

Psychological treatments for problem gambling (PROGRESS) study: a pragmatic randomised controlled trial and qualitative study – 12 month outcomes and final report

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Psychological treatments for problem gambling (PROGRESS) study: a pragmatic randomised controlled trial and qualitative study – 12 month outcomes and final report

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The trial is registered with Current Controlled Trials and has an assigned International Standard Randomised Controlled Trial Number of ISRCTN01629698 (see <http://www.controlled-trials.com/ISRCTN01629698>). The acronym used to describe this trial is the PROGRESS trial (Psychological treatments for PROblem Gambling REsearch Study or PROGRESS)

Ethics approvals to conduct the study were obtained as follows:

- Department of Justice Human Research Ethics Committee (approval CF/11/22867),
- Monash University Human Research Ethics Committee (approval A1/2012) and the
- University of Melbourne Human Research Ethics Committee (CD/12/536402).

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Main report

Executive summary

This report describes the outcomes for the Psychological Treatments for Problem Gambling (PROGRESS) Study: A Pragmatic Randomised Controlled Trial and Qualitative Study. This is a longitudinal study of treatment outcomes for a sample of 297 Victorians who enrolled in a research study involving four different types of psychological treatment for problem gambling.

Study importance and background:

Problem gambling is a high impact disorder that affects many people in Australia and globally. Psychological treatments are commonly used to treat problem gambling but there were knowledge gaps concerning the relative effectiveness of the different types of treatment, the durability of the treatment effects and the experiences of people undergoing and following their treatment. A parallel four group, pragmatic randomised controlled trial was conducted with an associated qualitative study to in part address these gaps.

Study objectives:

The objectives of this study were:

1. To study the relative effectiveness of four manualised psychological interventions; Cognitive-Behaviour Therapy (CBT), Behaviour Therapy (BT), Motivational Interviewing (MI) and Client-Centred Therapy (CCT) in the treatment of problem gambling.
2. To determine the durability of any therapeutic gains obtained by the four psychological interventions as measured by the four key outcome variables
 - (a) Instances of gambling in the past four weeks,
 - (b) Hours spent gambling in the past four weeks,
 - (c) Dollars spent gambling in the past four weeks and
 - (d) Gambling symptom severity as measured by G-SAS.
3. To study the experiences of problem gamblers seeking treatment throughout the course of the treatment and following its cessation.

Trial design¹:

A parallel independent four group, pragmatic randomised controlled trial was conducted with an associated qualitative study. The design for this study included features that were intended to address potential design problems that could bias the outcomes identified in a Cochrane review of previous studies of the effectiveness of psychological treatments. These features included:

1. Use of a group allocation sequence generated independently and provided by the NHMRC Clinical Trials Centre. A list of randomly ordered intervention groups was used to assign sequentially enrolled participants to their intervention groups.
2. Use of full allocation concealment in the study. The allocation sequence of participants was hidden from those assigning participants to intervention groups until the moment of assignment.
3. The outcome assessors were blind to the intervention group of the person they interviewed and standardised tools and protocols were used to assess participant treatment outcomes.
4. The key outcome measures were announced at the commencement of the study and utilized in the study as announced.
5. Procedures were also implemented to assess and maintain high treatment fidelity and integrity. Samples of the intervention sessions were independently assessed to determine adherence to the treatment protocols as specified in the treatment manuals.

Recruitment into the study:

The participants were recruited using a variety of different recruitment channels. 442 participant enquiries were received by the recruitment staff between April 15th, 2012 and February 11th, 2014. Most enquiries were by telephone (n=304, 72%); the remainder were by email. Advertisements calling for participation were run in major Victorian newspapers including The Herald Sun and The Age, on the study website (which included contact details), in Google Ads provided by a service provider and referrals from family members and friends.

Prospective participants interested in participating in the study contacted the research team, and were then assessed for eligibility for study entry. Eligible participants were sent an explanatory statement and informed consent form, to be returned to the research team. Once informed consent was obtained, trained research assistants conducted the baseline assessment (t=0) and participants were subsequently randomly allocated to one of the four interventions using an independently randomly generated and concealed allocation sequence. The study interventions included: Cognitive-Behaviour Therapy (CBT), Behaviour Therapy (BT), Motivational Interviewing (MI) and Client-Centred Therapy (CCT). Participants in each intervention received up to six individual face-to-face sessions of their allocated treatment, with a registered psychologist. Follow up assessments were conducted at the end of their treatment (t=1) and also at 6 months post-treatment (t=2) and 12 months (t=3) post-

¹ The protocol for this study is published at Thomas, S.A., Merkouris, S., Browning, C.J., Radermacher, H., Feldman, S., Enticott, J. & Jackson, A.C. (2015). The PROblem Gambling REsearch Study (PROGRESS) research protocol: A pragmatic randomised controlled trial of psychological interventions for problem gambling. *BMJ Open*, 2015 Nov 24;5(11):e009385. doi: 10.1136/bmjopen-2015-009385.

treatment for all participants. All assessments were conducted by interviewers were blinded to the patient's intervention group. The following schematic shows the flow of participants in the study:

