the 12month assessment than Maori in the MI group.

Discussion

This study demonstrated that brief motivational and cognitive-behavioural interventions can be readily integrated into the everyday operations of an existing problem gambling helpline. Prior to the present study, efficacy had only been demonstrated in trials involving volunteers, recruited via advertising and conducted by research teams led by the person who developed these interventions. The present study demonstrated that these interventions are also effective, producing sustained statistically and clinically significant outcomes in people seeking help from an existing treatment service. Given the nature of both the setting and the study population it is likely that these brief interventions would perform well in other services that provide clinical assistance to problem gamblers. This may well extend to face-to-face and internet delivery services. TAU participants did as well as those in the two interventions (MI+W and MI+W+B) that had previously been shown to produce significantly better outcomes than wait-list controls. This suggests that standard helpline treatment would also perform well relative to wait-list controls. The finding that participants receiving a single motivational interview did as well as those receiving the more intensive TAU, MI+W and MI+W+B interventions regarding the primary outcome measures is consistent with a growing body of treatment literature in the gambling and wider addictions field that indicates that 'more' is not necessarily better than 'less'.

The study design did not allow determination of the various therapy components that contributed to the significant positive outcomes, across a range of gambling and other measures, or provide a clear indication of why similar outcomes were generally achieved in the four intervention groups. Identification of the major ingredients of effective gambling treatment remains an important object for further investigation. The finding that particular subgroups of participants, including those with different treatment goals and problem severity, did significantly better with some interventions than with others is of particular note. While further research and replication is required prior to reaching firm conclusions, the study provides an indication of client groups that may do significantly better with particular types and intensities of intervention. It is also possible that further differences in treatment response will be found over time, for participants overall in each of the treatments and/or for subgroups within these treatments. It is anticipated that a further follow-up assessment will be conducted to assess longer term impacts. The inclusion of cost-benefit analysis in future studies would assist in making decisions regarding the incorporation of these and other evidence-based interventions into existing services and their optimal application to different client groups.

1. BACKGROUND

Problem gambling is a significant public health issue, contributing to a broad spectrum of morbidity and harm to individuals, families and communities. Maori, Pacific people and populations in areas of high deprivation are disproportionately impacted. The Ministry of Health accords high priority to the prevention and reduction of gambling-related harm and funds intervention services including the gambling helpline and face-to-face counselling. It is not known how effective these services are, in general, or for particular groups. A weak evidence base internationally further impedes service improvement. Only three forms of psychological intervention (cognitive treatments, cognitive behavioural treatments, and brief motivational plus self-help interventions) can be considered 'possibly efficacious' (Ladouceur et al., 2001; Echeburua et al., 1996; Hodgins et al., 2001; Hodgins et al., 2004; Petry et al., 2006; Petry et al., 2008). The brief intervention approach involving a motivational interview and self-help workbook appears to produce outcomes comparable to more intensive therapies. However, none of these interventions has been demonstrated to be effective when conducted in every day clinical or community settings.

Reflecting on their examination of the gambling intervention literature, Westphal and Abbott (2006) concluded: "In sum gamblers respond to several possibly efficacious treatments ... with the majority benefiting, at least in the short term, when conducted by the original investigators. There is no evidence that the beneficial effects occur when the treatments are performed by other investigators or community based clinicians" (p.131). This is clearly a very serious shortcoming. These authors identified barriers to the development of evidence-based treatments including low sample size, heterogeneous samples, lack of protocol driven treatments, single site clinical trials, lack of replication of studies by independent investigators and high rates of non-specific treatment response. They examined other fields that have overcome many of these barriers by, among other things, developing close collaborations between treatment providers and investigators and conducting multi-site studies. The trial detailed in the present report was designed to address most of the forementioned deficiencies.

In addition to the foregoing limitations, the small sample size of studies and lack of outcome and effectiveness research means that little is known about individual characteristics associated with success in different treatments. This information would enable clients to be matched to particular interventions and treatment outcomes improved.

The reviews suggest that, for most problem gamblers, short-term and less intense ('minimal' or 'brief') interventions might be as effective as longer, more intensive therapies. Such approaches, typically including brief motivational interviews and/or self-help workbooks, have been shown to be effective with a variety of problems including alcohol and substance misuse. Meta-analyses comparing self-help workbooks and no treatment controls or therapist-directed interventions indicate that workbooks are more effective than no treatment controls and as effective as the same programmes administered by therapists (Gould & Clum, 1993). While it appears that workbooks are generally effective, it remains unclear which particular types of intervention are most beneficial to which type of individual (Babor, 1994). In the alcohol field, however, there are indications that brief interventions are particularly effective, and highly cost effective, for people with less serious forms of disorder (Bertholet et al., 2005).

The current trial progressed the evaluation of brief motivational interviews and self-help workbooks from efficacy testing with community volunteers to an assessment of effectiveness with a representative sample of problem gamblers who sought information and help for gambling from a telephone helpline. In addition to assessing the effectiveness of a 'probably efficacious' treatment in a real life clinical setting, the current trial assessed whether or not the addition of follow-up telephone booster sessions enhanced treatment outcomes, both generally and for particular client groups. The current trial also included a 'dismantling' component via the addition of a motivational interview only condition, to contribute to our understanding of how therapy works. From the previous Hodgins et al. randomised controlled trials (2001; 2004) it was not known whether it was the motivational interview or the combination of motivational interview and cognitive-behavioural workbook that was responsible for the treatment effect.

The current trial assessed whether or not the interview alone could produce results comparable to those of the original combination, as well as enable comparison of the motivational interview with the other treatment conditions. Petry and colleagues' (2008) findings suggest that 'more' is not necessarily 'better'.

The main purpose of the current trial was to examine the effectiveness of three 'experimental' brief telephone interventions relative to standard helpline treatment⁴ (the control group), and to compare their performance relative to each other. However, it also provided important information about client uptake, choice, nature of, and evaluation of currently available treatments. The control group for this trial is of particular note in this regard. Assessment of this group documented the nature of 'standard' care currently accessed by helpline callers during and following their initial helpline contact. This condition can be regarded as an uncontrolled outcome study (but not an efficacy or effectiveness study) in its own right.

The current study is a definitive randomised controlled trial involving four groups with repeated measures (pre-treatment, three months, six months and 12 months) enabling investigation of independent and some interaction effects of the different interventions.

The four groups are:

- Group 1: Helpline standard care (control group; 'Treatment as Usual')
- Group 2: Single brief motivational interview
- Group 3: Single brief motivational interview plus self-help workbook
- Group 4: Single brief motivational interview plus self-help workbook plus four follow-up motivational booster sessions.

The primary hypotheses were:

- 5. All four groups will evidence significant reduction in gambling
- 6. The Motivational Interview (MI) group will show similar improvement to Treatment as Usual (TAU)
- 7. The Motivational Interview plus Workbook group (MI+W) and the Motivational Interview plus Workbook plus Booster (MI+W+B) group will show greater improvement than the MI and TAU groups
- 8. The MI+W+B group will show greater improvement than the other three groups at the 12-month follow-up

In December 2008, the Gambling and Addictions Research Centre at Auckland University of Technology was commissioned by the Ministry of Health to conduct the research project *National problem gambling intervention effectiveness* which is reported in this document titled *Effectiveness of problem gambling brief telephone interventions: A randomised controlled trial.*

⁴ Includes brief screening, reflective listening to clients' concerns, referral to face-to-face problem gambling counselling services, and/or suggestions for self-care.

2. LITERATURE REVIEW

Gambling has been a major growth industry during the last 20 years. Increased availability of some forms of gambling, particularly electronic gaming machines (EGMs) and casino table games, have been associated with a rise in gambling-related problems. In a number of jurisdictions, 15% to 30% of regular EGM participants experience gambling problems (Abbott, 2006). Pathological gambling has long been included in psychiatric classification manuals (Abbott & Volberg, 2006). The public health significance of the wider spectrum of gambling-related harms experienced by individuals, families and communities has also received recognition with the Ministry of Health (2005, 2007a, 2010) developing policies and strategies to prevent and reduce gambling-related harms.

Approximately one to two percent of adult New Zealanders are estimated to be problem gamblers, with about twice as many experiencing less serious problems (Abbott & Volberg, 2000; Ministry of Health, 2006, 2009). The Ministry of Health estimates that the effects of problem gambling result in a loss of 3,300 to 10,600 years of 'quality of life' in this country per year, or \$330 million to \$1.06 billion per annum (Ministry of Health, 2004). Prevalence is particularly high for Maori and Pacific people (four to six times higher than for European/Pakeha). Other risk factors include being aged 25 to 34 years, residence in lower socio-economic areas, lower educational attainment, having paid employment and living alone.

General population and clinical studies indicate significant comorbidity, with elevated rates of numerous mental health and physical disorders (Abbott, Williams, & Volberg, 2004a; Petry & Weinstock, 2007). The 2006/07 New Zealand Health Survey found that when compared to people with no gambling problems, problem gamblers were 3.73 times more likely to be a current smoker and 5.20 times more likely to be engaging in hazardous drinking behaviour (Ministry of Health, 2009). The nature of relationships between gambling and comorbid behaviours and conditions (e.g. temporal sequence and causality) are not well understood since few prospective studies have been conducted (Abbott & Clarke, 2007). However, problematic alcohol consumption has been found to predict more persistent gambling problems (Abbott, Williams, & Volberg, 2004b; Hodgins & Holub, 2007).

Many other impacts have been identified including impaired quality of life for gamblers, suicide and financial, legal, family and social problems (Abbott, Volberg, Bellringer, & Reith, 2004; Grinols, 2007). The Australian Productivity Commission concluded that, on average, seven other people were affected by each problem gambler's behaviour and reported "enormous" family pressures with relationship breakdown and domestic violence (Productivity Commission, 1999). In addition to the financial costs borne by problem gamblers and their families, the Australian Productivity Commission estimated that each problem gambler costs society between A\$10,000 and A\$30,000 (Productivity Commission, 2010). Problem gamblers commit high rates of gambling-related crime. National prison surveys in New Zealand found 15% of male and 26% of female prisoners reported having committed a crime to gamble or pay gambling debts (Abbott & McKenna, 2005; Abbott, McKenna, & Giles, 2005).

From the foregoing it is evident that problem gambling is a significant health issue, both directly and through its negative impacts in various other domains. These impacts (harms) fall most heavily on Maori and Pacific people, and populations in high deprivation areas (Ministry of Health, 2006, 2008). Consequently, measures to prevent and reduce problem gambling are highly relevant to the goal of reducing health inequalities. Maintaining and

developing accessible, responsive and effective interventions is one of the objectives specified in the Ministry of Health's strategic plan to reduce gambling harm (Ministry of Health, 2010).

New Zealand was one of the first jurisdictions to introduce services for problem gamblers (from 1992 onwards). In 2009/10 the Ministry of Health allocated over \$11 million to intervention services (Ministry of Health, 2010). The gambling helpline had 2,122 new clients in 2011, of which 1,242 were problem gamblers and 600 were people affected by others' gambling (Gambling Helpline, 2012). Including brief interventions, the total number of gambling clients assisted face-to-face over a similar period (July 2010 to June 2011) was 7,594 (Ministry of Health, 2012). The gambling helpline provides information, screening, brief intervention, referral and follow-up services. Ministry 2007-2010 purchasing plans included further development of the gambling helpline and expansion of screening and early intervention in other settings including primary care (Ministry of Health, 2007a). New service specifications introduced in 2008 broadened the scope of intervention to include more brief and public health modalities as well as full intervention. The Ministry moved to a 24-hour helpline service in late 2008 which also began providing full intervention services, ensuring access for people in areas without face-to-face services and for people who prefer a telephone-based service (Ministry of Health, 2010).

Although substantial financial resources are allocated to problem gambling treatment in New Zealand, it is not yet known how effective these services are or whether or not comparable outcomes could be produced more effectively using different approaches. Internationally, a variety of interventions have been developed (Abbott, Volberg, et al., 2004; Hodgins & Holub, 2007). A meta-analysis of relevant studies concluded that, in general, psychological interventions for problem gamblers are associated with favourable outcomes compared with no treatment (Pallesen, Mitsem, Kvale, Johnsen, & Molde, 2005). However, a recent comprehensive review of psychological interventions, conducted by Australian researchers at the Problem Gambling Research and Treatment Centre, revealed large diversity in treatment strategies, mode of delivery, materials used, location, dose and practitioner involvement in treatment in the gambling field (Problem Gambling Research and Treatment Centre, 2011). The authors commented that to date, despite widespread agreement that one is needed, there is no standard taxonomy for describing the content of gambling interventions. In addition, the psychological treatment outcome literature tends to be heavily compromised by methodological limitations such as small sample size, high attrition and lack of intention to treat analyses (Problem Gambling Research and Treatment Centre, 2011). Failure to include comparative or control groups, randomly assign to treatment, or evaluate manualised interventions has contributed to the relatively weak evidence base in comparison to the substance addiction treatment fields. This recent review also shows little movement from the findings of earlier reviews (Abbott, Volberg, et al., 2004; Hodgins & Holub, 2007; Petry, 2005; Toneatto & Ladouceur, 2003; Toneatto & Millar, 2004; Westphal & Abbott, 2006) where it is evident that problem gambling treatment efficacy, effectiveness and outcome studies are limited.

Some interventions, however, correspond to the "possibly efficacious" category (Chambless & Ollendick, 2001) of at least one randomised controlled trial from one investigator group. Psychological therapies in this category include a cognitive treatment (Ladoucer, et al., 2001), cognitive behavioural treatments (Echeburúa, Báez, & Fernández-Montalvo, 1996; Gooding & Tarrier, 2009; Petry, et al., 2006) and brief motivational and self-help interventions (Hodgins, Currie, Currie, & Fick, 2009; Hodgins, Currie, & el-Guebaly, 2001; Hodgins, Currie, el-Guebaly, & Peden, 2004; Petry, Weinstock, Ledgerwood, & Morasco, 2008; Petry, Weinstock, Morasco, & Ledgerwood, 2009). While these and similar interventions are apparently being used in every day clinical settings, few have been evaluated in effectiveness

or benchmarking studies (controlled studies of efficacious treatment) and just one has been evaluated in a naturally occurring community treatment setting (Carlbring et al., 2010). There are also few outcome studies (uncontrolled reports of treatment characteristics, number of clients and client characteristics and outcomes).

Reflecting on their examination of the gambling intervention literature, Westphal and Abbott (2006) concluded: "In sum gamblers respond to several possibly efficacious treatments... with the majority benefitting, at least in the short term, when conducted by the original investigators. There is no evidence that the beneficial effects occur when the treatments are performed by other investigators or community based clinicians" (p.131). This is clearly a very serious shortcoming. To date, one study has examined the effectiveness of either motivational interviewing (MI) or cognitive behavioural group therapy (CBGT) with participants recruited and treated through an outpatient dependency clinic. Carlbring et al. (2010) found both face-to-face MI and CBGT produced significant within-group effects on problem gambling screening scores up to 12-month follow up. However, because wait-listed controls were treated prior to follow-up, between-group comparisons at the various time points were not possible.

A recent Cochrane review of psychological therapies for pathological and problem gambling examined 14 randomised controlled trials using CBT, motivational interviewing therapy, integrative therapy or other psychological therapy. The authors of the review concluded that CBT is efficacious in reducing problematic gambling behaviour and other related symptoms in the short-term with sustainability of treatment effects remaining unknown. They also noted that there was preliminary evidence for motivational interviewing therapy reducing gambling behaviour though there was less evidence for reduction in other problem gambling symptoms. The evidence was too scant to evaluate integrative and other psychological therapies (Cowlishaw, Merkouris, Dowling, Anderson, Jackson, & Thomas, 2012).

Barriers to the development of evidence-based treatments identified by Westphal and Abbott (2006) and Cowlishaw et al. (2012) remain including low sample size leading to low statistical power, heterogeneous samples, lack of protocol driven treatments, missing or skewed data, single site clinical trials, lack of replication of studies by independent investigators and high rates of non-specific treatment response. Westphal and Abbott (2006) examined other fields that have overcome many of these barriers by, among other things, developing close collaborations between treatment providers and investigators and conducting multi-site studies. In addition to the foregoing limitations, the small sample size of studies and lack of outcome and effectiveness research means that little is known about individual characteristics associated with success in different treatments. This information would enable clients to be matched to particular interventions and treatment outcomes improved.

The reviews suggest that, for most problem gamblers, short-term and less intense ('minimal' or 'brief') interventions might be as effective as longer, more intensive therapies. Such approaches, typically including brief motivational interviews and/or self-help workbooks, have been shown to be effective with a variety of problems including alcohol and substance misuse. Meta-analyses comparing self-help workbooks and therapist-directed interventions have suggested that workbooks are as effective as the same programmes administered by therapists (Gould & Clum, 1993). Conflicting results have been found in regard to comparison of workbook (mainly CBT-style) interventions with wait-list control, prompting recommendations for further Randomised Controlled Trials (RCT) of their effectiveness (Problem Gambling Research and Treatment Centre, 2011). While it appears that workbooks can be effective, it remains unclear which particular types of intervention are most beneficial to which type of individual (Babor, 1994). In the alcohol field, however, there are indications

that brief interventions are particularly effective, and highly cost effective, for people with less serious forms of disorder (Bertholet et al., 2005).

Brief motivational interviews and self-help tools are beginning to be examined specifically in the gambling field. Seven RCTs have been conducted looking at the effectiveness of brief motivational interviewing techniques. Three have found brief MI conducted face-to-face to be as effective as cognitive treatments (Carlbring, et al., 2010; Larimer, et al., 2012; Petry, et al., 2009) and two studies have involved telephone delivery of MI and the trial of a self-help workbook (Hodgins, et al., 2009; Hodgins, et al., 2001; Hodgins, et al., 2004). One RCT has examined the effectiveness of a particular brief self-help toolkit intervention in comparison to wait-list control (LaBrie, et al., 2012). One study compared single-session face-to-face MI with a control interview (Diskin & Hodgins, 2009).

Recent review of RCT research suggests that motivational interviewing is superior to wait-list control in reducing gambling behaviour (Problem Gambling Research and Treatment Centre, 2011). In our view the most promising application of brief interventions to problem gambling to date involves a short motivational telephone interview, followed by a self-help workbook (Hodgins, et al., 2001; Hodgins, et al., 2004). As indicated earlier, this is one of three psychological interventions that meet criteria for possible efficacy. Hodgins and colleagues (2001) compared this intervention with receipt of the workbook alone, and a wait-list control in a Randomised Controlled Trial. The interview in the efficacy study used motivational enhancement therapy principles directed towards building commitment to change. The workbook was based on a cognitive-behavioural model of problem gambling, relapse prevention and the findings of research on problem gambling recovery processes.

Participants who received a motivational telephone interview and workbook in the mail, but not those who received the workbook only, had significantly better outcomes at one-month follow-up than participants in the wait-list control. Participants in the combined motivational interview plus workbook group also gambled less frequently and spent less money gambling at three and six months than those who only received the workbook. At three months, 42% of the former group was abstinent compared with 19% of the latter. At six months their respective outcomes were 33% and 22%. While there was no overall difference at 12 months, motivational interview plus workbook participants with less severe gambling problems maintained a therapeutic advantage.

Hodgins and colleagues (2004) followed up 67 participants 24 months after they had completed the programme. While motivational interview plus workbook and workbook only participants did not differ with respect to abstinence rates during the preceding six months, those in the former group gambled less often, lost less money, had lower problem gambling scores and were more often rated as having improved. Overall, more than three-quarters of the total participants were rated as improved, over half scored below the cut-off for past year pathological gambling and over a third reported six months of abstinence.

The foregoing indicates that brief interventions involving no face-to-face contact can have clinically significant, enduring impact. Hodgins and colleagues (2001) recommended that future studies examine the impact of treatment on other areas such as psychological distress and family and social functioning. They also suggested that the addition of further motivational interviewing 'booster' sessions might enhance outcomes.

Across a variety of mental disorders, motivational interviewing has been shown to improve outcomes by enhancing treatment compliance (Arkowitz et al., 2007). A growing body of literature supports the value of specifically targeting motivation to change as part of brief interventions for gambling (Diskin & Hodgins, 2009; Hodgins, et al., 2004). A pilot study with pathological gamblers (Wulfert, Blanchard, Freidenberg, & Martell, 2006) found that treatment drop-out was significantly higher for treatment-as-usual than it was for a combined motivational interview-cognitive behaviour therapy intervention. This study did not assess whether or not greater compliance was associated with improved outcome. Diskin and Hodgins (2009) found that a single session motivational interview conducted face-to-face had larger impact on gambling outcomes than a non-motivational interview.

In contrast to the previous study, a recent trial of brief face-to-face interventions (Petry et al., 2008) did not find that a motivational interviewing component enhanced outcomes for problem gamblers recruited from substance abuse programmes and medical clinics. Furthermore, this study found that relative to participants who received assessment only (no treatment control), those who received 10 minutes of brief behavioural advice significantly decreased their gambling behaviour at a six-week follow-up. Additionally, participants in that group had clinically meaningful reductions in gambling at nine months. That study also examined some participant characteristics in relation to outcome. Participants with less severe gambling problems and fewer medical problems had better outcomes. Contrary to expectation, comorbid substance misuse/dependence and psychological distress did not influence outcome.

More recently, Hodgins (2009) compared a brief intervention (motivational interviewing plus self-help workbook), to brief intervention and additional MI 'booster sessions' delivered on six occasions over the follow-up period. This RCT included a six-week wait-list condition and a workbook-only condition. As hypothesised by the authors, the brief intervention and brief intervention with booster treatment participants reported less gambling at six weeks than those assigned to the control groups. Intervention and intervention plus booster treatment participants gambled significantly less often over the first six months of the follow-up than workbook only participants. However, the workbook only participants were as likely to have significantly reduced their losses over the year and to have not met criteria for pathological gambling. Contrary to the hypothesis, participants in the brief booster treatment group showed no greater improvement than brief treatment participants.

The foregoing studies raise interesting and important questions about the optimal length, format and content of brief interventions. They also raise questions about which groups respond best to which form or mix of interventions. It is unclear whether or not the addition of follow-up booster sessions can enhance treatment outcomes, both generally and for particular client groups.

This review highlights the need for definitive Randomised Controlled Trials that evaluate the effectiveness of a well-developed and documented brief intervention for problem gambling (Hodgins et al., 2001; 2004) and modifications to it with representative samples of problem gamblers who seek information and help for gambling. Boosters may increase workbook use and application and lead to improved outcomes, particularly at 12 months follow-up. It is also possible that clients with more serious problems will do better in this condition.

From the previous Hodgins et al. (2001; 2004; 2009) RCTs it remains unclear whether it was the motivational interview or the combination of motivational interview and cognitivebehavioural workbook that was responsible for the treatment effect. Petry and colleagues' (2008) and Hodgins and colleagues' (2009) findings suggest that 'more' is not necessarily 'better'. A recent study of patients in a hospital trauma centre with alcohol problems supports assessing the value of motivational interview alone (Apodaca, Miller, Schermer, & Amrhein, 2007). While compromised by small sample size, that study found similar reductions in drinking and related problems following brief assessment/interview and brief assessment/ interview that is the most important ingredient. If so, efficiencies would be made through removing unnecessary intervention components (i.e. workbook, workbook plus booster follow-up calls), at least for some clients.

Currently it is not known whether interventions provided in this country for problem gamblers do better than natural or self-recovery, or non-specific 'placebo' effects associated with seeking help and being assessed. Evaluating the effectiveness of a probably efficacious intervention and extensions of it in a clinical setting will contribute to the understanding of current gambling treatment provision in New Zealand while addressing a number of deficiencies identified in the literature and enabling more robust conclusions to be reached regarding treatment effectiveness in various populations.

3. RESEARCH METHODOLOGY

3.1 Ethics approval

The trial proposal was submitted to the Multi-Region Health and Disability Ethics Committee which is a Health Research Council accredited human ethics committee. All participant materials (i.e. survey questionnaires, information sheets and consent forms) and other relevant documents were submitted to the Committee, which considers the ethical implications of proposals for research projects with humans where participants are asked questions in relation to their health.

The ethics approval for the trial was granted on 3 June 2009 (Appendix 1). The Ethics Committee was kept apprised of any changes to the trial at the study progressed.

During the research the following measures were taken to protect the identity of the participants:

- All participants were allocated a code by the research team to protect their identities
- No personal identifying information has been reported.

In addition:

• Participants were informed that participation in the research was voluntary and that they could withdraw at any time, prior to data reporting.

3.2 Trial design

This was a single-site Randomised Controlled Trial (RCT) with gambler callers to the gambling helpline randomly assigned to one of four parallel groups in a 1:1:1:1 ratio:

- Group 1: Helpline standard care (control group; 'Treatment as Usual' (TAU))
- Group 2: Single brief motivational interview (MI)
- Group 3: Single brief motivational interview plus self-help workbook (MI+W)
- Group 4: Single brief motivational interview plus self-help workbook plus four follow-up motivational booster sessions (MI+W+B).

Participants were randomly assigned (computer generated) to the four groups until each group contained a minimum of 110 participants (described in more detail in section 3.7).

3.3 Participants

3.3.1 Eligibility criteria

Participants were recruited from callers to the gambling helpline who sought information or assistance for their own gambling problem.

The inclusion criteria were:

- Minimum age of 18 years
- Perception of having a gambling problem
- Willingness to:

- Read a short workbook (to ensure reading ability)
- Have calls recorded
- Provide follow-up data on gambling
- Provide the name of collateral/s.

Present or past involvement in treatment or mutual help groups for gambling or other mental health problems was documented and did not preclude participation.

Callers were excluded from the trial if:

- They were considered by the counsellor to be actively psychotic
- They required immediate crisis or police intervention because they posed a serious risk to themselves or others.

3.3.2 Setting and location

The study took place at the gambling helpline, Auckland, New Zealand in that the interventions were delivered by trained gambling helpline counsellors. As the interventions were delivered by telephone, participants were based throughout New Zealand. Recruitment and delivery of interventions occurred from August 2009 to February 2011.

Follow-up assessment calls were made by telephone by trained university research assistants from the North Shore Campus of Auckland University of Technology (AUT), Auckland, New Zealand. Research assistants were blind to participants' treatment group.

3.4 Interventions

All callers to the helpline initially received brief non-directive counselling to identify presenting concern/s and establish rapport. If the caller met eligibility criteria they were asked if they would like to participate in the study. Immediately after consenting to take part in the study, participants underwent an initial baseline assessment (detailed in section 3.5) and then received their randomly allocated intervention which was delivered by telephone by a trained gambling helpline counsellor.

The counsellors were trained to deliver all four interventions, removing potential contamination of the RCT design by therapist effects. The training included practice in introducing the project, recruitment of participants, the initial assessment questions, treatment option selection and delivery, and booster session delivery. The training also incorporated how to use the protocol developed to facilitate consistency and integrity in the delivery of the standard care interview (TAU) and specific motivational interviewing training. All training included pilot interviews with volunteers that were digitally recorded and assessed for compliance and consistency by Dr Sean Sullivan and Professor David Hodgins, both of whom are very experienced in use of motivational interviewing techniques with problem gamblers. The training included additional ad hoc sessions, particularly at the beginning of the trial, to address any issues; this was an opportunity for counsellors to air any difficulties or to state their confidence in the trial to others.

Dr Sullivan also trained the AUT researchers who conducted the follow-up assessments. The training included identification of risk level of participants and how to safely intervene when participants expressed symptoms of risk or suicidal ideation.

3.4.1 Group 1: Helpline standard care (TAU)

Group 1 participants received a protocolled version of the helpline's standard care. This included brief screening, listening to clients' concerns (problem identification) and, in the instance of first time callers or regular callers who were experiencing persistent difficulties, referral to face-to-face problem gambling counselling services or other services and websites and/or suggestions for self-care (e.g. controlling access to money, coping with gambling urges, alternative activities to gambling, and goals around saving money). No motivational interviewing aspects were included to differentiate this intervention from the three trial interventions (Groups 2, 3 and 4)⁵. The protocol was developed with staff to ensure it was functional and similar to their normal practice. Additionally, participants were offered an information pack (relevant information pamphlets, for example detailing venue self-exclusion processes, or budgeting advice). In this respect it is similar to one of the control conditions in the original Hodgins et al. (2001; 2004) efficacy study.

3.4.2 Group 2: Single brief motivational interview (MI)

Group 2 participants received a brief motivational interview, as used in the Hodgins et al. (2001; 2004) study. The interview was structured to encourage the client to build a commitment to change by emphasising the reasons why change is desirable. This approach was shaped by five therapeutic guidelines, namely: (1) expression of empathy (acceptance of individual and recognition that ambivalence about change is normal), (2) development of a discrepancy between the individuals' present behaviour and their goals and self-image, (3) avoidance of argumentation and confrontation, (4) rolling with resistance (looking for opportunities to reinforce accurate perceptions versus correcting misperceptions), and (5) support of self-efficacy. Interviews ended with a summary of participants' stated reasons for changing and specific therapeutic goals.

3.4.3 Group 3: MI plus self-help workbook (MI+W)

Group 3 participants received a brief motivational interview, as for Group 2, combined with the use of a workbook. Within 24 hours of the initial interview, participants were mailed a self-help workbook⁶ adapted from the Hodgins et al. (2001; 2004) study, along with a written summary of the clients' stated reasons for changing and their specific goals. Changes to the original workbook were minimal, reflecting differences in phrasing and common word usage between Canada and New Zealand.

3.4.4 Group 4: MI+W plus four follow-up motivational booster sessions (MI+W+B)

Group 4 participants received the same intervention as Group 3 and also received four followup motivational booster sessions of 10 to 15 minutes duration at one week after the initial interview and at one, three and six months. These booster sessions focused on motivation of, and reinforcement for, behaviour change through the use of the workbook. At each session, progress was reviewed, motivation and commitment renewed, and new short-term goals

⁵ To further differentiate this intervention from the three trial interventions, counsellors specifically did <u>not</u> do any of the following with participants: send the Gambling Helpline workbook (which was similar to the trial workbook); provide gambling screen feedback; ask about behaviour changes; ask about commitment, motivation, confidence or likelihood of success; or offer additional telephone calls. ⁶ Becoming a Winner: Defeating Problem Gambling.

developed. If a participant could not be contacted for a particular booster session, that session was missed and the next attempt at contact was at the next scheduled booster session.

3.4.5 Treatment integrity and fidelity

To assess how well the counsellors delivered each intervention and to ensure that there was no cross-contamination between interventions (i.e. to assess treatment integrity and fidelity). particularly between the Group 1 standard care (TAU) (which had no motivational interviewing elements) and the three treatment groups (which were based on motivational interviewing techniques), approximately 20% of telephone calls (including intervention delivery) with participants were randomly digitally recorded. The recordings were subsequently (usually within one month) listened to by Dr Sean Sullivan who is an experienced psychologist with substantial knowledge of motivational interviewing techniques. The recordings were coded based on the Motivational Interviewing Treatment Integrity (MITI) scale (Movers, Martin, Manuel, Hendrickson, & Miller, 2004) and tailored for this trial to assess for shared processes between the TAU and other interventions, for motivational interviewing aspects, and for TAU specific aspects. Following assessment of the recordings, personal feedback and, where required, additional training was provided to counsellors by Dr Sullivan. Approximately 33% of the recordings was also assessed by Professor David Hodgins in order to assess reliability of the first assessment of the recordings.

Assessment of the recordings was based on three categories: Motivational interviewing elements (eight or nine elements), TAU only elements (eight elements), and elements shared across the treatment and control (TAU) interventions (five elements).

The motivational interviewing elements included:

- Reflective listening
- Potential benefits of not gambling
- Affirmation
- Offer feedback around Problem Gambling Severity Index score
- Summarise concerns, motivations
- Ask for commitment
- Rating of commitment and/or success
- Connect with workbook (MI+W and MI+W+B groups only)
- Ask about other change attempts (e.g., smoking).

TAU only elements included:

- Soft/hard referral to face-to-face service
- Information regarding other helplines/websites
- Offer of postal 'information pack'
- Discussion of options for controlling access to money
- Discussion of options for coping with urge to gamble
- Discussion of options for keeping busy with alternative activities
- Advice to set saving goal
- Advice in other area (unspecified).

Shared elements included:

- Reasons for contacting gambling helpline/concerns about gambling
- Financial concerns

- Relationship problems
- Emotional difficulties
- Legal problems.

3.5 Outcome measures

Primary outcome measures were self-reports of:

- Days gambled
- Money lost gambling
- Treatment goal success.

Secondary outcome measures included control over gambling, gambling impacts, problem gambling severity, psychiatric comorbidity and substance use, tobacco and psychotropic medication use, general psychological distress and quality of life.

Collateral assessment (at three months and one year) from people nominated by participants included participant's gambling over the past month, observed changes and confidence in accuracy of their (collateral) reports.

3.5.1 Initial assessment

The initial assessment was conducted with the participant by a helpline counsellor prior to the participant receiving a randomly allocated intervention. Due to the length of the initial assessment, some of the baseline initial assessment was conducted by an AUT researcher within seven days of a participant receiving the intervention. This is detailed at the end of this section.

Gambling/problem gambling history, impacts and past help-seeking

A brief gambling history was obtained including length of gambling problem; type/s of gambling causing problems; number, nature and outcomes of past attempts to quit or reduce gambling; and past treatment and mutual help involvement. The impacts of gambling on financial status, employment, family and other relationships, criminal offending and general health (adapted from Abbott & Volberg, 1992; Abbott, 2001b) were also assessed.

Problem gambling

The nine-item Problem Gambling Severity Index (PGSI) (Ferris & Wynne, 2001) was used to measure severity of gambling problems. It was administered in both a past 12-month and a past three-month time frame (reported as PGSI-12 and PGSI-3, respectively). The two-item Lie-Bet screen was also administered to assess problem or non-problem status (Johnson et al., 1997). Both the PGSI and the Lie-Bet screen have been validated against clinician-derived DSM-IV pathological gambling diagnoses and other problem gambling measures including the widely used South Oaks Gambling Screen/South Oaks Gambling Screen-Revised (SOGS/SOGS-R) (Abbott & Volberg, 2006).

Comorbidity and substance use

A brief version (10-item scale) of the Drug Abuse Screening Test (DAST; Skinner, 1982) was administered to assess drug abuse. The DAST has very good internal reliability in samples of substance abusers and psychiatric patients and correlates strongly with a number of drug use measures (Cocco & Carey, 1998).

To identify hazardous alcohol consumption or active alcohol use disorders (including alcohol abuse or dependence) a brief version (AUDIT-C, three-item scale) of the Alcohol Use Disorders Identification Test (AUDIT; Saunders et al., 1993) was administered. In a review of research using the AUDIT and shortened versions, the AUDIT-C was reported as showing promise in being time-efficient and accurate when compared with full AUDIT results (Reinert & Allen, 2002).

Participants were also asked about lifetime and current tobacco use and any previous success at quitting a problematic behaviour (i.e. smoking, alcohol, other drugs and other behaviour).

The Kessler-10 (K-10) questionnaire was included to provide a continuous measure of general psychological distress that is responsive to change over time. The K-10 has been well validated internationally. Its brevity and simple response format are attractive features. It also produces a summary measure indicating probability of currently experiencing an anxiety or depressive disorder (Kessler & Mroczek, 1994).

Quality of life

Quality of life was assessed by the WHOQoL-8, an eight item version of a widely used measure. This short form has been used in a number of countries, is robust psychometrically, and overall performance is strongly correlated with scores from the original WHOQoL instrument (Schmidt, Muhlan & Power, 2005).

Treatment goal

Participants were asked whether their goal was to stop all forms of gambling, stop only problematic forms of gambling, or to reduce their gambling.

Self-efficacy

A simple rating was employed to assess belief in likelihood of a participant achieving their treatment goal (0 "not at all confident" to 10 "extremely confident") in the next six months.

Motivation and perceived control over gambling

Treatment goal motivation was measured on the same 0 to 10-point scale ("not at all" to "extremely"). Participant-rated sense of control over gambling was assessed using a similar 0 to 10-point scale ("no control" to "total control").

Socio-demographics

Age, gender, ethnicity, marital status, highest educational level, employment status and area of residence data were collected.

Within seven days of the initial assessment and delivery of the intervention, an AUT researcher asked some follow-up baseline questions of each participant. These included:

Gambling/problem gambling history

A detailed timeline of types of gambling, frequency and money spent gambling over the past two months was administered (based on Sobell & Sobell, 1992). Participants were provided with memory cues such as recent holidays and news events to facilitate retrieval of this information.

Comorbidity and substance use

The mood module of the Primary Care Evaluation of Mental Disorders (PRIME-MD, Spitzer et al., 1994) was administered to provide diagnoses of major depressive disorder, dysthymia, minor depressive disorder, and alcohol abuse/dependence. This is a structured interview designed for primary care clinicians and researchers to diagnose these and other current DSM-IV mental health disorders. It has been validated against the Structured Clinical Interview for the DSM-IV (Spitzer et al., 1992) and has been administered by telephone and shown to yield valid diagnoses (Spitzer et al., 1994; Kobak et al., 1997). The use of psychotropic medication and history of manic episodes was assessed using questions modified from the Gambling Impact Study (Gerstein et al., 1999).

Socio-demographics

The eight-item New Zealand Index of Socio-economic Deprivation for Individuals (Salmond, 2005) was administered.

3.5.2 Follow-up assessments

Participants were contacted by an AUT researcher to complete a follow-up assessment at three, six and 12 months post-intervention. At each follow-up assessment, a timeline follow-back interview was conducted to capture the number of days gambling during the follow-up period and the amount of money lost on each occasion. Participants were asked whether they had met their goal ('not at all', 'partially', 'mostly', 'completely') and what their present goal and personal sense of control over their gambling were (0 'no control' to 10 'total control'). Participants were also asked whether they had received the 'Becoming a Winner' workbook and if so, whether they had read it ('not at all', 'some sections', 'completely'), whether they had followed the procedures ('not at all', 'to some extent', 'completely'), and whether they had used the strategies ('not at all', 'occasionally', 'regularly'). They were asked what they had found to be most and least helpful from: (a) the initial interview, and (b) the workbook, in reaching their goal during the follow-up period, and why.

At each assessment, participants were asked what other treatment or help, if any, they received for their problem gambling during the follow-up period. These forms of treatment/ help were listed and, for each, they were asked how often the treatment or help was obtained (number of occasions) and how helpful it was in reaching their goal ('not at all', 'partially', 'mostly', 'completely'). At the three- six- and 12-month assessments, in addition to the previously mentioned assessments, the current tobacco use, gambling impacts, AUDIT-C, K-10 and WHOQol-8 were re-administered. At the 12-month assessment point, participants were also re-administered the DAST and PRIME-MD mood module as well as being asked to reflect on their overall experience during the past 12 months in seeking and receiving help for gambling and making changes in their lives. They were also asked about the cultural appropriateness of the help they received (linked to source/type of help) and, if inappropriate, what could be changed to make it more appropriate. They were invited to comment on other changes that could make help more accessible, appropriate and effective.

3.5.3 Collateral assessments

After the three-month assessment, and again at 12 months, at least one collateral person per participant (where details for collateral participants had been provided by the trial participants) were contacted by telephone and asked about the participant's involvement with

gambling over the last month. They were also asked how confident they were about the accuracy of their reports ('not at all', 'somewhat', 'fairly', 'extremely').

3.6 Sample size

A power of \geq 80% in finding a primary hypothesised effect is considered acceptable in most well-designed clinical studies, and this level of power was taken as the minimum for the current trial. Based on Hodgins and colleagues similar Canadian study (Hodgins et al., 2001; 2004) it was expected that 8.6%, 11.1% and 15.0% baseline participants would attrite from the study at the three-month, six-month and 12-month assessment points, respectively.

Exploiting the longitudinal design (with baseline and three follow-up measurements), and information for the MI+W treatment group reported by Hodgins and colleagues for the three primary outcome variables, a significance level of 5%, power of 80%, and the sample size calculations described by Twisk (2003), a total sample size of 110 per treatment group with attrition occurring as described above has a time-averaged minimal detectable difference between treatment groups as tabulated below. This implies that the study has 80% power to significantly detect a one-day difference in mean days gambled between treatment groups (after accounting for time changes), a \$20/day difference in dollars gambled between treatment groups and a quit or improved gambling rate difference of 0.13. These are meaningful minimal detectable differences allowing the primary hypotheses to be investigated with acceptable power.

| | Mean baseline | Average | Intra-participant | Minimal |
|--------------------------------|---------------|---------------------------|-------------------|------------|
| | score | $rac{(\sigma^2)}{\sigma}$ | conclation | difference |
| Duin and in the office and the | | 0(0) | μ | unterence |
| Primary variable of interest | | | | |
| Days gambled | 10.2 | 4.9 (24.0) | 0.25 | 1 day |
| Dollars/gambling day | 158 | 96 (9,216) | 0.25 | \$20/day |
| | Proportion in | | | Minimal |
| | control group | | | detectable |
| | 0 1 | | | difference |
| Gambling -Quit or improved* | 0.74 | | | 0.13 |

* By definition there were no 'quit or improved' outcomes at baseline. Changes were only assessed in the follow-up component of the study.

3.7 Randomisation

To allocate participants to intervention groups, a computer-generated block randomisation procedure was used. The block size was 20, allocating participants to one of the four treatment groups in a 1:1:1:1 ratio. Thus, five of every 20 callers were allocated to each of the four groups. No stratification procedure was used due to the large number of criteria on which to stratify. Once a minimum of 110 participants had been recruited to each of the four groups, the randomisation procedure was terminated.

The computer programme for treatment allocation was written by an independent computer specialist. Treatment allocation was concealed from counsellors until they activated the programme, after the initial assessment and immediately prior to intervention delivery.

3.8 Blinding

Counsellors were aware of allocated interventions as they had to deliver the interventions to the participants. AUT research assistants conducting the follow-up assessments were kept blinded to the allocations; the blinding was only broken at the end of the trial for data analyses.

3.9 Trial hypotheses and statistical methods

3.9.1 Study hypotheses

Study hypotheses are briefly described in this section. They are fully described together with statistical notation in Appendix 2.