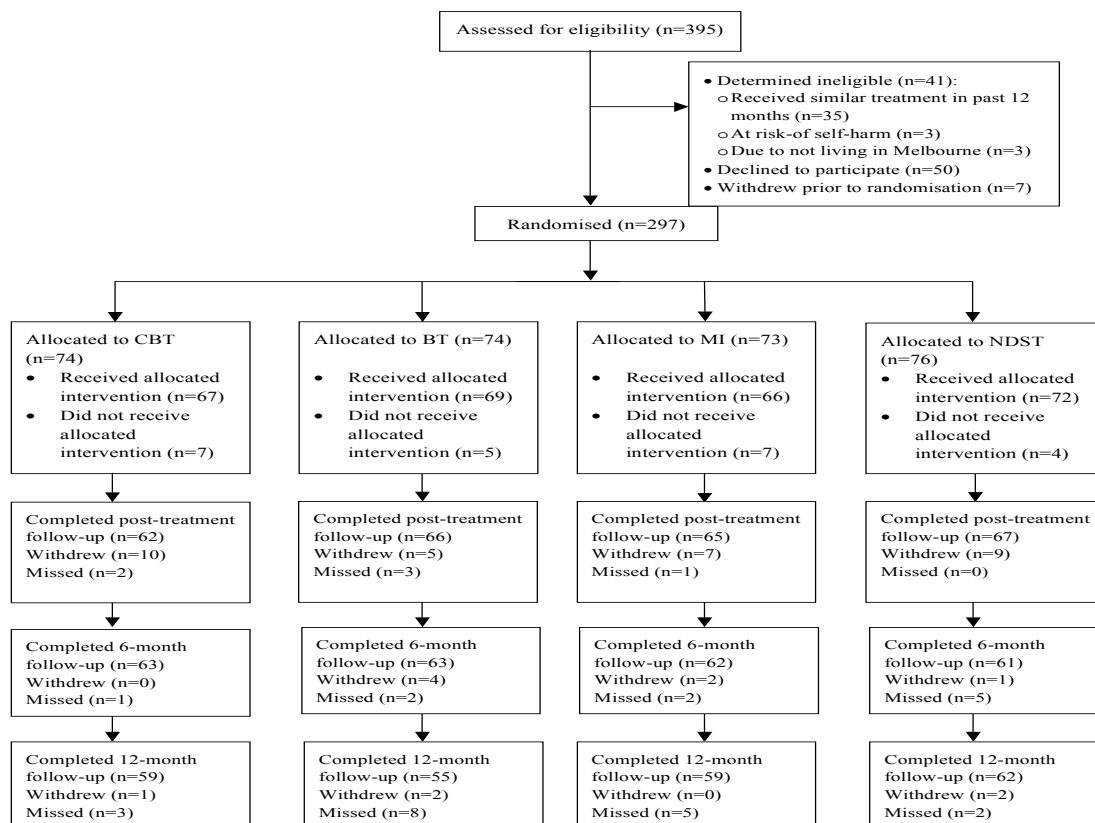


Figure 1 Recruitment Flow Diagram for study

Research Setting and Participants:

Participants:

The 297 participants were randomly allocated to the four treatment groups in the RCT study.

Individuals were eligible to participate if they:

- Were aged 18 years and over;
- Wished to receive treatment for a self-identified gambling problem; and
- Could communicate in English.

Individuals were not eligible to participate if they were:

- Unable to understand the study instructions and provide informed consent;

- At risk of self-harm; or
- Currently receiving other treatments for their gambling problems from a counsellor or therapist, or had received such treatment in the past 12 months.

The following table shows the demographic characteristics for the participants in the treatment trial:

Table 1 Study participants age and sex broken down by treatment group (n=297)

Treatment Group	Age of Participant					Sex of participant	
	n	Minimum Age	Maximum Age	Mean Age	SD Age	Male	Female
CBT	74	23	79	51.68	12.997	36	38
BT	74	19	79	46.16	15.288	45	29
MI	73	20	77	50.74	14.892	40	33
CCT	76	22	79	49.38	13.477	41	35
TOTAL	297	19	79	49.48	14.27	162	135

A sub-sample of the participants was selected for participation in an associated qualitative study. Fifty-six participants in the qualitative study were interviewed at the completion of their 6-session treatment program. The following table shows the post treatment qualitative sample characteristics.

Table 2 Post treatment (n=53) and 12 month qualitative study (n=47) participants age and sex broken down by treatment group

Interview phase	Treatment arm#		PGSI at baseline	Age	Sex
Post Treatment		n	Mean (SD)	Mean (SD)	%Female
	CBT	12	14.7 (6.5)	46.3 (12.9)	50.0
	BT	13	15.8 (7.1)	44.6 (15.9)	38.5
	MI	15	14.3 (5.2)	51.9 (13.4)	46.7
	CCT	13	14.9 (5.9)	51.2 (12.5)	53.8
	ALL	53	14.9 (6.0)	48.7 (13.7)	47.2
12 month Follow-up		n	Mean (SD)	Mean (SD)	% Female
	CBT	11	16.0 (6.3)	44.7 (12.6)	36.4
	BT	11	15.7 (6.4)	47.0 (16.2)	36.4
	MI	13	14.1 (5.8)	49.8 (15.0)	46.2
	CCT	12	14.3 (5.8)	53.3 (10.3)	58.3
	ALL	47	15.0 (5.9)	48.9 (13.7)	44.7

#BT: Behavioural Therapy; CCT: Client Centred Therapy; MI: Motivational Interviewing; CBT: Cognitive Behavioural Therapy.

Intervention details:

The interventions delivered to participants in this study were one of Cognitive-Behavioural Therapy (CBT), Behaviour therapy (BT), Motivational Interviewing (MI) and Client-Centred Therapy (CCT). In

all treatment groups, each participant received up to six individual, face-to-face sessions with a psychologist. The sessions were normally conducted on a weekly basis, ranging from 45 to 60 minutes a session. There was a 12-week limit for conclusion of all sessions to allow for clients to suspend treatment for work and other legitimate commitments. This design was implemented in order to support the pragmatic design philosophy of the trial. The psychologists providing treatment for this trial were required to have current registration with the Australian Health Practitioner Regulation Agency (AHPRA). Treatment was provided in the psychologists' places of usual practice to maximise the realism of the treatment episodes and the translation of the results to real clinic conditions. For the purpose of this trial, a detailed treatment guide was developed for each of the four psychological interventions. As outlined in this report, the guides were subjected to extensive quality testing and review. Two Australian Psychological Society Fellows reviewed each of the manuals.

Main outcome(s) and measure(s):

Three of the primary outcome measures assessed gambling behaviours. The questions used to measure gambling behaviours were based on a previously utilised framework for reporting outcomes in problem gambling treatment research.

The gambling behaviour questions assessed

- Frequency of gambling sessions (in days on which the person gambled in the past 4 weeks),
- Total time spent gambling (in hours in the past four weeks) and
- Amount of money spent gambling (net loss in the past four weeks).

These gambling behaviour questions were asked for each gambling activity the participant had gambled or played on in the past 4 weeks and then summed to form total scores for the three measures.