Efficacy hypotheses

Primary equivalence hypothesis

A. The Motivational Interview (MI) group will show similar improvement to Treatment as Usual (TAU).

Primary superiority hypotheses

- B. (Superiority is associated to lower values in the generic hypothesis statements below)
 - a. The Motivational Interview plus Workbook group (MI+W) will show greater improvement than the TAU group.
 - b. The Motivational Interview plus Workbook group (MI+W) will show greater improvement than the MI group.
 - c. The Motivational Interview plus Workbook plus Booster group (MI+W+B) will show greater improvement than the TAU group.
 - d. The Motivational Interview plus Workbook plus Booster group (MI+W+B) will show greater improvement than the MI group.
- C. (Superiority is associated to lower values in the hypothesis statements below)
 - a. The MI+W+B group will show greater improvement than the TAU group at the 12-month follow-up.
 - b. The MI+W+B group will show greater improvement than the MI group at the 12-month follow-up.
 - c. The MI+W+B group will show greater improvement than the MI+W group at the 12-month follow-up.

Secondary efficacy hypotheses

- C*. (Superiority is associated to lower values in the hypothesis statements below)
 - d. The MI+W+B group will show greater improvement than the TAU group between three and 12 months.
 - e. The MI+W+B group will show greater improvement than the MI group between three and 12 months.
 - f. The MI+W+B group will show greater improvement than the MI+W group between three and 12 months.
- D. (Superiority is associated to lower values in the generic hypothesis statements below)a. The TAU group will evince significant reduction in gambling.

- b. The MI group will evince significant reduction in gambling.
- c. The MI+W group will evince significant reduction in gambling.
- d. The MI+W+B group will evince significant reduction in gambling.

E.

(Superiority is associated to lower values in the generic hypothesis statement below) High levels of engagement within conditions will be associated with better gambling outcomes (gambling participation, attainment of goal and sense of control over gambling).

Engagement secondary hypotheses

F.

(Superiority is associated to higher values in the generic hypothesis statements below)

- a. The highest level of engagement will be in the 'booster' condition (MI+W+B), followed by the non-'booster' experimental condition (MI+W).
- b. The level of engagement will be higher in the non-'booster' experimental condition (MI+W) then in the standard treatment group (TAU).

G.

(Superiority is associated to higher values in the generic hypothesis statements below) Use of, and degree of, engagement in other treatment services will be significantly lower in the two conditions involving motivational interviewing and workbooks (MI+W; MI+W+B) than in the standard (TAU) and motivational interview (MI) groups. This difference is expected to be greatest during the first three months.

3.9.2 Study endpoints

Efficacy endpoints

The primary efficacy endpoints are the primary efficacy outcomes (self-reported average monthly numbers of days gambled, average monthly amount of money lost and Gamblingquit or improved indicator), time-averaged over the three assessment points. In the case of the number of days gambled in one month and amount of money spent gambling in one month, these endpoints correspond to an annual average of monthly values over the 12 months post-randomisation. The Gambling-quit or improved indicator is defined as 1 if either the average number of days in the previous three months of follow-back is zero (quit) or the average amount of money spent in the previous three months of follow-back is less than half the declared 12-month average at baseline. It has value zero otherwise. The time-averaged Gambling-quit or improved is thus a value between 0 and 1 inclusively.

Secondary efficacy endpoints consist of the primary outcomes at the individual assessment time points, as well as the endpoints listed in the Summary table of analyses (Appendix 3).

Engagement endpoints

The trial introduces engagement endpoints. The engagement endpoints are the time-averaged versions of the workbook usage variables in the relevant treatment groups, and the endpoints listed in the Summary table of analyses (Appendix 3).

Safety and tolerability endpoints

None.

3.9.3 Analysis sets

The Intention to Treat (ITT) and Per Protocol (PP) analysis sets are defined for analysis of efficacy data. The Workbook Engagement (WE) set is defined for the analysis of some engagement outcomes.

If a participant was randomised but not treated, or randomised but did not complete the treatment schedule, then she or he was included in both the efficacy and workbook analysis sets to the extent that she or he did provide data (as clarified below).

Intention to Treat

The primary analysis set of interest will be the Intention to Treat (ITT) set, which consists of all randomised participants who have at least one baseline measurement. All randomised participants were analysed in the group to which they were randomised, even if they did not receive the allocated treatment, did not commence treatment, or were lost to follow-up.

Per Protocol

Participants were included in the Per Protocol (PP) analysis set if they fulfilled the criteria of the ITT set, had completed at least one primary endpoint measurement and did not present any major protocol violation. Participants in the PP set were assigned to the treatment group corresponding to the intervention they actually received at the baseline telephone call.

The following describes the major protocol deviations that excluded participants from the PP population:

- Eligibility violation
- Absence of any efficacy data.

All other protocol deviations were considered as minor and did not lead to excluding participants from the PP population for analysis.

Workbook Engagement

Participants were included in the Workbook Engagement (WE) analysis set if they fulfilled the criteria of the ITT set and received the workbook.

3.9.4 Statistical methods

The types of analyses of treatment effects were categorised as outcomes into primary and secondary efficacy and engagement analyses, confirmatory analyses and exploratory analyses. Primary and secondary analyses relate to the reported treatment effects on all primary and secondary efficacy endpoints respectively. Confirmatory analyses were focused on ancillary statistics and informed methodological choices in the primary and secondary analyses. Exploratory analyses included all other analyses, for the essential planned and unplanned variations on the primary and secondary analyses.

Descriptive statistics

All continuous measurements subject to descriptive statistics have been reported by treatment group as number and proportion of non-missing observations, mean, standard deviation, minimum, first quartile, median, third quartile and maximum.

All categorical measurements have been reported as number and proportion of non-missing observations, and proportion in each valid category.

Covariates

We distinguish between (independent) predictors related to outcome and unrelated to the allocation; potential confounders, related to outcome and imbalanced by chance across the treatment groups; and potential effect modifiers, that may moderate the treatment group effect.

Independent predictors

Generalities

Independent predictors are covariates that were sometimes included in the model for interpretive purposes. The baseline value of the outcome being modelled was an independent predictor. The time point, seen as an ordered factor or as a (continuous) time since baseline, was another independent predictor. Independent predictors were sometimes included in the model as a result of a specific hypothesis being tested. They are identified as such in Appendix 3. The baseline outcome value was included in all models when available.

Baseline data collected post-randomisation

Due to feasibility considerations, some baseline data were collected seven days postrandomisation, post-intervention. These concern the primary efficacy outcomes Days Gambled and Money Lost, and the secondary efficacy outcomes PRIME-MD (Major Depression, Dysthymia, Minor Depression, Bipolar Disorder) and New Zealand Deprivation Index (NZDI). These values were used as baseline adjustments.

Potential confounders

Prior selection of potential confounders

Potential confounders were selected from amongst baseline outcomes and demographic and personal history covariates as detailed below and identified in context in Appendix 3. Comparisons of important and known potential confounders were conducted at baseline to ensure that distributions were approximately equal between groups. If baseline separation between groups in some covariates emerged, outcome differences were adjusted for these covariates if they proved significant (but all potential confounders were assessed if the model retained did not involve an identity or exponential link). Baseline separation between groups in a covariate occurred for this purpose if any two mean estimates amongst the groups differed by one or more pooled standard deviations. In the case of the age group, this criterion was applied to the continuous age covariate instead.

Significance testing of potential confounders

All potential confounders were assessed for significance first as a single block, the significance of which was assessed using an appropriate F or x^2 test. If the block was retained as a result of this test, the individual covariates were tested using backward selection based on the appropriate t, z, F or x^2 tests. The significance threshold for retention of potential confounders for adjustment purposes was 0.1 for all tests. The estimates associated with the retained confounders were not reported but the retained confounders were reported by name:

- Gender
- Marital status, dichotimised
- Age group at randomisation
- Primary ethnicity
- Gross family income in last 12 months, dichotomised
- PGSI-12 (at baseline only)

- Electronic gaming machines as primary gambling type
- Current goal, dichotomised (quit vs. control gambling)
- Dichotomised level of belief in success within 12 months

Effect modifiers

Effect modifiers are covariates that may affect the treatment group effect (interactions involving treatment). Some analyses involve the time point as a treatment effect modifier. The subgroup analyses implicitly define variables that may modify the treatment effect.

There were no other considerations of effect modification.

Variance-covariance structure

In repeated measures analysis, the clustering between repeated measures were accounted for by participant-specific and counsellor-specific random effects. No further correlation structure was imposed.

Follow-back data resulting from the average of several measurements (as with the primary outcomes) were associated with a weight corresponding to the number of valid observations entering into the average. This overall weight was also applied in the time point-specific analyses.

Inferential framework

Significance threshold

All tests of significance of hypotheses concerning treatment effect parameters were carried out using a level of significance of 5% and two-sided alternatives. The significance threshold of potential confounders was set at 10%, to promote unbiased and conservative inference. All estimates were produced as point estimates and as 95% confidence intervals. Unless otherwise noted, model selection, when required, was performed using backward selection from the largest model dictated by the situation.

Family-wise error rate adjustment

Each composite hypothesis (Hypotheses B, C, D, F, G) was assessed by controlling False Discovery Rate at the stated significance threshold, in accordance with the procedure outlined in Benjamini and Hochberg (1995). Sub-hypotheses thus retained were deemed statistically significant. The composite hypothesis was deemed statistically significant if all sub-hypotheses were retained. No FWER adjustment was carried out across outcomes.

Analytical framework for continuous endpoint analysis

Normality assumption

The analysis described below assumes that normality of residuals is a reasonable assumption. Contingencies for non-normality are described below.

Regression model

Repeated measures analyses fitted available endpoints as repeated measures over the three assessment time points (excluding baseline) to an appropriate normal mixed effects model using residual maximum likelihood (REML).

Baseline outcome value was included as an independent predictor in all models, when available.

Specific covariates and interactions were included in specific analyses, such as subgroup analyses.

As per potential confounders above, models may potentially have been adjusted for baseline covariates, subject to achieving significance as per the significance threshold above.

Inclusion of treatment group; univariate and multivariate settings

When time point-specific (TPS) estimation was required, the assessment time (0, 3, 6 and 12 months) was entered as an ordinal factor in interaction with the treatment group. The analysis-appropriate estimand (e.g. effect at three months) was retained for estimation and reporting.

When time-averaged outcome (TAO)-based estimation was required, the 3, 6 and 12 month levels were collapsed into a single level, yielding a baseline/post-baseline dichotomous factor.

In the cases when there were no repeated measures, this analysis reduced to a least-squares regression.

Variance structure

A zero-mean, normally distributed random effect was assigned to participants based on their counsellor's identity, to account for heterogeneity between counsellors.

A nested, zero-mean, participant-specific normally distributed random effect was assigned to observations from a single participant to account for within-participant correlation in a simple compound-symmetry structure. *This random effect was only used when there was more than one measurement per participant (e.g. not in the case of PGSI-12).*

When the outcome was an average of other observations, the number of valid observations entered into the average was included as a weight in the regression.

Results

In most cases the estimated treatment contrasts represented differences in location, themselves interpretable as differences in changes from baseline under the adjustment for baseline value. In the case of treatment interactions with continuous covariates, the contrasts were differences in slopes. Estimated treatment contrasts were produced as point estimates and as 95% confidence intervals.

Trend models

The analyses described herein do not account for a time trend.

Absence of repeated measures

When outcome data were collected only at 12 months (e.g. PGSI-12), the above framework reduced to a baseline-adjusted ANCOVA, with variance estimated in the full repeated measures setting across the counsellors. For such analyses the individual random effects were removed from the model, although the counsellor-specific random effects were retained.

<u>Alternative analytical frameworks for continuous endpoints under non-normality I:</u> <u>Alternative family and transformation</u>

This section also applies to binomial outcomes with logit link and multinomial outcomes with cumulative logit link.

If non-normality of residuals was demonstrated or a non-normal family and/or non-identity link were called for, analyses equivalent to the analytical framework for continuous endpoint analyses (above) using an alternative generalised linear model as a first choice, a data transformation as a second choice, or both as a third choice, was investigated based on the estimated variance function from the residuals.

If a generalised linear model was selected, potential confounders were automatically assessed for significance in the model, without verification of baseline separation.

Any estimate produced under a non-identity link was converted to natural units with firstdegree bias correction, and their confidence intervals produced by applying the inverse link to the confidence interval bounds of the linear predictor, rather than use of the delta method.

Alternative analytical frameworks for continuous endpoints under non-normality II: Dichotomisation

If the provisions of non-normality I failed to apply satisfactorily, the outcomes were dichotomised based on thresholds commonly held in the literature, or failing the existence of such a threshold on the basis of the approximate median of the outcome in the TAU group, without consideration of the time point. The analyses then proceeded according to non-normality I using a binomial family and logit link, i.e. using mixed effects logistic regression.

In most cases the estimated treatment contrasts represented odds ratios with respect to a reference category, usually TAU, adjusted for baseline odds. In the case of treatment interactions with continuous covariates, the estimand was odds ratio per unit difference of the continuous covariate. Estimated odds ratios were produced as point estimates and as 95% confidence intervals.

Analytical framework for dichotomous (polytomous) endpoint analysis

The analyses proceeded according to non-normality I using a binomial (respectively, multinomial) family and logit (respectively, cumulative logit) link, i.e. using mixed effects logistic regression. Participant-level random effects were only used in the presence of repeated measures.

In most cases the estimated treatment contrasts represented odds ratios with respect to a reference category, usually TAU, adjusted for baseline odds. In the case of treatment interactions with continuous covariates, the estimand was odds ratio per unit difference of the continuous covariate. Estimated odds ratios were produced as point estimates and as 95% confidence intervals.

Software

Analyses were undertaken with R version 13.0 or higher, SAS version 9.2 or higher and SPSS (PASW) version 16.0 or higher.

Detail of the efficacy and engagement analyses

Primary vs. secondary analyses

The primary analyses consist of analyses of primary outcomes and primary hypotheses in the ITT analysis set.

The secondary analyses consist of the following:

- PGSI-12 and Hypothesis A in the ITT analysis set
- Primary outcomes and PGSI-12 within primary hypotheses in the PP analysis set
- Primary outcomes and PGSI-12 within secondary hypotheses in the ITT analysis set
- Primary and selected secondary outcomes (PGSI-12, attainment of goal and control) and Hypothesis E
- Secondary outcomes and primary superiority hypotheses in the ITT analysis set
- Engagement outcomes and engagement hypotheses in the ITT analysis set.

Description of the main analyses

I: Time-averaged continuous endpoints

Time-averaged analysis, as per analytical framework for continuous endpoint analysis (above), of a continuous primary outcome.

II.1: Time point-specific continuous endpoint, in the presence of repeated measures Time point-specific analysis, as per analytical framework for continuous endpoint analysis (above), of a continuous primary outcome in the ITT analysis set.

II.2: Time point-specific continuous endpoint, in the absence of repeated measures Time point-specific analysis, as per analytical framework for continuous endpoint analysis (above), of a continuous primary outcome in the ITT analysis set.

III: Time-averaged dichotomous endpoints

Time-averaged analysis, as per analytical framework for dichotomous (polytomous) endpoint analysis (above), of a dichotomous primary outcome in the ITT analysis set.

IV.1: Time point-specific dichotomous endpoint, in the presence of repeated measures Time point-specific analysis, as per analytical framework for dichotomous (polytomous) endpoint analysis (above), of a dichotomous primary outcome in the ITT analysis set.

IV.2: Time point-specific dichotomous endpoint, in the presence of repeated measures Time point-specific analysis, as per analytical framework for dichotomous (polytomous) endpoint analysis (above), of a dichotomous primary outcome in the ITT analysis set.

V: Time-averaged multinomial endpoint

Time-averaged analysis, as per analytical framework for dichotomous (polytomous) endpoint analysis (above), of a multinomial family random variable with cumulative logit link and weight variable corresponding to the number of valid responses over which the response was computed.

VI: Time point-specific multinomial endpoint

Time point-specific analysis, as per analytical framework for dichotomous (polytomous) endpoint analysis (above), of a multinomial family random variable with cumulative logit link and weight variable corresponding to the number of valid responses over which the response was computed.

VII: Time-averaged binomial endpoint

Time-averaged analysis, as per analytical framework for dichotomous (polytomous) endpoint analysis (above), of a binomial family random variable with logit link and weight variable corresponding to the number of valid responses over which the response was computed.

VIII: Time point-specific binomial endpoint

Time point-specific analysis, as per analytical framework for dichotomous (polytomous) endpoint analysis (above), of a binomial family random variable with logit link and weight

variable corresponding to the number of valid responses over which the response was computed.

Subgroup analyses

The primary analyses were repeated by considering possible interaction of the treatment group with the following subgroups defined at baseline:

- 1. Gender
- 2. Ethnicity: "Yes" responses only to each of:
 - a. European
 - b. Maori
 - c. Pacific
 - d. Asian or Other

Ethnicity subgroups were defined according to response, so that participants could contribute data to more than one subgroup.

- 3. Gambling problem severity based on PGSI-12 score (past 12-month time frame): Dichotomised with 17 (median score at baseline) as cut-off score. Note that the usual cut-off of 8 to identify problem gambling is not material here, as problem gambling at baseline was an inclusion criterion.
- 4. EGM anywhere or any other as primary gambling type
- 5. Mental health comorbidities based on Kessler-10 score: Dichotomised with 30 (median score at baseline) as cut-off score.
- 6. Alcohol abuse/dependence based on AUDIT-C score, cut point of 4 for males and 3 for females: Dichotomised
- 7. Current goal (quit or control gambling): Dichotomised
- 8. Belief level in treatment success: Dichotomised with 10 (median score at baseline) as cut-off score

Analyses involving Hypothesis E

The assistance- and engagement-related variables in the analyses involving Hypothesis E were collected at the post-randomisation time points. As such their status as covariates is questionable.

Missing data

Assessment of the significance of potential confounders and effect modifiers was based on complete-case analysis. If any confounder or effect modifier was retained based on the complete-case analysis, the final model relied on multiple imputation to produce adjusted treatment effect estimates. Confounders or effect modifiers with significance beyond the stated threshold after the multiple imputation stage were removed from the model.

Missing outcome values were accommodated without further adjustment in mixed effects models, under an assumption of missingness completely at random or missingness at random. Modelling of missingness and outcomes were performed in confirmatory analyses.

Confirmatory Analyses

Normality assessment

Normality of continuous outcomes was assessed using q-q plots, Kolmogorov-Smirnov and Shapiro-Wilks tests on the residuals of the mixed effects models involving treatment and time point interaction, as well as baseline outcome value, when available. If the normal family proved unsuitable, visual assessment of the estimated variance function was used to determine whether a transformation of the data or a different generalised linear model was required. All

analyses (univariate at each time point and repeated measures) associated with an outcome were effected using the same transformation and/or generalised linear model.

Influence and outlier analyses

All presented analyses had residual checks and influence diagnostics examined to ensure model validity and robustness.

Influence and outlier analyses were carried out but in accordance with the ITT and PP population definitions; no case was removed from the analyses if they proved overly influential or to be outliers.

Collateral data

Correlations or polychoric correlations of collateral data were produced to inform discussions of the reliability of the outcomes. Collateral data were not entered in the primary or secondary analyses.

Missingness

Confirmatory analyses regarding missingness included survival analysis of attrition (dropouts) based on treatment group, baseline primary outcomes and demographic covariates. It was not expected that pattern-mixture analysis would be used but the possibility of doing so was retained. The purpose of these analyses was to identify or discount possible links between treatment assignment and attrition.

The results of the confirmatory analyses served to inform the interpretation of the primary and secondary analysis results, by corroborating or weakening the assumption of ignorable missingness.

Baseline data collected post-randomisation

In the case of primary outcomes Days Gambled and Money Lost, partial pre-randomisation baseline data were available to potentially identify bias in the baseline data collected postrandomisation that was used for baseline adjustment. The correlation between pre- and postrandomisation data was reported, as well as the estimate of their difference and their respective variances, pooled and by treatment group. These results served to inform the discussion.

Testing of random effects

Random effects associated with counsellors and participants were tested using likelihood ratio tests against equivalent null models not involving the target random effect (but involving the remaining random effect) in the main analyses, concerning the non-composite primary outcomes Days Gambled and Money Lost under the time-averaged scheme.

The random effects were tested based on a likelihood ratio test, with models fitted using maximum likelihood only (not REML). The resulting p-value was based on a null distribution of $(\chi 21 + \chi 22)/2$ distribution.

Random effects that did not appear significant were removed from the model. If a random effect was removed from both models it was removed from all analyses.

Exploratory analyses

Any other analyses were deemed exploratory. In particular, analyses of association (correlation or otherwise) between endpoints were deemed exploratory.

4. **RESULTS**

This chapter details the results of data analyses from this Randomised Controlled Trial.

Section 4.1 shows the number of participants including the flow of participants through the clinical trial and study key dates and timings.

In section 4.2 are the descriptive statistics covering participant numbers in the Intention To Treat data set; socio-demographic characteristics; gambling characterisation; treatment assistance, goal and prospects; co-existing issues at baseline; primary efficacy outcomes; secondary efficacy outcomes; and treatment engagement.

Primary analyses for the Intention To Treat data set are detailed in section 4.3 relating to Hypotheses A, B and C for the three primary variables (Days Gambled, Money Lost gambling, and Gambling-quit or improved).

Subgroup analyses for the Intention To Treat data set are detailed in section 4.4 relating to Hypotheses A, B and C for gender, ethnicity, gambling mode, baseline PGSI score, baseline Kessler-10 score, baseline AUDIT-C score, baseline gambling goal, baseline belief in treatment success, and goal achievement.

Analyses for the Per Protocol data set are detailed in section 4.5 relating to Hypotheses A, B and C for the three primary variables (Days Gambled, Money Lost gambling, and Gamblingquit or improved).

Secondary analyses for the Intention To Treat data set are detailed in section 4.6 relating to Hypotheses C*, D and E for the three primary variables; PGSI-12 (PGSI, 12-month time frame); motivation to overcome gambling problem; control over gambling; Kessler-10, AUDIT-C, DAST, WHOQoL-8 and NZDI; PRIME-MD; tobacco use; treatment for co-existing issues; gambling impacts; and legal problems. In addition, analyses for hypotheses F and G are presented for workbook engagement and engagement in other formal treatment services.

Section 4.7 details the correlation between collateral and participants' reports of gambling, whilst section 4.8 details treatment integrity, fidelity and inter-rater reliability results.

4.1 **Participants**

4.1.1. Participant flow and study sample

A total of 1,298 gambler callers to the gambling helpline was assessed for eligibility in the trial; 836 were excluded as they did not meet inclusion criteria, met exclusion criteria or they declined to participate. A total of 462 participants was randomised: 116 to the TAU group, 112 to the MI group, 118 to the MI+W group and 116 to the MI+W+B group. These were the participants included in the Intention To Treat analyses. The number of participants receiving the full intervention after randomisation was 115, 107, 116 and 113 for the TAU, MI, MI+W and MI+W+B groups respectively; these participants comprise the Per Protocol analysis set. Participant flow is detailed in Figure 1.



Note: Not contactable participants were not contactable at those assessment points but may have been contacted at subsequent assessments.

4.1.2. Recruitment dates

Eligible participants were recruited from August 2009 to February 2011 and received their randomly allocated intervention at recruitment. The median length of intervention delivery was approximately half an hour (30 to 34 minutes) across all groups. Data are presented in

Appendix 7, Table 7.1 which also details mean, standard deviation, and minimum and maximum length of intervention delivery time.

Participants received a follow-up assessment telephone call at three- (median 92 to 93 days), six- (median 181 to 183 days) and 12-months (362 to 364 days) post recruitment. Data are presented in Appendix 7, Table 7.2 which also details mean, standard deviation, and minimum and maximum number of days in which participants were contacted at each assessment time point.

Participants in the MI+W+B group received motivational booster sessions from a helpline counsellor at one week after the initial interview (median 7 days) and at one- (median 31.5 days), three- (median 93 days) and six-months (median 183 days) after the initial intervention. The number of participants who received a booster call at each time point was 79, 78, 73 and 62 respectively. Data are presented in Appendix 7, Table 7.3 which also details mean, standard deviation, and minimum and maximum number of days in which participants were contacted at each booster call time point.

Of the 116 participants randomised to the MI+W+B group, 34% received all four booster calls, 22% received three booster calls, one-fifth (20%) received two booster calls, 10% only received one booster call and 14% did not receive any booster calls (not contactable) (Table 1).

| No. booster | No. of | Percentage |
|----------------|--------------|------------|
| calls received | participants | |
| 0 | 16 | 13.8% |
| 1 | 12 | 10.3% |
| 2 | 23 | 19.8% |
| 3 | 26 | 22.4% |
| 4 | 39 | 33.6% |
| Total | 116 | |

Table 1: Number of booster calls received

4.2 Descriptive statistics

This section details the number of participants in the Intention To Treat (ITT) and Per Protocol (PP) data sets for each of the four groups, and demographic characteristics of the participants in the ITT groups.

4.2.1. Number of participants

Intention To Treat data set

In total, 462 participants were recruited into the trial with between 112 and 118 participants allocated per group; this is the Intention to Treat data set as detailed in section 3.9.3. A total of 373 participants (81%) remained in the trial at the three-month assessment, 340 participants (74%) at the six-month assessment and 295 participants (64%) at the 12-month assessment. Participant retention varied between the groups at each assessment. Numbers are detailed in Table 2.

The 36% attrition at the 12-month assessment is greater than the 15% attrition predicted prior to study commencement and means that for outcomes at 12 months there was 70% power or a 30% Type II error rate compared with the expected 80% power, 20% Type II error rate.

| Time point | | | | | | | |
|------------|----------|---------------------------|---------------------------|----------------------------|--|--|--|
| Group | Baseline | 3 months (% retention) | 6 months (% retention) | 12 months (% retention) | | | |
| TAU | 116 | 100 (86%) | 92 (79%) | 78 (67%) | | | |
| MI | 112 | 88 (79%) | 78 (70%) | 66 (59%) | | | |
| MI+W | 118 | 98 (83%) | 88 (75%) | 78 (66%) | | | |
| MI+W+B | 116 | 87 (75%) | 82 (71%) | 73 (63%) | | | |
| N | 462 | 373 (81%) | 340 (74%) | 295 (64%) | | | |

Table 2: ITT data set at each time point

Per Protocol data set

In total, 451 participants were included in the Per Protocol analyses (as detailed in section 3.9.3) with between 107 and 116 participants per group. A total of 289 participants remained in the Per Protocol data set at the 12-month assessment, indicating a 64% retention rate. Individual group retention varied between 59% (MI group) and 67% (TAU group). Numbers are detailed in Table 3.

| | Time point | | | | | |
|--------|------------|----------|----------|-----------|-----------------------------|--|
| Group | Baseline | 3 months | 6 months | 12 months | % retention at 12 months | |
| TAU | 115 | 99 | 91 | 77 | 67% | |
| MI | 107 | 84 | 75 | 63 | 59% | |
| MI+W | 116 | 96 | 87 | 77 | 66% | |
| MI+W+B | 113 | 85 | 81 | 72 | 64% | |
| N | 451 | 364 | 334 | 289 | 64% | |

Table 3: PP data set at each time point

4.2.2. Socio-demographic characteristics

Socio-demographic characteristics of the participants are detailed in Appendix 4, Table 4.1.

There were slightly more females than males in all groups (53% to 59% female) apart from the MI+W+B group (45% female). These profiles differed slightly from the overall gambler caller profile to the gambling helpline from 2009 to 2011 (the period of trial recruitment) where the gender split across the years was 47% to 49% female and 52% to 53% male (Gambling Helpline, 2012).

Marital status was similar across the groups apart from the MI+W+B group. Generally just over half of the participants were partnered (52% to 58%) apart from the MI+W+B participants of whom 48% were partnered.

The median age of participants across the groups was similar and ranged from 36 years to 40 years with the youngest participant aged 18 years and the oldest aged 79 years. The proportion of participants of the major ethnicities was also similar across groups with just under half identifying primary ethnicity as European (42% to 47%), one-third to two-fifths (36% to 41%) identifying primarily as Maori, eight percent to 16% identifying as Pacific and three percent to six percent identifying as Asian/Other. The ethnicity profiles differed slightly from the overall new gambler caller profile to the gambling helpline from 2009 to 2011 where: 28% to 35% (in each individual year) were European, 18% to 23% were Maori, seven percent to nine percent were Pacific, six percent to nine percent were Asian, and 25% to 27% were Other/multiple ethnicity (Gambling Helpline, 2012). Based on this, the trial recruited more participants of European, Maori or Pacific ethnicity and less of Asian/Other ethnicity than the general gambling helpline gambler caller profile at that time.

The highest educational qualification achieved was similar across groups with one-quarter or slightly less of participants (18% to 26%) having no qualification, approximately one-third (31% to 37%) being educated to secondary school level, one-quarter or slightly less of participants (18% to 24%) having a trade or technical certificate, and the remainder having a tertiary or professional qualification.

Employment status of the participants was similar across the groups with 42% to 49% in fulltime employment, 10% to 14% in part-time employment and 11% to 18% unemployed. Gross family income in the past 12-months was also similar across groups with one-third to two-fifths (33% to 43%) of participants' family income being \$30,000 or less.

Participants were recruited from around the country with a larger proportion residing in the three major cities of Auckland, Christchurch and Wellington (Appendix 4, Table 4.2).

4.2.3. Gambling characterisation

Gambling characteristics of the participants at the baseline assessment are detailed in Appendix 4, Table 4.3.

Participants' primary gambling mode was similar across the groups with a majority citing electronic gaming machines (85% to 89%) in pubs (69% to 74%), clubs (6% to 12%) and casinos (4% to 12%). The remaining participants cited casino table games, track betting, sports betting, card gambling, Lotto, keno or other forms of gambling.

The median duration of participants' gambling problems was 60 months (range 0.3 to 588 months) across all groups apart from the MI+W+B group where it was lower at 48 months (range 0.5 to 360 months). The median number of days since the last gambling session was similar across groups at 1.0 to 1.5 days (range 0 to 97 days).

Almost all participants responded affirmatively to both of the questions in the Lie-Bet screen. Between 93% and 99% had ever felt the need to bet more and more money, and 86% to 93% had ever had to lie to people important to them about how much they gambled.

4.2.4. Treatment assistance, goal and prospects

At the baseline assessment, between 16% and 20% of participants across the four groups were currently receiving assistance for their gambling problems with one-third to two-fifths (31% to 41%) having previously received assistance (Table 4).

| Group | | TAU | MI | MI+W | MI+W+B |
|---------------------|-----------|-------|-------|-------|--------|
| Currently receiving | Yes | 17.3% | 19.8% | 19.1% | 15.7% |
| assistance | N | 110 | 111 | 115 | 115 |
| | N MISSING | 6 | 1 | 3 | 1 |
| Previously received | Yes | 34.4% | 31.5% | 41.2% | 31.3% |
| assistance | N | 93 | 92 | 97 | 96 |
| | N MISSING | 23 | 20 | 21 | 20 |

Table 4: Current and past treatment

There was little variation between the four groups in regard to participants' treatment goal, at the baseline assessment, being to quit all/some modes of gambling or control their gambling. Three-quarters to four-fifths (74% to 85%) of the participants reported a desire to quit gambling (Table 5).

| Group | | TAU | MI | MI+W | MI+W+B |
|---------------|-----------|-------|-------|-------|--------|
| Current goal, | Quit | 79.1% | 82.9% | 74.4% | 84.5% |
| dichotomised | Control | 20.9% | 17.1% | 25.6% | 15.5% |
| | Ν | 115 | 111 | 117 | 116 |
| | N MISSING | 1 | 1 | 1 | 0 |

Table 5: Treatment goal

At the baseline assessment, participants were asked to rate their level of belief in success in achieving their treatment goal in six- and 12-months' time, rated on a scale of 0 ('none at all') to 10 ('extremely'). The median for belief in success within six months was between 8 and 10 (range 0 to 10) and for belief within 12 months was 10 (range 0 to 10). The median score for the level of difficulty expected in achieving the treatment goal was 8 (range 0 to 10 where 0 = 'not very' and 10 = 'very') (Appendix 4, Table 4.4).

4.2.5. Co-existing issues

At the baseline assessment, four-fifths or greater (79% to 91%) of participants across the groups reported some psychological distress in the past four weeks, measured by the Kessler-10 scale. Over half (61% to 65%) of the participants showed some level of alcohol abuse or

dependence (via the AUDIT-C scale) in the past 12-months, and approximately one-quarter to two-fifths (23% to 37%) had thoughts of suicide in the past 12-months. Four percent to eight percent had actually made a suicide plan and one percent to six percent had tried to harm themselves (Table 6).

| Group | • | TAU | MI | MI+W | MI+W+B |
|----------------------------------|--------------------------------|-------|-------|-------|--------|
| Psychological | Little or no disorder (K10<20) | 15.5% | 21.4% | 9.3% | 15.5% |
| distress Kessler-10. | Some disorder (K10≥20) | 84.5% | 78.6% | 90.7% | 84.5% |
| past 4 weeks, | Ν | 116 | 112 | 118 | 116 |
| dichotomised | N MISSING | 0 | 0 | 0 | 0 |
| Alcohol abuse | Little or no disorder | 38.8% | 34.8% | 39.3% | 36.2% |
| or dependence, past 12 months | Some disorder | 61.2% | 65.2% | 60.7% | 63.8% |
| dichotomised | Ν | 116 | 112 | 117 | 116 |
| | N MISSING | 0 | 0 | 1 | 0 |
| Suicidal | No thoughts in last 12 months | 67.0% | 65.8% | 52.1% | 59.5% |
| previous 12 | Just thoughts | 28.7% | 23.4% | 36.8% | 26.7% |
| months | Plan | 3.5% | 5.4% | 6.0% | 7.8% |
| | Tried to harm myself | 0.9% | 5.4% | 5.1% | 6.0% |
| | Ν | 115 | 111 | 117 | 116 |
| | N MISSING | 1 | 1 | 1 | 0 |

Table 6: Co-existing issues

4.2.6. Primary efficacy outcomes

Primary efficacy outcomes of the participants are detailed in Appendix 4, Table 4.5.

The self-reported number of days per month when gambling occurred (Days Gambled) at each time point was similar across the groups with the median between 6.0 to 7.5 days at baseline, decreasing to 1.7 to 2.2 days at the three month assessment and remaining fairly static at this level at the six and 12 month assessments (Figure 2).





The self-reported amount of money lost per day (Money Lost) at each time point was similar across the groups with the median between \$29 to \$33 at baseline, decreasing to \$2.50 to \$3 per day at the three month assessment and remaining fairly static at this level at the six and 12 month assessments (Figure 3). The maximum amount of money lost per day by individuals was variable with no trends apparent at the follow-up time points.



Figure 3: Median Money Lost per day

Four-fifths (82% to 83%) of participants in the TAU, MI and MI+W groups self-reported that they had ceased gambling or improved control over their gambling (Gambling-quit or improved) at the three month assessment. At the six-month assessment the percentage of participants decreased slightly for the TAU and MI+W groups (72%), increasing again to similar levels to the three-month assessment at the 12-month assessment (87%, 85% respectively). The percentage was slightly lower for the MI+W+B group at all follow-up assessments at 76%, 73% and 75% respectively (Figure 4).



Figure 4: Percentage Gambling-quit or improved

4.2.7. Secondary efficacy outcomes

Problem Gambling Severity Index

Problem Gambling Severity Index data are presented in Appendix 4, Table 4.6.

At the baseline assessment, almost all participants across the four groups were categorised as problem gamblers via the past 12-month PGSI (95% to 97%), with a median PGSI score of 17 (of a possible 27). At the 12-month assessment, improvement was noted for all groups with just over half of the participants being categorised as problem gamblers (55% to 67%) with a median score of 9 to 10.

When a past three-month PGSI was administered there was some evidence of a trend for reduction in problem severity across time for all groups. However, a greater reduction was noted for the MI+W and MI+W+B groups with a median PGSI score of 2.5 and 2.0 respectively at the 12-month assessment, in comparison with the TAU and MI groups which showed median scores of 6.0 and 4.5 respectively (Figure 5).



Figure 5: Median PGSI score, past 3-month time frame

Control over gambling behaviour

Control over gambling behaviour data are presented in Appendix 4, Table 4.7.

Participants were asked to rate their control over their gambling on a scale of 0 to 10 (0 = 'no control', 10 = 'total control'). At the baseline assessment, the median was 2.0 to 3.0 across the four groups. At each of the follow-up assessments for each group, the median was 7.0 to 8.5, though the range was from 0 to 10 (Figure 6).

Figure 6: Control over gambling behaviour



Co-existing issues

Various psychological distress and substance abuse/dependence screens were administered to participants at the baseline and follow-up assessments. The data are presented in Appendix 4, Table 4.8.

Psychological distress

Using the Kessler-10 screen, the median score for participants in each group at baseline ranged from 28.5 to 32 (of a total score of 50). At the three-month assessment, the median score had decreased to 14.5 to 17, and this appeared generally stable at the six-month assessment. A further slight improvement in score was noted at the 12-month assessment with median scores ranging from 11.5 to 14 (Figure 7).



Figure 7: Median Kessler-10 score

Similarly, the percentage of participants in each group showing major or minor depressive disorder or dysthymia decreased at the 12-month assessment in relation to the baseline assessment. However, there did not appear to be much difference in percentages of participants across the groups with bipolar disorder or who were receiving treatment or

prescriptions for mental health (past 12-month time frame) at the 12-month assessment in relation to the baseline assessment.

Substance abuse/dependence

Median scores for alcohol abuse/dependence using AUDIT-C were similar across groups (3.0 to 5.0 of a total score of 12) at the baseline and 12-month assessments (Figure 8).



Figure 8: Median AUDIT-C score

Note: The TAU line is masked by the MI line as both are identical

Very few participants scored on the DAST screen for drug abuse/dependence. Just over half (55% to 60%) of the participants smoked tobacco at the baseline assessment; this remained fairly constant across time. Of those smokers, the majority (at least 85%) smoked at least once a day.

Quality of life

Quality of life of the participants across the groups was similar at each assessment (measured using WHOQoL-8). At the baseline assessment the median score was 24 to 26 (maximum 40), increasing slightly at the other assessment points to 30 to 33.

Gambling impacts

Participants were asked how their gambling had impacted on various life domains in the past month with impacts rated from 0 to 10, where 0 represented 'not at all' and 10 represented 'very severely'. The data are presented in Appendix 4, Table 4.9.

The measured impacts related to how the following were affected: work, social life, family and home, and health. At the baseline assessment for each domain, the median impact score was similar across the groups. It was relatively low for impacts on work (median range 2.0 to 3.5) and higher for the other domains (median range 5.0 to 8.5). The median values indicated zero impacts at all follow-up assessments, although some individuals did report impacts. This indicates sustained improvement over the year following treatment intervention.

Participants were also asked if they had experienced any legal problems in the past 12 months (baseline assessment) or past three months (follow-up assessments). Less than one-fifth (10% to 17%) of participants at the baseline assessment reported legal problems. The percentage was slightly lower at the three-month assessment (6% to 11%), lower still at the

six-month assessment (1.4% to 5.2%) and increased slightly at the 12-month assessment (9% to 10%).

Median levels of deprivation, measured with the New Zealand Deprivation Index, did not show differences between the groups with baseline scores ranging from 1.19 to 1.69 (possible total score of 8). Median scores at the 12-month follow-up assessment again showed no major difference between the groups but were lower than at the baseline assessment (range 0.63 to 0.90).

Goal setting and motivation

At each follow-up assessment, participants were asked if they had met their goal (to quit some or all gambling or to control their gambling). Data are presented in Appendix 4, Table 4.10.

There were no major differences noted over time for the TAU and MI+W+B groups with between one-fifth and two-fifths (22% to 40%) each reporting that their goal had been met partly, mostly or completely at each follow-up assessment. In these groups, the percentage of participants reporting that their goal had not been met at all ranged from nine percent to 14% at the three- and six-month assessments, but increased slightly to 23% at the 12-month assessment. A slightly different profile was noted for the MI group whereby a greater percentage reported 'not at all' across the assessments (24% to 26%) and a lower percentage reported 'mostly' (14% to 16%). Participants in the MI+W group also differed in that 18%/ 19% reported 'not at all' at the three- and six-month assessments respectively, with the percentage decreasing to 13% at the 12-month assessment (Figure 9).



Figure 9: Percentage goal met in past three months

Participants across all groups and assessment periods remained motivated to overcome their gambling problems with a median score of 9.5 or 10 (where 0 = 'not at all' and 10 = 'extremely').

4.2.8. Treatment engagement

Workbook reception and use

Participants in the MI+W and MI+W+B groups were sent, by post, a self-help workbook ('Becoming a Winner: Defeating Problem Gambling') which was discussed as part of the intervention at the booster calls for participants in the MI+W+B group. Participants in the TAU and MI groups were not sent any workbook.

At each of the follow-up assessments, all participants were asked if they had received the 'Becoming a Winner' workbook and were asked about workbook use. Data are presented in Appendix 4, Table 4.11.

Almost all of the participants (89% to 94%) in the MI+W and MI+W+B groups recalled receiving the workbook and this recall stayed constant over time. Interestingly, half (52% to 54%) of the TAU participants apparently 'recalled' receiving the workbook when asked at the three- and six-month assessments; the percentage apparently 'recalling' receiving the workbook increased to 65% at the 12-month assessment. Similarly, a proportion of participants in the MI group apparently 'recalled' receiving the workbook; 21%, 28% and 41% at the three-, six-, and 12-month assessments respectively. No participants in the TAU and MI groups were sent the workbook,

Participants were asked if they had read the workbook 'not at all', 'some sections' or 'completely' (scored as 1, 2 or 3). The median score was 1 or 2 for respondents in all groups and at all assessment points.

When asked whether they had completed the exercises in the workbook, participants in the MI+W and MI+W+B groups did not differ despite the workbook being discussed as part of the booster calls for the latter group. At the three-month assessment approximately half (51% MI+W, 45% MI+W+B) of the participants reported completing some of the exercises with nine percent and 13% respectively, reporting completing all the exercises. The percentages decreased over time. Again, whilst the majority of participants in the TAU and MI groups (who did not receive the 'Becoming a Winner' workbook) stated that completing the exercises was not applicable, 12% or less indicated completing some or all of the exercises.

A similar profile was noted for participants reporting using some or all of the strategies in the workbook as was noted for participants reporting completing the exercises (though the actual percentages were slightly different).

Treatment service assistance

At each follow-up assessment, participants were asked if they had received any assistance (formal or informal) (additional to their initial gambling helpline intervention) in the previous three months for their gambling problems. Overall data are presented in Appendix 4, Table 4.12. Data for individual formal services are presented in Appendix 4, Table 4.13.

Overall, approximately one-fifth to one-quarter (20% to 28%) of participants had received some form of formal assistance (from a professional person) for their gambling problems over the past three months, at the three-month assessment. For all groups apart from the MI group, the percentage decreased slightly at the subsequent assessments (15% to 18%). For participants in the MI group, the percentage receiving formal assistance at the six- and 12-month assessments remained fairly constant at 23% and 26% respectively.

Overall, a slightly higher percentage of participants reported receiving some form of informal assistance (e.g. from family, friends or other non-professional person) than those receiving formal assistance at the three-month assessment (37% to 42%). The percentage remained at a similar level for participants in all groups at the six- and 12-month assessments (30% to 44%).

4.3 Primary analyses ITT data set

This section details the primary analyses of the trial for the Intention To Treat data set, focusing on results relating to Hypotheses A, B and C as detailed in section 3.9 and re-iterated below. The data are analysed by the three primary variables (Days Gambled, Money Lost gambling, and Gambling-quit or improved).

Primary equivalence hypothesis A

A. The Motivational Interview (MI) group will show similar improvement to Treatment as Usual (TAU).

Linear mixed effects

No statistically significant differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group (Table 7).

| Table 7. | MI vo | TAII | Dove | Combled | Monor | Loct |
|----------|----------|------|------|----------|--------|------|
| | IVII VS. | IAU | Days | Gambieu, | wioney | LUSI |

| | TEST | 95% Confidence Limits | | |
|-----------------------------|---------------------------------|--------------------------|------|--|
| | | | | |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, $\delta=1$ | -0.40 | 1.61 | |
| Money Lost, time-averaged | hyp. A : TAU vs MI, $\delta=20$ | -2.38 | 8.15 | |

Logistic mixed effects

Participants in the MI group showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved (Table 8).

| Table | 8∙ MI | vs TAI | I time-avera | ged Gambli | ng-auit or | improved |
|--------|---------|----------|--------------|------------|------------|----------|
| 1 auto | 0. 1011 | vs. 1710 | | geu Gamon | ng-quit or | mproved |

| | <u> </u> | | | |
|---|----------------------------|---------------|-----------------------|-----------------------|
| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB |
| Gambling-quit or improved, time- averaged | hyp. A : TAU vs MI, δ=0.13 | 0.70 | 0.30 | 1.66 |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

Primary superiority hypotheses B and C

B.

- a. The Motivational Interview plus Workbook group (MI+W) will show greater improvement than the TAU group.
- b. The Motivational Interview plus Workbook group (MI+W) will show greater improvement than the MI group.
- c. The Motivational Interview plus Workbook plus Booster group (MI+W+B) will show greater improvement than the TAU group.
- d. The Motivational Interview plus Workbook plus Booster group (MI+W+B) will show greater improvement than the MI group.

C.

- a. The MI+W+B group will show greater improvement than the TAU group at the 12-month follow-up.
- b. The MI+W+B group will show greater improvement than the MI group at the 12-month follow-up.

c. The MI+W+B group will show greater improvement than the MI+W group at the 12-month follow-up.

Linear mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to Days Gambled, Money Lost gambling or in relation to PGSI-12 scores (PGSI, past 12-month time frame) at the 12-month assessment (Table 9).

| | TEST | Estimated | Standard | P-value | Alternative |
|----------------|--------------------------|-----------|----------|-----------------|-------------|
| | | change | error | (one- sided) | accepted |
| Days Gambled, | hyp. B.a: TAU vs MI+W | 0.32 | 0.49 | 0.74 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -0.29 | 0.51 | 0.29 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.02 | 0.51 | 0.49 | No |
| | hyp. B.d: MI vs MI+W+B | -0.34 | 0.51 | 0.25 | No |
| Days Gambled, | hyp. C.a: TAU vs MI+W+B | -0.13 | 0.59 | 0.41 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B | -0.83 | 0.62 | 0.09 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.17 | 0.59 | 0.38 | No |
| Money Lost, | hyp. B.a: TAU vs MI+W | -1.35 | 2.60 | 0.30 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -4.24 | 2.69 | 0.06 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.05 | 2.66 | 0.49 | No |
| | hyp. B.d: MI vs MI+W+B | 1.30 | 2.66 | 0.69 | No |
| Money Lost, at | hyp. C.a: TAU vs MI+W+B | -1.41 | 3.07 | 0.32 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -4.57 | 3.20 | 0.08 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.76 | 3.07 | 0.72 | No |
| PGSI-12, at 12 | hyp. B.a: TAU vs MI+W | -0.03 | 0.99 | 0.49 | No |
| months | hyp. B.b: MI vs MI+W | -0.44 | 1.03 | 0.33 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.78 | 1.01 | 0.78 | No |
| | hyp. C.b: MI vs MI+W+B | 0.37 | 1.04 | 0.64 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.81 | 1.00 | 0.79 | No |

Table 9: Hypotheses B and C - Days Gambled, Money Lost, PGSI

Logistic mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to timeaveraged self-reported Gambling-quit or improved and self-reported Gambling-quit or improved at the 12-month assessment (Table 10).

| | TEST | Odds | Odds | Odds | P-value | Alternative |
|----------------------------------|-----------------------------|-------|-------|-------|----------------|-------------|
| | | ratio | Ratio | Ratio | (one- | accepted |
| | | | CILB | CIUB | sided) | |
| Gambling-quit | hyp. B.a: TAU vs MI+W | 1.25 | 0.53 | 2.96 | 0.31 | No |
| or improved, time-averaged | hyp. B.b: MI vs MI+W | 1.78 | 0.74 | 4.29 | 0.10 | No |
| time-averageu | hyp. B.c: TAU vs MI+W+B | 1.23 | 0.51 | 2.93 | 0.32 | No |
| | hyp. B.d: MI vs MI+W+B | 0.98 | 0.40 | 2.39 | 0.52 | No |
| Gambling-quit or improved, at | hyp. C.a: TAU vs MI+W+B | 1.52 | 0.57 | 4.03 | 0.20 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | 2.67 | 0.99 | 7.24 | 0.03 | No* |
| | hyp. C.c: MI+W vs MI+W+B | 0.36 | 0.13 | 1.04 | 0.97 | No |

Table 10: Hypotheses B and C - Gambling-quit or improved

* False discovery rate control requires the p-value to be smaller than 0.017 for acceptance of the alternative in this particular instance

4.4 Subgroup analyses ITT data set

This section details the subgroup analyses of the trial for the Intention To Treat data set, focusing on results relating to hypotheses A, B and C as detailed in section 3.9 and re-iterated below. The data are analysed by gender, ethnicity, gambling mode, baseline PGSI score, baseline Kessler-10 score, baseline AUDIT-C score, baseline gambling goal, baseline belief in treatment success, and goal achievement.

4.4.1. Gender subgroups

The number of participants by gender is detailed in Table 11.

| Valid number of participants | | | | | |
|------------------------------|-----|----|------|--------|--|
| Group Gender | TAU | MI | MI+W | MI+W+B | |
| Male | 48 | 53 | 53 | 64 | |
| Female | 68 | 59 | 64 | 52 | |

Table 11: Number of participants by gender

Primary equivalence hypothesis A

Data are presented in Appendix 5, Tables 5.1 and 5.2.

Linear mixed effects

When examined by gender, no statistically significant differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group.

Logistic mixed effects

When examined by gender, participants in the MI group showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved.

Primary superiority hypotheses B and C

Linear mixed effects

The MI+W group showed statistically significant (p=0.011) greater improvement than the MI group for males in relation to time-averaged money lost gambling. No statistically significant differences were noted for males for each of the other hypotheses B and C tested in regard to days gambled, money lost gambling or in relation to PGSI-12 scores at the 12-month assessment (Table 12). No statistically significant differences were noted for females for hypotheses B and C (Appendix 5, Table 5.3).

| | TEST | Estimated change | Standard error | P-value (one- sided) | Alternative accepted |
|-------------------------------|-----------------------------|---------------------|-------------------|----------------------------|-------------------------|
| Days Gambled, | hyp. B.a: TAU vs MI+W | 0.63 | 0.75 | 0.80 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -0.74 | 0.75 | 0.16 | No |
| | hyp. B.c: TAU vs MI+W+B | 0.13 | 0.75 | 0.57 | No |
| | hyp. B.d: MI vs MI+W+B | -1.24 | 0.75 | 0.05 | No |
| Money Lost, | hyp. B.a: TAU vs MI+W | -1.18 | 3.94 | 0.38 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -8.97 | 4.75 | 0.011 | Yes |
| | hyp. B.c: TAU vs MI+W+B | 2.02 | 3.92 | 0.70 | No |
| | hyp. B.d: MI vs MI+W+B | -5.76 | 3.91 | 0.07 | No |
| Days Gambled, at 12 months | hyp. C.a: TAU vs MI+W+B | -0.22 | 0.89 | 0.40 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B | -1.52 | 0.89 | 0.04 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.77 | 0.87 | 0.19 | No |
| Money Lost, at | hyp. C.a: TAU vs MI+W+B | 1.17 | 4.56 | 0.60 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -7.03 | 4.57 | 0.06 | No |
| | hyp. C.c: MI+W vs MI+W+B | 4.89 | 4.47 | 0.86 | No |
| PGSI-12, at 12 | hyp. B.a: TAU vs MI+W | -0.28 | 1.51 | 0.43 | No |
| months | hyp. B.b: MI vs MI+W | -1.08 | 1.52 | 0.24 | No |
| | hyp. C.a: TAU vs MI+W+B | -1.30 | 1.50 | 0.19 | No |
| | hyp. C.b: MI vs MI+W+B | -2.11 | 1.50 | 0.08 | No |
| | hyp. C.c: MI+W vs MI+W+B | -1.02 | 1.47 | 0.24 | No |

Table 12: Hypotheses B and C - days gambled, money lost, PGSI - males

Logistic mixed effects

No statistically significant differences were noted when analysed by gender for hypotheses B and C in regard to time-averaged self-reported Gambling-quit or improved and self-reported Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.4).

4.4.2. Ethnicity subgroups

The number of participants by ethnicity is detailed in Table 13.

| | Valid number of participants | | | | | | |
|--------------------|------------------------------|----|------|--------|--|--|--|
| Group Ethnicity | TAU | MI | MI+W | MI+W+B | | | |
| European | 58 | 53 | 64 | 62 | | | |
| Maori | 47 | 44 | 51 | 42 | | | |
| Pacific | 13 | 18 | 10 | 12 | | | |
| Asian & Other | 5 | 4 | 5 | 8 | | | |

Table 13: Number of participants by gender

Primary equivalence hypothesis A

Data are presented in Appendix 5, Tables 5.5 and 5.6.

Linear mixed effects

When examined by ethnicity, no statistically significant differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group.

Logistic mixed effects

When examined by ethnicity, participants in the MI group showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved.

Primary superiority hypotheses B and C

Linear mixed effects

The MI+W+B group showed statistically significant (p=0.004) greater improvement than the MI group for Maori in relation to money lost gambling at the 12-month assessment (Table 14). No statistically significant differences were noted when examined by ethnicity for each of the other hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI-12 scores at the 12-month assessment (Appendix 5, Table 5.7).

| | TEST | Estimated change | Standard error | P-value (one- sided) | Alternative accepted |
|----------------|---|------------------|-------------------|----------------------------|-------------------------|
| | hyp. C.a: TAU vs MI+W+B European | -2.36 | 4.11 | 0.28 | No |
| | hyp. C.a: TAU vs MI+W+B Maori | -2.62 | 4.97 | 0.30 | No |
| | hyp. C.a: TAU vs MI+W+B Pacific | -1.44 | 10.73 | 0.45 | No |
| | hyp. C.a: TAU vs MI+W+B Asian & Other | 8.91 | 14.87 | 0.73 | No |
| | hyp. C.b: MI vs MI+W+B European | -0.71 | 4.36 | 0.44 | No |
| Money Lost, at | hyp. C.b: MI vs MI+W+B Maori | -14.33 | 5.46 | 0.004 | Yes |
| 12 months | hyp. C.b: MI vs MI+W+B Pacific | -1.79 | 9.49 | 0.43 | No |
| | hyp. C.b: MI vs MI+W+B Asian & Other | 0.39 | 14.83 | 0.51 | No |
| | hyp. C.c: MI+W vs MI+W+B European | 4.44 | 4.18 | 0.86 | No |
| | hyp. C.c: MI+W vs MI+W+B Maori | -0.77 | 4.85 | 0.44 | No |
| | hyp. C.c: MI+W vs MI+W+B Pacific | -13.56 | 10.30 | 0.09 | No |
| | hyp. C.c: MI+W vs MI+W+B Asian & Other | 4.02 | 14.28 | 0.61 | No |

Table 14: Hypothesis C - Money Lost gambling at 12-months by ethnicity

Logistic mixed effects

No statistically significant differences were noted when analysed by ethnicity for hypotheses B and C in regard to time-averaged self-reported Gambling-quit or improved and self-reported Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.8).

4.4.3. Gambling mode

The number of participants by dichotomised primary gambling mode causing the gambling problem (EGM vs. non-EGM) is detailed in Table 15.

| Valid number of participants | | | | | | |
|------------------------------|-----|-----|------|--------|--|--|
| Group | TAU | MI | MI+W | MI+W+B | | |
| Mode | | | | | | |
| EGM | 108 | 102 | 108 | 107 | | |
| Non-EGM | 8 | 10 | 10 | 9 | | |

Table 15: Number of participants by gambling mode

Primary equivalence hypothesis A

Data are presented in Appendix 5, Tables 5.9 and 5.10.

Linear mixed effects

When examined by primary gambling mode, no statistically differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or timeaveraged days spent gambling, i.e. the MI group showed similar improvement to the TAU group.

Logistic mixed effects

When examined by primary gambling mode, participants in the MI group showed similar improvement to the TAU group in regard to time-averaged gambling-quit or improved.

Primary superiority hypotheses B and C

Linear mixed effects

No statistically significant differences were noted when examined by gambling mode for hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI-12 scores at the 12-month assessment (Appendix 5, Table 5.11).

Logistic mixed effects

No statistically significant differences were noted when analysed by gambling mode for hypotheses B and C in regard to time-averaged self-reported Gambling-quit or improved and self-reported Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.12).

4.4.4. Baseline PGSI score

As previously detailed, at the baseline assessment, almost all participants across the four groups were categorised as problem gamblers via the past 12-month PGSI (95% to 97%), with a median PGSI score of 17. Therefore, the equivalence and superiority hypotheses by PGSI score were examined using baseline PGSI scores dichotomised to ≤ 17 or > 17 (i.e. either side of the median score).

The number of participants by dichotomised baseline PGSI score is detailed in Table 16.

| Valid number of participants | | | | | | |
|------------------------------|-----------------|----|----|----|--|--|
| Group | TAU MI MI+W MI+ | | | | | |
| PGSI | | | | | | |
| Baseline ≤17 | 66 | 62 | 68 | 63 | | |
| Baseline >17 | 50 | 50 | 50 | 53 | | |

Table 16: Number of participants by dichotomised PGSI baseline score

Primary equivalence hypothesis A

Data are presented in Appendix 5, Tables 5.13 and 5.14.

Linear mixed effects

When examined by dichotomised baseline PGSI score, no statistically significant differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group.

Logistic mixed effects

When examined by dichotomised baseline PGSI score, participants in the MI group showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved.

Primary superiority hypotheses B and C

Linear mixed effects

The MI+W+B group with a dichotomised PGSI baseline score of > 17 (i.e. those with higher than the median PGSI score) showed statistically significant (p=0.005) greater improvement than the MI group in relation to money lost gambling at the 12-month assessment (Table 17). No statistically significant differences were noted when examined by dichotomised baseline PGSI score of > 17 or of \leq 17 for each of the other hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI scores at the 12-month assessment (Appendix 5, Table 5.15).

Logistic mixed effects

The MI+W+B group with a dichotomised PGSI baseline score of > 17 showed statistically significant greater improvement than both the TAU and MI groups (P=0.004 and p=0.001 respectively) in relation to self-reported Gambling-quit or improved at the 12-month assessment (Table 18).

No statistically significant differences were noted for time-averaged Gambling-quit or improved for hypotheses B and C in the PGSI score > 17 groups, or the score \leq 17 groups for time-averaged Gambling-quit or improved or Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.16).

| | TEST | Estimated change | Standard error | P-value (one- sided) | Alternative accepted |
|----------------|----------------------------------|---------------------|-------------------|----------------------------|-------------------------|
| Days Gambled, | hyp. B.a: TAU vs MI+W | -0.36 | 0.75 | 0.32 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -1.26 | 0.76 | 0.05 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.35 | 0.77 | 0.33 | No |
| | hyp. B.d: MI vs MI+W+B | -1.24 | 0.77 | 0.05 | No |
| Money Lost, | hyp. B.a: TAU vs MI+W | -5.37 | 3.93 | 0.09 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -7.28 | 3.97 | 0.03 | No |
| | hyp. B.c: TAU vs MI+W+B | -5.12 | 4.01 | 0.10 | No |
| | hyp. B.d: MI vs MI+W+B | -7.03 | 4.04 | 0.04 | No |
| Days Gambled, | hyp. C.a: TAU vs MI+W+B | 0.86 | 0.86 | 0.57 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B | -1.68 | 0.91 | 0.03 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.68 | 0.89 | 0.78 | No |
| Money Lost, at | hyp. C.a: TAU vs MI+W+B | -7.50 | 4.62 | 0.05 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -12.02 | 4.71 | 0.005 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | 1.10 | 4.58 | 0.60 | No |
| PGSI-12, at 12 | hyp. B.a: TAU vs MI+W | -1.19 | 1.57 | 0.22 | No |
| months | hyp. B.b: MI vs MI+W | -1.47 | 1.65 | 0.19 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | -0.50 | 1.53 | 0.37 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | -0.79 | 1.62 | 0.31 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.68 | 1.51 | 0.67 | No |

Table 17: Hypotheses B and C - Days Gambled, Money Lost, PGSI by baseline PGSI >17

Table 18: Hypotheses B and C - Gambling-quit or improved by baseline PGSI > 17

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one- sided) | Alternative accepted |
|----------------------------------|-----------------------------|---------------|-----------------------|-----------------------|----------------------------|-------------------------|
| Gambling-quit | hyp. B.a: TAU vs MI+W | 2.47 | 0.70 | 8.79 | 0.08 | No |
| or improved, time-averaged | hyp. B.b: MI vs MI+W | 1.95 | 0.55 | 6.97 | 0.15 | No |
| unit al tragta | hyp. B.c: TAU vs MI+W+B | 4.43 | 1.19 | 16.54 | 0.0134 | No |
| | hyp. B.d: MI vs MI+W+B | 1.50 | 0.45 | 5.07 | 0.28 | No |
| Gambling-quit or improved, at | hyp. C.a: TAU vs MI+W+B | 7.88 | 1.76 | 35.33 | 0.004 | Yes |
| 12 months | hyp. C.b: MI vs MI+W+B | 11.00 | 2.42 | 50.08 | 0.001 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | 0.88 | 0.18 | 4.44 | 0.56 | No |

4.4.5. Baseline Kessler-10 score

As previously detailed, at the baseline assessment, four-fifths or greater (79% to 91%) of participants across the groups had some psychological distress in the past four weeks, as indicated by the Kessler-10 scale; the median score was 30. Therefore, the equivalence and

superiority hypotheses by Kessler-10 score were tested using baseline Kessler-10 scores dichotomised to ≤ 30 or > 30 (i.e. either side of the median score).

The number of participants by dichotomised baseline Kessler-10 score is detailed in Table 19.

| Valid number of participants | | | | | | |
|------------------------------|-----|----|------|--------|--|--|
| Group | TAU | MI | MI+W | MI+W+B | | |
| K-10 | | | | | | |
| Baseline ≤ 30 | 60 | 67 | 55 | 67 | | |
| Baseline > 30 | 56 | 45 | 63 | 59 | | |

Table 19: Number of participants by dichotomised Kessler-10 baseline score

Primary equivalence hypothesis A

Data are presented in Appendix 5, Tables 5.17 and 5.18.

Linear mixed effects

When examined by dichotomised baseline Kessler-10 score, no statistically significant differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group.

Logistic mixed effects

When examined by dichotomised baseline Kessler-10 score, participants in the MI group showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved.

Primary superiority hypotheses B and C

Linear mixed effects

The MI+W+B group with a dichotomised Kessler-10 baseline score of > 30 (i.e. those with higher than the median Kessler-10 score) showed statistically significant (p=0.0053) greater improvement than the MI group in relation to money lost at the 12-month assessment (Table 20). No statistically significant differences were noted when examined by dichotomised baseline Kessler-10 score of > 30 or of \leq 30 for the other hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI-12 scores at the 12-month assessment (Appendix 5, Table 5.19).

| | TEST | Estimated change | Standard error | P-value (one- | Alternative accepted |
|----------------|----------------------------------|---------------------|-------------------|------------------|-------------------------|
| | | 8- | | sided) | |
| Days Gambled, | hyp. B.a: TAU vs MI+W | -0.28 | 0.69 | 0.34 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -1.25 | 0.74 | 0.046 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.04 | 0.72 | 0.48 | No |
| | hyp. B.d: MI vs MI+W+B | -1.02 | 0.77 | 0.09 | No |
| Money Lost, | hyp. B.a: TAU vs MI+W | -1.55 | 3.61 | 0.33 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -6.72 | 3.92 | 0.043 | No |
| | hyp. B.c: TAU vs MI+W+B | -3.44 | 3.80 | 0.18 | No |
| | hyp. B.d: MI vs MI+W+B | -8.61 | 4.08 | 0.017 | No |
| Days Gambled, | hyp. C.a: TAU vs MI+W+B | 0.13 | 0.85 | 0.56 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B | -1.61 | 0.93 | 0.042 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.26 | 0.84 | 0.62 | No |
| Money Lost, at | hyp. C.a: TAU vs MI+W+B | -4.12 | 4.43 | 0.18 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -12.26 | 4.79 | 0.0053 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | -0.46 | 4.39 | 0.46 | No |
| PGSI-12, at 12 | hyp. B.a: TAU vs MI+W | 0.10 | 1.41 | 0.53 | No |
| months | hyp. B.b: MI vs MI+W | -1.86 | 1.55 | 0.11 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 1.34 | 1.41 | 0.83 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | -1.79 | 1.61 | 0.13 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.08 | 1.43 | 0.52 | No |

Table 20: Hypotheses B and C - Days gambled, Money lost, PGSI by baseline K-10 score > 30

Logistic mixed effects

The MI+W+B group with a dichotomised Kessler-10 baseline score of > 30 showed statistically significant greater improvement than the MI group (p=0.00005) in relation to self-reported Gambling-quit or improved at the 12-month assessment (Table 21). No statistically significant differences were noted for time-averaged Gambling-quit or improved in the score > 30 groups, or the score \leq 30 groups for hypotheses B and C for time-averaged Gambling-quit or improved or Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.20).

| <u> </u> | 01 | | P = = + = = = | | | |
|----------------------------------|-----------------------------|-------|----------------------|--------|---------|-------------|
| | TEST | Odds | Odds | Odds | P-value | Alternative |
| | | ratio | Ratio | Ratio | (one- | accepted |
| | | | CILB | CIUB | sided) | |
| Gambling-quit | hyp. B.a: TAU vs MI+W | 0.93 | 0.28 | 3.05 | 0.55 | No |
| or improved, time-averaged | hyp. B.b: MI vs MI+W | 2.35 | 0.68 | 8.08 | 0.09 | No |
| viine wierugeu | hyp. B.c: TAU vs MI+W+B | 1.45 | 0.41 | 5.22 | 0.28 | No |
| | hyp. B.d: MI vs MI+W+B | 1.97 | 0.56 | 6.88 | 0.14 | No |
| Gambling-quit or improved, at | hyp. C.a: TAU vs MI+W+B | 3.38 | 0.73 | 15.70 | 0.060 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | 21.70 | 4.46 | 105.54 | 0.00005 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | 1.33 | 0.27 | 6.61 | 0.36 | No |

Table 21: Hypotheses B and C - Gambling-quit or improved by Kessler-10 score > 30

4.4.6. Baseline AUDIT-C score

As previously detailed, at the baseline assessment, over half (61% to 65%) of the participants showed some level of alcohol abuse or dependence using the AUDIT-C. The equivalence and superiority hypotheses by AUDIT-C results were tested using baseline AUDIT-C scores dichotomised to low risk or high risk (score 3 or more for females, 4 or more for males).

The number of participants by dichotomised baseline AUDIT-C score is detailed in Table 22.

| Valid number of participants | | | | | | |
|------------------------------|-----|----|------|--------|--|--|
| Group | TAU | MI | MI+W | MI+W+B | | |
| AUDÌT-C | | | | | | |
| Low risk | 45 | 39 | 46 | 42 | | |
| High risk | 71 | 73 | 71 | 74 | | |

Table 22: Number of participants by dichotomised AUDIT-C baseline score

Primary equivalence hypothesis A

Data are presented in Appendix 5, Tables 5.21 and 5.22.

Linear mixed effects

When examined by dichotomised baseline AUDIT-C score, no differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group.

Logistic mixed effects

When examined by dichotomised baseline AUDIT-C score, participants in the MI group showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved.

Primary superiority hypotheses B and C

Linear mixed effects

No statistically significant differences were noted when examined by dichotomised baseline AUDIT-C score for hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI scores at the 12-month assessment (Appendix 5, Table 5.23).

Logistic mixed effects

The MI+W+B group with a low risk AUDIT-C baseline score showed statistically significant greater improvement than the MI group (P=0.013) in relation to self-reported Gambling-quit or improved at the 12-month assessment (Table 23). No statistically significant differences were noted for time-averaged Gambling-quit or improved in the low risk score groups (Table 23), or the high risk score groups for time-averaged Gambling-quit or improved or Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.24).

| | TEST | Odds | Odds | Odds | P-value | Alternative |
|----------------------------------|-----------------------------|-------|-------|-------|---------|-------------|
| | | ratio | Ratio | Ratio | (one- | accepted |
| | | | CILB | CIUB | sided) | |
| Gambling-quit | hyp. B.a: TAU vs MI+W | 1.14 | 0.26 | 5.05 | 0.43 | No |
| time-averaged | hyp. B.b: MI vs MI+W | 4.15 | 0.89 | 19.46 | 0.035 | No |
| | hyp. B.c: TAU vs MI+W+B | 0.96 | 0.21 | 4.43 | 0.52 | No |
| | hyp. B.d: MI vs MI+W+B | 3.50 | 0.72 | 17.03 | 0.06 | No |
| Gambling-quit or improved, at | hyp. C.a: TAU vs MI+W+B | 2.00 | 0.37 | 10.88 | 0.21 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | 7.54 | 1.27 | 44.90 | 0.013 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | 0.65 | 0.11 | 3.84 | 0.68 | No |

Table 23: Hypotheses B and C - gambling-quit or improved by low risk AUDIT-C score

4.4.7. Baseline gambling goal

As previously detailed, at the baseline assessment, three-quarters to four-fifths (74% to 85%) of the participants reported a desire to quit all/some modes of gambling versus controlling their gambling. The equivalence and superiority hypotheses by gambling goal results were tested using data dichotomised to quit (all/some modes) or control gambling.

The number of participants by dichotomised baseline gambling goal is detailed in Table 24.

| Valid number of participants | | | | |
|------------------------------|-----|----|------|--------|
| Group | TAU | MI | MI+W | MI+W+B |
| Goal | | | | |
| Quit | 91 | 92 | 87 | 98 |
| Control | 24 | 19 | 30 | 18 |

Primary equivalence hypothesis A

Linear mixed effects

When examined by dichotomised baseline gambling goal, no differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or timeaveraged days spent gambling, i.e. the MI group showed similar improvement to the TAU group (Table 25).

| | TEST | 95% Cor Lin | nfidence nits |
|-----------------------------|-------------------------------------|----------------|------------------|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, $\delta=1$ Quit | -0.76 | 1.43 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ=20 Quit | -4.87 | 6.77 |

Table 25: TAU vs. MI days gambled, money lost by dichotomised baseline gambling goal

| | TEST | 95% Con Lin | nfidence nits |
|-----------------------------|---|----------------|------------------|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 Control | -0.57 | 4.16 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ=20 Control | -0.45 | 24.69 |

Logistic mixed effects

When examined by dichotomised baseline gambling goal, participants in the MI group whose goal was to quit some or all modes of gambling showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved. However, participants in the MI group whose goal was to control their gambling, gambled significantly more (Odds Ratio 0.06) than participants in the TAU group in regard to time-averaged Gambling-quit or improved (Table 26).

| | 0.11 | 0.11 | 0.11 | |
|--|-----------|----------|----------|------|
| Table 26: TAU vs. MI Gambling-quit or improved by dich | notomised | baseline | gambling | goal |

| | TEST | Odds | Odds | Odds |
|------------------|--|-------|-------|-------|
| | | ratio | Ratio | Ratio |
| | | 1.20 | | |
| Gambling-quit or | hyp. A : TAU vs MI, δ =0.13 Quit | 1.39 | 0.53 | 3.65 |
| improved, time- | | | | |
| averaged | | | | |
| Gambling-quit or | hyp. A : TAU vs MI, δ =0.13 Control | 0.06 | 0.01 | 0.46 |
| improved, time- | | | | |
| averaged | | | | |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

Primary superiority hypotheses B and C

Linear mixed effects

The MI+W+B group by dichotomised baseline gambling goal to control gambling showed statistically significant (p=0.009) greater improvement than the MI group in relation to money lost at the 12-month assessment. The MI+W+B group by dichotomised baseline gambling goal to control gambling also showed statistically significant greater improvement than both the MI and the MI+W groups (p=0.006 and p=0.004 respectively) in relation to number of days gambled at the 12-month assessment. No statistically significant differences were noted when examined by dichotomised baseline gambling goal to control gambling for the other hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI scores at the 12-month assessment (Table 27).

No statistically significant differences were noted when examined by dichotomised baseline gambling goal to quit some or all modes of gambling for hypotheses B and C in regard to

days gambled, money lost gambling or in relation to PGSI scores at the 12-month assessment (Appendix 5, Table 5.25).

| | TEST | Estimated change | Standard error | P-value (one- sided) | Alternative accepted |
|----------------|----------------------------------|------------------|-------------------|----------------------------|-------------------------|
| Days Gambled, | hyp. B.a: TAU vs MI+W | 1.44 | 1.05 | 0.92 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -0.35 | 1.12 | 0.38 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.65 | 1.21 | 0.30 | No |
| | hyp. B.d: MI vs MI+W+B | -2.45 | 1.27 | 0.027 | No |
| Money Lost, | hyp. B.a: TAU vs MI+W | 4.04 | 5.56 | 0.77 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -8.07 | 5.91 | 0.09 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.17 | 6.44 | 0.49 | No |
| | hyp. B.d: MI vs MI+W+B | -12.29 | 6.75 | 0.03 | No |
| Days Gambled, | hyp. C.a: TAU vs MI+W+B | -1.47 | 1.39 | 0.14 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B | -3.72 | 1.49 | 0.006 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | -3.39 | 1.29 | 0.004 | Yes |
| Money Lost, at | hyp. C.a: TAU vs MI+W+B | -0.38 | 7.24 | 0.48 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -18.45 | 7.77 | 0.009 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | -6.46 | 6.76 | 0.17 | No |
| PGSI-12, at 12 | hyp. B.a: TAU vs MI+W | 2.22 | 2.04 | 0.86 | No |
| months | hyp. B.b: MI vs MI+W | -1.97 | 2.32 | 0.20 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | -0.51 | 2.28 | 0.41 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | -4.71 | 2.54 | 0.03 | No |
| | hyp. C.c: MI+W vs MI+W+B | -2.74 | 2.13 | 0.10 | No |

Table 27: Hypotheses B and C - Days gambled, Money lost, PGSI by baseline control gambling goal

Logistic mixed effects

The MI+W and MI+W+B groups by dichotomised baseline gambling goal to control gambling showed statistically significant greater improvement than the MI group (p=0.015 and p=0.0008 respectively) in relation to time-averaged Gambling-quit or improved (Table 28). No statistically significant differences were noted for self-reported Gambling-quit or improved at the 12-month assessment, or for groups by dichotomised baseline gambling goal to quit some/all modes of gambling for time-averaged Gambling-quit or improved or Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.26).

| | | | | J | 0 | |
|----------------------------------|-----------------------------|---|---------------|---------------|------------------|-------------------------|
| | TEST | Odds ratio | Odds Ratio | Odds Ratio | P-value (one- | Alternative accepted |
| | | | CILR | CIUB | sided) | |
| Gambling-quit | hyp. B.a: TAU vs MI+W | 0.45 | 0.07 | 2.81 | 0.81 | No |
| or improved, time-averaged | hyp. B.b: MI vs MI+W | 7.18 | 1.22 | 42.20 | 0.015 | Yes |
| 6 | hyp. B.c: TAU vs MI+W+B | 1.50 | 0.16 | 13.74 | 0.36 | No |
| | hyp. B.d: MI vs MI+W+B | 11.85 | 2.57 | 54.55 | 0.0008 | Yes |
| Gambling-quit or improved, at | hyp. C.a: TAU vs MI+W+B | 3.22 | 0.24 | 43.09 | 0.19 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | Unreliable results due to numerical instability | | | | |
| | hyp. C.c: MI+W vs MI+W+B | 3.59 | 0.31 | 41.33 | 0.15 | No |

Table 28: Hypotheses B and C - gambling-quit or improved by control gambling goal

4.4.8. Baseline belief in treatment success

As previously detailed, at the baseline assessment, participants were asked to rate their level of belief in success in achieving their treatment goal in 12-months; the overall median value was 10. The equivalence and superiority hypotheses by gambling goal results were tested using data dichotomised to low belief level (lower than median) or high belief level (median value).

The number of participants by dichotomised belief in treatment success is detailed in Table 29.

| | Valid number of participants | | | | |
|------------|------------------------------|----|------|--------|--|
| Group | TAU | MI | MI+W | MI+W+B | |
| Belief | | | | | |
| Low level | 55 | 61 | 72 | 65 | |
| High level | 61 | 51 | 46 | 51 | |

Table 29: Number of participants by dichotomised belief in treatment success

Primary equivalence hypothesis A

Linear mixed effects

When examined by dichotomised belief in treatment success, no differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group (Table 30).

| | TEST | 95% Confidence Limits | |
|-----------------------------|---|--------------------------|-------|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ=1 Low belief | -0.82 | 2.17 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Low belief | -4.54 | 11.58 |

| Table 30: TAU vs. MI days gambled | d, money lost by belief in treatment success |
|-----------------------------------|--|
|-----------------------------------|--|

| | TEST | 95% Confidence Limits | |
|-----------------------------|---|--------------------------|------|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ=1 High belief | -1.04 | 1.57 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ=20 High belief | -5.15 | 8.94 |

Logistic mixed effects

When examined by dichotomised belief in treatment success, participants in the MI group whose baseline belief in treatment success at 12-months was high showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved. However, participants in the MI and TAU groups whose baseline belief in treatment success was low showed inequivalence in regard to time-averaged Gambling-quit or improved, i.e. participants in the MI group whose baseline belief in treatment success was low gambled (days and money) significantly more (Odds Ratio 0.20) than participants in the TAU group in regard to time-averaged Gambling-quit or improved (Table 31).

Table 31: TAU vs. MI Gambling-quit or improved by dichotomised belief in treatment success

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB |
|---|--|---------------|-----------------------|-----------------------|
| Gambling-quit or improved, time- averaged | hyp. A : TAU vs MI, δ=0.13 Low belief | 0.20 | 0.05 | 0.73 |
| Gambling-quit or improved, time- averaged | hyp. A : TAU vs MI, δ=0.13 High belief | 2.64 | 0.78 | 8.93 |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

Primary superiority hypotheses B and C

Linear mixed effects

No statistically significant differences were noted when examined by dichotomised belief in treatment success for hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI scores at the 12-month assessment (Appendix 5, Table 5.27).

Logistic mixed effects

The MI+W+B group whose belief in treatment success was low showed statistically significant greater improvement than the MI group (p=0.0007) in relation to self-reported Gambling-quit or improved at the 12-month assessment (Table 32). No statistically significant differences were noted for self-reported time-averaged Gambling-quit or improved in the low belief groups, or the high belief groups for time-averaged Gambling-quit or improved at the 12-month assessment (Appendix 5, Table 5.28).

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one- sided) | Alternative accepted |
|----------------------------------|-----------------------------|---------------|-----------------------|-----------------------|----------------------------|-------------------------|
| Gambling-quit | hyp. B.a: TAU vs MI+W | 0.47 | 0.13 | 1.70 | 0.88 | No |
| or improved, time-averaged | hyp. B.b: MI vs MI+W | 2.34 | 0.72 | 7.59 | 0.08 | No |
| time-averageu | hyp. B.c: TAU vs MI+W+B | 0.64 | 0.16 | 2.52 | 0.74 | No |
| | hyp. B.d: MI vs MI+W+B | 3.19 | 0.89 | 11.35 | 0.26 | No |
| Gambling-quit or improved, at | hyp. C.a: TAU vs MI+W+B | 1.00 | 0.21 | 4.73 | 0.50 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | 10.87 | 2.53 | 46.74 | 0.0007 | Yes |
| | hyp. C.c: MI+W vs MI+W+B | 0.41 | 0.09 | 1.89 | 0.87 | No |

Table 32: Hypotheses B and C - Gambling-quit or improved by low belief treatment success

4.4.9. Goal achievement

Multinomial mixed regression

No statistically significant differences were noted when examined by whether the participants' goal was met in the past three-months (time-averaged) for hypotheses B or C, or whether the goal was met in the past three-months at the 12-month assessment (Appendix 5, Table 5.29).

4.5 Primary analyses PP data set

This section details analyses of the trial for the Per Protocol data set, focusing on results relating to hypotheses A, B and C as detailed in section 3.9 and re-iterated below. The data are analysed by the three primary variables (Days Gambled, Money Lost gambling, and Gambling-quit or improved).

Primary equivalence hypothesis A

B. The Motivational Interview (MI) group will show similar improvement to Treatment as Usual (TAU).

Linear mixed effects

No statistically significant differences were noted between the MI and the TAU participants in regard to time-averaged money lost gambling or time-averaged days spent gambling, i.e. the MI group showed similar improvement to the TAU group (Table 33).

| | TEST | 95% Confidence | | |
|-----------------------------|---------------------------------|----------------|------|--|
| | | Limits | | |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, $\delta=1$ | -0.59 | 1.46 | |
| Money Lost, time-averaged | hyp. A : TAU vs MI, $\delta=20$ | -3.90 | 4.70 | |

Logistic mixed effects

Participants in the MI group showed similar improvement to the TAU group in regard to time-averaged Gambling-quit or improved (Table 34).

Table 34: TAU vs. MI time-averaged Gambling-quit or improved

| | <u> </u> | | | |
|------------------|-----------------------------------|---------------|-----------------------|-----------------------|
| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB |
| Gambling-quit or | hyp. A : TAU vs MI, $\delta=0.13$ | 0.85 | 0.35 | 2.06 |
| averaged | | | | |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

Primary superiority hypotheses B and C

B.

- a. The Motivational Interview plus Workbook group (MI+W) will show greater improvement than the TAU group.
- b. The Motivational Interview plus Workbook (MI+W) group will show greater improvement than the MI group.
- c. The Motivational Interview plus Workbook plus Booster (MI+W+B) group will show greater improvement than the TAU group.
- d. The Motivational Interview plus Workbook plus Booster (MI+W+B) group will show greater improvement than the MI group.

C.

- a. The MI+W+B group will show greater improvement than the TAU group at the 12-month follow-up.
- b. The MI+W+B group will show greater improvement than the MI group at the 12-month follow-up.
c. The MI+W+B group will show greater improvement than the MI+W group at the 12-month follow-up.

Linear mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to days gambled, money lost gambling or in relation to PGSI-12 scores (PGSI, past 12-month time frame) at the 12-month assessment (Table 35).

| | TEST | Estimated change | Standard error | P-value (one- sided) | Alternative accepted |
|----------------|--------------------------|---------------------|-------------------|----------------------------|-------------------------|
| Days Gambled, | hyp. B.a: TAU vs MI+W | -0.42 | 0.50 | 0.20 | No |
| time-averaged | hyp. B.b: MI vs MI+W | 0.02 | 0.52 | 0.51 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.04 | 0.51 | 0.47 | No |
| | hyp. B.d: MI vs MI+W+B | 0.40 | 0.54 | 0.77 | No |
| Days Gambled, | hyp. C.a: TAU vs MI+W+B | -0.12 | 0.60 | 0.42 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B | -0.64 | 0.63 | 0.16 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.20 | 0.60 | 0.37 | No |
| Money Lost, | hyp. B.a: TAU vs MI+W | 0.56 | 2.11 | 0.61 | No |
| time-averaged | hyp. B.b: MI vs MI+W | 0.96 | 2.20 | 0.67 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.49 | 2.16 | 0.41 | No |
| | hyp. B.d: MI vs MI+W+B | -0.09 | 2.26 | 0.48 | No |
| Money Lost, at | hyp. C.a: TAU vs MI+W+B | -1.36 | 2.55 | 0.30 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -0.93 | 2.68 | 0.36 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.56 | 2.55 | 0.73 | No |
| PGSI-12, at 12 | hyp. B.a: TAU vs MI+W | -0.23 | 1.00 | 0.41 | No |
| months | hyp. B.b: MI vs MI+W | -0.35 | 1.04 | 0.37 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.57 | 1.02 | 0.71 | No |
| | hyp. C.b: MI vs MI+W+B | 0.45 | 1.06 | 0.66 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.80 | 1.01 | 0.79 | No |

Table 35: Hypotheses B and C - Days Gambled, Money Lost, PGSI

Logistic mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to timeaveraged self-reported Gambling-quit or improved and self-reported Gambling-quit or improved at the 12-month assessment (Table 36).

| 51 | TEST | Odds | Odds | Odds Datia | P-value | Alternative |
|---|-----------------------------|------|------|---------------|-----------------|-------------|
| | | rauo | CILB | CIUB | (one- sided) | accepteu |
| Gambling-quit | hyp. B.a: TAU vs MI+W | 0.81 | 0.34 | 1.92 | 0.68 | No |
| or improved, time-averaged | hyp. B.b: MI vs MI+W | 0.69 | 0.28 | 1.70 | 0.79 | No |
| | hyp. B.c: TAU vs MI+W+B | 0.83 | 0.34 | 1.99 | 0.67 | No |
| | hyp. B.d: MI vs MI+W+B | 0.71 | 0.28 | 1.76 | 0.77 | No |
| Gambling-quit or improved, at 12 months | hyp. C.a: TAU vs MI+W+B | 1.51 | 0.56 | 4.02 | 0.21 | No |
| | hyp. C.b: MI vs MI+W+B | 2.19 | 0.79 | 6.08 | 0.07 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.36 | 0.13 | 1.05 | 0.97 | No |

Table 36: Hypotheses B and C - Gambling-quit or improved

4.6 Secondary analyses ITT data set

This section details the secondary efficacy analyses of the ITT data set, focusing on results from analyses relating to hypotheses C*, D, and E for the three primary variables (Days Gambled, Money Lost gambling, and Gambling-quit or improved); hypotheses A, B and C for PGSI which underwent the same analyses as the primary outcomes; hypotheses B and C for other secondary outcomes (such as motivation to overcome gambling problem, co-existing issues, and gambling impacts); and secondary engagement hypotheses F and G as discussed in section 3.9 and re-iterated below.