The Gambling Symptom Assessment Scale (G-SAS), a 12-item scale designed for the purpose of assessing change in gambling symptom severity during treatment, was also used as the 4th primary outcome measure. This scale utilises a past week timeframe, and items are rated on a 5-point scale. The G-SAS has been shown to be a valid and reliable tool for assessing gambling symptom severity and changes in symptoms during treatment. Three GSAS scores were calculated and reported:

- GSAS total scores
- GSAS urge scores
- GSAS frequency scores

The four primary outcome measures formed the central variable set for which analyses were reported in this study.

Results:

Tables of means were constructed for all of the four primary outcome measures. These were then subjected to ANOVA and ANCOVA repeated measures analyses to examine whether there were time effects i.e. whether there were statistically significant changes in the outcome measures over time (i.e.

pre-treatment (t0), post treatment (t1), 6 months post treatment (t2), and 12 months post treatment (t3) and whether any changes were different across the four treatment groups Cognitive Behaviour Therapy (CBT), Behaviour therapy (BT), Motivational Interviewing (MI) and Client-Centred Therapy (CCT) and whether there were interactions between these effects i.e. whether some treatments resulted in different patterns of change. The following table includes the means for the gambling frequency measures for the treatment groups across t=0 to t=3.

Table 3 Table of raw means for gambling behaviour measures for all treatment groups for pre-treatment, post treatment, 6 months following treatment and 12 months following treatment

	Group	Gambling frequency (Occasions per 4 weeks)		Gambling time (hours per 4 weeks)		Amount Lost (AUD per 4 weeks)	
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Baseline (t=0)	CBT	74	18.67 (17.63)	74	31.55 (25.77)	73	\$3,577 (4,033)
	BT	74	17.81 (13.93)	74	38.74 (45.41)	74	\$4,648 (7,420)
	MI	73	18.74 (16.12)	73	42.73 (61.12)	73	\$4,667 (7,048)
	CCT	76	16.14 (18.94)	76	28.11 (31.86)	76	\$4,382 (6,808)
	Total	297	17.82 (16.73)	297	35.21 (43.26)	296	\$4,320 (6,457)
Post-treatment (t=1)	CBT	62	9.56 (10.83)	62	15.63 (21.81)	62	\$4,190 (22,792)
	BT	66	8.20 (7.28)	66	13.92 (18.9)	66	\$1,827 (4,651)
	MI	65	11.00 (11.97)	65	21.19(30.75)	65	\$1,690 (3,305)
	CCT	67	9.52 (12.30)	67	14.93(27.37)	67	\$1,859 (3,341)
	Total	260	9.57 (10.77)	260	16.41 (25.18)	260	\$2,365 (11,592)
Six month (t=2)	CBT	63	10.75 (14.74)	63	15.33 (19.95)	63	\$1,819 (3,371)
	BT	63	9.14 (8.48)	63	16.38 (21.67)	63	\$2,526 (8,072)
	MI	62	10.79 (11.59)	62	14.56 (20.06)	62	\$2,219 (6,413)
	CCT	61	10.51 (11.77)	61	15.53 (31.50)	61	\$1,419 (1,920)
	Total	249	10.29 (11.80)	249	15.46 (23.50)	249	\$2,000 (5,507)
12 month (t=3)	CBT	59	7.25 (9.80)	59	13.47 (18.13)	59	\$1,112 (1,579)
	BT	55	9.89 (10.70)	55	15.3 (19.06)	55	\$1,259 (2,329)
	MI	59	12.27 (13.19)	59	20.93 (33.29)	59	\$3,220 (15,031)
	CCT	62	9.87 (11.44)	62	16.18 (27.36)	62	\$1,929 (4,073)
	Total	235	9.82 (11.43)	235	16.49 (23.35)	235	\$1,891 (7,943)

Thus the results showed a robust post treatment drop in gambling behaviours across all treatment groups that were sustained up to the 12-month post treatment measurement point.

The following table includes the means for GSAS gambling symptom measures for all treatment groups for pre-treatment, post treatment, 6 months following treatment and 12 months following treatment.

Table 4 Table of raw means for GSAS symptom measures for all treatment groups for pre-treatment, post treatment, 6 months following treatment and 12 months following treatment

Gambling symptoms		GSAS total scores		GSAS urge scores		GSAS frequency scores	
	Group	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Baseline (t=0)	CBT	74	25.82 (7.01)	74	8.58 (2.75)	74	6.55 (2.13)
	BT	73	27.48 (8.17)	73	8.71 (3.49)	73	7.12 (2.89)
	MI	72	26.14 (8.93)	72	8.33 (3.52)	72	6.65 (2.43)
	CCT	76	26.14 (8.04)	76	8.33 (3.25)	76	6.55 (2.31)
	Total	295	26.40 (8.05)	295	8.49 (3.25)	295	6.72 (2.45)
Post-treatment (t=1)	CBT	62	18.19 (8.86)	62	6.11 (3.25)	62	4.77 (2.38)
	BT	63	19.63 (9.11)	63	6.32 (3.84)	65	4.94 (2.56)
	MI	65	17.37 (8.82)	65	5.63 (3.42)	65	4.43 (2.47)
	CCT	66	18.48 (8.87)	66	5.86 (3.36)	67	4.78 (2.59)
	Total	256	18.41 (8.90)	256	6.17 (3.46)	259	4.73 (2.50)
6 months (t=2)	CBT	63	18.10 (8.97)	63	5.98 (3.42)	63	4.56 (2.58)
	BT	63	18.65 (9.18)	63	5.81 (3.84)	63	4.60 (2.84)
	MI	62	16.65 (9.29)	62	5.06 (3.65)	62	4.24 (2.80)
	CCT	61	20.16 (9.91)	61	5.98 (4.20)	61	4.98 (3.15)
	Total	249	18.38 (9.37)	249	5.71 (3.78)	249	4.60 (2.84)
12 months (t=3)	CBT	59	17.81 (9.14)	59	5.58 (3.90)	59	4.63 (2.67)
	BT	55	17.78 (11.73)	55	5.60 (4.74)	55	4.55 (3.24)
	MI	59	17.74 (9.33)	59	5.83 (3.94)	59	4.27 (2.61)
	CCT	62	18.19 (10.85)	62	5.35 (4.48)	62	4.81 (2.87)
	Total	235	17.89 (10.24)	235	5.59 (4.25)	235	4.57 (2.84)

For the GSAS scores a similar pattern of results was observed, i.e. post treatment means fell and the reductions were maintained at the 6 month and 12-month data collection points.