4.6.1 Primary variables

Secondary efficacy hypotheses

C*.

- d. The MI+W+B group will show greater improvement than the TAU group between three and 12 months.
- e. The MI+W+B group will show greater improvement than the MI group between three and 12 months.
- f. The MI+W+B group will show greater improvement than the MI+W group between three and 12 months.

D.

- a. The TAU group will evince significant reduction in gambling.
- b. The MI group will evince significant reduction in gambling.
- c. The MI+W group will evince significant reduction in gambling.
- d. The MI+W+B group will evince significant reduction in gambling.

E.

High levels of engagement within conditions will be associated with better gambling outcomes (gambling participation, attainment of goal and sense of control over gambling).

Mixed linear regression

No statistically significant differences were noted for hypothesis C* in regard to days gambled and money lost gambling between the three and 12-month assessments. However, all treatment groups showed a statistically significant reduction ($p \le 0.0001$) for time-averaged days gambling and money lost gambling as well as for time-averaged PGSI (past 12-month time frame) (hypothesis D) (Table 37).

In regard to hypothesis E, high levels of workbook engagement were associated with less time-averaged money lost gambling (p=0.03) and high levels of receiving informal assistance for the gambling problem were associated with higher time-averaged control over gambling (p=0.01). No statistically significant differences were noted between levels of engagement and PGSI (past 12-month time frame) at the 12-month assessment (Table 38).

| | TEST | Estimated change | Standard error | P-value (one- sided) | Alternative accepted |
|----------------------------|------------------------------|---------------------|-------------------|----------------------------|-------------------------|
| Days Gambled, | hyp. C*.d: TAU vs MI+W+B | -0.13 | 0.64 | 0.42 | No |
| between 3 and 12 months | hyp. C*.e: MI vs MI+W+B | -0.62 | 0.67 | 0.18 | No |
| | hyp. C*.f: MI+W vs MI+W+B | 0.10 | 0.65 | 0.56 | No |
| Money Lost, | hyp. C*.d: TAU vs MI+W+B | -0.56 | 3.18 | 0.43 | No |
| between 3 and 12 months | hyp. C*.e: MI vs MI+W+B | -4.05 | 3.31 | 0.11 | No |
| | hyp. C*.f: MI+W vs MI+W+B | 1.66 | 3.20 | 0.70 | No |
| Days Gambled, | hyp. D.a: TAU | -6.08 | 0.66 | < 0.0001 | Yes |
| time-averaged | hyp. D.b: MI | -4.67 | 0.71 | < 0.0001 | Yes |
| | hyp. D.c: MI+W | -5.79 | 0.66 | < 0.0001 | Yes |
| | hyp. D.d: MI+W+B | -5.30 | 0.69 | < 0.0001 | Yes |
| Money Lost, | hyp. D.a: TAU | -35.38 | 5.58 | < 0.0001 | Yes |
| time-averaged | hyp. D.b: MI | -37.64 | 5.99 | < 0.0001 | Yes |
| | hyp. D.c: MI+W | -42.41 | 5.61 | < 0.0001 | Yes |
| | hyp. D.d: MI+W+B | -37.16 | 5.91 | < 0.0001 | Yes |
| PGSI-12, time- | hyp. D.a: TAU | -7.32 | 0.76 | < 0.0001 | Yes |
| averaged | hyp. D.b: MI | -7.01 | 0.82 | < 0.0001 | Yes |
| | hyp. D.c: MI+W | -7.48 | 0.75 | < 0.0001 | Yes |
| | hyp. D.d: MI+W+B | -6.53 | 0.78 | < 0.0001 | Yes |

Table 37: Hypotheses C* and D: Days Gambled, Money Lost and PGSI

| | TEST | Estimated change | Standard error | P-value (one- sided) | Alternative accepted |
|---------------------|----------------------|---------------------|-------------------|----------------------------|-------------------------|
| Days gambled, time- | hyp. E: Workbook | -0.33 | 0.24 | 0.09 | No |
| averaged | engagement (per unit | | | | |
| _ | change) | | | | |
| Days gambled, time- | hyp. E: Formal | -0.02 | 0.33 | 0.47 | No |
| averaged | assistance | | | | |
| Days gambled, time- | hyp. E: Informal | -0.31 | 0.27 | 0.12 | No |
| averaged | assistance | | | | |
| Money lost, time- | hyp. E: Workbook | -1.68 | 0.90 | 0.03 | Yes |
| averaged | engagement (per unit | | | | |
| | change) | | | | |
| Money lost, time- | hyp. E: Formal | 0.93 | 1.56 | 0.72 | No |
| averaged | assistance | | | | |
| Money lost, time- | hyp. E: Informal | -1.98 | 1.29 | 0.06 | No |
| averaged | assistance | | | | |
| Control over | hyp. E: Workbook | 0.20 | 0.14 | 0.08 | No |
| gambling, time- | engagement (per unit | | | | |
| averaged | change) | | | | |
| Control over | hyp. E: Formal | 0.09 | 0.21 | 0.34 | No |
| gambling, time- | assistance | | | | |
| averaged | | | | | |
| Control over | hyp. E: Informal | 0.44 | 0.17 | 0.01 | Yes |
| gambling, time- | assistance | | | | |
| averaged | | | | | |
| PGSI-12, at 12 | hyp. E: Workbook | 0.72 | 0.65 | 0.87 | No |
| months | engagement (per unit | | | | |
| | change) | | | | |
| PGSI-12, at 12 | hyp. E: Formal | 1.95 | 0.95 | 0.98 | No |
| months | assistance | | | | |
| PGSI-12, at 12 | hyp. E: Informal | -0.22 | 0.78 | 0.39 | No |
| months | assistance | | | | |

Table 38: Hypothesis E - Days Gambled, Money Lost, control over gambling and PGSI

Mixed logistic regression

The MI+W+B group showed statistically significant greater improvement than the MI+W group (p=0.0001) in relation to self-reported Gambling-quit or improved at the 12-month assessment (Hypothesis C*). All treatment groups showed a statistically significant reduction in gambling (p \leq 0.0001) when time-averaged (Hypothesis D) (Table 39).

In relation to Hypothesis E, high levels of workbook engagement were associated with less time-averaged gambling (p=0.03) and high levels of receiving informal assistance for the gambling problem were associated with higher time-averaged goal being met (p \leq 0.01) (Table 39).

| | TEST | Odds | Odds | Odds | P-value | Alternative |
|--|----------------------|-------|-------|-------|----------|-------------|
| | | ratio | Ratio | Ratio | (one- | accepted |
| | | | CILB | CIUB | sided) | |
| Gambling-quit | hyp. C*.d: TAU vs | 0.71 | 0.31 | 1.63 | 0.79 | No |
| or improved, at | MI+W+B | | | | | |
| 12 months | hyp. C*.e: MI vs | 0.49 | 0.21 | 1.14 | 0.95 | No |
| | MI+W+B | | | | | |
| | hyp. C*.f: MI+W vs | 5.76 | 2.31 | 14.38 | 0.0001 | Yes |
| | MI+W+B | | | | | |
| Gambling-quit | hyp. D.a: TAU | 11.32 | 6.23 | 20.57 | < 0.0001 | Yes |
| or improved, time-averaged | hyp. D.b: MI | 7.94 | 4.26 | 14.79 | < 0.0001 | Yes |
| ······· ······························ | hyp. D.c: MI+W | 14.15 | 7.61 | 26.31 | < 0.0001 | Yes |
| | hyp. D.d: MI+W+B | 13.87 | 7.33 | 26.24 | < 0.0001 | Yes |
| Gambling-quit | hyp. E: Workbook | 1.42 | 0.97 | 2.08 | 0.03 | Yes |
| or improved, | engagement (per unit | | | | | |
| time-averaged | change) | | | | | |
| Gambling-quit | hyp. E: Formal | 0.95 | 0.59 | 1.51 | 0.41 | No |
| or improved, | assistance | | | | | |
| time-averaged | | | | | | |
| Gambling-quit | hyp. E: Informal | 1.05 | 0.71 | 1.54 | 0.41 | No |
| or improved, | assistance | | | | | |
| time-averaged | | | | | | |
| Goal met, time- | hyp. E: Workbook | 1.03 | 0.73 | 1.47 | 0.43 | No |
| averaged | engagement (per unit | | | | | |
| | change) | | | | | |
| Goal met, time- | hyp. E: Formal | 1.11 | 0.67 | 1.85 | 0.34 | No |
| averaged | assistance | | | | | |
| Goal met, time- | hyp. E: Informal | 1.76 | 1.15 | 2.69 | 0.00 | Yes |
| averaged | assistance | | | | | |

Table 39: Hypotheses C*, D and E - Gambling-quit or improved and goal met

4.6.2 PGSI

Equivalence hypothesis A

A. The Motivational Interview (MI) group will show similar improvement to Treatment as Usual (TAU).

Linear mixed effects

No differences were noted between the MI and the TAU participants in regard to PGSI (past 12-month time frame) (Table 40).

Table 40: TAU vs. MI PGSI

| | TEST | 95% Con Lin | nfidence nits |
|---------|--------------------------------|----------------|------------------|
| PGSI-12 | hyp. A : TAU vs MI, $\delta=1$ | -2.45 | 1.62 |

Primary superiority hypotheses B and C

B.

a. The Motivational Interview plus Workbook group (MI+W) will show greater improvement than the TAU group.

- b. The Motivational Interview plus Workbook (MI+W) group will show greater improvement than the MI group.
- c. The Motivational Interview plus Workbook plus Booster (MI+W+B) group will show greater improvement than the TAU group.
- d. The Motivational Interview plus Workbook plus Booster (MI+W+B) group will show greater improvement than the MI group.

C.

- a. The MI+W+B group will show greater improvement than the TAU group at the 12-month follow-up.
- b. The MI+W+B group will show greater improvement than the MI group at the 12-month follow-up.
- c. The MI+W+B group will show greater improvement than the MI+W group at the 12-month follow-up.

Linear mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to PGSI (past three-month time frame) time-averaged or at the 12-month assessment (Table 41).

| | TEST | Estimated change | Standard error | P-value (one- | Alternative accepted |
|-------------------------|--------------------------|------------------|-------------------|------------------|-------------------------|
| | | | | sided) | |
| PGSI-3, time- | hyp. B.a: TAU vs MI+W | -0.57 | 0.81 | 0.24 | No |
| averaged | hyp. B.b: MI vs MI+W | -1.37 | 0.84 | 0.05 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.71 | 0.83 | 0.20 | No |
| | hyp. B.d: MI vs MI+W+B | -1.52 | 0.86 | 0.04 | No |
| PGSI-3, at 12 months | hyp. C.a: TAU vs MI+W+B | -0.45 | 1.02 | 0.33 | No |
| | hyp. C.b: MI vs MI+W+B | -1.46 | 1.05 | 0.08 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.73 | 1.02 | 0.76 | No |

Table 41: Hypotheses B and C - PGSI

Logistic mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to dichotomised PGSI scores (≤ 17 or > 17) either for PGSI in a past 12-month time frame at the 12-month assessment, or for PGSI in a past three-month time frame time-averaged or at the 12-month assessment (Table 42).

| | TEST | Odds ratio | 95% CI Lower | 95% CI Upper | P-value (two- sided) | Alternative accepted |
|----------------------------|-----------------------------|---------------|-----------------|-----------------|----------------------------|-------------------------|
| PGSI-12 | hyp. B.a: TAU vs MI+W | 1.13 | 0.58 | 2.20 | 0.72 | No |
| dichotomised, at | hyp. B.b: MI vs MI+W | 1.41 | 0.71 | 2.79 | 0.32 | No |
| 12 months | hyp. B.c: TAU vs MI+W+B | 1.29 | 0.65 | 2.56 | 0.47 | No |
| | hyp. B.d: MI vs MI+W+B | 1.61 | 0.80 | 3.25 | 0.18 | No |
| | hyp. C.a: TAU vs MI+W+B | 1.29 | 0.65 | 2.56 | 0.47 | No |
| | hyp. C.b: MI vs MI+W+B | 1.61 | 0.80 | 3.25 | 0.18 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.14 | 0.58 | 2.26 | 0.70 | No |
| PGSI-3 | hyp. B.a: TAU vs MI+W | 0.85 | 0.46 | 1.60 | 0.62 | No |
| dichotomised, | hyp. B.b: MI vs MI+W | 0.77 | 0.40 | 1.48 | 0.44 | No |
| time uverageu | hyp. B.c: TAU vs MI+W+B | 0.89 | 0.47 | 1.68 | 0.71 | No |
| | hyp. B.d: MI vs MI+W+B | 0.80 | 0.42 | 1.55 | 0.51 | No |
| PGSI-3 dichotomised, at | hyp. C.a: TAU vs MI+W+B | 0.85 | 0.27 | 2.68 | 0.78 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | 0.90 | 0.27 | 2.97 | 0.87 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.13 | 0.35 | 3.62 | 0.84 | No |

Table 42: Hypotheses B and C - dichotomised PGSI

4.6.3 Motivation to overcome gambling problem

At each assessment, participants were asked how motivated they were to overcome their gambling problem. Responses were reported on a scale of 0 to 10 where 0 = 'not at all' and 10 = 'extremely'.

Superiority hypotheses B and C

Linear mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to motivation to overcome gambling problem, time-averaged or at the 12-month assessment (Appendix 6, Table 6.1)

4.6.4 Control over gambling

Superiority hypotheses B and C

Linear mixed effects

The MI+W and MI+W+B groups showed statistically significant (p=0.016 and p=0.009 respectively) greater improvement than the MI group in relation to time-averaged control over gambling. No statistically significant differences were noted for hypothesis C when examined by control over gambling at the 12-month assessment (Table 43).

| | TEST | Estimated change | Standard error | P-value (one- | Alternative accepted |
|---------------|--------------------------|---------------------|-------------------|------------------|-------------------------|
| | | | | sided) | |
| Control over | hyp. B.a: TAU vs MI+W | 0.42 | 0.33 | 0.10 | No |
| time-averaged | hyp. B.b: MI vs MI+W | 0.74 | 0.34 | 0.016 | Yes |
| | hyp. B.c: TAU vs MI+W+B | 0.52 | 0.34 | 0.06 | No |
| | hyp. B.d: MI vs MI+W+B | 0.83 | 0.35 | 0.009 | Yes |
| Control over | hyp. C.a: TAU vs MI+W+B | 0.25 | 0.43 | 0.28 | No |
| months | hyp. C.b: MI vs MI+W+B | 0.62 | 0.45 | 0.08 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.38 | 0.43 | 0.81 | No |

Table 43: Hypotheses B and C - Control over gambling

4.6.5 Psychological distress, alcohol abuse/dependence, drug abuse, quality of life and deprivation index

Superiority hypotheses B and C

Linear mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to psychological distress (measured by Kessler-10), alcohol abuse/dependence (AUDIT-C) or quality of life (WHOQoL) scores time-averaged or at the 12-month assessment. Similarly, no statistically significant differences were noted for hypotheses B and C in regard to drug abuse (DAST) and deprivation index (NZDI) scores at the 12-month assessment (Appendix 6, Table 6.2).

4.6.6 Mental disorders mood module

Superiority hypotheses B and C

Logistic mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to any of the PRIME-MD mood modules (major depressive disorder, dysthymia, minor depressive disorder, bipolar disorder) at the 12-month assessment (Appendix 6, Table 6.3).

4.6.7 Tobacco use

Superiority hypotheses B and C

Logistic mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to currently not smoking tobacco or decreasing smoking frequency, both time-averaged and at the 12-month assessment (Appendix 6, Table 6.4).

4.6.8 Treatment for co-existing issues

At the 12-month assessment participants were asked if, in the previous 12-months, they had received any treatment for a mental health issue (other than gambling), if they had been prescribed medication for an emotional, nervous or mental health issue or if they had received treatment for an alcohol or drug problem.

Superiority hypotheses B and C

Logistic mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to treatment for co-existing issues at the 12-month assessment (Appendix 6, Table 6.5).

4.6.9 Gambling impacts

At each assessment, participants were asked if their gambling, in the past month, had affected their work, social life, family life/home responsibilities or physical health. Responses were reported on a scale of 0 to 10 where 0 = 'not at all' and 10 = 'very severely'.

Superiority hypotheses B and C

Linear mixed effects No statistically significant differences were noted for hypotheses B and C in regard to gambling impacts time-averaged or at the 12-month assessment (Appendix 6, Table 6.6).

4.6.10 Legal problems

At each assessment, participants were asked if they had experienced any legal problems (in the past three or 12-months) as a result of their gambling.

Superiority hypotheses B and C

Logistic mixed effects

No statistically significant differences were noted for hypotheses B and C in regard to legal problems time-averaged or at the 12-month assessment (Appendix 6, Table 6.7).

4.6.11 Workbook and other formal treatment engagement

As detailed previously in section 4.2.8, as part of their intervention, participants in the MI+W and MI+W+B groups were sent, by post, a self-help workbook ('Becoming a Winner: Defeating Problem Gambling') which was the workbook referred to in the follow-up assessment interviews. Participants in the TAU and MI groups were not sent any workbook.

The number of participants who reported receiving the workbook ('Becoming a Winner') is detailed in Table 44.

| | Valid number of participants | | | | | | | | |
|---------------------|------------------------------|----|------|--------|--|--|--|--|--|
| Group Time point | TAU | MI | MI+W | MI+W+B | | | | | |
| 3 months | 46 | 17 | 85 | 78 | | | | | |
| 6 months | 45 | 20 | 75 | 72 | | | | | |
| 12 months | 49 | 26 | 70 | 67 | | | | | |

 Table 44: Number of participants reporting receiving workbook

Engagement secondary hypotheses

F.

- a. The highest level of engagement will be in the 'booster' condition (MI+W+B), followed by the non-booster experimental condition (MI+W).
- b. The level of engagement will be higher in the non-booster experimental condition (MI+W) then in the standard treatment group (TAU).

G.

- a. Use of, and degree of, engagement in other treatment services will be significantly lower (and higher for engagement in workbook) in the two conditions involving motivational interviewing and workbooks (MI+W and MI+W+B) than in the standard (TAU) and motivational interview (MI) groups.
- b. This difference is expected to be greatest during the first three months.

There were no statistically significant differences for hypotheses F and G in relation to reading the workbook, although a level of statistical significance was only just missed for participants in the MI+W and MI+W+B groups in comparison with the TAU and MI groups. There were also no statistically significant differences noted for using the strategies in the workbook. However, in relation to completing some or all of the exercises in the workbook (time-averaged), a level of statistical significance was attained for the MI+W group in relation to the TAU group (p=0.0002), and for the MI+W and MI+W+B groups in comparison with the TAU and MI groups (p=0.008) at the three-month assessment (Table 45).

There were no statistically significant differences for hypotheses F and G in relation to participant engagement in formal (professional) treatment services (other than the gambling helpline) for gambling problems (Appendix 6, Table 6.8).

| <u> </u> | TEST | Odda | 050/ CT | 050/ CT | Drelue | Altomativo |
|-------------------------------|------------------------------------|-------|---------|---------|-------------|-------------|
| | 1651 | Udds | 95% CI | 95% CI | P-value | Alternative |
| | | ratio | Lower | Upper | (two-sided) | accepted |
| | | | | | | |
| Read workbook, | hyp. F.a: MI+W vs | 0.94 | 0.63 | 1.41 | 0.78 | No |
| time-averaged | MI+W+B | | | | | |
| | hyp. F.b: TAU vs MI+W | 1.51 | 0.95 | 2.40 | 0.08 | No |
| | hyp. G.a: TAU/MI vs MI+W/MI+W+B | 2.13 | 0.99 | 4.60 | 0.053 | No |
| Read workbook, at 3 months | hyp. G.b: TAU/MI vs MI+W/MI+W+B | 2.49 | 0.57 | 10.84 | 0.22 | No |
| Completed workbook | hyp. F.a: MI+W vs MI+W+B | 0.85 | 0.39 | 1.87 | 0.68 | No |
| exercises, time- | hyp. F.b: TAU vs MI+W | | 2.74 | 22.82 | 0.0002 | Yes |
| averaged | hyp. G.a: TAU/MI vs MI+W/MI+W+B | 25.85 | 4.55 | 146.80 | 0.0003 | Yes |
| Completed | hyp. G.b: TAU/MI vs | 26.20 | 2.37 | 289.20 | 0.008 | Yes |
| workbook | MI+W/MI+W+B | | | | | |
| exercises, at 3 months | | | | | | |
| Used workbook | hyp. F.a: MI+W vs | 0.62 | 0.21 | 1.77 | 0.37 | No |
| strategies, time- | MI+W+B | | | | | |
| averaged | hyp. F.b: TAU vs MI+W | 1.35 | 0.40 | 4.61 | 0.63 | No |
| | hyp. G.a: TAU/MI vs MI+W/MI+W+B | 1.04 | 0.13 | 8.27 | 0.97 | No |
| Used workbook | hyp. G.b: TAU/MI vs | 0.81 | 0.04 | 15.38 | 0.890 | No |
| strategies, at 3 | MI+W/MI+W+B | | | | | |
| months | | | | | | |

Table 45: Hypotheses F and G - Workbook engagement, time-averaged and at 3-months

4.7 Collateral assessments

At the three- and 12-month assessments, collateral participants were asked about the respective gambler's gambling (days gambled and dollars gambled) over the previous two months. There was moderate correlation between gambler participants' self-reports of gambling and collateral reports (Table 46).

| | | | | Gamble | r | | Collatera | ıl | | | |
|-----------------|--------------------|----------------------|-----|--------|--------|----|-----------|--------|----|-------------------------|----------|
| | | | Ν | Mean | SD | Ν | Mean | SD | Ν | Spearman Correlation | p-value |
| At 3 months | Days gambled | Most recent month | 109 | 2.79 | 4.24 | 95 | 3.83 | 11.43 | 94 | 0.33 | 0.001 |
| | | Month prior | 109 | 2.74 | 4.62 | 92 | 3.23 | 6.02 | 91 | 0.41 | < 0.0001 |
| | Dollars gambled | Most recent month | 109 | 220.04 | 490.81 | 94 | 215.36 | 589.22 | 93 | 0.35 | 0.001 |
| | | Month prior | 108 | 177.41 | 416.28 | 92 | 317.40 | 708.95 | 91 | 0.53 | < 0.0001 |
| At 12 months | Days gambled | Most recent month | 97 | 2.82 | 3.87 | 86 | 4.53 | 4.53 | 84 | 0.43 | < 0.0001 |
| | | Month prior | 97 | 2.68 | 4.28 | 86 | 4.56 | 4.56 | 84 | 0.39 | 0.0002 |
| | Dollars gambled | Most recent month | 97 | 275.21 | 605.79 | 87 | 262.16 | 262.16 | 85 | 0.47 | <0.0001 |
| | | Month prior | 97 | 253.59 | 558.54 | 87 | 306.46 | 306.46 | 85 | 0.39 | 0.0003 |

Table 46: Gambler and collateral reports of gambling

Collateral participants were asked how confident they were in their responses. Those who reported being 'fairly' or 'extremely' confident also showed moderate correlation with gamblers' self-reports of gambling (Table 47). However, there was substantially less correlation between the gambler and collateral reports when the collateral participant was 'not at all' or only 'somewhat' confident in their responses (Table 48).

| Table 47: Gambler and collateral | reports of ga | ambling by co | ollateral confidence | 'fairly' or | 'extremely' |
|----------------------------------|---------------|---------------|----------------------|-------------|-------------|
| | 1 0 | 0, | | 2 | <i>.</i> |

| | | | | Gamble | r | | Collatera | al | | | |
|-----------------|-----------------|----------------------|----|--------|--------|----|-----------|--------|----|-------------------------|----------|
| | | | N | Mean | SD | N | Mean | SD | N | Spearman Correlation | p-value |
| At 3 months | Days gambled | Most recent month | 77 | 2.78 | 4.19 | 75 | 1.85 | 4.02 | 74 | 0.39 | 0.0005 |
| | | Month prior | 77 | 2.69 | 4.67 | 73 | 2.40 | 4.72 | 72 | 0.43 | 0.0002 |
| | Dollars gambled | Most recent month | 77 | 242.55 | 540.10 | 76 | 200.87 | 60.63 | 75 | 0.40 | 0.0004 |
| | | Month prior | 77 | 188.04 | 454.09 | 75 | 337.03 | 764.55 | 74 | 0.53 | < 0.0001 |
| At 12 months | Days gambled | Most recent month | 69 | 2.97 | 4.27 | 70 | 2.46 | 4.88 | 69 | 0.45 | < 0.0001 |
| | | Month prior | 69 | 2.87 | 4.85 | 69 | 2.61 | 4.86 | 68 | 0.41 | 0.0005 |
| | Dollars gambled | Most recent month | 69 | 255.29 | 568.30 | 70 | 129.59 | 253.76 | 69 | 0.53 | <0.0001 |
| | | Month prior | 69 | 231.62 | 544.60 | 69 | 146.16 | 263.75 | 68 | 0.41 | 0.0006 |

| | | | | Gamble | r | Collateral | | | | | |
|-----------------|--------------------|----------------------|----|--------|--------|------------|--------|--------|----|-------------------------|---------|
| | | | N | Mean | SD | N | Mean | SD | Ν | Spearman Correlation | p-value |
| At 3 months | Days gambled | Most recent month | 25 | 1.88 | 2.13 | 19 | 11.42 | 23.20 | 19 | 0.07 | 0.78 |
| | | Month prior | 25 | 2.24 | 2.73 | 18 | 6.33 | 9.22 | 18 | 0.46 | 0.05 |
| | Dollars gambled | Most recent month | 25 | 110.52 | 200.79 | 18 | 276.56 | 373.95 | 18 | 0.21 | 0.41 |
| | | Month prior | 25 | 100.40 | 185.86 | 17 | 230.82 | 381.25 | 17 | 0.51 | 0.04 |
| At 12 months | Days gambled | Most recent month | 15 | 3.33 | 2.74 | 15 | 2.60 | 2.67 | 14 | 0.03 | 0.92 |
| | | Month prior | 15 | 2.73 | 2.19 | 15 | 3.60 | 3.18 | 14 | 0.08 | 0.78 |
| | Dollars gambled | Most recent month | 15 | 293.20 | 650.30 | 16 | 226.25 | 297.25 | 15 | -0.08 | 0.78 |
| | | Month prior | 15 | 302.87 | 637.53 | 16 | 339.38 | 431.87 | 15 | 0.12 | 0.67 |

Table 48: Gambler and collateral reports of gambling by collateral confidence 'not at all' or 'somewhat'

4.8 Treatment integrity and fidelity

Seventy-four digital recordings of intervention delivery were listened to for treatment integrity and fidelity purposes. All counsellors and all treatment conditions were represented in the recordings which were made throughout the recruitment and intervention delivery period. Additionally, nine booster calls were recorded and listened to.

Adherence to treatment intervention was very good with no difference between shared elements across the treatments groups and with minimal motivational interviewing elements in the TAU group (expected), and minimal TAU only elements in the three treatment groups (expected) (Figure 10).



Figure 10: Treatment adherence

N=74

Inter-rater reliability was very good across the 30 recordings assessed throughout data collection (Figure 11 and Table 49). Most counsellors and treatment conditions were represented in the recordings.



Figure 11: Mean elements

Effectiveness of problem gambling brief telephone interventions: A randomised controlled trial Provider No: 467589, Contract No: 326673/00 and 326673/01 Gambling and Addictions Research Centre, Auckland University of Technology Final Report, 13 December 2012 86

Table 49: Reliability

| Element | Pearson r | ICC |
|---------|-----------|-------|
| Shared | 0.962 | 0.959 |
| MI | 0.980 | 0.979 |
| TAU | 0.982 | 0.982 |

5. DISCUSSION

5.1. Limitations

5.1.1. Differential attrition and imbalance

No difference between the proportions in each group having received partial interventions was found to be significant (smallest unadjusted p-value 0.11). Likewise there was no significant differential loss to follow-up between the groups overall (p=0.16) nor over time (p=0.08). There is, thus, no evidence for the presence of a bias in the outcome summary statistics due to differential attrition.

There was no imbalance found amongst baseline covariates across the groups in the sense expressed in section 3.9. There is, therefore, no reason to believe that chance confounding has occurred.

5.1.2. Multiplicity

The method chosen to adjust for multiplicity was to control false discovery rate for families of hypotheses tested using the same model on the same outcome. This is not an especially conservative approach, but given that: a) the p-values used in the application of false discovery rate control were all derived from likelihood ratio-based statistics and were thus monotonic for the likelihood (and therefore evidentially interpretable to a degree); b) that a number of hypotheses were excluded from significance, as compared with per comparison error rate control; and c) that only a modest number of hypotheses were found significant, the approach displayed face usefulness.

The analysis plan was completed before unblinding of the data and with only the knowledge supplied by an allocation-blinded analysis of the data collected at three months post-randomisation. The analyses selected, therefore, cannot introduce bias in the conclusions reached.

5.1.3. Ascertainment bias

Counsellors were responsible both for delivering the interventions and carrying out the initial assessment. As the initial assessment was conducted prior to intervention allocation the counsellor had no knowledge of intervention group at the time of initial assessment data collection and thus ascertainment bias is unlikely. In the course of the analyses, we found that the random effects corresponding to counsellors in the models for the primary outcomes and PGSI at 12 months, did not reach significance. This lack of significance is consistent with homogeneity of bias across the counsellors and intervention groups. In particular it is consistent with, though it does not entail, a bias of 0. Participants and research assistants conducting the follow-up assessments were blind to treatment intervention and again ascertainment bias is unlikely.

5.1.4. Selection bias

As counsellors did not activate the intervention random allocation computer programme until after eligible clients had agreed to participate in the trial and had responded to the initial assessment questions, selection bias is unlikely to have occurred.

5.1.5. Post-intervention baseline assessment

As detailed in section 3.5, a few baseline assessment questions were asked of participants within seven days of receiving their intervention. These questions related to a detailed time line follow-back of gambling/problem gambling history over the previous two months, comorbidity and substance abuse (measured by PRIME-MD), and the New Zealand Index of Socio-economic Deprivation for Individuals. This may have biased the affected ANCOVA-derived estimates toward the null by causing nominal baseline values to align more closely with their values at three-, six- and 12 months than a pre-intervention baseline value might have.

5.2. Discussion and interpretation

5.2.1 Scene setting

The major purpose of the present study is to examine the effectiveness of three brief telephone interventions relative to standard helpline treatment (TAU) and to compare their performance relative to each other. One of the interventions (motivational interview and workbook; MI+W) had been shown to produce clinically significant outcomes in two previous efficacy studies (Hodgins et al., 2001; 2004; 2009). Both studies were conducted by teams that included one of the developers of these interventions (Hodgins) and involved volunteers recruited through the mass media and other avenues rather than people seeking help from problem gambling or other clinical services. The present study differed from these earlier trials in that it involved embedding this and related brief interventions within the everyday operations of a national gambling helpline. Hodgins et al. (2009) expressed the view that these interventions would fit "very well with the existing helplines that provide information and support to pathological gamblers in most Canadian provinces, U.S. states, and elsewhere". The study was developed to examine the feasibility of integrating these brief therapies into a helpline service and to evaluate them in this context. To our knowledge this is the first time that a manualised psychological intervention for problem gambling, previously assessed in two efficacy trials, has been formally and independently evaluated in a real-life service setting. The study is also distinctive in that relative to previous gambling trials it included a large number of participants, enabling potential subgroup differences in treatment response to be assessed.

As mentioned in the literature review, in the initial efficacy trial (Hodgins et al., 2001) a cognitive behavioural self-help workbook (Hodgins & Makarchuk, 1997) provided with or without a motivational enhancement interview was compared with a wait-list control group. At one month follow-up, participants who received the interview and the workbook (MI+W) substantially reduced their frequency of gambling participation and expenditure. These reductions were statistically and clinically significant. Less substantial reductions were also found both in the group that received the workbook only and the wait-list control group. For ethical reasons the wait-list group was terminated at one month and participants were given the option of receiving an intervention. While at three and six month follow-ups MI+W participants continued to show less frequent gambling and lower expenditure than those in the

workbook-only group, at 12 months there were no significant differences between the two groups. However, when participants were followed up at 24 months, group differences were again evident (Hodgins et al., 2004). Although participants in both groups generally maintained therapeutic gains (overall 77% improved, 37% reported six months abstinence and 55% were below the SOGS-R cut-off for pathological gambling) MI+W participants gambled significantly less often, lost less money, had lower SOGS-R scores and were more likely to be categorised as improved.

In the second trial (Hodgins et al., 2009), in addition to the MI+W intervention, participants were also allocated to a group that received this intervention plus six follow-up motivational booster sessions spread over a nine-month period. As in the earlier study, there were also workbook only and wait-list (six week) control groups. Again, at the time the wait-list group was terminated, MI+W participants (in both the original and booster conditions) reduced their gambling frequency and losses more than those in the control groups. They were also significantly more likely to be abstinent or improved at six weeks than were wait-list and workbook only participants. As hypothesised, participants in the MI+W groups gambled significantly less often than the workbook only participants during the first nine months of the trial. However, contrary to expectation, workbook only participants were as likely as other participants to have significantly reduced their gambling losses over the year of the follow-up, to be abstinent, and to not meet the criteria for pathological gambling. The investigators had hypothesised that the addition of six booster phone calls would help motivate or maintain changes in gambling behaviour. Although participants who received booster calls reported slightly higher self-efficacy ratings and generally reported calls as helpful and wanted more, there were no significant differences in gambling outcomes between booster and non-booster participants.

In addition to examining the effectiveness of the interventions used in the previous efficacy trials (MI+W with and without booster sessions) the present study included a single motivational interview without the workbook (MI). This was added to see whether it was the motivational interview per se rather than the combination of interview and workbook that was responsible for the treatment effect. As indicated previously in this report, in the wider addictions field, as well as from a small number of gambling studies, it is apparent that 'more' treatment is not necessarily 'better'. While some studies indicate that many people benefit equally well from brief or longer interventions, research suggests that other people benefit more from longer, more intensive interventions. The latter may include those with more serious problems and/or comorbid disorders. In the present trial, further to seeking to determine how well each of the brief interventions performed relative to each other and to helpline standard care, there was an interest in identifying groups of people that do better with different types and levels of intervention. This is of particular importance to the development of evidence-based stepped-care treatment models that match clients to treatments and engage, in a cost-effective manner, the wide spectrum of problem gamblers, including the majority that do not currently access specialist problem gambling services. Little is known about this topic with respect to gambling. Given that problem gambling is highly comorbid with a range of other addictions and mental health disorders, there was particular interest in seeing whether the presence of substance misuse and mental health disorders compromised response to treatment and whether or not reduced gambling problems are associated with improved mental health status. A further object of the present study is to determine how well the standard helpline interventions, which have not been evaluated relative to natural or selfrecovery or to other interventions, perform relative to the brief interventions included in the trial that has been compared with wait-list and placebo control groups.

5.2.2 Study interpretation

While not without initial challenges, the large majority of helpline counsellors were successfully trained to deliver motivational interviews and conduct follow-up booster sessions as well as deliver standard (TAU) helpline interviews in a consistent manner. Prior to the trial most had limited or no experience of motivational interviewing or its application to encourage the use of workbook cognitive behavioural interventions. Following training, the new counselling approach and other trial procedures became integrated into the operations of the Over a third of potentially eligible clients were recruited into the trial and helpline. counsellors delivered the interventions with a very high level of integrity, i.e. the four interventions were for the most part delivered as intended. Treatment adherence was high, the counsellors were proficient in delivering both standard care and the new interventions and the standard and new interventions were differentiated in the ways intended. The great majority of the 462 clients recruited into the trial and randomised to the four groups received the applicable interview intervention and, where appropriate, the workbook or helpline manual. Delivery of the four booster sessions to MI+W+B participants, however, was partial with only a third receiving all four and 14% receiving none. The involvement of Hodgins in the counsellor training and integrity assessment helped ensure that the MI, MI+W and MI+W+B interventions corresponded to those that had been included in the previous efficacy trials.

Some of the major study hypotheses were corroborated, others not. It was predicted that the MI and TAU participants would show similar improvements on the three primary measures and that there would be a variety of outcome differences between these participants and participants in the other, more intensive, groups (MI+W; MI+W+B). While there were no significant differences between MI and TAU participants on the three primary measures, the most notable study finding was that participants in all four intervention groups evidenced statistically and clinically significant and sustained improvement on the three primary variables (days gambled, money lost gambling and having quit gambling or improved control over gambling) and, that contrary to expectation, no group was superior to any of the others. This applied both when performance on these measures was time-averaged across the duration of the trial and when considered at 12 months. This was also the case for problem gambling severity as measured by PGSI and a number of other outcome measures including participant self-ratings of control over gambling, gambling impacts on work, social life, family and home and health, psychological distress (Kessler-10) and quality of life (WHOQoL). There was also a substantial reduction in participants in each group meeting the criteria for major and minor depressive disorder and dysthymia. These disorders were assessed at intake into the trial and at 12 months. In contrast to these significant improvements little or no change was evident in any of the groups with respect to alcohol misuse (AUDIT-C and PRIME-MD) and tobacco use. Overall more than half of participants reported that their treatment goals had been completely or mostly met at three months and slightly more reported similarly at 12 months. At intake almost all participants (95% to 97% across the groups) met PGSI criteria for problem gambling. This reduced to 65% to 67% across the groups at the 12-month assessment.

Thus it can be concluded, as proposed by Hodgins et al. (2009), that these brief interventions can be integrated into the routine operations of an existing helpline service. Furthermore, it is evident that these interventions are effective, producing clinically significant outcomes in a help-seeking population. With regard to the primary outcome measures and problem gambling severity (PGSI) the effects appear to be comparable to those achieved in the earlier efficacy studies that involved volunteers who responded to advertisements to participate. While not involving a population seeking formal help from an existing problem gambling service, these volunteers did have substantial gambling and other mental health problems.

While it appears that they were similar to client groups in this regard, the study authors indicated that they differed in that most were not interested in formal treatment and wanted to overcome their problems in other ways.

It was hypothesised that the more intensive MI+W+B intervention would have a greater impact than the other three interventions during the latter part of the trial. As predicted, between the three- and 12-month assessment points, the MI+W+B group showed greater improvement than the MI+W group in relation to reporting having quit gambling or improved control over gambling. Participants in this group did not, however, evidence more improvement on this measure than those in the MI or TAU groups. During this time period, the MI+W and MI+W+B participants reported experiencing greater time-averaged control over gambling than MI participants. They did not, however, do better in this regard than TAU participants. Outcome differences between groups were not found for days gambled, money lost or problem gambling severity (time-averaged PGSI). Increased workbook involvement and receiving informal assistance for gambling problems were found to be associated with better outcomes (the former in regard to time-averaged money lost and time-averaged quit gambling or improved control over gambling; the latter in regard to time-averaged control over gambling or improved control over gambling; the latter in regard to time-averaged control over gambling and time-averaged goal being met).

Although there were no significant primary outcome differences between participants in each of the four treatment groups overall, differences were found for a number of subgroups. Males in the MI+W group (but not MI+W+B group) showed significantly more improvement than males in the MI group with respect to time-averaged money lost gambling. Maori participants in the MI+W+B group performed significantly better than Maori in the MI group with respect to money reported lost gambling at the 12 month assessment. On this measure, participants in MI+W+B group with more serious gambling problems also had better outcomes than their counterparts in the MI group. Significantly more participants with more serious problems in this group than in the MI and TAU group also reported that they had stopped gambling or improved at 12 months. People in the MI+W+B group with higher levels of psychological disorder (Kessler-10) had better outcomes with respect to both money lost and reporting having quit gambling or improved control over gambling than their MI counterparts. There was, however, no difference between the MI+W+B and TAU groups in this regard. In the case of alcohol misuse (AUDIT-C) MI+W+B participants with lower problem levels had better Gambling-quit or improved outcomes at 12 months than their counterparts in the MI group.

Subgroup differences were also found in relation to treatment goal and belief in treatment success. While the majority of people who entered the trial reported that they wanted to quit all or some modes of gambling, a significant minority indicated that they sought to decrease or control their gambling. With respect to time-averaged self-assessment of having quit or improved control over their gambling, participants who sought to control their gambling did significantly better in the MI group than they did in TAU. The MI+W+B participants who sought to control their gambling also did better than their MI counterparts with respect to money losses at 12 months, number of days gambled and time-averaged assessment of having quit gambling or improved control over gambling at 12 months. The MI+W participants in this category also did significantly better than those with this treatment goal in the MI treatment group. Participants with lower levels of belief in their success in achieving their treatment goal in 12 months were also found to do significantly worse in the MI group than in the TAU group with respect to time-averaged self-assessment of having quit gambling or improved control over gambling and those with lower levels of belief in the MI+W+B group showed significantly more improvement than their counterparts in the MI group on this measure.

While noting these subgroup differences in response to the trial interventions on some measures, as indicated, the most important finding is that overall, on the primary outcome measures and problem gambling severity, all groups evidenced statistically and sustained (to 12 months) clinically significant improvement. Given that TAU performed similarly to two of the interventions that had previously been shown in efficacy studies to produce significantly better outcomes than waiting for treatment, it is likely that it would too. All study participants had sought help because they wanted to stop or reduce gambling and the large majority had long-standing, serious gambling problems as measured by the PGSI and the self-reported impacts of gambling on work, social life, family and heath, as well as significant comorbidity. Most had problems primarily with electronic gaming machines (EGMs). Approximately a third had previously received assistance for a gambling problem, 17% were receiving assistance at the time they contacted the helpline and 20% had received treatment for a mental health problem in the past 12 months. At intake over 80% reported significant psychological distress, over 60% met diagnostic criteria for major or minor depressive disorder and the same percentage was classified as likely to abuse or be dependent on alcohol. Over a half smoked tobacco. All four trial interventions can be regarded as brief or minimal in that they involved a telephone interview, and in some cases receipt of a workbook with or without follow-up booster phone calls, rather than face-to-face therapy sessions with a clinician. Participants not only evidenced substantial improvement with regard to their gambling problems, they improved considerably in a number of other areas including psychological distress and depression. These findings are consistent with those from the earlier efficacy studies and problem gambling treatment literature generally. Less change was evident in the case of tobacco and alcohol use/misuse. Both are highly comorbid with problem gambling and significant health issues in their own right. Given that they do not respond, or respond minimally, to the interventions offered, consideration needs to be given to whether or not they should be addressed via gambling helplines in conjunction with gambling interventions or responded to in some other way. This could be a focus for future research.

A growing literature supports the view that motivational interviewing makes a significant contribution to behaviour change, both on its own and as part of other interventions (Hodgins et al., 2004; Wulfert et al., 2006). Diskin and Hodgins (2009) found that a motivational interview had a larger impact on gambling than a non-motivational interview. However, in the present study it was hypothesised that TAU and MI alone would be equally effective. This was because both were expected to be of similar length and that while MI on its own was considered likely to have more impact, TAU was more intensive in that participants also received an information pack. There was also emphasis on seeking face-to-face and other forms of support. In the present study, the addition of workbook and workbook and booster sessions to motivational interviewing was not found to produce superior outcomes for participants overall, although they did for some categories of participant. This suggests that for many callers the motivational interview, or other factors common to all four interventions, were the important ingredients. Hodgins et al. (2009) found that both MI and MI+W+B participants reported less gambling at six weeks than both those in a wait-list control and those who received the workbook alone. However, while superiority was demonstrated at six weeks, as mentioned earlier, 12 months post- treatment the workbook only participants were just as likely as the MI+W+B group to have reduced their past year gambling losses and no longer meet the criteria for pathological gambling. All of these findings support the value of offering brief interventions and suggest that even 'less' within already minimal interventions can produce comparable outcomes to 'more'. However, it remains unclear what the most important factors are in producing therapeutic gain.

Why did the four interventions produce similar overall outcomes on a number of measures? From prospective general population studies it is evident that many people with gambling problems, especially if less severe, overcome them without professional or specialist intervention (Abbott & Clark, 2007). However, fluctuation over time including relapse is common, especially when problems are more severe and comorbid with alcohol misuse disorders (Abbott, Williams & Volberg, 2004). Thus it is likely that a significant proportion of participants would have improved during the 12 month trial period, whether they participated or not. In addition, all participants recognised that they had gambling problems and were seeking help. In this situation it is likely that many people already had, or would subsequently, take measures, informally and or formally, to stop or reduce their gambling and make other changes in their lives. The present study did not include a wait-list control group. The helpline does not have a wait-list and to include one in the trial would have been unacceptable and unethical. However, as mentioned, the two previous efficacy studies did. In these studies between 14% and 18% of wait-list controls were abstinent and between 26% and 45% improved. In the treatment groups approximately an additional ten percent were abstinent at four or six weeks.

Westphal and Abbott (2006) have also pointed out that previous trials have found high rates of non-specific or 'placebo' response, even higher than those generally in trials involving other mental health disorders. In other words, many participants seeking to change do well irrespective of the particular form of intervention offered. Therapist characteristics and the perceived credibility of the intervention are also important. The challenge is to identify interventions that add additional value by enhancing outcomes further, either overall, or for one or more groups of client. As mentioned, the four interventions were differentiated and delivered as intended, other than there being a short-fall in the number of follow-up booster sessions in the MI+M+B group. It is possible that increasing the percentage of participants who received all or most of the four booster sessions would have made a difference. However, this was not the case in the Hodgins et al. (2009) trial which involved six booster calls over a longer time period. Hodgins et al. (2009) were of the view that the assessment process per se may have an impact, for example by increasing caller awareness of the negative effects of gambling and by serving a "motivational-supportive purpose". Thev noted that more consistent differences were evident over the two years of their earlier trial that involved much briefer and less frequent assessment. The present study more resembled that 2009 trial in this regard so it might be that the researcher contact, which was fairly considerable and consistent across the four interventions, played a role in diminishing outcome differences. The present design does not allow the impact of these different factors to be assessed.

The helpline has a role both in providing direct service to callers, by way of receiving initial calls and providing an interview along the lines of TAU in the present study, sending out a self-help manual and indicating other options including face-to-face counselling from other service providers. Callers may also re-contact the helpline for further counselling or support. As mentioned above, in the present study it was expected that TAU participants would make greater use of other treatment services than participants who received the workbook and workbook and booster sessions. It was also considered likely MI participants would seek other forms of help more frequently because they would not receive the workbook or booster sessions. It was expected that these differences would be greatest during the first three months. As it transpired, relatively few participants in any of these conditions re-contacted the helpline during the trial (1.3% to 7.1% in any three month period). While approximately 20% received some other type of formal assistance for gambling problems, contrary to prediction there were no differences between the four intervention groups with regard to engagement in non-helpline formal gambling treatment services. There were also no differences between groups with respect to participants who reported receiving treatment for mental health problems, including medication, and treatment for alcohol or drug problems. Approximately a third of trial participants also indicated that they had received informal support or help for their gambling problems within the past three month period. These findings underline the reality that people who seek help for gambling problems from helplines, or other specialist services, concurrently and subsequently seek formal and informal assistance for their gambling problems as well as other related and non-related mental health and other problems. This makes it difficult to determine the impact that any particular intervention makes.

The identification of the major ingredients for effective gambling treatment remains an important focus for further investigation. The earlier trials also indicated that treatment effects and differences between groups change over time. Given that problem gambling is often relapsing in nature, the value of different interventions is best judged, both clinically and financially, over a longer time frame than most studies employ. In this regard it is anticipated that participants in the present study will be re-assessed three years after they entered the study. It may be found that some interventions included in the study have more enduring effects, at least for some client subgroups.

As discussed earlier the identification of subgroups of problem gamblers who do better with different forms and intensities of intervention is also an important focus for future research. The present study sheds some light on this topic, an area that has been little investigated in the gambling field to date, largely because of the small sample size of previous trials and various methodological shortcomings indicted in the literature review. Where there were significant outcome differences between different groups in the various interventions it mostly applied to differences between the MI (the least intensive) and MI+W+B (most intensive) interventions. Thus, if MI was the primary intervention being used in a helpline, or perhaps other service setting, there may be added value in including the option of the workbook and booster sessions for some clients including Maori, people with more serious gambling problems and those with higher levels of psychological disturbance. People with more serious gambling problems also had better outcomes in the MI+W+B condition than in TAU, as did those who sought to control/reduce their gambling rather than quit. This group also did better in MI+W+B than in MI. For clients with initially low levels of belief in their success in achieving their treatment goal it was found that MI alone produced worse outcomes than TAU. While a number of the foregoing differences were only found with respect to one or a small number of outcome measures, they provide an indication of groups of clients who may do significantly better with particular types and intensities of intervention. This requires more focused investigation in future studies that include cost-benefit analysis.

6. OTHER INFORMATION

6.1 Registration

The trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), study registration number: ACTRN12609000560291.

6.2 Protocol

Full details of the trial protocol are maintained by the Gambling and Addictions Research Centre, National Institute for Public Health and Mental Health Research, School of Public Health and Psychosocial Studies, Faculty of Health and Environmental Sciences, Auckland University of Technology, Private Bag 92006, Auckland 1142, New Zealand.

6.3 Funding

The trial was funded by the New Zealand Ministry of Health. The funder had no role in study design, data collection and analysis, or reporting, although they approved each of those stages and had the right to suggest changes. Final decision on content was exclusively retained by the trial investigators.

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APPENDIX 1 Ethical approval



Multi-region Ethics Committee

Ministry of Health Level 2, 1–3 The Terrace PO Box 5013 Wellington Phone (04) 470 0655 (04) 470 0646 Fax (04) 496 2191 Email: multiregion_ethicscommittee@moh.govt.nz

3 June 2009

Prof. Max Abbott Auckland University of Technology Faculty of Health & Environmental Sciences Private Bag 92006 Auckland 1142

Dear Prof. Abbott

Effectiveness study of problem gambling standard and brief interventions Lead Investigator: Prof. Max Abbott, Co-Investigators: Dr. Maria Bellringer, Dr David Hodgins, Dr Phillip Schluter, Dr Valery Feigin, Dr Justin Pulford Approved site: AUT University MEC/09/04/043

The above study has been given ethical approval by the Multi-region Ethics Committee.

Approved Documents

- Initial Assessment Questionnaire
- Follow-up questionnaire one (one month post assessment)
- Follow-up questionnaire two (three months post assessment) .
- Follow-up questionnaire three (twelve months post assessment)
- Collateral questionnaire one (three months post assessment)
- Collateral questionnaire two (twelve months post assessment)
- Participant Information Sheet Version 1
- Helpline Script for Obtaining Participant Consent
- **Collateral Information Sheet**
- Self Help Workbook Version 1 entitled 'Becoming a Winner: Defeating Problem Gambling'

Certification

The Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out.

Accreditation

The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

Progress Reports

The study is approved until June 2012. The Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator's responsibility to forward a progress report covering all sites prior to ethical review of the project in **June 2010**. The report form is available on http://www.ethicscommittees.health.govt.nz. Please note that failure to provide a progress report may result in the withdrawal of ethical approval. A final report is also required at the conclusion of the study.

Requirements for SAE Reporting

- The Principal Investigator will inform the Committee as soon as possible of the following:
- Any related study in another country that has stopped due to serious or unexpected adverse events
- withdrawal from the market for any reason

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- all serious adverse events occurring during the study in New Zealand which result in the investigator breaking the blinding code at the time of the SAE or which result in hospitalisation or death.
- all serious adverse events occurring during the study worldwide which are considered related to the study medicine. Where there is a data safety monitoring board in place, serious adverse events occurring outside New Zealand may be reported quarterly.

All SAE reports must be signed by the Principal Investigator and include a comment on whether he/she considers there are any ethical issues relating to this study continuing due to this adverse event. It is assumed by signing the report, the Principal Investigator has undertaken to ensure that all New Zealand investigators are made aware of the event.

Amendments

All amendments to the study must be advised to the Committee prior to their implementation, except in the case where immediate implementation is required for reasons of safety. In such cases the Committee must be notified as soon as possible of the change.

Please quote the above ethics committee reference number in all correspondence.

The Principal Investigator is responsible for advising any other study sites of approvals and all other correspondence with the Ethics Committee.

It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider within whose facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Yours sincerely

a Stewart Repec Multi-region Ethics Committee Administrator Email: rebecca_stewart@moh.govt.nz

APPENDIX 2 Trial hypotheses notation

The outcome as a function of time *t* from baseline assessment is denoted Y(t). The subscript g = 0,1,2,3 denotes the TAU, MI, MI+W and MI+W+B groups; the subscript j=0,1,2,3 denotes the baseline, three-month, six-month and 12-month time points⁷; the subscript $k=1,...,K_g$ identifies the participant in group *g*, that has size K_g . The quantities t_{kgj} are the actual assessment times elapsed for participant *k* in arm *g* since baseline assessment. We define $Y_{kgj} = Y(t_{kgj})$, with common expectation μ_{gj} . A single subscript present refers to the treatment arm and indicates that a common mean for the outcome involved is posited across the three non-baseline time points.

Averaging over post-randomisation time points, or time-averaging, is represented by ", \bullet ". (Time-averaging was implemented indirectly through use of suitably weighted repeated measures models rather than the computation of time-averaged outcomes).

Averaging over groups is represented by "•,".

Averaging of a parameter indicates that it is assumed in the hypothesis concerned to be equal over the distributions being averaged. It does not necessarily indicate that a composite outcome is being computed, since the averaging can be effected in a repeated measures setting with appropriate re-parameterisation.

Parameters identified by subscripted letters are understood to represent the effect of the level in the category identified by the subscript. Thus μ_g , • is the true mean time-averaged outcome associated with the *g*th treatment group.

Covariates entering hypotheses are expressed as continuous covariates for simplicity, although they may in fact be categorical.

Interactions are indicated by a colon (:).

Note that baseline true means are assumed to be equal $(\mu_{g,0} = \mu \bullet_{.0})$ and so are not included in several of the hypotheses.

The hypotheses are not fully detailed below. They detail, often implicitly, what underlying distribution and other adjustments may enter into defining the hypotheses. Whatever these additional aspects are, they appear in the null and alternative hypotheses simultaneously.

Efficacy hypotheses

With $Y_{g,j,k}$ an efficacy outcome, the basic model is either $E(Y_{g,j,k}) = \mu_g, \bullet$, or $E(Y_{g,j,k}) = \mu_{g,j}$, where E(.) represents expectation. Adjustments may be added to these models; adjustments for baseline, when available, are systematic in continuous outcomes analysis: the interpretation of the treatment effects are, therefore, as an average change from baseline in these cases. In some cases (e.g. gambling-quit or improved), a link function may have been used and/or the inequalities presented may be reversed to correctly reflect superiority.

⁷ Note that Y_{kg0} is treated as an independent covariate, systematically included in all continuous variable models when available. Thus the subscript *j*=0 does not enter hypotheses below.

Primary equivalence hypothesis

B. The Motivational Interview (MI) group will show similar improvement to Treatment as Usual (TAU).

 H_{A0} : $|µ_1, ● -µ_0, ●| ≤ δ$ vs. H_{A1} : $|µ_1, ● -µ_0, ●| > δ$ where δ is a present equivalence threshold for each outcome.

Primary superiority hypotheses

- B. (Superiority is associated to lower values in the generic hypothesis statements below)
 - a. The Motivational Interview/Workbook group (MI+W) will show greater improvement than the TAU group.

 $H_{Ba0}: \ \mu_2, \bullet \geq \mu_0, \bullet \qquad vs. \qquad H_{Ba1}: \quad \mu_2, \bullet < \mu_0, \bullet$

b. The Motivational Interview plus Workbook group (MI+W) will show greater improvement than the MI group.

 H_{Bb0} : $\mu_2, \bullet \ge \mu_1, \bullet$ vs. H_{Bb1} : $\mu_2, \bullet < \mu_1, \bullet$

c. The Motivational Interview plus Workbook plus Booster group (MI+W+B) will show greater improvement than the TAU group.

$$H_{Bc0}: \mu_3, \bullet \geq \mu_0, \bullet \qquad \text{vs.} \qquad H_{Bc1}: \quad \mu_3, \bullet < \mu_0, \bullet$$

d. The Motivational Interview plus Workbook plus Booster group (MI+W+B)will show greater improvement than the MI group.

 $H_{Bd0}:\,\mu_3,\bullet\geq\mu_1,\bullet\qquad vs.\qquad H_{Bd1}:\quad \mu_3,\bullet<\mu_1,\bullet$

C. (Superiority is associated to lower values in the hypothesis statements below)

a. The MI+W+B group will show greater improvement than the TAU group at the 12-month follow-up.

 H_{Ca0} : $\mu_{3,3} \ge \mu_{0,3}$ vs. H_{Ca1} : $\mu_{3,3} < \mu_{0,3}$

b. The MI+W+B group will show greater improvement than the MI group at the 12month follow-up.

 $H_{Cb0}: \mu_{3,3} \ge \mu_{1,3}$ vs. $H_{Cb1}: \mu_{3,3} < \mu_{1,3}$

c. The MI+W+B group will show greater improvement than the MI+W group at the 12-month follow-up.

 $H_{Cc0}: \mu_{3,3} \ge \mu_{2,3}$ vs. $H_{Cc1}: \mu_{3,3} < \mu_{2,3}$

Secondary efficacy hypotheses

C*.

- (Superiority is associated to lower values in the hypothesis statements below)
 - d. The MI+W+B group will show greater improvement than the TAU group between 3 and 12 months.
 - H_{Cd0} : $\mu_{3,3} \mu_{3,1} \ge \mu_{0,3} \mu_{0,1}$ vs. H_{Cd1} : $\mu_{3,3} \mu_{3,1} < \mu_{0,3} \mu_{0,1}$
 - e. The MI+W+B group will show greater improvement than the MI group between 3 and 12 months.

 H_{Ce0} : $\mu_{3,3} - \mu_{3,1} \ge \mu_{1,3} - \mu_{1,1}$ vs. H_{Ce1} : $\mu_{3,3} - \mu_{3,1} < \mu_{1,3} - \mu_{1,1}$

f. The MI+W+B group will show greater improvement than the MI+W group between 3 and 12 months.

$$H_{Cf0}: \ \mu_{3,3} - \mu_{3,1} \ge \mu_{1,3} - \mu_{1,1} \quad vs. \qquad H_{Cf1}: \quad \mu_{3,3} - \mu_{3,1} < \mu_{1,3} - \mu_{1,1}$$

- D. (Superiority is associated to lower values in the generic hypothesis statements below)a. The TAU group will evince significant reduction in gambling.
 - $H_{Da0}: \mu_0, \bullet \ge \mu_{0,0}$ vs. $H_{Da1}: \mu_0, \bullet < \mu_{0,0}$
 - b. The MI group will evince significant reduction in gambling.

$$H_{Db0}: \mu_1, \bullet \ge \mu_{1,0}$$
 vs. $H_{Db1}: \mu_1, \bullet < \mu_{1,0}$

c. The MI+W group will evince significant reduction in gambling.

 $\begin{array}{ll} H_{Dc0}:\ \mu_2,\bullet\geq\mu_{2,0} & vs. & H_{Dc1}: \quad \mu_2,\bullet<\mu_{2,0} \\ \text{d. The MI+W+B group will evince significant reduction in gambling.} \\ H_{Dd0}:\ \mu_3,\bullet\geq\mu_{3,0} & vs. & H_{Dd1}: \quad \mu_3,\bullet<\mu_{3,0} \end{array}$

E.

(Superiority is associated to lower values in the generic hypothesis statement below) High levels of engagement within conditions will be associated with better gambling outcomes (gambling participation, attainment of goal and sense of control over gambling). In the model, $E(Y_{g,j,k}) = \mu_{g,j} + \alpha A_{g,j,k}$, where $A_{g,k}$ represents the level of engagement of participant *k* in group *g*=0,2,3, to which other adjustments may be added:

 $H_{E0}: \alpha \ge 0 \qquad \text{vs.} \qquad H_{E1}: \quad \alpha < 0.$

Engagement secondary hypotheses

F.

(Superiority is associated to higher values in the generic hypothesis statements below) With $V_{g,j,k}$ the level of engagement in other treatment services, the basic model is $E(V_{g,j,k}) = v_{g,j}$, to which other adjustments may be brought.

a. The highest level of engagement will be in the 'booster' condition (MI+W+B), followed by the non-'booster' experimental condition (MI+W).

 $H_{Fa0}: v3, \bullet u \le v_2, \bullet \quad vs. \qquad H_{Fa1}: \quad v_3, \bullet > v_2, \bullet$

b. The level of engagement will be higher in the non-'booster' experimental condition (MI+W) then in the standard treatment group (TAU).

 $H_{Fb0}: v_{2,\bullet} \le v_{0,\bullet}$ vs. $H_{Fb1}: v_{2,\bullet} > v_{0,\bullet}$ (Note that the third alternative, $v_{3,\bullet} > v_{0,\bullet}$ is not considered here, as the group sizes are comparable and transitiveness is almost guaranteed, not warranting family-wise error rate adjustment.)

G.

(Superiority is associated to higher values in the generic hypothesis statements below) Use of, and degree of, engagement in other treatment services will be significantly lower in the two conditions involving motivational interviewing and workbooks (MI+W; MI+W+B) than in the standard (TAU) and motivational interview (MI) groups. This difference is expected to be greatest during the first three months.

With $R_{g,j,k}$ the level of engagement in other treatment services, the basic model is $E(R_{g,j,k}) = \mu_{g,j}$, to which adjustments may be brought.

 $\begin{array}{ll} a. \ H_{Ga0} & \mu_{3, \bullet} + \mu_{2, \bullet} \leq \mu_{1, \bullet} + \mu_{0, \bullet} \\ b. \ H_{Ga0} & \mu_{3, 1} + \mu_{2, 1} \leq \mu_{1, 1} + \mu_{0, 1} \end{array} \quad \begin{array}{ll} vs. \ H_{Ga1} & \mu_{3, \bullet} + \mu_{2, \bullet} > \mu_{1, \bullet} + \mu_{0, \bullet} \\ vs. \ H_{Ga1} & \mu_{3, 1} + \mu_{2, 1} > \mu_{1, 1} + \mu_{0, 1} \end{array}$

Safety and tolerability hypotheses None.
APPENDIX 3 Summary table of analyses

| Code | Endpoint | Analysis ID | Set | Focus | Statistical model | Hypotheses | Comment |
|------------|---|---------------------|-----------|--------------------|--|-----------------------|--|
| Primary a | nalyses | | | | | | |
| 01 | Days Gambled, time- averaged | I | ITT | Тх | Linear mixed effects, weighted Baseline-adjusted No time point covariate | A, δ=1 Ba,b,c,d | Report A with 95% CI FWER adjustment for B |
| 02 | Days Gambled at 12 months | 11.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 03 | Money Lost, time-averaged | I | ITT | Tx | Linear mixed effects, weighted Baseline-adjusted No time point covariate | A, δ=20 Ba,b,c,d | FWER adjustment for B |
| 04 | Money Lost at 12 months | 11.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 05 | Gambling-quit or improved, time-averaged | Ш | ITT | Тх | Logistic mixed effects, weighted No time point covariate | A, δ=0_13 Ba,b,c,d | FWER adjustment for B |
| 06 | Gambling-quit or improved, at 12 months | IV.1 | ІТТ | Tx: (Timepoint=12) | Logistic mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| Secondary | analyses | | | | | | |
| Equivalenc | e hypothesis for PGSI-12 | | 1 | | | | |
| 07 | PGSI-12, at 12 months | 1 | ITT | Тх | Linear regression, unweighted Baseline-adjusted | Α, δ=1 | Report A with 95% CI |
| Primary ou | itcomes and PGSI-12 and primar | <u>y hypotheses</u> | in the Pl | P analysis set | | | |
| 08 | Days Gambled, time- averaged | 1 | РР | Тх | Linear mixed effects, weighted Baseline-adjusted No time point covariate | A, δ=1 Ba,b,c,d | FWER adjustment for B |
| 09 | Days Gambled at 12 months | 11.1 | РР | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |

| 10 | Money Lost, time-averaged | I | РР | Тх | Linear mixed effects, weighted Baseline-adjusted No time point covariate | A, δ=20 Ba,b,c,d | FWER adjustment for B |
|------------|--|--------------|-------------|---|---|-----------------------|--|
| 11 | Money Lost at 12 months | II.1 | РР | Tx:(Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 12 | Gambling-quit or improved, time-averaged | III | РР | Тх | Logistic mixed effects, weighted No time point covariate | A, δ=0_13 Ba,b,c,d | FWER adjustment for B |
| 13 | Gambling-quit or improved, at 12 months | IV.1 | РР | Tx: (Timepoint=12) | Logistic mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 14 | PGSI-12, at 12 months | 11.2 | РР | Tx (no repeated measures) | Linear mixed effects, counsellor- specific random effects only, if indicated, unweighted Baseline-adjusted | Ca,b,c | FWER adjustment |
| Primary oi | utcomes and PGSI-12 within seco | ondary hypot | heses in th | he ITT analysis set | | | |
| 15 | Days Gambled, contrast at 3 and 12 months | II.1 | ITT | Tx:(Timepoint=12) – Tx:(Timepoint=3) | Linear mixed effects, weighted Baseline-adjusted Time point covariate Time point-treatment interaction | C*d,e,f | FWER adjustment Null is alternative less the interaction |
| 16 | Money Lost, time-averaged | II.1 | ITT | Tx:(Timepoint=12) – Tx:(Timepoint=3) | Time point covariate Time point-treatment interaction | C*d,e,f | FWER adjustment Null is alternative less the interaction |
| 17 | Gambling-quit or improved, time-averaged | 111 | ITT | Tx:(Timepoint=12) – Tx:(Timepoint=3) | Logistic mixed effects, weighted Time point covariate Time point-treatment interaction | C*d,e,f | FWER adjustment Null is alternative less the interaction |
| 18 | Days Gambled, time- averaged minus baseline | Ι | ITT | Тх | Linear mixed effects, weighted Baseline-adjusted No time point covariate | Da,b,c,d | FWER adjustment Baseline subtraction not strictly necessary but indicated for ease of interpretation |
| 19 | Money Lost, time-averaged minus baseline | Ι | ITT | Тх | Linear mixed effects, weighted Baseline-adjusted No time point covariate | Da,b,c,d | FWER adjustment Baseline subtraction not strictly necessary but indicated for ease of interpretation |
| 20 | Gambling-quit or improved, time-averaged | III | ITT | Tx | Logistic mixed effects, weighted No time point covariate | Da,b,c,d | $ \begin{array}{ll} FWER \ adjustment \\ H_{Dx0} \colon & p_{g,\bullet} \geq 0.05 \ vs. \\ H_{Dx1} \colon & p_{g,\bullet} < 0.05 \end{array} $ |
| 21 | S1_1_1_PGSI-12, at 12 months minus baseline | I | ITT | Tx | Linear regression, unweighted Baseline-adjusted | Da,b,c,d | FWER adjustment Baseline subtraction not strictly necessary but indicated for ease of interpretation |

| Primary an | d selected secondary outcomes a | and Hypothesi | is E | | | | |
|------------|---|---------------|------|---|---|---|---|
| 22 | Days Gambled, time- averaged | II.1 | WE | Workbook Engagement | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | E | Effect of workbook engagement; null is alternative less engagement term |
| 23 | Money Lost, time-averaged | II.1 | WE | Workbook Engagement | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Е | Effect of workbook engagement; null is alternative less engagement term |
| 24 | Gambling-quit or improved, time-averaged | IV.1 | WE | Workbook Engagement | Logistic mixed effects, weighted Time point-adjusted Time point-treatment interaction | Е | Effect of workbook engagement; null is alternative less engagement term |
| 25 | PGSI-12, at 12 months | 11.2 | WE | Workbook Engagement | Linear mixed effects, counsellor- specific random effects only, if indicated, unweighted Baseline-adjusted | Е | Effect of workbook engagement; null is alternative less engagement term |
| 26 | Goal met in past 3 months, time-averaged | V | WE | Workbook Engagement | Multinomial mixed effects, weighted Time point-adjusted Time point-treatment interaction | Е | Effect of workbook engagement; null is alternative less engagement term |
| 27 | Control over gambling, time- averaged | II.1 | WE | Workbook Engagement | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | E | Effect of workbook engagement; null is alternative less engagement term |
| 28 | Days Gambled, time- averaged | II.1 | ITT | Assistance - formal, Assistance - informal (simultaneous inclusion of terms) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | E | Effect of workbook engagement; null is alternative less engagement term |
| 29 | Money Lost, time-averaged | II.1 | ITT | Assistance - formal, Assistance - informal (simultaneous inclusion of terms) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | E | Effect of workbook engagement; null is alternative less engagement term |
| 30 | Gambling-quit or improved, time-averaged | IV.1 | ITT | Assistance - formal, Assistance - informal (simultaneous inclusion of terms) | Logistic mixed effects, weighted Time point-adjusted Time point-treatment interaction | E | Effect of workbook engagement; null is alternative less engagement term |

| 31 | PGSI-12, at 12 months | 11.2 | ITT | Assistance - formal, Assistance - informal (simultaneous inclusion of terms) | Linear mixed effects, counsellor- specific random effects only, if indicated, unweighted Baseline-adjusted | E | Effect of workbook engagement; null is alternative less engagement term |
|-----------|---|--------------|-------------|---|---|----------------|--|
| 32 | Goal met in past 3 months, time-averaged | V | ITT | Assistance - formal, Assistance - informal (simultaneous inclusion of terms) | Multinomial mixed effects, weighted Time point-adjusted Time point-treatment interaction | E | Effect of workbook engagement; null is alternative less engagement term |
| 33 | Control over gambling, time- averaged | 11.1 | ПТ | Assistance - formal, Assistance - informal (simultaneous inclusion of terms) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | E | Effect of workbook engagement; null is alternative less engagement term |
| Secondary | outcomes and primary superiorit | y hypotheses | s in the IT | T analysis set | · · · | • | |
| 34 | PGSI-12, at 12 months | II.2 | ITT | Tx (no data collected at 3 and 6 months) | Linear mixed effects, counsellor- specific random effects only, if indicated, unweighted Baseline-adjusted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 35 | PGSI-12-Dichotomised, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 36 | PGSI-3, time-averaged | Ι | ITT | Тх | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 37 | PGSI-3-Dichotomised, time- averaged | III | ITT | Tx | Logistic mixed effects, weighted | Ba,b,c,d | FWER adjustment |
| 38 | PGSI-3, at 12 months | II.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 39 | PGSI-3-Dichotomised, at 12 months | IV.1 | ITT | Tx: (Timepoint=12) | Logistic mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 40 | Control over gambling, time- averaged | I | ITT | Tx | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 41 | Control over gambling, at 12 months | II.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 42 | Kessler-10, time-averaged | I | ITT | Тх | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |

| 43 | Kessler-10, at 12 months | II.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
|----|--|------|-----|--|---|-------------------------------------|--|
| 44 | AUDIT-C, time-averaged | Ι | ITT | Tx | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 45 | AUDIT-C, at 12 months | II.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 46 | DAST, at 12 months | П.2 | ITT | Tx (no data collected at 3 and 6 months) | Linear mixed effects, counsellor- specific random effects only, if indicated, unweighted Baseline-adjusted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 47 | PRIME-MD Major Depression, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 48 | PRIME-MD Dysthymia, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 49 | PRIME-MD Minor Depression, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 50 | PRIME-MD Bipolar Disorder, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 51 | Tobacco use current, time- averaged | III | ITT | Tx | Logistic mixed effects, weighted | Ba,b,c,d | FWER adjustment |
| 52 | Tobacco use current, at 12 months | IV.1 | ITT | Tx: (Timepoint=12) | Logistic mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 53 | Tobacco use frequency, time- averaged | V | ITT | Тх | Multinomial mixed effects, weighted | Ba,b,c,d 2-sided alternatives | FWER adjustment |
| 54 | Tobacco use frequency, at 12 months | V | ITT | Tx: (Timepoint=12) | Multinomial mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c 2-sided alternatives | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |

| 55 | Mental health treatment in past 12 months, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
|----|---|------|-----|--|--|----------------|--|
| 56 | Prescribed medication for mental health in past 12 months, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 57 | Comorbity treatment in past 12 months, at 12 months | IV.2 | ITT | Tx (no data collected at 3 and 6 months) | Logistic mixed effects, counsellor- specific random effects only, if indicated, unweighted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 58 | WHOQoL-8, time-averaged | Ι | ITT | Тх | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 59 | WHOQoL-8, at 12 months | II.1 | ITT | Tx: (C1_2_Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 60 | Affect on Work, time- averaged | Ι | ITT | Tx | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 61 | Affect on Work, at 12 months | II.1 | ITT | Tx: (C1_2_Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 62 | Affect on Social Life, time- averaged | Ι | ITT | Tx | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 63 | Affect on Social Life, at 12 months | II.1 | ITT | Tx: (C1_2_Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 64 | Affect on Family/Home, time-averaged | Ι | ITT | Tx | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 65 | Affect on Family/Home, at 12 months | II.1 | ITT | Tx: (C1_2_Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 66 | Affect on Health, time- averaged | Ι | ITT | Тх | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |

| 67 | Affect on Health, at 12 months | II.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
|-----------|---|---------------|-----------|--|--|---|--|
| 68 | Legal Problems, time- averaged | III | ITT | Тх | Logistic mixed effects, weighted | Ba,b,c,d | FWER adjustment |
| 69 | Legal Problems, at 12 months | IV.1 | ITT | Tx: (Timepoint=12) | Logistic mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 70 | NZDI, at 12 months | II.2 | ITT | Tx (no data collected at 3 and 6 months) | Linear mixed effects, counsellor- specific random effects only, if indicated, unweighted Baseline-adjusted | Ba,b Ca,b,c | FWER adjustment across all 5 sub- hypotheses |
| 71 | Goal met in past 3 months, time-averaged | V | ITT | Тх | Multinomial mixed effects, weighted | Ba,b,c,d | FWER adjustment |
| 72 | Goal met in past 3 months, at 12 months | VI | ITT | Tx: (Timepoint=12) | Multinomial mixed effects, weighted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| 73 | Motivation level, time- averaged | Ι | ITT | Tx | Linear mixed effects, weighted Baseline-adjusted | Ba,b,c,d | FWER adjustment |
| 74 | Motivation level, at 12 months | П.1 | ITT | Tx: (Timepoint=12) | Linear mixed effects, weighted Baseline-adjusted Time point-adjusted Time point-treatment interaction | Ca,b,c | FWER adjustment Null is alternative less only the Tx: (Timepoint=12) interaction |
| Engagemen | nt outcomes and engagement hyp | otheses in th | e ITT ana | lysis set | | | |
| 75 | E2_1_Wkbk_Read, time- averaged | V | WE | Tx | Multinomial mixed effects, weighted by number of valid responses | Fa,b With 2- sided alternative Ga | FWER of F adjustment based on whole contrasts between treatments Null is model of common mean. |
| 76 | E2_1_Wkbk_Read, at 3 months | VI | WE | Tx: (Timepoint=3) | Multinomial mixed effects, weighted by number of valid responses Time point-adjusted Time point-treatment interaction | Gb | Null is alternative less only the Tx: (Timepoint=3) interaction |
| 77 | E2_2_Wkbk_Exercise, time- averaged | V | WE | Tx | Multinomial mixed effects, weighted by number of valid responses | Fa,b With 2- sided alternative Ga | FWER adjustment of F Null is model of common mean. |

| 78 | Workbook Exercise, at 3 | VI | WE | Tx: (Timepoint=3) | Multinomial mixed effects, weighted | Gb | Null is alternative less only the Tx: |
|----|-----------------------------|------|-----|-------------------|-------------------------------------|-------------|---------------------------------------|
| | months | | | | by number of valid responses | | (Timepoint=3) interaction |
| | | | | | Time point-adjusted | | |
| | | | | | Time point-treatment interaction | | |
| 79 | Workbook Strategies, time- | V | WE | Tx | Multinomial mixed effects, weighted | Fa,b | FWER adjustment of F |
| | averaged | | | | by number of valid responses | With 2- | Null is model of common mean. |
| | | | | | | sided | |
| | | | | | | alternative | |
| | | | | | | Ga | |
| 80 | Workbook Strategies, at 3 | VI | WE | Tx: (Timepoint=3) | Multinomial mixed effects, weighted | Gb | Null is alternative less only the Tx: |
| | months | | | | by number of valid responses | | (Timepoint=3) interaction |
| | | | | | Time point-adjusted | | |
| | | | | | Time point-treatment interaction | | |
| 81 | Assistandce Any, time- | VII | ITT | Tx | Binomial mixed effects, weighted | Fa,b | FWER adjustment of F |
| | averaged | | | | | Ga | Null is model of common mean. |
| 82 | Assistance Any, at 3 months | VIII | ITT | Tx: (Timepoint=3) | Binomial mixed effects, weighted by | Gb | Null is alternative less only the Tx: |
| | | | | | number of valid responses | | (Timepoint=3) interaction |
| | | | | | Time point-adjusted | | |
| | | | | | Time point-treatment interaction | | |

Notes: 1) All alternative hypotheses bar A are one-sided.

2) Time points entered as covariates are entered as categorical covariates unless otherwise indicated.

APPENDIX 4 Tables - Descriptive statistics

Table 4.1: Socio-demographics

| | | TAU | MI | MI+W | MI+W+B |
|---------------------------|---------------|-------|-------|-------|--------|
| | Male | 41.4% | 47.3% | 45.3% | 55.2% |
| Condor | Female | 58.6% | 52.7% | 54.7% | 44.8% |
| Genuer | Ν | 116 | 112 | 117 | 116 |
| | N MISSING | 0 | 0 | 1 | 0 |
| | Never married | 25.2% | 30.3% | 34.2% | 32.8% |
| | Married | 23.5% | 21.1% | 22.8% | 25.0% |
| | De facto | 24.3% | 21.1% | 25.4% | 26.7% |
| Marital status | Separated | 13.9% | 14.7% | 10.5% | 10.3% |
| Waritar status | Divorced | 8.7% | 12.8% | 4.4% | 3.4% |
| | Widowed | 4.3% | 0.0% | 2.6% | 1.7% |
| | N | 115 | 109 | 114 | 116 |
| | N MISSING | 1 | 3 | 4 | 0 |
| | Partnered | 52.2% | 57.8% | 51.8% | 48.3% |
| Marital status, | Not partnered | 47.8% | 42.2% | 48.2% | 51.7% |
| dichotomised | N | 115 | 109 | 114 | 116 |
| | N MISSING | 1 | 3 | 4 | 0 |
| | 18-24 years | 15.2% | 11.6% | 8.5% | 19.0% |
| Age group | 25-34 years | 22.3% | 33.0% | 27.1% | 29.3% |
| | 35-44 years | 23.2% | 19.6% | 30.5% | 17.2% |
| | 45-54 years | 24.1% | 22.3% | 22.0% | 25.0% |
| | 55+ years | 15.2% | 13.4% | 11.9% | 9.5% |
| | N | 112 | 112 | 118 | 116 |
| | N MISSING | 4 | 0 | 0 | 0 |
| | MEAN YEARS | 40.3 | 39.1 | 39.9 | 37.5 |
| | STD | 13.6 | 13.1 | 11.7 | 13.1 |
| | MIN YEARS | 18.0 | 19.0 | 19.0 | 19.0 |
| | Q1 YEARS | 28.0 | 27.0 | 31.0 | 26.0 |
| Age | MEDIAN YEARS | 40.0 | 37.0 | 39.0 | 36.0 |
| | Q3 YEARS | 49.5 | 50.0 | 46.0 | 46.0 |
| | MAX YEARS | 79.0 | 71.0 | 76.0 | 72.0 |
| | N | 112 | 112 | 118 | 116 |
| | N MISSING | 4 | 0 | 0 | 0 |
| | Maori | 40.5% | 39.3% | 43.2% | 36.2% |
| | Pacific | 11.2% | 16.1% | 7.6% | 10.3% |
| Primary ethnicity | European | 47.0% | 42.0% | 44.9% | 47.4% |
| | Asian & Other | 3.0% | 2.7% | 4.2% | 6.0% |
| | N | 116 | 112 | 118 | 116 |
| | N MISSING | 0 | 0 | 0 | 0 |
| European ethnicity | Yes | 50.0% | 47.3% | 54.2% | 53.4% |
| Maori ethnicity | Yes | 40.5% | 39.3% | 43.2% | 36.2% |
| Pacific ethnicity | Yes | 11.2% | 16.1% | 8.5% | 10.3% |
| Asian ethnicity | Yes | 4.3% | 1.8% | 2.5% | 4.3% |
| Other ethnicity | Yes | 0.9% | 1.8% | 1.7% | 3.4% |
| Asian and Other ethnicity | Yes | 4.3% | 3.6% | 4.2% | 6.9% |
| | N | 116 | | 118 | 116 |
| | N MISSING | 0 | 0 | 0 | 0 |

| | | TAU | MI | MI+W | MI+W+B |
|--|--------------------------------|-------|-------|-------|--------|
| | Full time | 44.3% | 44.1% | 41.5% | 48.7% |
| | Part time | 13.0% | 11.7% | 14.4% | 9.6% |
| | Homemaker | 7.8% | 8.1% | 5.1% | 9.6% |
| | Student | 5.2% | 3.6% | 5.1% | 3.5% |
| | Retired | 2.6% | 1.8% | 2.5% | 3.5% |
| Employment status | Unemployed | 11.3% | 18.0% | 11.9% | 11.3% |
| | Illness/sick leave | 6.1% | 3.6% | 5.9% | 3.5% |
| | Maternity Leave | 0.9% | 0.0% | 0.0% | 0.0% |
| | Other | 8.7% | 9.0% | 13.6% | 10.4% |
| | Ν | 115 | 111 | 118 | 115 |
| | N MISSING | 1 | 1 | 0 | 1 |
| | None | 25.9% | 19.6% | 21.4% | 18.3% |
| | Secondary school qualification | 33.6% | 31.3% | 36.8% | 36.5% |
| | Trade or technical certificate | 18.1% | 24.1% | 21.4% | 22.6% |
| | Professional qualification | 3.4% | 7.1% | 4.3% | 4.3% |
| Highest educational | Undergrad. Dip. or Cert. | 7.8% | 6.3% | 6.0% | 8.7% |
| qualification achieved | Undergrad. Degree | 6.0% | 3.6% | 6.0% | 7.0% |
| | Postgrad. Dip. or Cert. | 1.7% | 1.8% | 1.7% | 0.0% |
| | Postgrad. Degree | 3.4% | 6.3% | 2.6% | 2.6% |
| | Ν | 116 | 112 | 117 | 115 |
| | N MISSING | 0 | 0 | 1 | 1 |
| | ≤\$20,000 | 26.9% | 17.6% | 23.0% | 19.3% |
| | \$20,001-\$30,000 | 16.3% | 22.2% | 14.2% | 13.8% |
| | \$30,001-\$50,000 | 23.1% | 19.4% | 32.7% | 33.9% |
| | \$50,001-\$100,000 | 24.0% | 31.5% | 23.0% | 23.9% |
| Gross family income in last 12 months | \$100,001-\$200,000 | 7.7% | 7.4% | 7.1% | 8.3% |
| | \$200,001-\$500,000 | 1.9% | 1.9% | 0.0% | 0.9% |
| | \$500,001+ | 0.0% | 0.0% | 0.0% | 0.0% |
| | Ν | 104 | 108 | 113 | 109 |
| | N MISSING | 12 | 4 | 5 | 7 |
| | ≤\$30,000 | 43.3% | 39.8% | 37.2% | 33.0% |
| Gross family income in last | >\$30,000 | 56.7% | 60.2% | 62.8% | 67.0% |
| 12 months, dichotomised | N | 104 | 108 | 113 | 109 |
| | N MISSING | 12 | 4 | 5 | 7 |