The data for all four primary outcome measures were subjected to statistical analysis.

The outcome measures of 'frequency', 'time' and 'expenditure' all demonstrated positively skewed data distributions. This meant that the raw data bunched closer towards the zero measure and had data points that more lightly scattered towards a larger number. To improve the accuracy of the repeated measures ANOVA analyses, these data were first transformed using a log function (base 10) to improve normality of the distribution. The analyses included all data. The analyses appear in the following table.

Table 5 Table of ANOVA results for longitudinal analysis for the outcome measures gambling 'frequency', 'time' and 'expenditure,' by time of assessment and treatment group (n=249)

Dependent Measure	Factor	Repeated measures ANOVA	Effect size (partial eta squared)
Frequency	Time (t ₀ , t ₁ & t ₂)	F(2,350) = 45.4, p < 0.001	0.21**
	Treatment group (CBT, BT, MI, CCT)	F(3, 175) = 0.6, p = 0.59	0.01
Time	Time (t ₀ , t ₁ & t ₂)	F(2,346) = 53.5, p < 0.001	0.24**
	Treatment group (CBT, BT, MI, CCT)	F(3, 173) = 0.2, p = 0.87	0.004
Expenditure	Time (t ₀ , t ₁ & t ₂)	F(2,338) = 48.6, p < 0.001	0.22*
	Treatment group (CBT, BT, MI, CCT)	F(3,169) = 0.1, p = 0.95	0.002
*Large effect, **medium effect			

The repeated measures ANOVA analyses indicated medium to large effects occurring over time in these outcome measures. Post hoc examination of the means showed that there was a significant decrease in all measures after therapy and this was maintained at the 12-month time point. There was no effects resulting from the treatment group and all interactions between time and treatment group were non-significant.

Repeated measures ANOVAs were conducted to investigate the effects of time and treatment group on GSAS scores. The following table summarises the repeated measures results for the GSAS outcome measures.

Table 6 Table of ANOVA results for longitudinal analysis for the GSAS symptom measures gambling 'total', 'urge' and 'frequency,' by time of assessment and treatment group (n=249)

Dependent Measure	Factor	Repeated measures ANOVA	Effect size (partial eta squared)
GSAS total	Time (t ₀ , t ₁ & t ₂)	F(2,434) = 98.3, p < 0.001	0.31*
	Treatment group (CBT, BT, MI, CCT)	F(3,217) = 1.3, p = 0.26	0.02
GSAS urge	Time (t ₀ , t ₁ & t ₂)	F(2,436) = 66.9, p < 0.001	0.24**
	Treatment group (CBT, BT, MI, CCT)	F(3, 218) = 1.1, p = 0.35	0.02
GSAS frequency	Time (t ₀ , t ₁ & t ₂)	F(2,440) = 72.2, p < 0.001	0.26*
	Treatment group (CBT, BT, MI, CCT)	F(3,220) = 0.6, p = 0.77	0.01
*Large effect, **medium effect			

This analysis included all data. There was a significant effect of time on GSAS score ($F(2,436) = 66.9$, $p < 0.001$) and post hoc examination of the means showed that there was a significant decrease in GSAS score after therapy and this was maintained at the 6-month time point. The effect size (see Table 6) indicated that the effect from time was a large effect. There was no effect of treatment group on GSAS score ($F(3,217) = 1.3$, $p = 0.26$) and the interaction between time and treatment group was also non-significant. Similar results were obtained for two GSAS sub-scores (GSAS-urge score and GSAS-frequency score). There were significant effects from time but not group.

Thus, the results for this trial are simple. All four treatment groups have experienced significant reductions in the behavioural and symptom gambling measures and these reductions have been sustained to 12-months post treatment.

This report also discusses other factors that may impact upon the obtained outcomes for the participants. The two areas analysed in this paper are clinician effects and the effects of the presence of psychological disorders and other addictions including drugs and alcohol upon the outcomes.

Analyses of the effects of “clinician” upon the four main treatment outcome measures demonstrated that “clinician” was not a statistically significant factor in explaining variance in treatment outcomes.

To address this issue of comorbidity effects various measures of psychological comorbidity were collected and then outcomes were modelled using these measures as covariates. These analyses addressed the issue as to whether existence of comorbidities may impact upon treatment outcomes.

The measures that were included in this analysis were:

- the DASS three sub scales, depression, anxiety and stress. The presence of “Depression” was indicated by a DASS sub-score of 10 and above; anxiety by a sub-score of 8 and above; and stress by a sub score of 15 and above.
- the AUDIT measures. A level of “risky” drinking was indicated by an AUDIT score of 8 and above, and high risk drinking by a score of 20 and above.
- drug use reported occurring at least monthly during the previous 12 months before the baseline.

The results indicated that the comorbidities used in this analysis were not providing additional statistical explanatory power in understanding the progression of the participants through the recovery outcome process. This does not suggest that comorbidity is not an important issue in the onset and treatment of problem gambling but the data presented using the analysis model adopted show that there were no statistically significant effects upon outcomes found in this study.

Qualitative study

The qualitative study associated with the RCT comprised semi-structured interviews at 3 data collection points. Interviews were administered face to face, and took between 40 and 60 minutes to complete. The time points and number of participants are summarised in Table 7. Sixty-six participants were interviewed at pre-treatment, and 56 of them were interviewed immediately after treatment. Ten participants were not available for the post-treatment interview. If participants did not complete their treatment, they were still invited to participate in subsequent interviews. For the

purpose of this report, which focuses on the experience of treatment, the analysis is primarily based on the post-treatment interview data as it includes the maximum number of completed participants.