Table 4.1: Socio-demographics - continued

| | TAU | MI | MI+W | MI+W+B |
|----------------|-----|----|------|--------|
| Ashburton | 1 | | 2 | 2 |
| Auckland | 29 | 27 | 27 | 32 |
| Bay of Plenty | 1 | - | | 2 |
| Blenheim | 1 | 1 | 2 | 1 |
| Cambridge | | | | 1 |
| Canterbury | | | 1 | |
| Christchurch | 12 | 9 | 14 | 13 |
| Clutha | | | 1 | |
| Coromandel | 1 | | | |
| Dannevirke | 2 | | | |
| Dunedin | 2 | 5 | 4 | 1 |
| Fielding | | | | 1 |
| Foxton | 2 | | | |
| Franklin | | | 1 | |
| Geraldine | | | | 1 |
| Gisborne | 2 | 2 | 1 | 3 |
| Hamilton | 3 | 9 | 6 | 4 |
| Hastings | 2 | 1 | 3 | 1 |
| Havelock | 1 | | | |
| Havelock North | | | | 1 |
| Hawera | | | | 1 |
| Hawkes Bay | 1 | | | |
| Helensville | | | | 1 |
| Hokitika | | 1 | | |
| Huntly | | | | 1 |
| Inglewood | | 1 | | |
| Invercargill | 1 | 1 | | 1 |
| Kaikohe | 1 | | | |
| Kaitaia | 1 | | | 1 |
| Kapiti | | | | 1 |
| Kapiti Coast | 1 | 1 | | |
| Kaukapakapa | | | | 1 |
| Kawerau | | 1 | | |
| Levin | 1 | | | 1 |
| Lower Hutt | | 3 | 3 | 1 |
| Manukau | 5 | 5 | 3 | 3 |
| Morrinsville | 1 | | | 2 |
| Motueka | 1 | | | |

Table 4.2: Area of residence

| | TAU | MI | MI+W | MI+W+B |
|------------------|-----|----|------|--------|
| Mt Maunganui | 1 | | 1 | |
| Napier | 1 | 4 | 3 | |
| Nelson | | 1 | 2 | 1 |
| New Plymouth | 1 | 2 | 4 | |
| North Auckland | | 1 | | |
| North Canterbury | | | | 2 |
| North Shore | 1 | 1 | | 1 |
| Northland | 1 | 1 | 1 | 1 |
| Oamaru | | | 1 | |
| Otaki | 1 | | | |
| Otane | | 1 | | |
| Paeroa | 1 | 1 | | |
| Palmerston | | | | 1 |
| Palmerston North | 4 | | 6 | 3 |
| Papakura | | | | 1 |
| Papamoa | 1 | | | 2 |
| Paraparaumu | | | 1 | |
| Pukekohe | | 1 | | |
| Putaruru | | | | 1 |
| Rotorua | 10 | 2 | 1 | 3 |
| South Auckland | | | 1 | |
| Southland | 1 | | | |
| Stratford | | | 1 | |
| Taihape | | | | 1 |
| Taranaki | | 1 | 1 | 1 |
| Taupo | 2 | | | 2 |
| Tauranga | 2 | 4 | 6 | 1 |
| Te Awamutu | | | | 2 |
| Te Kuiti | | | 1 | 1 |
| Te Puke | | 1 | | |
| Thames | | 1 | 1 | 1 |
| Timaru | 2 | | | 1 |
| Upper Hutt | | 2 | 2 | |
| Waikato | | 1 | 1 | |
| Waimate | | | 1 | 1 |
| Waitakere | 1 | 1 | | |
| Waitara | | 1 | | |
| Wanganui | 1 | 2 | 4 | 2 |

Table 4.2: Area of residence - continued

| | TAU | MI | MI+W | MI+W+B |
|--------------|-----|-----|------|--------|
| Warkworth | | 1 | 1 | |
| Wellington | 11 | 11 | 7 | 6 |
| Westport | | | | 1 |
| Whakatane | 1 | 1 | 1 | 1 |
| Whangamata | | 1 | | |
| Whanganui | | | | 1 |
| Whangaparaoa | | 1 | 1 | |
| Whangarei | | | | 1 |
| Whitby | 1 | | | |
| Whitianga | | | 1 | |
| N | 116 | 111 | 118 | 116 |
| N MISSING | 0 | 1 | 0 | 0 |

Table 4.2: Area of residence - continued

| _ | | TAU | MI | MI+W | MI+W+B |
|--------------------------------|------------------------|-------|-------|-------|--------|
| | Yes | 0.9% | 4.5% | 2.5% | 0.9% |
| Gambling type: | Ν | 116 | 112 | 118 | 116 |
| Carus | N MISSING | 0 | 0 | 0 | 0 |
| Gambling type: | Yes | 19.0% | 25.9% | 15.3% | 17.2% |
| Casino gaming | N | 116 | 112 | 118 | 116 |
| machines | N MISSING | 0 | 0 | 0 | 0 |
| Combling type | Yes | 6.9% | 4.5% | 2.5% | 7.8% |
| Casino tables | N | 116 | 112 | 118 | 116 |
| Casillo tables | N MISSING | 0 | 0 | 0 | 0 |
| Combling type | Yes | 28.4% | 22.3% | 23.7% | 25.9% |
| Gambing type: Club machines | N | 116 | 112 | 118 | 116 |
| Club machines | N MISSING | 0 | 0 | 0 | 0 |
| Combling | Yes | 81.9% | 83.0% | 83.9% | 82.8% |
| Gambling type: | N | 116 | 112 | 118 | 116 |
| r ub macinnes | N MISSING | 0 | 0 | 0 | 0 |
| | Yes | 0.9% | 0.9% | 0.0% | 0.0% |
| Gambling type: | N | 116 | 112 | 118 | 116 |
| nousie | N MISSING | 0 | 0 | 0 | 0 |
| | Yes | 1.7% | 0.9% | 0.8% | 0.9% |
| Gambling type: | Ν | 116 | 112 | 118 | 116 |
| Kello | N MISSING | 0 | 0 | 0 | 0 |
| | Yes | 6.9% | 5.4% | 5.1% | 6.0% |
| Gambling type: | Ν | 116 | 112 | 118 | 116 |
| Lotto | N MISSING | 0 | 0 | 0 | 0 |
| Comble Annu | Yes | 2.6% | 6.3% | 3.4% | 7.8% |
| Gambling type: | Ν | 116 | 112 | 118 | 116 |
| sports betting | N MISSING | 0 | 0 | 0 | 0 |
| Combling tons | Yes | 5.2% | 15.2% | 16.9% | 15.5% |
| Gambling type: | N | 116 | 112 | 118 | 116 |
| ITACK | N MISSING | 0 | 0 | 0 | 0 |
| Combling tons | Yes | 5.2% | 3.6% | 4.2% | 2.6% |
| Gambling type: | Ν | 116 | 112 | 118 | 116 |
| Other | N MISSING | 0 | 0 | 0 | 0 |
| | Cards | 0.9% | 0.0% | 0.9% | 0.0% |
| | Casino Gaming Machines | 3.5% | 11.7% | 6.0% | 5.4% |
| | Casino Tables | 4.4% | 1.0% | 1.7% | 3.6% |
| | Club Gaming Machines | 11.5% | 5.8% | 9.5% | 9.9% |
| | Pub Gaming Machines | 73.5% | 71.8% | 69.0% | 72.1% |
| Primary Gambling | Keno | 0.9% | 0.0% | 0.0% | 0.0% |
| Туре | Lotto | 0.0% | 1.0% | 0.0% | 0.9% |
| | Sports Betting | 0.9% | 2.9% | 0.9% | 2.7% |
| | Track | 3.5% | 4.9% | 7.8% | 3.6% |
| | Other | 0.9% | 1.0% | 4.3% | 1.8% |
| | N | 113 | 103 | 116 | 111 |
| | N MISSING | 3 | 9 | 2 | 5 |
| Electronic gaming | Yes | 93.1% | 91.1% | 91.5% | 92.2% |
| machines as | N | 116 | 112 | 118 | 116 |
| gambling type | N MISSING | 0 | 0 | 0 | 0 |

Table 4.3: Gambling characterisation

| | - | TAU | MI | MI+W | MI+W+B |
|--------------------|-----------|-------|-------|-------|--------|
| | MEAN | 81.5 | 84.0 | 86.4 | 73.9 |
| | STD | 85.3 | 98.9 | 99.9 | 70.1 |
| | MIN | 1.0 | 1.0 | 0.3 | 0.5 |
| How long has | Q1 | 18.0 | 18.0 | 18.0 | 18.0 |
| gambling been a | MEDIAN | 60.0 | 60.0 | 60.0 | 48.0 |
| problem (months) | Q3 | 120.0 | 120.0 | 120.0 | 108.0 |
| | MAX | 480.0 | 588.0 | 564.0 | 360.0 |
| | Ν | 113 | 112 | 115 | 115 |
| | N MISSING | 3 | 0 | 3 | 1 |
| | MEAN | 4.8 | 4.0 | 3.0 | 3.2 |
| | STD | 11.5 | 9.2 | 4.5 | 5.8 |
| | MIN | 0.0 | 0.0 | 0.0 | 0.0 |
| How long since the | Q1 | 1.0 | 1.0 | 1.0 | 1.0 |
| last time you | MEDIAN | 1.0 | 1.5 | 1.0 | 1.0 |
| gambled (days) | Q3 | 4.0 | 3.5 | 3.0 | 3.0 |
| | MAX | 97.0 | 67.0 | 30.0 | 35.0 |
| | Ν | 116 | 112 | 118 | 116 |
| | N MISSING | 0 | 0 | 0 | 0 |
| Even felt the need | Yes | 93.1% | 95.5% | 99.2% | 94.8% |
| to bet more | Ν | 116 | 112 | 118 | 116 |
| to bet more | N MISSING | 0 | 0 | 0 | 0 |
| Even felt the need | Yes | 86.1% | 88.2% | 93.2% | 86.2% |
| to lie? | Ν | 115 | 110 | 118 | 116 |
| 10 110. | N MISSING | 1 | 2 | 0 | 0 |

Table 4.3: Gambling characterisation - continued

Table 4.4: Treatment prospects

| Level of belief inMEAN8.68.27.9 | 8.3 |
|--|-------|
| months STD 2.0 2.2 2.2 | 1.9 |
| (10-point Likert MIN 0.0 0.0 0.0 | 3.0 |
| Q1 8.0 7.0 6.0 | 7.0 |
| MEDIAN 10.0 9.0 8.0 | 9.0 |
| Q3 10.0 10.0 10.0 | 10.0 |
| MAX 10.0 10.0 10.0 | 10.0 |
| N 111 106 107 | 111 |
| N MISSING 5 6 11 | 5 |
| Level of belief in MEAN 9.1 8.9 8.6 | 9.0 |
| success within 12 STD 1.7 1.7 2.0 | 1.7 |
| (10-point Likert MIN 0.0 0.0 0.0 | 1.0 |
| Q1 9.0 8.0 7.0 | 8.0 |
| MEDIAN 10.0 10.0 10.0 | 10.0 |
| Q3 10.0 10.0 10.0 | 10.0 |
| MAX 10.0 10.0 10.0 | 10.0 |
| N 112 106 109 | 109 |
| N MISSING 4 6 9 | 7 |
| Level of belief in Lower level 47.4% 54.5% 61.0% | 56.0% |
| success within 12 months. Higher level 52.6% 45.5% 39.0% | 44.0% |
| dichotomised N 116 112 118 | 116 |
| N MISSING 0 0 0 | 0 |
| Level of difficulty MEAN 7.5 8.0 8.1 | 7.8 |
| expected in next 12 STD 2.4 2.3 2.2 | 2.1 |
| (10-point Likert MIN 0.0 0.0 0.0 | 0.0 |
| Q1 6.0 7.0 7.0 | 6.0 |
| MEDIAN 8.0 8.0 8.0 | 8.0 |
| Q3 10.0 10.0 10.0 | 10.0 |
| MAX 10.0 10.0 10.0 | 10.0 |
| N 115 111 114 | 116 |
| N MISSING 1 1 4 | 0 |

| | | | TA | U | | | Μ | I | | | MI | ⊦W | | | MI+V | N+B | |
|------------------|-----------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| Days Gambled | MEAN | 9.0 | 3.2 | 2.6 | 3.0 | 8.2 | 3.3 | 3.4 | 3.5 | 8.8 | 3.5 | 3.4 | 3.2 | 8.3 | 3.1 | 2.6 | 2.7 |
| per month | STD | 7.2 | 4.3 | 3.5 | 4.0 | 6.0 | 4.4 | 4.8 | 4.8 | 6.6 | 5.2 | 5.7 | 4.4 | 6.2 | 3.8 | 3.1 | 3.2 |
| | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.5 | 0.0 | 0.0 | 0.0 | 0.5 | 0.0 | 0.0 | 0.0 |
| | Q1 | 3.5 | 0.3 | 0.0 | 0.5 | 4.0 | 0.8 | 0.7 | 0.3 | 4.5 | 0.3 | 0.0 | 0.5 | 4.5 | 0.3 | 0.0 | 0.2 |
| | MEDIAN | 7.5 | 1.7 | 1.0 | 1.5 | 7.0 | 2.2 | 2.0 | 2.0 | 6.0 | 1.7 | 1.0 | 1.8 | 6.5 | 1.7 | 1.5 | 1.5 |
| | Q3 | 13.0 | 4.7 | 4.0 | 4.3 | 11.5 | 4.3 | 4.3 | 4.3 | 12.0 | 4.7 | 4.5 | 4.3 | 10.0 | 5.0 | 4.3 | 4.5 |
| | MAX | 30.0 | 25.3 | 16.7 | 25.3 | 30.0 | 28.7 | 30.0 | 29.7 | 31.5 | 30.0 | 30.0 | 24.0 | 30.0 | 18.0 | 16.3 | 13.2 |
| | Ν | 111 | 100 | 92 | 78 | 95 | 88 | 78 | 66 | 109 | 98 | 88 | 78 | 109 | 87 | 82 | 73 |
| | N MISSING | 5 | 0 | 0 | 0 | 17 | 0 | 0 | 0 | 9 | 0 | 0 | 0 | 7 | 0 | 0 | 0 |
| Money Lost per | MEAN | 42.9 | 9.5 | 7.2 | 9.7 | 53.2 | 9.8 | 14.3 | 13.4 | 48.6 | 9.2 | 9.0 | 7.5 | 49.2 | 9.0 | 10.6 | 8.4 |
| day | STD | 45.7 | 20.8 | 13.2 | 18.3 | 58.8 | 17.4 | 42.2 | 35.4 | 69.1 | 18.3 | 20.9 | 12.0 | 59.5 | 14.6 | 25.0 | 16.1 |
| | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 3.9 | 0.0 | 0.0 | 0.0 | 0.3 | 0.0 | 0.0 | 0.0 |
| | Q1 | 14.1 | 0.6 | 0.0 | 0.4 | 16.4 | 0.4 | 0.7 | 0.3 | 18.1 | 0.2 | 0.0 | 0.3 | 16.5 | 0.0 | 0.0 | 0.1 |
| | MEDIAN | 29.3 | 2.6 | 1.6 | 2.7 | 33.1 | 2.9 | 2.9 | 2.5 | 32.1 | 3.2 | 1.7 | 1.8 | 31.8 | 2.5 | 2.1 | 2.2 |
| | Q3 | 60.6 | 9.3 | 6.3 | 7.3 | 70.7 | 11.5 | 8.6 | 9.3 | 52.6 | 9.9 | 7.4 | 6.6 | 59.5 | 9.8 | 10.7 | 10.1 |
| | MAX | 263.6 | 166.7 | 52.6 | 85.4 | 327.2 | 99.1 | 320.7 | 260.1 | 646.4 | 131.6 | 156.8 | 55.8 | 388.2 | 66.0 | 168.9 | 110.7 |
| | Ν | 111 | 100 | 92 | 78 | 95 | 88 | 78 | 66 | 109 | 98 | 88 | 78 | 110 | 87 | 82 | 73 |
| | N MISSING | 5 | 0 | 0 | 0 | 17 | 0 | 0 | 0 | 9 | 0 | 0 | 0 | 6 | 0 | 0 | 0 |
| Gambling-quit or | YES | • | 82.0% | 71.7% | 87.2% | • | 83.0% | 87.2% | 84.8% | • | 82.7% | 71.6% | 84.6% | • | 75.9% | 73.2% | 75.3% |
| ппргоуеа | N | | 100 | 92 | 78 | | 88 | 78 | 66 | | 98 | 88 | 78 | | 87 | 82 | 73 |
| | N MISSING | | 0 | 0 | 0 | | 0 | 0 | 0 | | 0 | 0 | 0 | | 0 | 0 | 0 |

Table 4.5: Primary efficacy - gambling, money lost and gambling cessation/improvement

| | | | ТА | U | | | Μ | Ι | | | MI- | ⊦W | | | MI+V | N+B | |
|-----------------------------|-----------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| Problem | MEAN | 16.8 | montus | montuis | 9.2 | 17.2 | montils | montus | 9.7 | 17.3 | montils | montils | 9.3 | 16.6 | montifs | montils | 10.0 |
| Gambling | | 10.0 | • | • | | 17.2 | • | • | 5.7 | 11.5 | • | • | 7.5 | 10.0 | • | • | 10.0 |
| Severity Index | STD | 4.6 | | | 6.3 | 4.7 | • | • | 7.3 | 4.8 | • | • | 6.1 | 4.6 | • | • | 6.4 |
| - 12 month | MIN | 3.0 | | | 0.0 | 7.0 | | • | 0.0 | 0.0 | | | 0.0 | 5.0 | | | 0.0 |
| time if ame | Q1 | 14.0 | | • | 3.0 | 14.0 | • | | 4.0 | 14.0 | • | • | 4.0 | 13.0 | | • | 5.5 |
| | MEDIAN | 17.0 | • | • | 9.0 | 17.0 | • | | 9.0 | 17.0 | • | • | 10.0 | 17.0 | | • | 10.0 |
| | Q3 | 20.0 | | | 13.0 | 21.0 | | • | 14.0 | 20.0 | | | 13.0 | 20.0 | | | 15.0 |
| | MAX | 25.0 | | | 23.0 | 26.0 | | | 25.0 | 27.0 | | | 25.0 | 25.0 | | | 24.0 |
| | Ν | 111 | | • | 74 | 104 | | | 65 | 106 | | | 77 | 110 | | • | 72 |
| | N MISSING | 5 | | | 4 | 8 | | | 1 | 12 | | | 1 | 6 | | | 1 |
| Problem | MEAN | 17.3 | 7.8 | 6.9 | 6.4 | 17.5 | 8.5 | 7.5 | 7.1 | 18.2 | 7.6 | 6.7 | 5.3 | 17.2 | 7.6 | 5.6 | 5.8 |
| Gambling Severity Index, | STD | 5.3 | 7.0 | 6.7 | 6.2 | 5.3 | 6.9 | 6.8 | 7.5 | 4.7 | 6.3 | 7.0 | 6.1 | 5.2 | 5.8 | 6.2 | 6.7 |
| 3 month time | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 3.0 | 0.0 | 0.0 | 0.0 | 6.0 | 0.0 | 0.0 | 0.0 | 5.0 | 0.0 | 0.0 | 0.0 |
| 11 and | Q1 | 14.0 | 1.0 | 1.0 | 0.0 | 14.0 | 3.0 | 1.0 | 0.0 | 15.0 | 2.0 | 0.0 | 0.0 | 14.0 | 2.0 | 1.0 | 0.0 |
| | MEDIAN | 18.0 | 7.0 | 5.0 | 6.0 | 17.0 | 7.0 | 6.0 | 4.5 | 18.0 | 6.0 | 4.0 | 2.5 | 18.0 | 7.0 | 3.0 | 2.0 |
| | Q3 | 21.0 | 13.0 | 11.0 | 10.0 | 22.0 | 13.0 | 12.0 | 13.0 | 22.0 | 13.0 | 12.0 | 10.5 | 21.0 | 12.0 | 9.0 | 11.0 |
| | MAX | 27.0 | 26.0 | 24.0 | 23.0 | 27.0 | 27.0 | 26.0 | 22.0 | 27.0 | 23.0 | 25.0 | 21.0 | 27.0 | 19.0 | 21.0 | 27.0 |
| | Ν | 110 | 92 | 85 | 76 | 106 | 82 | 71 | 66 | 110 | 89 | 83 | 76 | 111 | 83 | 77 | 73 |
| | N MISSING | 6 | 8 | 7 | 2 | 6 | 6 | 7 | 0 | 8 | 9 | 5 | 2 | 5 | 4 | 5 | 0 |

Table 4.6: Secondary efficacy outcomes - PGSI

| | | | ТА | U | | | Μ | I | | | MI- | ⊦W | | | MI+V | W+B | |
|------------------------|-----------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|
| | | Baseline | 3 | 6 | 12 |
| | | | months | months | months |
| PGSI, 12 month time | ≥ 8 | 97.2% | | | 60.8% | 97.7% | | | 55.4% | 96.9% | | | 63.6% | 95.2% | | | 66.7% |
| frame, dichotomised | Ν | 111 | | | 74 | 104 | | • | 65 | 106 | | | 77 | 110 | • | | 72 |
| (≥8 vs. <8) | N MISSING | 5 | | | 4 | 8 | • | • | 1 | 12 | | | 1 | 6 | • | • | 1 |
| PGSI, 3 month time | ≥ 8 | 96.2% | 43.5% | 40.0% | 40.8% | 94.4% | 48.8% | 43.7% | 39.4% | 99.0% | 44.9% | 36.1% | 34.2% | 96.2% | 48.2% | 35.1% | 37.0% |
| frame, dichotomised | N | 110 | 92 | 85 | 76 | 106 | 82 | 71 | 66 | 110 | 89 | 83 | 76 | 111 | 83 | 77 | 73 |
| (≥8 vs. <8) | N MISSING | 6 | 8 | 7 | 2 | 6 | 6 | 7 | 0 | 8 | 9 | 5 | 2 | 5 | 4 | 5 | 0 |

Table 4.6: Secondary efficacy outcomes - PGSI - continued

Table 4.7: Secondary efficacy outcomes - Control over gambling

| | | | ТА | U | | | Μ | Ι | | | MI- | -W | | | MI+ | W+B | |
|--------------|-----------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|
| | | Baseline | 3 | 6 | 12 |
| | | | months | months | months |
| Control over | MEAN | 3.4 | 6.9 | 7.2 | 7.1 | 2.8 | 6.7 | 6.6 | 6.7 | 2.4 | 6.9 | 7.4 | 7.6 | 2.5 | 7.3 | 7.7 | 7.2 |
| behaviour | STD | 2.9 | 2.6 | 2.8 | 2.8 | 2.3 | 2.8 | 3.0 | 2.9 | 2.3 | 2.8 | 3.0 | 2.4 | 2.4 | 2.5 | 2.3 | 3.0 |
| (10-point | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| scale) | Q1 | 1.0 | 5.0 | 5.0 | 6.0 | 0.0 | 5.0 | 5.0 | 5.0 | 0.0 | 5.0 | 5.5 | 7.0 | 0.0 | 5.0 | 7.0 | 5.0 |
| | MEDIAN | 3.0 | 7.0 | 8.0 | 8.0 | 2.5 | 7.0 | 7.0 | 7.5 | 2.0 | 7.5 | 8.5 | 8.0 | 2.0 | 8.0 | 8.0 | 8.0 |
| | Q3 | 5.0 | 9.0 | 10.0 | 10.0 | 5.0 | 9.0 | 9.0 | 9.0 | 4.0 | 9.0 | 10.0 | 10.0 | 4.0 | 10.0 | 10.0 | 10.0 |
| | MAX | 10.0 | 10.0 | 10.0 | 10.0 | 8.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| | N | 114 | 93 | 87 | 78 | 109 | 84 | 74 | 66 | 118 | 94 | 84 | 78 | 113 | 84 | 77 | 73 |
| | N MISSING | 2 | 7 | 5 | 0 | 3 | 4 | 4 | 0 | 0 | 4 | 4 | 0 | 3 | 3 | 5 | 0 |

| | | | ТА | U | | | Μ | I | | | MI | +W | | | MI+V | N+B | |
|-------------------|-----------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| Psychological | MEAN | 30.2 | 18.3 | 18.2 | 16.2 | 29.5 | 19.1 | 17.5 | 17.1 | 32.1 | 19.6 | 18.7 | 15.9 | 30.3 | 16.7 | 16.6 | 15.1 |
| Kessler-10, | STD | 8.1 | 8.4 | 7.7 | 8.6 | 9.3 | 8.0 | 8.4 | 7.7 | 8.9 | 9.6 | 8.8 | 7.4 | 9.2 | 7.0 | 7.5 | 6.7 |
| 4 week time frame | MIN | 14.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 12.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| | Q1 | 24.0 | 12.0 | 12.0 | 10.0 | 24.0 | 13.0 | 11.0 | 11.0 | 26.0 | 11.0 | 12.0 | 10.0 | 23.0 | 11.0 | 10.0 | 10.0 |
| | MEDIAN | 31.0 | 16.0 | 16.0 | 13.0 | 28.5 | 17.0 | 15.0 | 14.0 | 32.0 | 16.0 | 16.0 | 13.0 | 31.0 | 14.5 | 14.0 | 11.5 |
| | Q3 | 36.0 | 22.0 | 24.0 | 19.0 | 36.0 | 25.0 | 21.0 | 24.0 | 39.0 | 26.0 | 23.0 | 20.0 | 37.0 | 20.0 | 21.0 | 19.0 |
| | MAX | 50.0 | 48.0 | 39.0 | 50.0 | 50.0 | 38.0 | 45.0 | 36.0 | 50.0 | 43.0 | 47.0 | 41.0 | 49.0 | 42.0 | 39.0 | 34.0 |
| | Ν | 111 | 92 | 87 | 78 | 104 | 83 | 73 | 65 | 117 | 93 | 84 | 78 | 114 | 84 | 76 | 72 |
| | N MISSING | 5 | 8 | 5 | 0 | 8 | 5 | 5 | 1 | 1 | 5 | 4 | 0 | 2 | 3 | 6 | 1 |
| AUDIT-C | MEAN | 4.5 | 3.5 | 3.3 | 3.7 | 5.1 | 3.8 | 3.5 | 3.6 | 4.9 | 3.5 | 3.6 | 3.6 | 5.2 | 4.4 | 4.0 | 4.5 |
| (12-point score) | STD | 3.5 | 3.2 | 3.2 | 3.1 | 3.5 | 3.3 | 3.4 | 3.4 | 3.6 | 3.2 | 3.6 | 3.4 | 3.7 | 2.8 | 3.1 | 3.4 |
| | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1 | 0.0 | 0.0 | 0.0 | 0.0 | 2.0 | 0.0 | 0.0 | 0.0 | 1.0 | 0.0 | 0.0 | 0.0 | 2.0 | 2.0 | 2.0 | 2.0 |
| | MEDIAN | 5.0 | 4.0 | 3.0 | 3.0 | 5.0 | 4.0 | 3.0 | 3.0 | 5.0 | 3.0 | 3.0 | 3.0 | 5.0 | 4.0 | 4.0 | 5.0 |
| | Q3 | 7.0 | 6.0 | 6.0 | 6.0 | 8.0 | 7.0 | 6.0 | 6.0 | 8.0 | 6.0 | 7.0 | 6.0 | 8.0 | 7.0 | 6.0 | 7.0 |
| | MAX | 12.0 | 12.0 | 10.0 | 10.0 | 12.0 | 12.0 | 12.0 | 12.0 | 12.0 | 11.0 | 11.0 | 12.0 | 12.0 | 10.0 | 10.0 | 12.0 |
| | Ν | 109 | 93 | 87 | 78 | 104 | 83 | 73 | 66 | 109 | 93 | 84 | 78 | 110 | 83 | 77 | 70 |
| | N MISSING | 7 | 7 | 5 | 0 | 8 | 5 | 5 | 0 | 9 | 5 | 4 | 0 | 6 | 4 | 5 | 3 |

Table 4.8: Secondary efficacy outcomes - Co-existing issues

| | | | ТА | U | | | Μ | I | | | MI | ⊦W | | | MI+V | W+B | |
|------------------------------|-----------|----------|--------|-----------|--------|----------|---------|--------|--------|----------|---------|--------|--------|----------|--------|---------|-------|
| | | Baseline | 3 | 6 | 12 | Baseline | 3 | 6 | 12 | Baseline | 3 | 6 | 12 | Baseline | 3 | 6 | 12 |
| Drug Abuse | MEAN | 0.76 | months | montins . | 0.23 | 0.92 | montins | montns | 0.38 | 0.82 | montins | montns | 0.44 | 0.78 | months | montins | 0.46 |
| Screening Test | STD | 1.83 | | | 1.21 | 2.20 | | | 1.08 | 1.95 | | | 1.39 | 1.94 | | | 1.27 |
| (DAST) (10-point score) | MIN | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 |
| | 01 | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 |
| | MEDIAN | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 |
| | 03 | 0.00 | • | • | 0.00 | 0.00 | • | • | 0.00 | 0.00 | • | • | 0.00 | 0.00 | • | • | 0.00 |
| | QJ MAV | 8.00 | • | • | 10.00 | 10.00 | • | • | 6.00 | 8.00 | • | • | 8.00 | 0.00 | • | | 6.00 |
| | MAA | 8.00 | • | • | 10.00 | 10.00 | • | • | 0.00 | 8.00 | • | • | 8.00 | 9.00 | • | • | 0.00 |
| | N | 106 | • | • | 77 | 105 | • | • | 66 | 108 | • | • | 78 | 110 | • | • | 71 |
| | N MISSING | 10 | • | | 1 | 7 | | | 0 | 10 | | | 0 | 6 | • | | 2 |
| PRIME-MD Major depressive | Yes | 57.4% | • | • | 17.9% | 49.0% | • | • | 22.7% | 62.9% | • | • | 16.7% | 50.9% | • | • | 20.5% |
| disorder | Ν | 108 | • | | 78 | 96 | • | • | 66 | 105 | | | 78 | 110 | • | | 73 |
| | N MISSING | 8 | • | | 0 | 16 | • | • | 0 | 13 | • | • | 0 | 6 | • | | 0 |
| PRIME-MD | Yes | 43.5% | | | 32.1% | 44.2% | | • | 30.3% | 44.2% | | | 39.7% | 39.1% | • | | 29.2% |
| Dysthymia | Ν | 108 | • | | 78 | 95 | | | 66 | 104 | | | 78 | 110 | | | 72 |
| | N MISSING | 8 | • | | 0 | 17 | • | | 0 | 14 | | | 0 | 6 | | • | 1 |
| PRIME-MD | Yes | 13.0% | | | 3.8% | 15.8% | • | | 4.5% | 15.4% | | | 2.6% | 16.4% | • | | 1.4% |
| Minor depressive disorder | N | 108 | • | | 78 | 95 | • | | 66 | 104 | | | 78 | 110 | | | 72 |
| | N MISSING | 8 | | | 0 | 17 | | | 0 | 14 | | | 0 | 6 | | | 1 |
| PRIME-MD Alcohol abuse | Yes | 23.3% | | | 17.3% | 19.1% | | | 10.6% | 28.3% | | | 16.2% | 20.2% | | | 22.9% |
| | Ν | 103 | | | 75 | 89 | | | 66 | 99 | | | 74 | 109 | | | 70 |
| | N MISSING | 13 | | | 3 | 23 | | | 0 | 19 | | | 4 | 7 | | | 3 |

Table 4.8: Secondary efficacy outcomes - Co-existing issues - continued

| | | | ТА | U | | | Μ | I | | | MI | -W | | | MI+V | N+B | |
|--------------------------|----------------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|
| | | Baseline | 3 | 6 | 12 |
| | | | months | months | months |
| PRIME-MD | Yes | 2.9% | • | • | 4.1% | 3.2% | • | • | 3.1% | 3.9% | • | • | 6.8% | 4.5% | • | • | 7.2% |
| Bipolar disorder | N | 105 | • | | 74 | 94 | | | 65 | 102 | | | 73 | 110 | • | • | 69 |
| | N MISSING | 11 | • | • | 4 | 18 | | | 1 | 16 | | | 5 | 6 | | | 4 |
| Current smoking | Yes | 59.6% | 57.0% | 55.2% | 52.6% | 54.6% | 48.2% | 45.9% | 40.9% | 56.0% | 47.9% | 51.2% | 51.3% | 60.0% | 58.3% | 58.4% | 55.6% |
| status | Ν | 99 | 93 | 87 | 78 | 108 | 83 | 74 | 66 | 116 | 94 | 84 | 78 | 90 | 84 | 77 | 72 |
| | N MISSING | 17 | 7 | 5 | 0 | 4 | 5 | 4 | 0 | 2 | 4 | 4 | 0 | 26 | 3 | 5 | 1 |
| Frequency of smoking | 1 | 95.5% | 98.1% | 95.8% | 92.7% | 88.3% | 90.0% | 85.3% | 96.3% | 93.9% | 93.3% | 93.0% | 92.5% | 93.0% | 91.8% | 90.9% | 95.0% |
| 1=At least once a | 2 | 3.0% | 1.9% | 2.1% | 4.9% | 6.7% | 7.5% | 8.8% | 0.0% | 4.5% | 6.7% | 4.7% | 7.5% | 2.8% | 6.1% | 6.8% | 2.5% |
| day 2=At least once a | 3 | 1.5% | 0.0% | 2.1% | 0.0% | 3.3% | 2.5% | 0.0% | 3.7% | 0.0% | 0.0% | 0.0% | 0.0% | 1.4% | 0.0% | 0.0% | 2.5% |
| week | 4 | 0.0% | 0.0% | 0.0% | 2.4% | 1.7% | 0.0% | 5.9% | 0.0% | 1.5% | 0.0% | 2.3% | 0.0% | 2.8% | 2.0% | 2.3% | 0.0% |
| 3=At least once a month | Ν | 66 | 53 | 48 | 41 | 60 | 40 | 34 | 27 | 66 | 45 | 43 | 40 | 71 | 49 | 44 | 40 |
| 4=Less than once a | N MISSING | 50 | 47 | 44 | 37 | 52 | 48 | 44 | 39 | 52 | 53 | 45 | 38 | 45 | 38 | 38 | 33 |
| Treatment received | Vac | 20.0% | | | 17.00/ | 24.20/ | | | 10.70/ | 19 60/ | | | 10.20/ | 21.60/ | | | 16 40/ |
| for montal health in | N | 20.9% | • | • | 17.9% | 24.5% | | • | 19.7% | 10.0% | • | • | 19.2% | 21.0% | • | • | 73 |
| nevious 12 months | N MISSING | 115 | • | • | | 111 | • | • | 00 | 0 | • | • | ,0 | 0 | • | • | 0 |
| Prescription | Yes | 22.8% | • | • | 18.2% | 27.7% | | | 28.8% | 27.6% | • | | 26.9% | 24.8% | • | • | 19.4% |
| received for mental | N | 101 | • | | 77 | 101 | • | | 66 | 105 | | • | 78 | 105 | | • | 72 |
| health in previous | N MISSING | 15 | | · · · | 1 | 11 | | | 0 | 13 | | | , e | 11 | | | 1 |
| 12 months | 11 11 10 11 10 | 10 | • | | - | | | | 0 | | | | 0 | | | • | - |
| Treatment received | Yes | 6.4% | • | | 3.8% | 8.0% | | | 9.1% | 5.2% | | | 6.4% | 8.6% | • | • | 7.0% |
| for drugs or alcohol | Ν | 110 | • | | 78 | 112 | | | 66 | 116 | | | 78 | 116 | | • | 71 |
| in previous 12 months | N MISSING | 6 | | | 0 | 0 | | | 0 | 2 | | | 0 | 0 | • | | 2 |

Table 4.8: Secondary efficacy outcomes - Co-existing issues - continued

| | | | TA | U | | | Μ | Ι | | | MI | ⊦W | | | MI+V | W+B | |
|----------------------|-----------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| WHO Quality of | MEAN | 25.0 | 29.5 | 31.2 | 31.1 | 24.8 | 30.1 | 31.3 | 30.8 | 23.9 | 30.1 | 30.1 | 31.8 | 24.4 | 31.0 | 31.5 | 31.8 |
| 8-item questionnaire | STD | 5.6 | 5.4 | 5.8 | 6.2 | 6.3 | 6.3 | 5.3 | 5.5 | 6.1 | 5.7 | 6.0 | 5.5 | 6.6 | 5.6 | 5.7 | 5.8 |
| | MIN | 10.0 | 17.0 | 16.0 | 11.0 | 9.0 | 16.0 | 19.0 | 20.0 | 9.0 | 14.0 | 14.0 | 18.0 | 9.0 | 16.0 | 11.0 | 15.0 |
| | Q1 | 21.0 | 26.0 | 27.0 | 27.0 | 21.0 | 26.0 | 28.0 | 27.0 | 20.0 | 27.0 | 26.0 | 28.0 | 19.0 | 27.0 | 29.0 | 28.0 |
| | MEDIAN | 26.0 | 30.0 | 32.0 | 32.0 | 25.0 | 31.0 | 31.0 | 31.0 | 24.0 | 31.0 | 30.0 | 32.0 | 25.0 | 32.0 | 32.0 | 33.0 |
| | Q3 | 29.0 | 33.0 | 36.0 | 35.0 | 29.0 | 36.0 | 35.0 | 35.0 | 28.0 | 35.0 | 34.5 | 36.0 | 31.0 | 35.0 | 36.0 | 36.0 |
| | MAX | 39.0 | 39.0 | 40.0 | 40.0 | 38.0 | 40.0 | 40.0 | 40.0 | 38.0 | 40.0 | 40.0 | 40.0 | 40.0 | 40.0 | 40.0 | 40.0 |
| | Ν | 109 | 93 | 87 | 78 | 106 | 83 | 73 | 65 | 107 | 92 | 84 | 77 | 111 | 84 | 77 | 72 |
| | N MISSING | 7 | 7 | 5 | 0 | 6 | 5 | 5 | 1 | 11 | 6 | 4 | 1 | 5 | 3 | 5 | 1 |

Table 4.8: Secondary efficacy outcomes - Co-existing issues - continued

| | | | ТА | U | | | M | [| | | MI | ⊦W | | | MI+V | V+B | |
|----------------------------|-----------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| How was work | MEAN | 3.2 | 1.4 | 1.1 | 0.7 | 3.4 | 1.7 | 1.1 | 1.1 | 3.8 | 1.7 | 1.1 | 1.0 | 3.6 | 0.8 | 1.1 | 0.6 |
| affected in past one month | STD | 3.5 | 2.8 | 2.5 | 1.7 | 3.6 | 3.1 | 2.4 | 2.4 | 3.6 | 3.2 | 2.4 | 2.3 | 3.8 | 2.2 | 2.6 | 1.7 |
| (10-point Likert | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| scale) | Q1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | MEDIAN | 2.0 | 0.0 | 0.0 | 0.0 | 3.0 | 0.0 | 0.0 | 0.0 | 3.5 | 0.0 | 0.0 | 0.0 | 2.0 | 0.0 | 0.0 | 0.0 |
| | Q3 | 6.0 | 1.0 | 0.0 | 0.0 | 6.0 | 1.5 | 0.0 | 0.0 | 7.0 | 1.0 | 0.0 | 0.0 | 7.0 | 0.0 | 0.0 | 0.0 |
| | MAX | 10.0 | 10.0 | 10.0 | 7.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| | Ν | 102 | 88 | 83 | 71 | 102 | 76 | 71 | 60 | 110 | 84 | 74 | 70 | 106 | 79 | 73 | 70 |
| | N MISSING | 14 | 12 | 9 | 7 | 10 | 12 | 7 | 6 | 8 | 14 | 14 | 8 | 10 | 8 | 9 | 3 |
| How was social life | MEAN | 5.1 | 1.6 | 1.5 | 1.2 | 5.0 | 2.6 | 1.9 | 1.8 | 5.8 | 1.9 | 1.9 | 1.7 | 5.7 | 1.2 | 1.5 | 1.7 |
| month? | STD | 3.4 | 3.0 | 3.0 | 2.4 | 3.7 | 3.5 | 2.8 | 3.0 | 3.5 | 3.3 | 3.1 | 2.9 | 3.5 | 2.4 | 2.9 | 3.0 |
| (10-point Likert | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| searc) | Q1 | 2.0 | 0.0 | 0.0 | 0.0 | 0.5 | 0.0 | 0.0 | 0.0 | 3.0 | 0.0 | 0.0 | 0.0 | 3.0 | 0.0 | 0.0 | 0.0 |
| | MEDIAN | 5.5 | 0.0 | 0.0 | 0.0 | 5.0 | 0.0 | 0.0 | 0.0 | 7.0 | 0.0 | 0.0 | 0.0 | 7.0 | 0.0 | 0.0 | 0.0 |
| | Q3 | 8.0 | 2.0 | 1.0 | 0.0 | 8.0 | 5.0 | 3.0 | 3.0 | 9.0 | 3.0 | 4.0 | 2.0 | 8.0 | 1.0 | 1.0 | 3.0 |
| | MAX | 10.0 | 10.0 | 10.0 | 9.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| | Ν | 114 | 93 | 87 | 78 | 112 | 84 | 74 | 66 | 117 | 93 | 84 | 78 | 113 | 84 | 77 | 72 |
| | N MISSING | 2 | 7 | 5 | 0 | 0 | 4 | 4 | 0 | 1 | 5 | 4 | 0 | 3 | 3 | 5 | 1 |