Table 7 Table of data collection schedule for qualitative interviews

Data collection point	Number of participants
Pre-treatment	66 (final)
Post-treatment	53 (final)
12 months post-treatment	47 (final)

Qualitative study results

The post-treatment interview data from all of the qualitative study participants were subjected to thematic coding and analysed specifically for this qualitative report. This section presents the findings generated by the thematic analysis of the participants' experiences and reflections of their treatment program.

Those who participated in this qualitative study came from a wide range of backgrounds and differed on a range of demographic factors including: sex, age, ethnicity, marital status, level of education, income, years spent gambling, previous treatment experience, co-morbidities, gambling preferences etc. While they had a commonality in that all had sought treatment, their expectations of treatment varied enormously. Furthermore, some participants expressed the view that their expectations were met and surpassed, while for others, their expectations were not met.

At the immediate post-treatment phase participants' expectations and preconceived ideas about treatment greatly influenced their experience of treatment. Participants who experienced the treatment as worthwhile and/or exceeding their expectations reported a range of benefits as indicated below:

- The gaining of greater insight in order to check self/behaviour when gambling;
- Benefitting from a professional face to face treatment as compared to previous experiences of telephone counsellors;
- Appreciation of the opportunity for self-reflection;
- Gaining a better understanding of gambling reduction as an ongoing process;
- Exploration of specific strategies during treatment to enable the reduction of problem gambling behaviour;
- Valuing the simplicity of the strategies in the treatment provided as compared to their previous treatment attempts.

At the 12-month post-treatment interviews the participants provided some interesting insights into the process and outcomes of the treatment program. The same themes as identified in the post treatment

interviews emerged but with the addition of some reflective discussion about the therapeutic process and the role of the clinician and the client-therapist relationship.

Many reported positive benefits of better control of their gambling. This included improvements in personal relationships, the ability to take holidays and an overall calmness in managing everyday life that had been denied to many for a long time.

There was a slight reluctance amongst some of the participants who had achieved individually very good results to talk expansively of what are obviously also very good group results. Perhaps this may be borne of a concern about “tempting fate” and the possibility of relapse. Although the results are strong and are durable for a year, many described in their interviews that their recovery was an ongoing process that required ongoing vigilance and effort. A handful of participants spoke of “cure” but most spoke in a more measured manner.

It would be very interesting to talk with this group again to gather their yet longer-term views of their progress. However, to control their gambling for a year following treatment is a fine achievement that deserves (cautious) celebration.

Conclusions and relevance of the study:

The study showed that manualised psychological treatments delivered by well-trained psychologists resulted in durable and significant reductions in gambling behaviour (frequency, time spent and losses) and gambling symptoms were achieved on average for the participants over a 12-month period. In this study, the reductions were unrelated to the type of psychological treatment used. In addition the reductions in gambling behaviour and symptoms appear to be maintained for at least twelve months across the group of study participants. The reductions obtained in gambling behaviour and symptoms were statistically significant and clinically large as shown in the following table.

For example, in the pre treatment phase the participants gambled on average on 17.8 days in a month whereas immediately post treatment the average number of days gambled was 9.57 days and at 6 months it was 10.29 and 9.82 at 12 months. The same pattern of durable major reductions was found in all of the outcome measures.

Table 8 Table of findings for the PROGRESS trial outcome measures for the combined study sample at Baseline (t₀, n=297), Post treatment (t₁, n=260), 6 months (t₂, n=249) and 12 months (t₃, n=235)

Study Phase	Frequency (days gambled in a 4 week period)	Time (hours spent gambling in a 4 week period)	Spend (Net Loss AUD in a 4 week period)	GSAS Total
Baseline (t ₀ , n=297)	17.82 (16.73)	35.21 (43.26)	\$4,320 (6,457)	26.40 (8.05)
Post treatment (t ₁ , n=260)	9.57 (10.77)	16.41 (25.18)	\$2,365 (11,592)	18.41 (8.90)
6 months (t ₂ , n=249)	10.29 (11.80)	15.46 (23.50)	\$2,000 (5,507)	18.38 (9.37)
12 months (t ₃ , n=235)	9.82 (11.43)	16.49 (23.35)	\$1,891 (7,943)	17.89 (10.24)
Δ 12 months- baseline	-8 (-45%)	-18.72 (-53%)	-\$2429 (-56%)	-8.51 (-32%)

From these data, it can be inferred that over a 12-month period in the study sample an “average” individual would nominally gamble on 104 less days, spend 243 less hours gambling per year and they would save \$31,577 per year in losses. Of course, there is high variability in the data so “average” losses certainly should not be construed to mean that all individuals would achieve those results. Some individuals would exceed these reductions and savings, whereas other individuals would achieve much less favourable results.

The interventions delivered in this study were manualised and delivered by experienced psychologists and hence caution should be exercised in generalizing the results to other clinician groups and also clinicians who are not using manualised interventions.

Notwithstanding these caveats, the magnitude and durability of the reductions in key outcome variables is a pleasing result. The interventions have achieved robust and sustainable reductions in gambling behaviours as measured by days gambled, time spent gambling, net losses and GSAS symptom scores.

Thus, it has been found in this study that manualised psychological treatments specifically Behavioural Therapy; CCT: Client Centred Therapy; MI: Motivational Interviewing; CBT: Cognitive Behavioural Therapy, when administered by registered psychologists are effective in the treatment of problem gambling and that the beneficial effects over the groups persist for 12 months.

Trial registration details:

The trial is registered with Current Controlled Trials and has an assigned International Standard Randomised Controlled Trial Number of ISRCTN01629698. The acronym used to describe this trial is the PROGRESS trial (Psychological treatments for PROblem Gambling REsearch Study or PROGRESS)

Ethics approval details:

- Department of Justice Human Research Ethics Committee (approval CF/11/22867),
- Monash University Human Research Ethics Committee (approval A1/2012) and the
- University of Melbourne Human Research Ethics Committee (CD/12/536402)

Background

Introduction to the present study

The evidence foundation for the present study is found in three previously published and linked reviews written by members of the current research team (Cowlshaw et al., 2012; Lorains, Cowlshaw, & Thomas, 2011; Problem Gambling Research and Treatment Centre (PGRTC), 2011), which we have supplied as companion papers to this report and are accessible by the relevant web-links (access the NHMRC guideline at <https://www.nhmrc.gov.au/guidelines/publications/ext5>, the Cochrane review at www.thecochranelibrary.com/details/file/1033479/CD006776.html and the Addiction review at <http://www.ncbi.nlm.nih.gov/pubmed/21210880>). These reviews provide the conceptual and evidence base that led to the conduct of the present study and its design and the analytical methods that have been used within it.