Table 4.9: Secondary efficacy outcomes - Gambling impacts

| | | | ТА | U | | | M | [| | | MI- | ⊦W | | | MI+V | V+B | |
|-------------------------------------|-----------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| How were family & | MEAN | 6.4 | 2.1 | 2.1 | 1.3 | 6.5 | 2.4 | 1.8 | 2.3 | 7.5 | 2.3 | 2.0 | 2.2 | 6.7 | 1.9 | 1.9 | 1.7 |
| home affected in past one month? | STD | 3.3 | 3.2 | 3.3 | 2.6 | 3.3 | 3.3 | 3.0 | 3.3 | 2.8 | 3.4 | 3.2 | 3.3 | 3.4 | 3.1 | 3.1 | 3.1 |
| (10-point Likert scale | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| | Q1 | 5.0 | 0.0 | 0.0 | 0.0 | 4.0 | 0.0 | 0.0 | 0.0 | 6.0 | 0.0 | 0.0 | 0.0 | 5.0 | 0.0 | 0.0 | 0.0 |
| | MEDIAN | 7.0 | 0.0 | 0.0 | 0.0 | 7.5 | 0.0 | 0.0 | 0.0 | 8.5 | 0.0 | 0.0 | 0.0 | 8.0 | 0.0 | 0.0 | 0.0 |
| | Q3 | 9.0 | 4.0 | 4.0 | 2.0 | 9.0 | 5.0 | 3.0 | 5.0 | 10.0 | 5.0 | 3.5 | 5.0 | 10.0 | 3.0 | 3.0 | 3.0 |
| | MAX | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| | Ν | 116 | 93 | 87 | 78 | 112 | 84 | 74 | 66 | 118 | 94 | 84 | 78 | 116 | 84 | 77 | 73 |
| | N MISSING | 0 | 7 | 5 | 0 | 0 | 4 | 4 | 0 | 0 | 4 | 4 | 0 | 0 | 3 | 5 | 0 |
| How was health | MEAN | 5.4 | 1.6 | 1.8 | 1.4 | 5.2 | 1.7 | 1.5 | 1.8 | 5.7 | 1.8 | 1.4 | 1.6 | 5.0 | 1.1 | 1.4 | 1.3 |
| month? | STD | 3.0 | 2.8 | 2.9 | 2.5 | 3.0 | 2.7 | 2.7 | 2.8 | 3.3 | 3.0 | 2.6 | 2.6 | 3.6 | 2.2 | 2.7 | 2.6 |
| (10-point Likert | MIN | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| searc) | Q1 | 3.0 | 0.0 | 0.0 | 0.0 | 3.0 | 0.0 | 0.0 | 0.0 | 3.0 | 0.0 | 0.0 | 0.0 | 1.0 | 0.0 | 0.0 | 0.0 |
| | MEDIAN | 6.0 | 0.0 | 0.0 | 0.0 | 5.3 | 0.0 | 0.0 | 0.0 | 6.0 | 0.0 | 0.0 | 0.0 | 5.0 | 0.0 | 0.0 | 0.0 |
| | Q3 | 8.0 | 3.0 | 3.0 | 2.0 | 8.0 | 2.5 | 2.0 | 4.0 | 8.0 | 3.0 | 2.0 | 3.0 | 8.0 | 0.0 | 1.0 | 2.0 |
| | MAX | 10.0 | 10.0 | 10.0 | 9.0 | 10.0 | 10.0 | 9.0 | 9.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 9.0 | 10.0 | 10.0 |
| | Ν | 114 | 93 | 87 | 78 | 110 | 84 | 74 | 66 | 114 | 93 | 84 | 78 | 116 | 84 | 77 | 73 |
| | N MISSING | 2 | 7 | 5 | 0 | 2 | 4 | 4 | 0 | 4 | 5 | 4 | 0 | 0 | 3 | 5 | 0 |

Table 4.9: Secondary efficacy outcomes - Gambling impacts - continued

| | | | ТА | U | | | M | [| | | MI | ⊦W | | | MI+V | W+B | |
|---|-----------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| Legal problems experienced in past | Yes | 12.6% | 9.7% | 3.5% | 9.0% | 17.1% | 10.7% | 1.4% | 9.1% | 17.2% | 8.6% | 4.8% | 9.1% | 9.6% | 6.0% | 5.2% | 9.6% |
| 12 months (baseline)/ 3 months (follow-up) (10-point Likert | N | 111 | 93 | 86 | 78 | 111 | 84 | 74 | 66 | 116 | 93 | 84 | 77 | 115 | 84 | 77 | 73 |
| scale) | N MISSING | 5 | 7 | 6 | 0 | 1 | 4 | 4 | 0 | 2 | 5 | 4 | 1 | 1 | 3 | 5 | 0 |
| New Zealand | MEAN | 1.44 | | | 1.09 | 1.48 | | | 1.19 | 1.65 | | | 1.21 | 1.34 | | | 1.11 |
| Deprivation Index | STD | 1.18 | | | 1.30 | 1.26 | | | 1.13 | 1.30 | | | 1.33 | 1.21 | | | 1.25 |
| | MIN | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 | 0.00 | | | 0.00 |
| | Q1 | 0.58 | | | 0.00 | 0.00 | | • | 0.00 | 0.58 | | | 0.00 | 0.00 | | | 0.00 |
| | MEDIAN | 1.23 | | | 0.63 | 1.24 | • | • | 0.90 | 1.69 | | | 0.66 | 1.19 | • | | 0.63 |
| | Q3 | 2.36 | | | 1.57 | 2.42 | • | • | 1.98 | 2.56 | | | 1.98 | 2.35 | • | | 1.89 |
| M N | MAX | 4.25 | | | 4.77 | 4.25 | • | • | 4.19 | 4.77 | | | 4.77 | 4.25 | | | 4.25 |
| | Ν | 100 | | | 76 | 93 | • | • | 66 | 103 | | | 77 | 108 | • | | 72 |
| | N MISSING | 16 | | • | 2 | 19 | • | • | 0 | 15 | • | | 1 | 8 | • | | 1 |

Table 4.9: Secondary efficacy outcomes - Gambling impacts - continued

| | | | T | AU | | | Ν | 11 | | | MI- | +W | | | M | I+W+B | |
|-----------------------|------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|-----------|
| | | Baseline | 3 months | 6 months | 12 months | Baseline | 3 months | 6 months | 12 months | Baseline | 3 months | 6 months | 12 months | Baseline | 3 months | 6 months | 12 months |
| Goal met in | Not at all | | 10.8% | 13.8% | 23.1% | | 25.0% | 24.3% | 26.2% | | 18.1% | 19.0% | 12.8% | | 14.3% | 9.1% | 23.3% |
| the last 3 months | Partly | | 37.6% | 26.4% | 21.8% | | 31.0% | 28.4% | 23.1% | | 29.8% | 20.2% | 20.5% | | 35.7% | 23.4% | 27.4% |
| | Mostly | | 23.7% | 25.3% | 26.9% | | 14.3% | 16.2% | 15.4% | | 18.1% | 21.4% | 30.8% | | 23.8% | 27.3% | 21.9% |
| | Completely | | 28.0% | 34.5% | 28.2% | | 29.8% | 31.1% | 35.4% | | 34.0% | 39.3% | 35.9% | | 26.2% | 40.3% | 27.4% |
| | Ν | | 93 | 87 | 78 | • | 84 | 74 | 65 | | 94 | 84 | 78 | | 84 | 77 | 73 |
| | N MISSING | | 7 | 5 | 0 | | 16 | 18 | 13 | | 6 | 8 | 0 | | 16 | 15 | 5 |
| How | MEAN | 8.9 | 8.8 | 8.9 | 8.8 | 9.2 | 8.6 | 8.5 | 8.5 | 9.0 | 8.9 | 9.0 | 8.8 | 9.0 | 8.5 | 9.1 | 8.7 |
| are you to | STD | 1.6 | 1.7 | 1.9 | 1.8 | 1.4 | 2.1 | 2.2 | 2.2 | 1.9 | 1.8 | 1.7 | 2.0 | 1.8 | 2.0 | 1.4 | 2.0 |
| overcome | MIN | 4.0 | 4.0 | 0.0 | 1.0 | 4.0 | 1.0 | 0.0 | 0.0 | 0.0 | 3.0 | 2.0 | 0.0 | 2.0 | 0.0 | 5.0 | 0.0 |
| gambling | Q1 | 8.0 | 8.0 | 8.0 | 8.0 | 9.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 | 8.0 | 9.0 | 8.0 |
| problem? (10-point | MEDIAN | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 9.5 | 10.0 | 10.0 |
| Likert scale) | Q3 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| | MAX | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| | N | 116 | 92 | 87 | 78 | 112 | 84 | 74 | 66 | 117 | 94 | 84 | 78 | 115 | 84 | 76 | 73 |
| | N MISSING | 0 | 8 | 5 | 0 | 0 | 4 | 4 | 0 | 1 | 4 | 4 | 0 | 1 | 3 | 6 | 0 |

Table 4.10: Secondary efficacy outcomes - Goal setting and motivation

| | | | TA | NU | | | Μ | Ι | | | MI | ⊦W | | | MI+V | N+B | |
|---------------------|-------------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| Did you | Yes | | 51.7% | 54.2% | 65.3% | | 21.0% | 28.2% | 40.6% | | 93.4% | 89.3% | 93.3% | | 94.0% | 93.5% | 93.1% |
| workbook? | Ν | | 89 | 83 | 75 | • | 81 | 71 | 64 | | 91 | 84 | 75 | | 83 | 77 | 72 |
| | N MISSING | | 11 | 9 | 3 | | 7 | 7 | 2 | | 7 | 4 | 3 | • | 4 | 5 | 1 |
| Have you | MEAN | | 2.02 | 1.40 | 1.47 | | 2.00 | 4.76 | 1.35 | | 2.21 | 1.63 | 1.44 | | 2.14 | 1.64 | 1.42 |
| workbook? | STD | | 0.77 | 0.62 | 0.65 | | 0.87 | 0.77 | 0.56 | | 0.67 | 0.73 | 0.69 | | 0.66 | 0.70 | 0.61 |
| | MIN | | 1.00 | 1.00 | 1.00 | | 1.00 | 1.00 | 1.00 | | 1.00 | 1.00 | 1.00 | | 1.00 | 1.00 | 1.00 |
| | Q1 | | 1.00 | 1.00 | 1.00 | | 1.00 | 1.00 | 1.00 | | 2.00 | 1.00 | 1.00 | | 2.00 | 1.00 | 1.00 |
| | MEDIAN | | 2.00 | 1.00 | 1.00 | | 2.00 | 2.00 | 1.00 | | 2.00 | 1.00 | 1.00 | | 2.00 | 2.00 | 1.00 |
| - | Q3 | | 3.00 | 2.00 | 2.00 | | 3.00 | 2.00 | 2.00 | | 3.00 | 2.00 | 2.00 | | 3.00 | 2.00 | 2.00 |
| | MAX | | 3.00 | 3.00 | 3.00 | | 3.00 | 3.00 | 3.00 | | 3.00 | 3.00 | 3.00 | | 3.00 | 3.00 | 3.00 |
| | Ν | | 47 | 45 | 47 | | 17 | 21 | 26 | | 85 | 75 | 71 | | 78 | 72 | 67 |
| | N MISSING | | 53 | 47 | 31 | | 71 | 57 | 40 | | 13 | 13 | 7 | | 9 | 10 | 6 |
| Did you complete | Not Applicable | | 61.8% | 80.2% | 79.7% | | 86.4% | 84.7% | 87.9% | • | 19.6% | 55.4% | 70.1% | | 18.1% | 50.6% | 67.6% |
| some of the | None | • | 21.3% | 15.1% | 12.2% | | 7.4% | 5.6% | 7.6% | | 20.7% | 12.0% | 9.1% | • | 24.1% | 16.9% | 9.9% |
| the | Some | • | 12.4% | 3.5% | 8.1% | | 4.9% | 8.3% | 4.5% | | 51.1% | 25.3% | 15.6% | • | 44.6% | 28.6% | 21.1% |
| workbook? | All | • | 4.5% | 1.2% | 0.0% | | 1.2% | 1.4% | 0.0% | | 8.7% | 7.2% | 5.2% | • | 13.3% | 3.9% | 1.4% |
| | Ν | | 89 | 86 | 74 | | 81 | 72 | 66 | | 92 | 83 | 77 | | 83 | 77 | 71 |
| | N MISSING | • | 11 | 6 | 4 | • | 7 | 6 | 0 | | 6 | 5 | 1 | • | 4 | 5 | 2 |

Table 4.11: Secondary efficacy outcomes - Workbook reception and use

| | | | TA | U | | | Μ | Ι | | | MI | ⊦W | | | MI+ | W+B | |
|-------------------------|-------------------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|----------|--------|--------|--------|
| | | Baseline | 3 | 6 | 12 |
| | | | months | months | months |
| Have you used any of | Not Applicable | | 63.2% | 80.5% | 78.7% | | 87.7% | 85.9% | 89.2% | | 21.8% | 56.1% | 70.1% | | 18.5% | 50.6% | 67.6% |
| the strategies | None | | 8.0% | 10.3% | 9.3% | • | 6.2% | 4.2% | 1.5% | | 25.3% | 14.6% | 6.5% | | 27.2% | 19.5% | 11.3% |
| in the | Some | | 19.5% | 6.9% | 8.0% | | 3.7% | 5.6% | 6.2% | | 37.9% | 11.0% | 16.9% | | 39.5% | 20.8% | 19.7% |
| workbook? | All | | 9.2% | 2.3% | 4.0% | | 2.5% | 4.2% | 3.1% | | 14.9% | 18.3% | 6.5% | | 14.8% | 9.1% | 1.4% |
| | Ν | | 87 | 87 | 75 | | 81 | 71 | 65 | | 87 | 82 | 77 | | 81 | 77 | 71 |
| | N MISSING | | 13 | 5 | 3 | • | 7 | 7 | 1 | | 11 | 6 | 1 | | 6 | 5 | 2 |
| Workbook engagement | MEAN | | 1.53 | 0.79 | 0.82 | | 1.35 | 1.22 | 0.76 | | 1.78 | 1.20 | 0.90 | | 1.79 | 1.17 | 0.86 |
| (numerical 1- | STD | | 0.90 | 0.66 | 0.73 | • | 0.91 | 0.93 | 0.72 | | 0.74 | 0.97 | 0.86 | | 0.74 | 0.87 | 0.75 |
| 3 averaged | MIN | | 0.33 | 0.33 | 0.33 | | 0.33 | 0.33 | 0.33 | | 0.33 | 0.33 | 0.33 | | 0.33 | 0.33 | 0.33 |
| outcomes) | Q1 | | 0.33 | 0.33 | 0.33 | | 0.33 | 0.33 | 0.33 | | 1.67 | 0.33 | 0.33 | | 1.33 | 0.33 | 0.33 |
| | MEDIAN | | 1.67 | 0.33 | 0.33 | | 1.33 | 1.17 | 0.33 | | 2.00 | 0.33 | 0.33 | | 2.00 | 1.33 | 0.33 |
| | Q3 | | 2.33 | 1.33 | 1.33 | | 2.17 | 2.00 | 1.33 | | 2.33 | 2.00 | 1.67 | | 2.33 | 2.00 | 1.67 |
| | MAX | | 3.00 | 2.67 | 2.67 | | 2.67 | 3.00 | 2.33 | | 3.00 | 3.00 | 3.00 | | 3.00 | 3.00 | 2.33 |
| | N | | 43 | 44 | 44 | • | 16 | 20 | 25 | | 80 | 73 | 71 | | 76 | 72 | 66 |
| | N MISSING | • | 57 | 48 | 34 | | 72 | 58 | 41 | | 18 | 15 | 7 | • | 11 | 10 | 7 |

Table 4.11: Secondary efficacy outcomes - Workbook reception and use - continued

| | TAU Baseline 3 6 12 | | | | Μ | I | | | MI | -W | | | MI+V | V+B | | | |
|---------------------------------|------------------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|----------|-------------|-------------|--------------|
| | | Baseline | 3 months | 6 months | 12 months |
| Received any | Yes | - | 39.8% | 31.0% | 29.5% | - | 36.9% | 31.5% | 34.8% | - | 41.5% | 32.1% | 34.6% | - | 40.5% | 44.2% | 35.6% |
| (formal and | Ν | - | 93 | 87 | 78 | - | 84 | 73 | 66 | - | 94 | 84 | 78 | - | 84 | 77 | 73 |
| informal) in past 3 months | N MISSING | - | 7 | 5 | 0 | - | 4 | 5 | 0 | - | 4 | 4 | 0 | - | 3 | 5 | 0 |
| Received formal assistance from | Yes | - | 28.0% | 18.4% | 15.4% | - | 25.0% | 23.0% | 25.8% | - | 20.2% | 15.5% | 16.7% | - | 23.8% | 18.2% | 19.2% |
| any treatment service in the | Ν | - | 93 | 87 | 78 | - | 84 | 74 | 66 | - | 94 | 84 | 78 | - | 84 | 77 | 73 |
| past 3 months | N MISSING | - | 7 | 5 | 0 | - | 4 | 4 | 0 | - | 4 | 4 | 0 | - | 3 | 5 | 0 |
| Received | Yes | - | 39.8% | 31.0% | 29.5% | - | 36.9% | 31.5% | 34.8% | - | 41.5% | 32.1% | 34.6% | - | 41.7% | 44.2% | 35.6% |
| assistance from | Ν | - | 93 | 87 | 78 | - | 84 | 73 | 66 | - | 94 | 84 | 78 | - | 84 | 77 | 73 |
| any person in past 3 months | N MISSING | - | 7 | 5 | 0 | - | 4 | 5 | 0 | - | 4 | 4 | 0 | - | 3 | 5 | 0 |

Table 4.12: Secondary efficacy outcomes - Treatment service assistance

| Received formal as | sistance from: | | Т | 'AU | | |] | MI | | | Μ | I+W | | | MI- | +W+B | |
|--------------------|----------------|-------|---------------------------------------|---------|---------|-------|---------------|---------|---------------------------------------|-------|---------|--------|--------|-------|---------|---------|---------|
| | | Base- | 3 | 6 | 12 | Base- | 3 | 6 | 12 | Base- | 3 | 6 | 12 | Base- | 3 | 6 | 12 |
| | | line | months | months | months | line | months | months | months | line | months | months | months | line | months | months | months |
| Gambling | Yes (N) | | 4 | 2 | 1 | | 3 | 3 | 2 | | 6 | 2 | 3 | | 6 | 2 | 2 |
| Helpline | No Sessions: | | 3 | 3 | 0 | | 4 | 1 | 2 | | 1 | 35 | 15 | | 25 | 2 | 6 |
| | Median | • | (2-6) | (2-4) | (9-9) | | (1-10) | (1-1) | (2-2) | | (1-4) | (1-6) | (1-2) | • | (1-4) | (1-3) | (2-10) |
| | (Min-Max) | | (= 3) | (= .) | (==) | | (110) | (1 1) | (= =) | | (1) | (1 0) | (1 =) | | (1 .) | (1 0) | (= 10) |
| Problem | Yes (N) | | 9 | 3 | 3 | • | 7 | 4 | 3 | | 7 | 4 | 3 | | 4 | 3 | 3 |
| Gambling | No Sessions: | | 5 | 6 | 12 | | 6 | 4.5 | 6 | | 6 | 4 | 2 | | 7 | 12 | 12 |
| Foundation | Median | • | (1-13) | (2-7) | (12-24) | • | (1-10) | (1-6) | (3-48) | • | (1-12) | (1-8) | (1-3) | • | (3-12) | (12-12) | (2-12) |
| | (Min-Max) | | , , , , , , , , , , , , , , , , , , , | | | | | 1 | , , , , , , , , , , , , , , , , , , , | | 1 | | | | 1 | | · · · |
| Salvation Army | Yes (N) | | 5 | / | 2 | • | | 1 | 2 | • | 1 | 2 | 2 | · · | 1 | 4 | 2 |
| Oasis Centres | No Sessions: | | 6 | 7 | 13.5 | | 1 | 10 | 2.5 | | 3 | 5 | 4 | | 12 | 5.5 | 24 |
| | (Min Max) | • | (2-12) | (1-12) | (3-24) | • | (1-5) | (10-10) | (2-3) | • | (3-3) | (4-6) | (2-6) | • | (12-12) | (1-12) | (24-24) |
| Gamblers | (WIIII-IVIAX) | | 1 | 2 | 2 | | 5 | 1 | 5 | | 5 | 3 | 1 | | 1 | 3 | 1 |
| | No Sessions: | • | + | 2 | 2 | • | 5 | 4 | 5 | • | 5 | 5 | 4 | • | 1 | 5 | 1 |
| Mionymous | Median | | 7 | 12 | 22 | | 12 | 11 | 24 | | 12 | 6 | 10 | | 1 | 2 | 2 |
| | (Min-Max) | • | (1.5-12) | (12-12) | (20-24) | • | (2-12) | (10-12) | (3-504#) | • | (6-12) | (2-12) | (4-24) | • | (1-1) | (1-3) | (2-2) |
| Other problem | Yes (N) | | 5 | 3 | 5 | | 5 | 6 | 7 | | 1 | 2 | 3 | | 6 | 4 | 7 |
| gambling support | No Sessions: | | - | - | | | | _ | _ | | | | - | | | | |
| service(s) | Median | | 6 | 6 | 4 | | $\frac{2}{1}$ | 5 | 5 | | 12 | 7.5 | 6 | | 1.5 | 4 | 12 |
| | (Min-Max) | | (3-12) | (2-12) | (1-12) | | (1-12) | (1-2/0) | (2-24) | | (12-12) | (3-12) | (2-24) | | (1-12) | (1-48) | (2-21) |
| Online/internet- | Yes (N) | | 1 | 0 | 0 | | 0 | 0 | 0 | | 0 | 1 | 0 | | 2 | 0 | 0 |
| based service | No Sessions: | | 2 | | | | | | | | | | | | | | |
| | Median | | (2-2) | - | - | | - | - | - | | - | NR | - | | NR | - | - |
| | (Min-Max) | | (2-2) | | | | | | | | | | | | | | |
| Total Formal | Yes (N)## | | 26 | 16 | 12 | • | 21 | 17 | 17 | • | 19 | 13 | 13 | • | 20 | 14 | 14 |
| Assistance | Yes (%) | | 28.0% | 18.4% | 15.4% | • | 25.0% | 23.0% | 25.8% | | 20.2% | 15.5% | 16.7% | | 23.8% | 18.2% | 19.2% |
| | Ν | | 93 | 87 | 78 | | 84 | 74 | 66 | | 94 | 84 | 78 | | 84 | 77 | 73 |
| | N MISSING | | 7 | 5 | 0 | | 4 | 4 | 0 | | 4 | 4 | 0 | | 3 | 5 | 0 |

Table 4.13: Secondary efficacy outcomes - Treatment service assistance

 [#] Involved multiple text messages per day
 ^{##} Note some participants received assistance from multiple agencies, therefore not mutually exclusive and total number of participants does not equal the sum of individual agency assistance NR Not reported

APPENDIX 5 Tables - Subgroup analyses

Table 5.1: TAU vs. MI Days Gambled, Money Lost by gender

| | TEST | 95% Con Lim | fidence its |
|-----------------------------|---|----------------|----------------|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 Male | -0.14 | 2.88 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Male | -0.13 | 15.70 |
| | | | |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 Female | -1.34 | 1.36 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Female | -8.44 | 5.67 |

Table 5.2: TAU vs. MI Gambling-quit or improved by gender

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB |
|-------------------------|---------------------------|---------------|-----------------------|-----------------------|
| Gambling-quit or | hyp. A : TAU vs MI Male | 0.36 | 0.09 | 1.42 |
| improved, time-averaged | | | | |
| Gambling-quit or | hyp. A : TAU vs MI Female | 1.04 | 0.22 | 3.76 |
| improved, time-averaged | | | | |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

Table 5.3: Hypotheses B and C - Days Gambled, Money Lost, PGSI - females

| | TEST | Estimated | Standard | P-value | Alternative |
|-----------------------------|--------------------------|-----------|----------|-------------|-------------|
| | | change | error | (one-sided) | accepted |
| | hyp. B.a: TAU vs MI+W | 0.18 | 0.66 | 0.61 | No |
| Days Gambled, | hyp. B.b: MI vs MI+W | 0.17 | 0.71 | 0.59 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | 0.00 | 0.70 | 0.50 | No |
| | hyp. B.d: MI vs MI+W+B | -0.01 | 0.74 | 0.49 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | -1.24 | 3.46 | 0.36 | No |
| averaged | hyp. B.b: MI vs MI+W | 0.14 | 3.69 | 0.52 | No |
| | hyp. B.c: TAU vs MI+W+B | -2.10 | 3.65 | 0.28 | No |
| | hyp. B.d: MI vs MI+W+B | -0.71 | 3.87 | 0.43 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.06 | 0.81 | 0.53 | No |
| Days Gambled, at | hyp. C.b: MI vs MI+W+B | -0.12 | 0.87 | 0.44 | No |
| 12 months | hyp. C.c: MI+W vs MI+W+B | 0.32 | 0.83 | 0.65 | No |
| | hyp. C.a: TAU vs MI+W+B | -3.85 | 4.19 | 0.18 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | -2.32 | 4.49 | 0.30 | No |
| montais | hyp. C.c: MI+W vs MI+W+B | -1.37 | 4.27 | 0.37 | No |
| | hyp. B.a: TAU vs MI+W | 0.35 | 1.32 | 0.60 | No |
| | hyp. B.b: MI vs MI+W | 0.40 | 1.40 | 0.61 | No |
| PGSI-12, at 12 months | hyp. C.a: TAU vs MI+W+B | 2.63 | 1.36 | 0.97 | No |
| montuis | hyp. C.b: MI vs MI+W+B | 2.68 | 1.45 | 0.97 | No |
| | hyp. C.c: MI+W vs MI+W+B | 2.28 | 1.37 | 0.95 | No |

| Table 5.4: Hype | theses B and | C - Gambl | ling-quit or | improved l | by gender |
|-----------------|--------------|-----------|--------------|------------|-----------|
| 21 | | | | 1 | 20 |

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|---|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 0.59 | 0.15 | 2.31 | 0.77 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.63 | 0.45 | 5.97 | 0.23 | No |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 0.63 | 0.16 | 2.39 | 0.75 | No |
| | hyp. B.d: MI vs MI+W+B | 1.71 | 0.48 | 6.16 | 0.20 | No |
| Gambling-quit or improved, at 12 months | hyp. C.a: TAU vs MI+W+B | 0.64 | 0.14 | 2.95 | 0.72 | No |
| | hyp. C.b: MI vs MI+W+B | 1.80 | 0.42 | 7.76 | 0.21 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.08 | 0.02 | 0.46 | 1.00 | No |

Males

Females

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|-----------------------------|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 1.93 | 0.61 | 6.06 | 0.13 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.86 | 0.55 | 6.26 | 0.16 | No |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 1.90 | 0.57 | 6.28 | 0.15 | No |
| | hyp. B.d: MI vs MI+W+B | 0.43 | 5.18 | 1.50 | 0.74 | No |
| | hyp. C.a: TAU vs MI+W+B | 3.41 | 0.85 | 13.69 | 0.04 | No |
| improved, at 12 | hyp. C.b: MI vs MI+W+B | 4.19 | 0.96 | 18.24 | 0.03 | No |
| months | hyp. C.c: MI+W vs MI+W+B | 0.95 | 0.21 | 4.24 | 0.53 | No |

| Table 5.5: TAU va | 3. MI Days | Gambled, Mon | ey Lost b | y ethnicity |
|-------------------|------------|--------------|-----------|-------------|
| | | | | J · · · J |

| | TEST | 95% Cont Lim | fidence its |
|-----------------------------|---|-----------------|----------------|
| | hyp. A : TAU vs MI, δ =1 European | -0.78 | 1.97 |
| | hyp. A : TAU vs MI, δ=1 Maori | -0.98 | 2.39 |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ=1 Pacific | -3.89 | 2.00 |
| | hyp. A : TAU vs MI, δ =1 Asian & Other | -4.33 | 6.53 |
| | hyp. A : TAU vs MI, δ=20 European | -6.26 | 8.25 |
| | hyp. A : TAU vs MI, δ=20 Maori | -1.53 | 16.09 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ=20 Pacific | -18.35 | 12.82 |
| | hyp. A : TAU vs MI, δ=20 Asian & Other | -20.39 | 37.03 |

| Table 5.6: TAU v | s. MI Gamblin | g-auit or improv | ved by ethnicity |
|------------------|---------------|------------------|------------------|
| | | 0 1 | |

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB |
|-------------------------|----------------------------------|----------------------------|-----------------------|-----------------------|
| | hyp. A : TAU vs MI European | 0.49 | 0.15 | 1.65 |
| Campling_quit or | hyp. A : TAU vs MI Maori | 0.84 | 0.20 | 3.44 |
| improved, time-averaged | hyp. A : TAU vs MI Pacific | 0.36 | 0.02 | 5.72 |
| | hyp. A : TAU vs MI Asian & Other | Number of observationsmall | | ions too |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

| | TEST | Estimated change | Standard error | P-value (one-sided) | Alternative accepted |
|---------------|--|------------------|-------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W European | -0.18 | 0.67 | 0.40 | No |
| | hyp. B.a: TAU vs MI+W Maori | 0.08 | 0.78 | 0.54 | No |
| | hyp. B.a: TAU vs MI+W Pacific | 0.76 | 1.66 | 0.68 | No |
| | hyp. B.a: TAU vs MI+W Asian & Other | 2.38 | 2.57 | 0.82 | No |
| | hyp. B.b: MI vs MI+W European | -0.77 | 0.70 | 0.14 | No |
| | hyp. B.b: MI vs MI+W Maori | -0.62 | 0.86 | 0.23 | No |
| | hyp. B.b: MI vs MI+W Pacific | 1.71 | 1.52 | 0.87 | No |
| Days Cambled | hyp. B.b: MI vs MI+W Asian & Other | 1.28 | 2.57 | 0.69 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B European | -0.38 | 0.69 | 0.29 | No |
| | hyp. B.c: TAU vs MI+W+B Maori | -0.34 | 0.82 | 0.34 | No |
| | hyp. B.c: TAU vs MI+W+B Pacific | 0.57 | 1.63 | 0.64 | No |
| | hyp. B.c: TAU vs MI+W+B Asian & Other | 0.38 | 2.52 | 0.56 | No |
| | hyp. B.d: MI vs MI+W+B European | -0.98 | 0.72 | 0.09 | No |
| | hyp. B.d: MI vs MI+W+B Maori | -1.05 | 0.89 | 0.12 | No |
| | hyp. B.d: MI vs MI+W+B Pacific | 1.52 | 1.50 | 0.84 | No |
| | hyp. B.d: MI vs MI+W+B Asian & Other | -0.72 | 2.52 | 0.39 | No |
| | hyp. B.a: TAU vs MI+W European | -2.23 | 3.53 | 0.26 | No |
| | hyp. B.a: TAU vs MI+W Maori | -1.37 | 4.08 | 0.37 | No |
| | hyp. B.a: TAU vs MI+W Pacific | 3.50 | 8.76 | 0.66 | No |
| | hyp. B.a: TAU vs MI+W Asian & Other | 2.18 | 13.54 | 0.56 | No |
| | hyp. B.b: MI vs MI+W European | -3.23 | 3.70 | 0.19 | No |
| | hyp. B.b: MI vs MI+W Maori | -8.65 | 4.48 | 0.03 | No |
| | hyp. B.b: MI vs MI+W Pacific | 6.26 | 7.98 | 0.78 | No |
| Money Lost, | hyp. B.b: MI vs MI+W Asian & Other | -6.14 | 13.48 | 0.32 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B European | -0.68 | 3.62 | 0.43 | No |
| | hyp. B.c: TAU vs MI+W+B Maori | 0.23 | 4.30 | 0.52 | No |
| | hyp. B.c: TAU vs MI+W+B Pacific | 0.27 | 8.66 | 0.51 | No |
| | hyp. B.c: TAU vs MI+W+B Asian & Other | 3.01 | 13.28 | 0.59 | No |
| | hyp. B.d: MI vs MI+W+B European | -5.35 | 3.97 | 0.09 | No |
| | hyp. B.d: MI vs MI+W+B Maori | -7.05 | 4.68 | 0.07 | No |
| | hyp. B.d: MI vs MI+W+B Pacific | 3.03 | 7.87 | 0.65 | No |
| | hyp. B.d: MI vs MI+W+B Asian & Other | -5.32 | 13.24 | 0.34 | No |

Table 5.7: Hypotheses B and C - Days Gambled, Money Lost, PGSI - by ethnicity

| | TEST | Estimated change | Standard error | P-value (one-sided) | Alternative |
|--------------------------|--|---------------------|-------------------|------------------------|-------------|
| | | go | | (0110 51404) | |
| | hyp. C.a: TAU vs MI+W+B European | -0.55 | 0.79 | 0.24 | No |
| | hyp. C.a: TAU vs MI+W+B Maori | -0.24 | 0.96 | 0.40 | No |
| | hyp. C.a: TAU vs MI+W+B Pacific | 0.71 | 2.08 | 0.63 | No |
| | hyp. C.a: TAU vs MI+W+B Asian & Other | 0.61 | 2.86 | 0.58 | No |
| | hyp. C.b: MI vs MI+W+B European | -0.53 | 0.84 | 0.27 | No |
| Dava Camblad | hyp. C.b: MI vs MI+W+B Maori | -2.08 | 1.06 | 0.02 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B Pacific | 0.05 | 1.84 | 0.51 | No |
| | hyp. C.b: MI vs MI+W+B Asian & Other | -0.51 | 2.86 | 0.43 | No |
| | hyp. C.c: MI+W vs MI+W+B European | 0.21 | 0.81 | 0.60 | No |
| | hyp. C.c: MI+W vs MI+W+B Maori | -0.57 | 0.94 | 0.27 | No |
| | hyp. C.c: MI+W vs MI+W+B Pacific | -2.65 | 2.00 | 0.09 | No |
| | hyp. C.c: MI+W vs MI+W+B Asian & Other | 1.87 | 2.77 | 0.75 | No |
| | hyp. B.a: TAU vs MI+W European | -0.75 | 1.32 | 0.72 | No |
| | hyp. B.a: TAU vs MI+W Maori | 0.10 | 1.58 | 0.48 | No |
| | hyp. B.a: TAU vs MI+W Pacific | 7.61 | 3.68 | 0.02 | No |
| | hyp. B.a: TAU vs MI+W Asian & Other | 0.60 | 5.00 | 0.45 | No |
| | hyp. B.b: MI vs MI+W European | -0.49 | 1.39 | 0.36 | No |
| | hyp. B.b: MI vs MI+W Maori | -0.75 | 1.75 | 0.33 | No |
| | hyp. B.b: MI vs MI+W Pacific | 5.20 | 3.28 | 0.94 | No |
| | hyp. B.b: MI vs MI+W Asian & Other | -8.07 | 5.00 | 0.05 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B European | -1.21 | 1.33 | 0.18 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B Maori | 2.06 | 1.65 | 0.89 | No |
| PGSI-12, at 12 months | hyp. B.c & C.a: TAU vs MI+W+B Pacific | 6.34 | 3.57 | 0.96 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B Asian & Other | 2.87 | 4.67 | 0.73 | No |
| | hyp. B.d & C.b: MI vs MI+W+B European | -0.95 | 1.40 | 0.25 | No |
| | hyp. B.d & C.b: MI vs MI+W+B Maori | 1.22 | 1.82 | 0.75 | No |
| | hyp. B.d & C.b: MI vs MI+W+B Pacific | 3.93 | 3.15 | 0.89 | No |
| | hyp. B.d & C.b: MI vs MI+W+B Asian & Other | -5.79 | 4.67 | 0.11 | No |
| | hyp. C.c: MI+W vs MI+W+B European | -0.46 | 1.35 | 0.37 | No |
| | hyp. C.c: MI+W vs MI+W+B Maori | 1.97 | 1.59 | 0.89 | No |
| | hyp. C.c: MI+W vs MI+W+B Pacific | -1.27 | 3.38 | 0.35 | No |
| | hyp. C.c: MI+W vs MI+W+B Asian & Other | 2.28 | 4.66 | 0.69 | No |

Table 5.7: Hypotheses B and C - Days Gambled, Money Lost, PGSI - by ethnicity - continued
| 51 | | | | , | | | |
|----------------------------|---|---|-----------------------|-----------------------|------------------------|-------------------------|--|
| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted | |
| | hyp. B.a: TAU vs MI+W European | 1.18 | 0.36 | 3.90 | 0.39 | No | |
| | hyp. B.a: TAU vs MI+W Maori | 1.71 | 0.44 | 6.54 | 0.22 | No | |
| | hyp. B.a: TAU vs MI+W Pacific | 0.13 | 0.01 | 2.44 | 0.91 | No | |
| | hyp. B.a: TAU vs MI+W Asian & Other | | Num | ber of observation | ations too small | | |
| | hyp. B.b: MI vs MI+W European | 2.40 | 0.71 | 8.15 | 0.08 | No | |
| | hyp. B.b: MI vs MI+W Maori | 2.03 | 0.48 | 8.61 | 0.17 | No | |
| | hyp. B.b: MI vs MI+W Pacific | | Unreliable | results due to | numerical insta | bility | |
| Gambling-quit or | hyp. B.b: MI vs MI+W Asian & Other | | Num | ber of observation | ations too small | | |
| improved, time-averaged | hyp. B.c: TAU vs MI+W+B European | 1.10 | 0.33 | 3.71 | 0.44 | No | |
| | hyp. B.c: TAU vs MI+W+B Maori | 1.20 | 0.31 | 4.73 | 0.40 | No | |
| | hyp. B.c: TAU vs MI+W+B Pacific | Unreliable results due to numerical instability | | | | | |
| | hyp. B.c: TAU vs MI+W+B Asian & Other | Number of observations too small | | | | | |
| | hyp. B.d: MI vs MI+W+B European | 1.66 | 0.46 | 5.95 | 1.00 | No | |
| | hyp. B.d: MI vs MI+W+B Maori | 2.99 | 0.77 | 11.60 | 1.00 | No | |
| | hyp. B.d: MI vs MI+W+B Pacific | 1.14 | 0.20 | 6.63 | 1.00 | No | |
| | hyp. B.d: MI vs MI+W+B Asian & Other | Number of observations too small | | | | | |
| | hyp. C.a: TAU vs MI+W+B European | 1.72 | 0.45 | 6.66 | 0.22 | No | |
| | hyp. C.a: TAU vs MI+W+B Maori | 0.94 | 0.20 | 4.45 | 0.53 | No | |
| | hyp. C.a: TAU vs MI+W+B Pacific | | Unreliable | results due to | numerical insta | bility | |
| | hyp. C.a: TAU vs MI+W+B Asian & Other | | Num | ber of observ | ations too small | | |
| | hyp. C.b: MI vs MI+W+B European | 2.41 | 0.58 | 10.02 | 0.11 | No | |
| Gambling-quit or | hyp. C.b: MI vs MI+W+B Maori | 3.15 | 0.61 | 16.24 | 0.09 | No | |
| improved, at 12 months | hyp. C.b: MI vs MI+W+B Pacific | | Unreliable | results due to | numerical insta | bility | |
| | hyp. C.b: MI vs MI+W+B Asian & Other | | Num | ber of observa | ations too small | | |
| | hyp. C.c: MI+W vs MI+W+B European | 0.29 | 0.07 | 1.27 | 0.95 | No | |
| | hyp. C.c: MI+W vs MI+W+B Maori | 0.27 | 0.05 | 1.37 | 0.94 | No | |
| | hyp. C.c: MI+W vs MI+W+B Pacific | | Unreliable | results due to | numerical insta | bility | |
| | hyp. C.c: MI+W vs MI+W+B Asian & Other | | Num | ber of observation | ations too small | | |

Table 5.8: Hypotheses B and C - Gambling-quit or improved by ethnicity

| | TEST | 95% Con Lim | fidence its |
|-----------------------------|-------------------------------------|----------------|----------------|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 EGM | -0.57 | 1.55 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ=20 EGM | -2.26 | 8.90 |
| | | | |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ=1 Non-EGM | -1.50 | 4.80 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ=20 Non-EGM | -17.90 | 15.15 |

Table 5.9: TAU vs. MI Days Gambled, Money Lost by gambling mode

Table 5.10: TAU vs. MI Gambling-quit or improved by gambling mode

| | TEST | Odds | Odds | Odds |
|-------------------------|----------------------------|-------|-------|-------|
| | | ratio | Ratio | Ratio |
| | | | CILB | CIUB |
| Gambling-quit or | hyp. A : TAU vs MI EGM | 0.87 | 0.35 | 2.18 |
| improved, time-averaged | | | | |
| Gambling-quit or | hyp. A : TAU vs MI Non-EGM | 0.06 | 0.00 | 1.29 |
| improved, time-averaged | | | | |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

Table 5.11: Hypotheses B and C - Days Gambled, Money Lost, PGSI by gambling mode

| | TEST | Estimated change | Standard error | P-value | Alternative |
|-----------------------------|----------------------------------|---------------------|-------------------|---------|-------------|
| | hyp. B.a: TAU vs MI+W | 0.36 | 0.53 | 0.75 | No |
| Davs Gambled. | hyp. B.b: MI vs MI+W | -0.13 | 0.55 | 0.41 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | -0.03 | 0.54 | 0.48 | No |
| | hyp. B.d: MI vs MI+W+B | -0.52 | 0.56 | 0.18 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | -1.05 | 2.80 | 0.35 | No |
| averaged | hyp. B.b: MI vs MI+W | -4.37 | 2.89 | 0.07 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.27 | 2.86 | 0.46 | No |
| | hyp. B.d: MI vs MI+W+B | -3.59 | 2.95 | 0.11 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.02 | 0.64 | 0.51 | No |
| Days Gambled, at | hyp. C.b: MI vs MI+W+B | -0.38 | 0.67 | 0.28 | No |
| 12 months | hyp. C.c: MI+W vs MI+W+B | -0.12 | 0.65 | 0.43 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.76 | 3.31 | 0.41 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | -3.64 | 3.45 | 0.15 | No |
| montais | hyp. C.c: MI+W vs MI+W+B | 2.39 | 3.36 | 0.76 | No |
| | hyp. B.a: TAU vs MI+W | 0.43 | 1.07 | 0.66 | No |
| PGSI-12, at 12 months | hyp. B.b: MI vs MI+W | 0.04 | 1.11 | 0.49 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 1.14 | 1.09 | 0.15 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 0.75 | 1.13 | 0.25 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.71 | 1.09 | 0.26 | No |

EGM

Effectiveness of problem gambling brief telephone interventions: A randomised controlled trial Provider No: 467589, Contract No: 326673/00 and 326673/01 Gambling and Addictions Research Centre, Auckland University of Technology Final Report, 13 December 2012

Non-EGM

| | TEST | Estimated change | Standard error | P-value (one-sided) | Alternative accepted |
|-------------------------------|----------------------------------|---------------------|-------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 0.36 | 1.38 | 0.60 | No |
| Days Gambled, | hyp. B.b: MI vs MI+W | -1.29 | 1.49 | 0.19 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | 0.34 | 1.43 | 0.59 | No |
| | hyp. B.d: MI vs MI+W+B | -1.31 | 1.53 | 0.20 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | -2.43 | 7.27 | 0.37 | No |
| averageu | hyp. B.b: MI vs MI+W | -1.05 | 7.84 | 0.45 | No |
| | hyp. B.c: TAU vs MI+W+B | 1.66 | 7.49 | 0.59 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.41 | 1.68 | 0.40 | No |
| Days Gambled, at 12 months | hyp. C.b: MI vs MI+W+B | -3.33 | 1.72 | 0.03 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.34 | 1.49 | 0.41 | No |
| | hyp. C.a: TAU vs MI+W+B | -3.17 | 8.64 | 0.36 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | -7.23 | 8.93 | 0.21 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.90 | 7.71 | 0.45 | No |
| | hyp. B.a: TAU vs MI+W | -1.82 | 2.74 | 0.25 | No |
| PGSI-12, at 12 months | hyp. B.b: MI vs MI+W | -2.56 | 2.75 | 0.18 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | -0.60 | 2.79 | 0.41 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | -1.34 | 2.79 | 0.32 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.22 | 2.45 | 0.69 | No |

Table 5.12: Hypotheses B and C - Gambling-quit or improved by gambling mode

EGM

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|----------------------------------|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 1.34 | 0.53 | 3.36 | 0.27 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.53 | 0.59 | 3.94 | 0.19 | No |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 1.28 | 0.50 | 3.24 | 0.30 | No |
| | hyp. B.d: MI vs MI+W+B | 2.95 | 0.46 | 18.97 | 0.13 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.68 | 0.24 | 1.91 | 0.77 | No |
| Gambling-quit or improved, at 12 | hyp. C.b: MI vs MI+W+B | 0.59 | 0.20 | 1.70 | 0.84 | No |
| months | hyp. C.c: MI+W vs MI+W+B | 2.44 | 0.79 | 7.55 | 0.06 | No |

Non-EGM

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted | |
|-----------------------------|-----------------------------|--|-----------------------|-----------------------|------------------------|-------------------------|--|
| | hyp. B.a: TAU vs MI+W | 1.80 | 0.02 | 6.03 | 0.23 | No | |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 4.31 | 0.45 | 74.21 | 0.09 | No | |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 6.98 | 0.50 | 96.88 | 0.07 | No | |
| | hyp. B.d: MI vs MI+W+B | 0.98 | 0.29 | 3.34 | 0.51 | No | |
| | hyp. C.a: TAU vs MI+W+B | | | | | | |
| improved, at 12 | hyp. C.b: MI vs MI+W+B | Number of valid observations too small | | | | | |
| months | hyp. C.c: MI+W vs MI+W+B | | | | | | |

Table 5.13: TAU vs. MI Days Gambled, Money Lost by dichotomised baseline PGSI score

| | TEST | 95% Con | fidence |
|-----------------------------|---|---------|---------|
| | | | lis |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 Baseline ≤ 17.0 | -1.11 | 1.61 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Baseline \leq 17.0 | -4.31 | 10.06 |
| | | | |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 Baseline > 17.0 | -0.60 | 2.39 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Baseline > 17.0 | -5.95 | 9.77 |

Table 5.14: TAU vs. MI Gambling-quit or improved by dichotomised baseline PGSI score

| | TEST | Odds | Odds | Odds |
|-------------------------|---|-------|-------|-------|
| | | ratio | Ratio | Ratio |
| | | | CILB | CIUB |
| Gambling-quit or | hyp. A : TAU vs MI Baseline ≤ 17.0 | 0.43 | 0.13 | 1.44 |
| improved, time-averaged | | | | |
| Gambling-quit or | hyp. A : TAU vs MI Baseline > 17.0 | 1.26 | 0.368 | 4.35 |
| improved, time-averaged | | | | |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

| | TEST | Estimated change | Standard error | P-value (one-sided) | Alternative accepted |
|-----------------------------|----------------------------------|---------------------|-------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 0.83 | 0.66 | 0.90 | No |
| Davs Gambled. | hyp. B.b: MI vs MI+W | 0.58 | 0.71 | 0.79 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | 0.21 | 0.67 | 0.62 | No |
| | hyp. B.d: MI vs MI+W+B | -0.04 | 0.72 | 0.48 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | 1.52 | 3.43 | 0.67 | No |
| averaged | hyp. B.b: MI vs MI+W | -1.35 | 3.72 | 0.36 | No |
| | hyp. B.c: TAU vs MI+W+B | 3.68 | 3.53 | 0.85 | No |
| | hyp. B.d: MI vs MI+W+B | 0.80 | 3.81 | 0.58 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.16 | 0.79 | 0.42 | No |
| Days Gambled, at | hyp. C.b: MI vs MI+W+B | -0.16 | 0.84 | 0.42 | No |
| 12 months | hyp. C.c: MI+W vs MI+W+B | -0.85 | 0.80 | 0.14 | No |
| | hyp. C.a: TAU vs MI+W+B | 3.08 | 4.09 | 0.77 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | 1.48 | 4.36 | 0.63 | No |
| montins | hyp. C.c: MI+W vs MI+W+B | 2.38 | 4.12 | 0.72 | No |
| | hyp. B.a: TAU vs MI+W | 0.79 | 1.31 | 0.73 | No |
| PGSI-12, at 12 months | hyp. B.b: MI vs MI+W | 0.33 | 1.43 | 0.59 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 1.87 | 1.37 | 0.91 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.42 | 1.48 | 0.83 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.08 | 1.37 | 0.79 | No |

Table 5.15: Hypotheses B and C - Days Gambled, Money Lost, PGSI by baseline PGSI ≤ 17

Table 5.16: Hypotheses B and C - Gambling-quit or improved by baseline $PGSI \le 17$

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|---|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 0.68 | 0.21 | 2.23 | 0.74 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.60 | 0.47 | 5.42 | 0.23 | No |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 0.42 | 0.13 | 1.37 | 0.92 | No |
| | hyp. B.d: MI vs MI+W+B | 2.06 | 0.02 | 7.81 | 0.28 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.40 | 0.10 | 1.54 | 0.91 | No |
| Gambling-quit or improved, at 12 months | hyp. C.b: MI vs MI+W+B | 0.84 | 0.21 | 3.38 | 0.60 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.18 | 0.04 | 0.76 | 0.99 | No |

| | TEST | 95% Confidence Limits | | |
|-----------------------------|---|--------------------------|-------|--|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 Baseline \leq 30 | -1.11 | 1.67 | |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Baseline \leq 30 | -6.31 | 8.45 | |
| | | | | |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 Baseline > 30 | -0.48 | 2.43 | |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Baseline > 30 | -2.54 | 12.87 | |

Table 5.17: TAU vs. MI Days Gambled, Money Lost by baseline Kessler-10 score

Table 5.18: TAU vs. MI Gambling-quit or improved by baseline Kessler-10 score

| | TEST | Odds | Odds | Odds |
|-------------------------|---------------------------------------|-------|-------|-------|
| | | ratio | Ratio | Ratio |
| | | | CILB | CIUB |
| Gambling-quit or | hyp. A : TAU vs MI Baseline ≤ 30 | 1.18 | 0.35 | 4.01 |
| improved, time-averaged | | | | |
| Gambling-quit or | hyp. A : TAU vs MI Baseline > 30 | 0.40 | 0.12 | 1.36 |
| improved, time-averaged | | | | |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

| Table 5.19: Hypothe | eses B and C - D | ays Gambled | , Money Los | t, PGSI by | y baseline K | $-10 \le 30$ |
|---------------------|------------------|-------------|-------------|------------|--------------|--------------|
| | | | 1 | | | |

| | TEST | Estimated | Standard | P-value | Alternative |
|-------------------------------|----------------------------------|-----------|----------|-------------|-------------|
| | | change | error | (one-sided) | accepted |
| | hyp. B.a: TAU vs MI+W | 0.99 | 0.71 | 0.92 | No |
| Days Gambled, | hyp. B.b: MI vs MI+W | 0.71 | 0.72 | 0.84 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | -0.01 | 0.71 | 0.50 | No |
| | hyp. B.d: MI vs MI+W+B | -0.29 | 0.72 | 0.35 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | -1.11 | 3.74 | 0.38 | No |
| averaged | hyp. B.b: MI vs MI+W | -2.18 | 3.82 | 0.28 | No |
| | hyp. B.c: TAU vs MI+W+B | 3.07 | 3.75 | 0.79 | No |
| | hyp. B.d: MI vs MI+W+B | 2.00 | 3.79 | 0.70 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.38 | 0.82 | 0.32 | No |
| Days Gambled, at 12 months | hyp. C.b: MI vs MI+W+B | -0.23 | 0.83 | 0.39 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.71 | 0.84 | 0.20 | No |
| | hyp. C.a: TAU vs MI+W+B | 1.10 | 4.28 | 0.60 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | 1.61 | 4.31 | 0.65 | No |
| monuns | hyp. C.c: MI+W vs MI+W+B | 3.57 | 4.35 | 0.79 | No |
| | hyp. B.a: TAU vs MI+W | -0.16 | 1.42 | 0.46 | No |
| | hyp. B.b: MI vs MI+W | 0.47 | 1.44 | 0.63 | No |
| PGSI-12, at 12 months | hyp. B.c & C.a: TAU vs MI+W+B | 1.34 | 1.41 | 0.83 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.96 | 1.43 | 0.92 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.49 | 1.41 | 0.85 | No |

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|-----------------------------|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 1.71 | 0.48 | 6.09 | 0.20 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.45 | 0.41 | 5.21 | 0.28 | No |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 1.09 | 0.32 | 3.69 | 0.44 | No |
| | hyp. B.d: MI vs MI+W+B | 0.93 | 0.27 | 3.16 | 0.55 | No |
| | hyp. C.a: TAU vs MI+W+B | 1.12 | 0.29 | 4.35 | 0.44 | No |
| improved, at 12 | hyp. C.b: MI vs MI+W+B | 0.61 | 0.15 | 2.45 | 0.76 | No |
| months | hyp. C.c: MI+W vs MI+W+B | 0.12 | 0.02 | 0.56 | 1.00 | No |

Table 5.20: Hypotheses B and C - Gambling-quit or improved by baseline K-10 \leq 30

Table 5.21: TAU vs. MI Days Gambled, Money Lost by baseline AUDIT-C score

| | TEST | 95% Con Lim | fidence its |
|-----------------------------|--|----------------|----------------|
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ=1 Low risk | -1.78 | 1.79 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 Low risk | -8.43 | 10.32 |
| | | | |
| Days Gambled, time-averaged | hyp. A : TAU vs MI, δ =1 High risk | -0.34 | 2.11 |
| Money Lost, time-averaged | hyp. A : TAU vs MI, δ =20 High risk | -2.92 | 9.96 |

Table 5.22: TAU vs. MI Gambling-quit or improved by baseline AUDIT-C score

| | TEST | Odds | Odds | Odds |
|-------------------------|------------------------------|-------|-------|-------|
| | | ratio | Ratio | Ratio |
| | | | CILB | CIUB |
| Gambling-quit or | hyp. A : TAU vs MI Low risk | 0.27 | 0.06 | 1.26 |
| improved, time-averaged | | | | |
| Gambling-quit or | hyp. A : TAU vs MI High risk | 1.07 | 0.37 | 3.09 |
| improved, time-averaged | | | | |

Conclude in inequivalence at 5% significance level if CIUB<0.88 or CILB>1.14

| Low risk | 1 | 1 | | | |
|-----------------------------|----------------------------------|-----------|----------|-------------|-------------|
| | TEST | Estimated | Standard | P-value | Alternative |
| | hup D of TALL vo ML W | cnange | error | (one-sided) | |
| | nyp. b.a. TAO vs wn+w | 1.45 | 0.88 | 0.95 | NO |
| Days Gambled, | hyp. B.b: MI vs MI+W | 1.45 | 0.91 | 0.94 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | -0.26 | 0.86 | 0.38 | No |
| | hyp. B.d: MI vs MI+W+B | -0.27 | 0.93 | 0.39 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | 2.74 | 4.40 | 0.73 | No |
| averaged | hyp. B.b: MI vs MI+W | 1.79 | 4.77 | 0.65 | No |
| | hyp. B.c: TAU vs MI+W+B | 1.38 | 4.54 | 0.62 | No |
| | hyp. B.d: MI vs MI+W+B | 0.43 | 4.90 | 0.54 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.06 | 0.99 | 0.47 | No |
| Days Gambled, at | hyp. C.b: MI vs MI+W+B | 0.50 | 1.11 | 0.67 | No |
| 12 months | hyp. C.c: MI+W vs MI+W+B | -1.06 | 1.00 | 0.14 | No |
| | hyp. C.a: TAU vs MI+W+B | 1.40 | 5.15 | 0.61 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | 2.72 | 5.70 | 0.68 | No |
| montuis | hyp. C.c: MI+W vs MI+W+B | -0.67 | 5.13 | 0.45 | No |
| | hyp. B.a: TAU vs MI+W | -0.59 | 1.64 | 0.36 | No |
| | hyp. B.b: MI vs MI+W | 0.11 | 1.86 | 0.52 | No |
| PGSI-12, at 12 months | hyp. B.c & C.a: TAU vs MI+W+B | 1.22 | 1.67 | 0.77 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.91 | 1.90 | 0.84 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.81 | 1.69 | 0.86 | No |

Table 5.23: Hypotheses B and C - Days Gambled, Money Lost, PGSI by baseline AUDIT-C

High risk

| | TEST | Estimated change | Standard error | P-value | Alternative |
|-------------------------------|----------------------------------|---------------------|-------------------|---------|-------------|
| | hyp. B.a: TAU vs MI+W | -0.32 | 0.65 | 0.31 | No |
| Davs Gambled. | hyp. B.b: MI vs MI+W | -1.21 | 0.65 | 0.03 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | 0.11 | 0.62 | 0.57 | No |
| | hyp. B.d: MI vs MI+W+B | -0.77 | 0.64 | 0.11 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | -3.45 | 3.28 | 0.15 | No |
| averaged | hyp. B.b: MI vs MI+W | -6.97 | 3.35 | 0.019 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.81 | 3.29 | 0.40 | No |
| | hyp. B.d: MI vs MI+W+B | -4.33 | 3.36 | 0.10 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.15 | 0.74 | 0.42 | No |
| Days Gambled, at 12 months | hyp. C.b: MI vs MI+W+B | -1.50 | 0.76 | 0.025 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.35 | 0.76 | 0.68 | No |
| | hyp. C.a: TAU vs MI+W+B | -3.02 | 3.85 | 0.22 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | -7.88 | 3.93 | 0.023 | No |
| | hyp. C.c: MI+W vs MI+W+B | 3.18 | 3.90 | 0.79 | No |
| | hyp. B.a: TAU vs MI+W | 0.54 | 1.31 | 0.66 | No |
| | hyp. B.b: MI vs MI+W | -0.43 | 1.33 | 0.37 | No |
| PGSI-12, at 12 months | hyp. B.c & C.a: TAU vs MI+W+B | 0.55 | 1.28 | 0.67 | No |
| monthly | hyp. B.d & C.b: MI vs MI+W+B | -0.42 | 1.32 | 0.38 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.01 | 1.29 | 0.50 | No |

| Table 5.24: Hypoth | neses B and C | - Gambling- | quit or i | improved | d by high | n risk AUDI | Γ-C score |
|--------------------|---------------|-------------|-----------|----------|-----------|-------------|-----------|
| | | | | | | | |

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|-------------------------------------|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 1.24 | 0.43 | 3.63 | 0.35 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.16 | 0.39 | 3.45 | 0.39 | No |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 1.38 | 0.47 | 4.04 | 0.28 | No |
| | hyp. B.d: MI vs MI+W+B | 1.38 | 0.36 | 5.34 | 0.32 | No |
| | hyp. C.a: TAU vs MI+W+B | 1.09 | 0.32 | 3.74 | 0.45 | No |
| Gambling-quit or improved, at 12 | hyp. C.b: MI vs MI+W+B | 1.68 | 0.49 | 5.71 | 0.20 | No |
| months | hyp. C.c: MI+W vs MI+W+B | 0.22 | 0.06 | 0.87 | 0.98 | No |

| | TEST | Estimated | Standard | P-value | Alternative |
|-----------------------------|----------------------------------|-----------|----------|-------------|-------------|
| | | change | error | (one-sided) | accepted |
| | hyp. B.a: TAU vs MI+W | -0.16 | 0.56 | 0.38 | No |
| Days Gambled, | hyp. B.b: MI vs MI+W | -0.50 | 0.58 | 0.19 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | 0.12 | 0.55 | 0.59 | No |
| | hyp. B.d: MI vs MI+W+B | -0.22 | 0.57 | 0.35 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | -3.09 | 2.96 | 0.15 | No |
| averaged | hyp. B.b: MI vs MI+W | -4.04 | 3.06 | 0.09 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.09 | 2.92 | 0.49 | No |
| | hyp. B.d: MI vs MI+W+B | -1.04 | 3.03 | 0.37 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.19 | 0.65 | 0.62 | No |
| Days Gambled, at | hyp. C.b: MI vs MI+W+B | -0.20 | 0.67 | 0.39 | No |
| 12 months | hyp. C.c: MI+W vs MI+W+B | 0.91 | 0.67 | 0.91 | No |
| | hyp. C.a: TAU vs MI+W+B | -1.76 | 3.40 | 0.30 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | -1.65 | 3.52 | 0.32 | No |
| | hyp. C.c: MI+W vs MI+W+B | 4.33 | 3.49 | 0.89 | No |
| | hyp. B.a: TAU vs MI+W | -0.93 | 1.12 | 0.20 | No |
| | hyp. B.b: MI vs MI+W | -0.69 | 1.15 | 0.27 | No |
| PGSI-12, at 12 months | hyp. B.c & C.a: TAU vs MI+W+B | 1.09 | 1.11 | 0.84 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.33 | 1.13 | 0.88 | No |
| | hyp. C.c: MI+W vs MI+W+B | 2.02 | 1.13 | 0.96 | No |

Table 5.25: Hypotheses B and C - Days Gambled, Money Lost, PGSI by baseline quit gambling goal

Table 5.26: Hypotheses B and C - Gambling-quit or improved by quit gambling goal

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|-------------------------------------|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 1.73 | 0.65 | 4.64 | 0.14 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.25 | 0.45 | 3.51 | 0.34 | No |
| averaged | hyp. B.c: TAU vs MI+W+B | 1.18 | 0.46 | 3.04 | 0.36 | No |
| _ | hyp. B.d: MI vs MI+W+B | 0.85 | 0.32 | 2.31 | 0.62 | No |
| | hyp. C.a: TAU vs MI+W+B | 1.37 | 0.47 | 3.95 | 0.28 | No |
| Gambling-quit or improved, at 12 | hyp. C.b: MI vs MI+W+B | 0.80 | 0.26 | 2.45 | 0.65 | No |
| months | hyp. C.c: MI+W vs MI+W+B | 0.21 | 0.06 | 0.70 | 0.99 | No |

Table 5.27: Hypotheses B and C - Days Gambled, Money Lost, PGSI by belief in treatment success

| Low | belief |
|-----|--------|
| | |

| | TEST | Estimated change | Standard error | P-value | Alternative |
|-------------------------------|----------------------------------|---------------------|-------------------|---------|-------------|
| | hyp. B.a: TAU vs MI+W | 0.86 | 0.74 | 0.88 | No |
| Davs Gambled. | hyp. B.b: MI vs MI+W | 0.18 | 0.71 | 0.60 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | -0.33 | 0.79 | 0.34 | No |
| | hyp. B.d: MI vs MI+W+B | -1.01 | 0.77 | 0.09 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | 0.42 | 3.99 | 0.54 | No |
| averaged | hyp. B.b: MI vs MI+W | -3.10 | 3.84 | 0.21 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.25 | 4.28 | 0.48 | No |
| | hyp. B.d: MI vs MI+W+B | -3.77 | 4.14 | 0.18 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.96 | 0.93 | 0.15 | No |
| Days Gambled, at 12 months | hyp. C.b: MI vs MI+W+B | -1.88 | 0.91 | 0.019 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.77 | 0.88 | 0.19 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.09 | 3.98 | 0.49 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | -7.40 | 4.79 | 0.06 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.30 | 4.64 | 0.53 | No |
| | hyp. B.a: TAU vs MI+W | -0.17 | 1.56 | 0.46 | No |
| | hyp. B.b: MI vs MI+W | -1.03 | 1.52 | 0.25 | No |
| PGSI-12, at 12 months | hyp. B.c & C.a: TAU vs MI+W+B | 0.68 | 1.60 | 0.66 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | -0.18 | 1.56 | 0.45 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.85 | 1.52 | 0.71 | No |

High belief

| | TEST | Estimated change | Standard error | P-value (one-sided) | Alternative accepted |
|-------------------------------|----------------------------------|---------------------|-------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | -0.48 | 0.64 | 0.23 | No |
| Davs Gambled. | hyp. B.b: MI vs MI+W | -0.74 | 0.70 | 0.15 | No |
| time-averaged | hyp. B.c: TAU vs MI+W+B | 0.12 | 0.63 | 0.58 | No |
| | hyp. B.d: MI vs MI+W+B | -0.14 | 0.69 | 0.42 | No |
| Money Lost, time- | hyp. B.a: TAU vs MI+W | -3.47 | 3.47 | 0.16 | No |
| averaged | hyp. B.b: MI vs MI+W | -5.37 | 3.77 | 0.08 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.01 | 3.41 | 0.50 | No |
| | hyp. B.d: MI vs MI+W+B | -1.91 | 3.72 | 0.30 | No |
| | hyp. C.a: TAU vs MI+W+B | 0.39 | 0.75 | 0.70 | No |
| Days Gambled, at 12 months | hyp. C.b: MI vs MI+W+B | 0.24 | 0.83 | 0.61 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.49 | 0.78 | 0.73 | No |
| | hyp. C.a: TAU vs MI+W+B | -0.09 | 3.98 | 0.49 | No |
| Money Lost, at 12 months | hyp. C.b: MI vs MI+W+B | -1.89 | 4.35 | 0.33 | No |
| | hyp. C.c: MI+W vs MI+W+B | 3.41 | 4.14 | 0.79 | No |
| | hyp. B.a: TAU vs MI+W | 0.05 | 1.31 | 0.52 | No |
| | hyp. B.b: MI vs MI+W | 0.10 | 1.42 | 0.53 | No |
| PGSI-12, at 12 months | hyp. B.c & C.a: TAU vs MI+W+B | 0.83 | 1.32 | 0.74 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 0.88 | 1.43 | 0.73 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.78 | 1.35 | 0.72 | No |

Table 5.28: Hypotheses B and C - Gambling-quit or improved by high belief treatment success

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|----------------------------------|-----------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 3.22 | 0.98 | 10.60 | 0.027 | No |
| Gambling-quit or | hyp. B.b: MI vs MI+W | 1.22 | 0.32 | 4.70 | 0.39 | No |
| improved, time- averaged | hyp. B.c: TAU vs MI+W+B | 1.88 | 0.61 | 5.77 | 0.13 | No |
| | hyp. B.d: MI vs MI+W+B | 0.38 | 0.10 | 1.48 | 0.92 | No |
| | hyp. C.a: TAU vs MI+W+B | 1.89 | 0.52 | 6.88 | 0.17 | No |
| Gambling-quit or improved, at 12 | hyp. C.b: MI vs MI+W+B | 0.36 | 0.08 | 1.63 | 0.91 | No |
| months | hyp. C.c: MI+W vs MI+W+B | 0.25 | 0.06 | 1.16 | 0.96 | No |

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|---------------------------------|-------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| | hyp. B.a: TAU vs MI+W | 1.18 | 0.68 | 2.02 | 0.28 | No |
| Goal met in the | hyp. B.b: MI vs MI+W | 1.54 | 0.87 | 2.75 | 0.07 | No |
| past 3-months, time-averaged | hyp. B.c: TAU vs MI+W+B | 1.09 | 0.63 | 1.89 | 0.38 | No |
| | hyp. B.d: MI vs MI+W+B | 1.43 | 0.80 | 2.57 | 0.11 | No |

Table 5.29: Hypotheses B and C - Goal met in past 3-months

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (two- sided) | Alternative accepted |
|-----------------|-----------------------------|---------------|-----------------------|-----------------------|----------------------------|-------------------------|
| Goal met in the | hyp. C.a: TAU vs MI+W+B | 0.89 | 0.33 | 2.42 | 0.83 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | 0.89 | 0.31 | 2.61 | 0.84 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.57 | 0.21 | 1.52 | 0.26 | No |

APPENDIX 6 Tables - Secondary analyses

| | TEST | Estimated change | Standard error | P-value (one-sided) | Alternative accepted |
|-------------------|--------------------------|---------------------|-------------------|------------------------|-------------------------|
| Motivation, time- | hyp. B.a: TAU vs MI+W | 0.06 | 0.20 | 0.39 | No |
| averageu | hyp. B.b: MI vs MI+W | 0.47 | 0.21 | 0.014 | No* |
| | hyp. B.c: TAU vs MI+W+B | 0.05 | 0.21 | 0.40 | No |
| | hyp. B.d: MI vs MI+W+B | 0.47 | 0.22 | 0.017 | No |
| Motivation, at 12 | hyp. C.a: TAU vs MI+W+B | -0.09 | 0.30 | 0.61 | No |
| months | hyp. C.b: MI vs MI+W+B | 0.25 | 0.31 | 0.21 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.09 | 0.30 | 0.62 | No |

Table 6.1: Hypotheses B and C - Motivation to overcome gambling

* FDR Threshold is 0.0125

| | TEST | Estimated | Standard | P-value | Alternative |
|-------------------------------|----------------------------------|-----------|----------|-------------|-------------|
| | | change | error | (one-sided) | accepted |
| Kessler-10, time- averaged | hyp. B.a: TAU vs MI+W | 0.13 | 0.93 | 0.56 | No |
| uverugeu | hyp. B.b: MI vs MI+W | -0.48 | 0.97 | 0.31 | No |
| | hyp. B.c: TAU vs MI+W+B | -1.17 | 0.96 | 0.11 | No |
| | hyp. B.d: MI vs MI+W+B | -1.79 | 0.99 | 0.04 | No |
| Kessler-10, at 12 | hyp. C.a: TAU vs MI+W+B | -0.63 | 1.22 | 0.26 | No |
| montus | hyp. C.b: MI vs MI+W+B | -1.90 | 1.27 | 0.07 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.42 | 1.22 | 0.37 | No |
| AUDIT-C, time- | hyp. B.a: TAU vs MI+W | -0.16 | 0.32 | 0.31 | No |
| averageu | hyp. B.b: MI vs MI+W | 0.19 | 0.34 | 0.71 | No |
| | hyp. B.c: TAU vs MI+W+B | 0.40 | 0.33 | 0.89 | No |
| | hyp. B.d: MI vs MI+W+B | 0.76 | 0.34 | 0.99 | No |
| AUDIT-C, at 12 | hyp. C.a: TAU vs MI+W+B | 0.32 | 0.38 | 0.80 | No |
| months | hyp. C.b: MI vs MI+W+B | 0.94 | 0.40 | 0.99 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.85 | 0.38 | 0.99 | No |
| DAST, at 12 | hyp. B.a: TAU vs MI+W | -0.11 | 0.18 | 0.26 | No |
| months | hyp. B.b: MI vs MI+W | -0.05 | 0.18 | 0.40 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | -0.21 | 0.18 | 0.13 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | -0.14 | 0.19 | 0.23 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.09 | 0.18 | 0.31 | No |
| WHO-QOL-8, | hyp. B.a: TAU vs MI+W | 0.21 | 0.65 | 0.37 | No |
| ume-averaged | hyp. B.b: MI vs MI+W | 0.50 | 0.67 | 0.23 | No |
| | hyp. B.c: TAU vs MI+W+B | 0.84 | 0.66 | 0.10 | No |
| | hyp. B.d: MI vs MI+W+B | 1.14 | 0.69 | 0.05 | No |
| WHOQoL-8, at | hyp. C.a: TAU vs MI+W+B | 0.74 | 0.82 | 0.18 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | 1.44 | 0.86 | 0.05 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.10 | 0.83 | 0.55 | No |
| NZDI, at 12 | hyp. B.a: TAU vs MI+W | 0.08 | 0.16 | 0.70 | No |
| montuis | hyp. B.b: MI vs MI+W | 0.11 | 0.16 | 0.74 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 0.02 | 0.16 | 0.56 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 0.05 | 0.17 | 0.62 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.06 | 0.16 | 0.36 | No |

Table 6.2: Hypotheses B and C - Kessler-10, AUDIT-C, DAST, WHOQoL and NZDI

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (one-sided) | Alternative accepted |
|-------------------------------|----------------------------------|---------------|-----------------------|-----------------------|------------------------|-------------------------|
| PRIME-MD major | hyp. B.a: TAU vs MI+W | 1.09 | 0.48 | 2.52 | 0.58 | No |
| depressive disorder, at 12 | hyp. B.b: MI vs MI+W | 1.47 | 0.64 | 3.38 | 0.82 | No |
| months | hyp. B.c & C.a: TAU vs MI+W+B | 0.85 | 0.37 | 1.91 | 0.34 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.14 | 0.50 | 2.56 | 0.62 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.77 | 0.34 | 1.77 | 0.27 | No |
| PRIME-MD | hyp. B.a: TAU vs MI+W | 0.72 | 0.37 | 1.38 | 0.16 | No |
| months | hyp. B.b: MI vs MI+W | 0.66 | 0.33 | 1.32 | 0.12 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 1.15 | 0.57 | 2.30 | 0.65 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.06 | 0.51 | 2.20 | 0.56 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.60 | 0.81 | 3.17 | 0.91 | No |
| PRIME-MD minor | hyp. B.a: TAU vs MI+W | 1.52 | 0.25 | 9.43 | 0.67 | No |
| disorder, at 12 | hyp. B.b: MI vs MI+W | 1.81 | 0.29 | 11.25 | 0.74 | No |
| months | hyp. B.c & C.a: TAU vs MI+W+B | 2.84 | 0.29 | 28.21 | 0.81 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 3.38 | 0.34 | 33.66 | 0.85 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.87 | 0.16 | 21.27 | 0.69 | No |
| PRIME-MD | hyp. B.a: TAU vs MI+W | 0.57 | 0.13 | 2.51 | 0.23 | No |
| at 12 months | hyp. B.b: MI vs MI+W | 0.43 | 0.08 | 2.32 | 0.16 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 0.54 | 0.12 | 2.37 | 0.21 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 0.41 | 0.08 | 2.19 | 0.15 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.94 | 0.26 | 3.42 | 0.46 | No |

Table 6.3: Hypotheses B and C - PRIME-MD

Table 6.4: Hypotheses B and C - Tobacco use

| | TEST | Odds rotio | Odds Potio | Odds Batia | P-value | Alternative |
|------------------|-----------------------------|---------------|---------------|---------------|-------------|-------------|
| | | Tatio | CILB | CIUB | (one-sided) | accepteu |
| Tobacco current, | hyp. B.a: TAU vs MI+W | 1.18 | 0.64 | 2.16 | 0.30 | No |
| time-aver ageu | hyp. B.b: MI vs MI+W | 0.79 | 0.42 | 1.49 | 0.76 | No |
| | hyp. B.c: TAU vs MI+W+B | 0.89 | 0.48 | 1.67 | 0.64 | No |
| | hyp. B.d: MI vs MI+W+B | 0.60 | 0.31 | 1.15 | 0.94 | No |
| Tobacco current, | hyp. C.a: TAU vs MI+W+B | 0.89 | 0.29 | 2.71 | 0.58 | No |
| at 12 months | hyp. C.b: MI vs MI+W+B | 0.55 | 0.17 | 1.79 | 0.84 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.84 | 0.28 | 2.57 | 0.62 | No |

Odds ratios of currently not smoking

Odds ratios of decreasing smoking frequency

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (two- sided) | Alternative accepted |
|----------|-----------------------------|---------------|-----------------------|-----------------------|----------------------------|-------------------------|
| Tobacco | hyp. B.a: TAU vs MI+W | 1.54 | 0.25 | 9.38 | 0.64 | No |
| averaged | hyp. B.b: MI vs MI+W | 0.62 | 0.12 | 3.14 | 0.56 | No |
| | hyp. B.c: TAU vs MI+W+B | 1.69 | 0.29 | 9.93 | 0.56 | No |
| | hyp. B.d: MI vs MI+W+B | 0.68 | 0.14 | 3.31 | 0.63 | No |
| Tobacco | hyp. C.a: TAU vs MI+W+B | 1.50 | 0.23 | 9.63 | 0.67 | No |
| months | hyp. C.b: MI vs MI+W+B | 0.74 | 0.06 | 8.80 | 0.81 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.49 | 0.23 | 9.58 | 0.67 | No |

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (two- sided) | Alternative accepted |
|-----------------|----------------------------------|---------------|-----------------------|-----------------------|----------------------------|-------------------------|
| Mental health | hyp. B.a: TAU vs MI+W | 0.92 | 0.41 | 2.07 | 0.42 | No |
| months | hyp. B.b: MI vs MI+W | 1.03 | 0.45 | 2.37 | 0.53 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 1.11 | 0.48 | 2.60 | 0.60 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.25 | 0.52 | 2.98 | 0.69 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.21 | 0.52 | 2.80 | 0.67 | No |
| Prescribed | hyp. B.a: TAU vs MI+W | 0.60 | 0.28 | 1.30 | 0.10 | No |
| months | hyp. B.b: MI vs MI+W | 1.10 | 0.53 | 2.29 | 0.60 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 0.92 | 0.40 | 2.10 | 0.42 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.67 | 0.76 | 3.70 | 0.90 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.53 | 0.71 | 3.30 | 0.86 | No |
| Alcohol or drug | hyp. B.a: TAU vs MI+W | 0.58 | 0.13 | 2.55 | 0.24 | No |
| months | hyp. B.b: MI vs MI+W | 1.46 | 0.42 | 5.05 | 0.73 | No |
| | hyp. B.c & C.a: TAU vs MI+W+B | 0.53 | 0.12 | 2.31 | 0.20 | No |
| | hyp. B.d & C.b: MI vs MI+W+B | 1.32 | 0.38 | 4.57 | 0.67 | No |
| | hyp. C.c: MI+W vs MI+W+B | 0.90 | 0.25 | 3.28 | 0.44 | No |

Table 6.5: Hypotheses B and C - Treatment for co-existing issues

| | TEST | Estimated change | Standard | P-value | Alternative |
|---------------------------|--------------------------|------------------|----------|---------|-------------|
| Work impact, | hyp. B.a: TAU vs MI+W | 0.08 | 0.29 | 0.61 | No |
| time-averaged | hyp. B.b: MI vs MI+W | -0.10 | 0.30 | 0.37 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.36 | 0.29 | 0.11 | No |
| | hyp. B.d: MI vs MI+W+B | -0.54 | 0.30 | 0.04 | No |
| Work impact, at | hyp. C.a: TAU vs MI+W+B | -0.31 | 0.40 | 0.22 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -0.62 | 0.41 | 0.07 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.56 | 0.40 | 0.08 | No |
| Social impact, | hyp. B.a: TAU vs MI+W | 0.33 | 0.32 | 0.85 | No |
| ume-averageu | hyp. B.b: MI vs MI+W | -0.40 | 0.33 | 0.12 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.01 | 0.33 | 0.49 | No |
| | hyp. B.d: MI vs MI+W+B | -0.73 | 0.34 | 0.016 | No |
| Social impact, at | hyp. C.a: TAU vs MI+W+B | 0.50 | 0.46 | 0.86 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -0.29 | 0.49 | 0.28 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.04 | 0.46 | 0.46 | No |
| Family/home | hyp. B.a: TAU vs MI+W | 0.04 | 0.36 | 0.54 | No |
| impact, time- averaged | hyp. B.b: MI vs MI+W | -0.24 | 0.38 | 0.27 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.06 | 0.37 | 0.43 | No |
| | hyp. B.d: MI vs MI+W+B | -0.33 | 0.38 | 0.19 | No |
| Family/home | hyp. C.a: TAU vs MI+W+B | 0.47 | 0.50 | 0.83 | No |
| impact, at 12 months | hyp. C.b: MI vs MI+W+B | -0.56 | 0.52 | 0.14 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.27 | 0.50 | 0.30 | No |
| Health impact, | hyp. B.a: TAU vs MI+W | -0.12 | 0.31 | 0.35 | No |
| ume-averaged | hyp. B.b: MI vs MI+W | -0.26 | 0.32 | 0.21 | No |
| | hyp. B.c: TAU vs MI+W+B | -0.31 | 0.32 | 0.16 | No |
| | hyp. B.d: MI vs MI+W+B | -0.46 | 0.33 | 0.08 | No |
| Health impact, at | hyp. C.a: TAU vs MI+W+B | 0.04 | 0.42 | 0.54 | No |
| 12 months | hyp. C.b: MI vs MI+W+B | -0.50 | 0.44 | 0.13 | No |
| | hyp. C.c: MI+W vs MI+W+B | -0.17 | 0.42 | 0.34 | No |

Table 6.6: Hypotheses B and C - Gambling impacts

| | TEST | Odds ratio | Odds Ratio CILB | Odds Ratio CIUB | P-value (two- sided) | Alternative accepted |
|---------------------------------|-----------------------------|---------------|-----------------------|-----------------------|----------------------------|-------------------------|
| Legal problems, | hyp. B.a: TAU vs MI+W | 1.09 | 0.32 | 3.70 | 0.55 | No |
| ume-averaged | hyp. B.b: MI vs MI+W | 1.26 | 0.34 | 4.74 | 0.63 | No |
| | hyp. B.c: TAU vs MI+W+B | 1.07 | 0.30 | 3.76 | 0.54 | No |
| | hyp. B.d: MI vs MI+W+B | 1.24 | 0.32 | 4.80 | 0.62 | No |
| Legal problems, at 12 months | hyp. C.a: TAU vs MI+W+B | 1.08 | 0.16 | 7.26 | 0.53 | No |
| | hyp. C.b: MI vs MI+W+B | 1.06 | 0.15 | 7.74 | 0.52 | No |
| | hyp. C.c: MI+W vs MI+W+B | 1.06 | 0.16 | 7.16 | 0.52 | No |

Table 6.7: Hypotheses B and C - Legal problems

Table 6.8: Hypotheses B and C - Other formal service engagement

| | TEST | Odds ratio | 95% CI Lower | 95% CI Upper | P-value (two- sided) | Alternative accepted |
|----------------------------|------------------------------------|---------------|-----------------|-----------------|----------------------------|-------------------------|
| Other service | hyp. F.a: MI+W vs | 0.80 | 0.33 | 1.94 | 0.62 | No |
| engagement, | MI+W+B | | | | | |
| time-averaged | hyp. F.b: TAU vs MI+W | 1.24 | 0.52 | 2.95 | 0.62 | No |
| | hyp. G.a: TAU/MI vs MI+W/MI+W+B | 1.79 | 0.52 | 6.19 | 0.36 | No |
| Other service | hyp. G.b: TAU/MI vs | 1.98 | 0.40 | 9.76 | 0.40 | No |
| engagement, at 3 months | MI+W/MI+W+B | | | | | |

APPENDIX 7 Tables - Call timings

| | | | . , | | | | | | |
|-----------|--------------------|------|------|--------|--|--|--|--|--|
| | Intervention group | | | | | | | | |
| | TAU | MI | MI+W | MI+W+B | | | | | |
| MEAN | 33.5 | 34.6 | 37.7 | 32.5 | | | | | |
| STD | 16.1 | 17.3 | 19.4 | 14.8 | | | | | |
| MIN | 10 | 5 | 10 | 6 | | | | | |
| Q1 | 20 | 21 | 20 | 20 | | | | | |
| MEDIAN | 30 | 34 | 32.5 | 30 | | | | | |
| Q3 | 45 | 45 | 50 | 45 | | | | | |
| MAX | 80 | 80 | 105 | 80 | | | | | |
| N | 102 | 104 | 110 | 108 | | | | | |
| N MISSING | 14 | 8 | 8 | 8 | | | | | |

Table 7.1: Intervention delivery timing (minutes)

| | | | TAU | | | MI | | | MI+W | | | MI+W+B | |
|------------|-----------|-------------|-------------|--------------|-------------|-------------|--------------|-------------|-------------|--------------|-------------|-------------|--------------|
| | | 3 months | 6 months | 12 months |
| Follow-up | MEAN | 96.3 | 185.7 | 369.2 | 94.8 | 183.2 | 367.8 | 94.4 | 183.7 | 369.0 | 97.1 | 185.6 | 368.7 |
| assessment | STD | 10.9 | 9.9 | 15.8 | 6.5 | 7.3 | 16.3 | 7.9 | 8.7 | 16.9 | 13.2 | 10.3 | 17.1 |
| | MIN | 60 | 170 | 339 | 87 | 170 | 350 | 77 | 168 | 351 | 59 | 171 | 351 |
| | Q1 | 91 | 180 | 361 | 90 | 180 | 361 | 90 | 180 | 361 | 90.5 | 180 | 360 |
| | MEDIAN | 93 | 183 | 364 | 92 | 181 | 362 | 92 | 181 | 364 | 92 | 182 | 363 |
| | Q3 | 99 | 186 | 369 | 98 | 186 | 368 | 96 | 185 | 370 | 101 | 187 | 370 |
| | MAX | 137 | 223 | 431 | 118 | 217 | 456 | 123 | 224 | 466 | 157 | 237 | 476 |
| | Ν | 93 | 87 | 78 | 84 | 74 | 66 | 94 | 84 | 78 | 84 | 77 | 73 |
| | N MISSING | 7 | 5 | 0 | 4 | 4 | 0 | 4 | 4 | 0 | 3 | 5 | 0 |

Table 7.2: Follow-up assessment timing (days)

Effectiveness of problem gambling brief telephone interventions: A randomised controlled trial Provider No: 467589, Contract No: 326673/00 and 326673/01 Gambling and Addictions Research Centre, Auckland University of Technology Final Report, 13 December 2012

| | Booster calls | | | | | | | |
|----------------------|---------------|---------|----------|----------|--|--|--|--|
| | 1 week | 1 month | 3 months | 6 months | | | | |
| MEAN | 8.9 | 34.0 | 96.0 | 186.1 | | | | |
| STD | 4.7 | 7.7 | 10.2 | 8.2 | | | | |
| MIN | 6 | 21 | 84 | 168 | | | | |
| Q1 | 7 | 28 | 91 | 182 | | | | |
| MEDIAN | 7 | 31.5 | 93 | 183 | | | | |
| Q3 | 8 | 40 | 98 | 187 | | | | |
| MAX | 36 | 64 | 139 | 223 | | | | |
| N | 69 | 70 | 66 | 58 | | | | |
| N date not recorded | 10 | 8 | 7 | 4 | | | | |
| N successful calls | 79 | 78 | 73 | 62 | | | | |
| N unsuccessful calls | 15 | 20 | 29 | 34 | | | | |
| N not contacted | 22 | 18 | 14 | 20 | | | | |

 Table 7.3: Booster call timing (days)