For the purposes of this report we have summarised the salient key findings and issues covered in these reviews. We have not repeated their full detail in this document. It is important to understand that the present study reported in this document was a key step in a staged research program conducted by the current research team. The research positioning and translational strategy surrounding the present study is summarised in the following flow-chart, Figure 2. The present report is focused on Step 3 of this process but also includes advice concerning treatment services based upon the results that will be formally incorporated in the revised NHMRC guideline in Step 4 following the completion of this study and review of other pertinent new evidence.

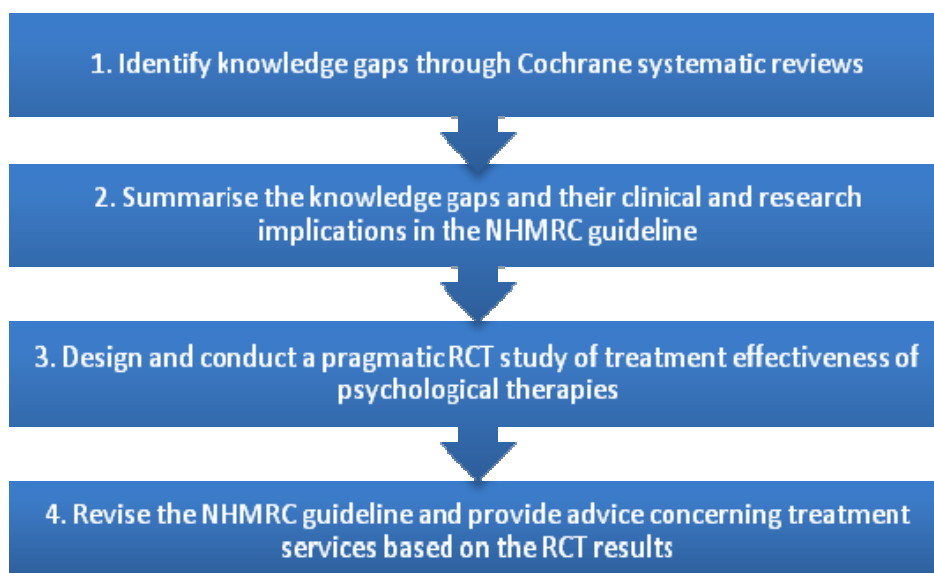


Figure 2 Research and translation strategy used in the study

The purpose in this overall program of work has been to contribute to an evidence base for effective treatments for problem gambling.

A discussion is now presented of the Cochrane systematic review and the NHMRC guideline and how these informed the design and implementation of the clinical trial reported in this document.

THE COCHRANE SYSTEMATIC REVIEW OF PSYCHOLOGICAL TREATMENTS IN PATHOLOGICAL AND PROBLEM GAMBLING

The purpose of the Cochrane Systematic Review was to synthesize evidence from randomized controlled trials of psychological therapies for pathological and problem gambling (including Cognitive-Behaviour Therapy (CBT), Behaviour Therapy, Motivational Interviewing therapy, and other psychological therapies), in order to review the efficacy of therapies and the durability of therapy effects, relative to control conditions.

Data collection and analysis in the Cochrane review

Data on the characteristics and results of in-scope studies were extracted according to the published Cochrane protocol. The primary outcomes used in the review were measures of gambling symptom severity, financial loss from gambling and frequency of gambling. The secondary outcomes used were occurrence of pathological gambling diagnoses and depression and anxiety symptoms. Treatment effects were defined by comparisons between therapy and control conditions at post-treatment assessments (conducted from 0 to 3 months following completion of treatment) and follow-up assessments (conducted from 9 to 12 months following completion of treatment), respectively, using the standardised mean difference (SMD) or risk ratio (RR). Any required results were synthesised through random-effects meta-analysis.

Main results of the Cochrane review

Fourteen studies (with a combined $n = 1245$ participants) met the review inclusion criteria. Eleven studies compared CBT with control and comparisons at 0 to 3 months post-treatment showed beneficial effects of therapy that ranged from medium (when defined by financial loss from gambling: SMD - 0.52; 95% confidence interval (CI) -0.71 to -0.33, $n = 505$) to very large (for gambling symptom severity: SMD -1.82; 95% CI -2.61 to -1.02, $n = 402$). Only one study ($n = 147$) compared groups at 9 to 12 months follow-up and produced smaller intervention effects that were not statistically significant.

Four studies of Motivational Interviewing therapy were identified and mainly considered samples demonstrating less severe gambling (relative to studies of pathological gamblers). Data suggested

reduced financial loss from gambling following Motivational Interviewing therapy at 0 to 3-months post-treatment (SMD -0.41; 95% CI -0.75 to -0.07, $n = 244$), although comparisons on other outcomes were not significant. The effect approached zero when defined by gambling symptom severity (SMD -0.03; 95% CI -0.55 to 0.50, $n = 163$). Studies compared groups at 9 to 12-months follow-up and found a significant effect of Motivational Interviewing therapy in terms of frequency of gambling (SMD -0.53; 95% CI -1.04 to -0.02, $n = 62$), with comparisons on other outcomes that were not significant.

Two studies of combination therapies also considered samples demonstrating overall low gambling severity, and found no significant effects of therapy at 0 to 3-months post-treatment. Comparisons at 9 to 12-months follow-up suggested a medium effect from therapy in terms of gambling symptom severity, with no significant differences for other outcomes. One study (with a very small sample size of $n = 18$) considered another psychological therapy (i.e. Twelve-Step Facilitated Group Therapy) and suggested beneficial effects in terms of most outcomes at 0 to 3-months post-treatment. The evidence supporting these various classes of therapy were classified as ranging from *very low* to *low* quality according to the criteria applied in the review.

The Cochrane review, therefore, supported a finding of efficacy of CBT in reducing gambling behaviour and other symptoms of pathological and problem gambling immediately following therapy. However, the durability of therapeutic gain provided by CBT in the treatment of problem gambling was found to be uncertain because of insufficient data. There was found to be some limited evidence for some benefits from Motivational Interviewing therapy in terms of reduced gambling behaviour, although not necessarily other symptoms of pathological and problem gambling. However, the findings were based on few studies and additional research was suggested as being needed to inform more definitive research conclusions. There was also some evidence suggestive of possible benefit from combination therapies, and other psychological therapies for pathological and problem gambling including Behaviour Therapy. However, there were insufficient studies and the evidence was insufficient to evaluate these therapies. The majority of studies in this review had multiple limitations in terms of risk of bias because of methodological problems.

It is also important to understand that lack of evidence of effectiveness does not constitute evidence of ineffectiveness of treatments. The study biases identified in the reviewed studies were generally too great to provide good strength of evidence in this review.

A key section in the Cochrane review was the assessment of risk of bias in the previous gambling RCT studies. The outcomes of this published assessment have been used to directly inform the design of the present study to attempt to avoid repetition of the identified sources of bias. Each of the biases identified in the Cochrane review is now discussed along with the methodological design responses utilised in the present study to attempt to minimise them.

Random allocation to groups (sequence generation): Only studies that indicated the use of random allocation of study participants to treatment and control groups were eligible for inclusion in our Cochrane review. However, the level of detail provided about the procedures made it impossible in some cases to fully evaluate the method of allocation from the provided data. We classified such studies with limited detail as 'Unclear' and as having a potentially high risk of bias. *To address this problem an allocation sequence generated independently and provided by the NHMRC Clinical Trials Centre was used in order to minimise any such bias.*

Allocation concealment: Effective randomisation depends on the adequate concealment of allocation sequence whereby participants and researchers are kept unaware, and are unable to foresee, the groups to which participants are allocated and hence bias the randomisation process. In our Cochrane review, studies that lacked allocation concealment were classified as having a high risk of bias. *Full allocation concealment was employed in the present study in order to address this bias.*

Blinding of outcome assessors: For the Cochrane review, blinding referred to the blinding of outcome assessors. In the review, we classified studies that failed to blind outcome assessors (including studies relying on measures self-completed by participants) as having a high risk of bias. *Outcome assessors for the current trial were blind to the treatment group of the person they interviewed. They used standardised tools and protocols to assess outcomes.*

Analysis of 'intention-to-treat' data: Where data from participants were missing because of attrition, the studies in our review generally reported analyses conducted on either: (a) data from participants providing complete information (i.e., 'completers only'); or (b) an intention-to-treat (ITT) sample, whereby data from all participants were included through use of various missing data strategies (e.g., last observation carried forward). Given that attrition often reflects a non-random process that varies across condition, results from analysis of 'completers only' data have a high risk of bias and we classified studies that did this in our review accordingly. There is also variability in risk of bias from simplistic missing data techniques (e.g., last observation carried forward). In the present study as it has transpired, very low dropout rates across the study have been achieved. Our analyses of the characteristics of the initial study sample and the participants who completed the study show very close correspondence between the two. *Thus, in the present study it has not been necessary to use synthesised data in the analyses.* The use of synthesised data is controversial and best avoided.

Selective outcome reporting: Selective outcome reporting refers to the selection and presentation of a limited subset of data or analyses, according to the nature (e.g., statistical significance) of the results (Hutton & Williamson, 2000). There are different types of selection bias (see (Higgins & Altman, 2008)), and these generally require access to study protocols to compare against published reports. As such, we classified studies as having a high risk of bias in the review if: (1) they had study protocols available which listed outcomes or measures that were not reported in the results; or (2)

outcomes were reported with inadequate detail for inclusion in the meta- analyses. *The key outcome measures were announced at the commencement of the current study and they have been reported as advised.*

Systematic pre- treatment differences between groups: If this is found, it may suggest a failure in the randomisation to groups at the pre-treatment stage. In the Cochrane review studies were categorised as having a high risk of bias if they identified pre-treatment differences and failed to control for these or if they did not evaluate differences, or if they did not indicate whether differences were adjusted for in the data analysis. In the present study full analyses of randomisation differences/ failures were proposed to be conducted. *Thus this bias was addressed by analysing for differences and then not requiring statistical adjustment to achieve group equality.*

Measurement of treatment fidelity: This indicates whether therapy was delivered as intended. Those studies that failed to conduct some measurement of therapist adherence to treatment were categorised as 'Unclear' and hence suspect. *As outlined in our methodology we took several measures to assess and maintain high treatment fidelity.*

Thus, the Cochrane review was a key foundation for the design of the present study. The risks of bias in previous studies identified in the Cochrane systematic review assessment process was used to drive the design of the present study.

A discussion is now presented of how we used the NHMRC guideline we authored to inform the design of the present study.

THE NHMRC GUIDELINE FOR THE SCREENING ASSESSMENT AND TREATMENT OF PROBLEM GAMBLING

The purpose of the NHMRC Guideline(<https://www.nhmrc.gov.au/guidelines/publications/ext5>) was to summarise the current state of knowledge concerning problem gambling treatment and to make recommendations concerning practice in interventions, screening and assessment

The NHMRC Guideline development was conducted according to the stringent requirements of the National Health and Medical Research Council. These requirements include the establishment of an expert Guideline Development Group with a membership composition determined by the NHMRC guideline group, public consultations with clinicians and the community and the following of a detailed review methodology.

Guideline developers can apply to the Council for approval of a guideline at the commencement of the development process. An expert panel throughout the process assesses the guideline and any

technical changes are made if the guideline is deemed to meet the quality criteria. The developer then attends a full meeting of the Council to answer any further questions and field comments from Council members.

As outlined in the guideline document we achieved the following approval from the Council:

"These guidelines were approved by the Chief Executive Officer of the National Health and Medical Research Council (NHMRC) on 11 August 2011, under Section 14A of the National Health and Medical Research Council Act 1992. In approving these guidelines the NHMRC considers that they meet the NHMRC standard for clinical practice guidelines. This approval is valid for a period of 5 years. NHMRC is satisfied that they are based on the systematic identification and synthesis of the best available scientific evidence and make clear recommendations for health professionals practising in an Australian health care setting. The NHMRC expects that all guidelines will be reviewed no less than once every five years."

Thus the relevant recommendations made in the guideline document related to clinical and research questions concerning problem gambling treatment and research. Although they were informed by the Cochrane review process which is stringent the guideline development process is much more stringent including wide public consultations and the clear identification of knowledge gaps and research recommendations. A guideline development process is a rigorous method of formulating research questions to inform clinical practice and this was the process that was followed. The guideline was also independently reviewed in a BMJ editorial (Bowden-Jones & Smith, 2012) and hence the guideline was an appropriate tool to use to inform the design and purposes of the current study.

The full detail of the guideline can be accessed at

http://www.nhmrc.gov.au/files/nhmrc/publications/attachments/ext0005_problem_gambling_guideline.pdf

In this document, excerpts are presented of the guideline recommendations that relate directly to the present study.

NHMRC recommendations use a four level evidence grade system as follows (NHMRC, 2009):

Table 9 Table NHRMC grades of recommendations

Letter code	Grade of evidence
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

The above scale was used in formulating our recommendations. The following practice recommendations were made:

Table 10 Evidence based recommendations for treatment and practice points

Evidence Grade	Recommendation	Practice points
B	Individual or group cognitive behaviour therapy (CBT) should be used to reduce gambling behaviour, gambling severity and psychological distress in people with gambling problems	Where CBT is to be prescribed, the following could be considered: <ul style="list-style-type: none"> • Appropriate qualifications and training of practitioners • Manualised delivery of the intervention
B	Motivational Interviewing and motivational enhancement therapy should be used to reduce gambling behaviour and gambling severity in people with gambling problems	Where Motivational Interviewing and motivational enhancement therapy are to be prescribed, the following could be considered: <ul style="list-style-type: none"> • Appropriate qualifications and training of practitioners • Manualised delivery of motivational enhancement therapy

B	Practitioner-delivered psychological interventions should be used to reduce gambling severity and gambling behaviour in people with gambling problems	<p>Where practitioner-delivered psychological interventions are to be prescribed, the following could be considered:</p> <ul style="list-style-type: none"> • Client preferences • Appropriate qualifications and training of practitioners • Availability of services • Manualised delivery of the intervention
B	Practitioner-delivered psychological interventions should be used over self-help psychological interventions to reduce gambling severity and gambling behaviour in people with gambling problems	<p>Where practitioner-delivered psychological interventions are to be prescribed, the following could be considered:</p> <ul style="list-style-type: none"> • Client preferences • Appropriate qualifications and training of practitioners • Availability of services • Manualised delivery of the intervention
C	Group psychological interventions could be used to reduce gambling behaviour and gambling severity in people with gambling problems	<p>Where group psychological interventions are to be prescribed, the following could be considered:</p> <ul style="list-style-type: none"> • Client preferences • Appropriate qualifications and training of practitioners • Availability of services • Manualised delivery of the intervention
B	Antidepressant medications should not be used to reduce gambling severity in people with gambling problems alone	<ul style="list-style-type: none"> • Due to the nature of the samples studied, this recommendation is applicable to those with gambling problems only, and not those who may have comorbidities such as depression and anxiety • This recommendation is predominantly based on evidence evaluating the effectiveness of selective serotonin reuptake inhibitors
C	Naltrexone could be used to reduce gambling severity in people with gambling problems	<p>Where naltrexone is to be prescribed, the following could be considered:</p> <ul style="list-style-type: none"> • Problem gambling is not (at the time of reporting) a registered indication for naltrexone, so a Pharmaceutical Benefits Scheme subsidy would not apply for this indication • Appropriate skills and training of the prescribing practitioner

It is notable that none of the NHMRC Guideline recommendations achieved an A grading because of the low to intermediate levels of the evidence ratings. This finding of bias issues in the literature was also consistent with the Cochrane review.

How the Cochrane and NHMRC Guideline reviews informed the design of the present RCT study

As outlined above the reviews revealed a series of potential biases that needed to be carefully addressed in the design of our trial.

While the efficacy of some psychological treatments had been partially demonstrated in previous studies the relative effectiveness of different psychological therapies had not yet been fully addressed. In addition, therapies such as client-centred therapy had not been researched intensively in terms of effectiveness in the treatment of problem gambling. However, this modality has been extensively researched in other addictions and found to be effective (Miller, Benefield, Tonigan, 1993). Similarly Motivational Interviewing had been the subject of limited studies (although it also has been extensively researched in the addictions area (Rubak, 2005). Thus it was desired that all viable and commonly used psychological therapies were investigated in the present study, while noting that this goal would require a large study sample to achieve. This requirement was also affected by the need for adequate statistical power.

Statistical power was found to be quite problematic in some of the reviewed studies. As outlined in our Cochrane review the sample sizes in the reviewed studies was an average total of 89 participants. The 12month delivered sample for the current study was 235 participants with 260 participants completing the treatments.

It was also clear that manuals should be used to guide the treatments used in the present trial because the literature suggested that such manualised interventions would be more effective. However the evidence was not of sufficient quality to allow for A-grade recommendations. This is also an area of research need and knowledge gaps.

Based upon these reviews it was attempted to avoid some of the more obvious flaws in the design and execution of this study. We now turn to a discussion of the study aims and methodology.

Study objectives and relationship to knowledge gaps

Following the conduct of the systematic reviews described in the introduction of this report, it is evident that there are knowledge gaps concerning the effectiveness of psychological treatments for problem gambling to guide evidence based therapeutic decisions for clinicians and policy makers. Which therapies are effective, their relative effectiveness and the durability of treatment effects are not sufficiently well known.

Therefore, the objectives of this study were to:

- 1. Study the relative effectiveness of four manualised psychological interventions (Cognitive Behaviour Therapy, Motivational Interviewing, Behaviour Therapy and Client Centred Therapy) in the treatment of problem gambling.**
- 2. Determine the durability of any therapeutic gains obtained by the four psychological interventions as measured by the key outcome variables (a) instances of gambling in the past four weeks, (b) hours spent gambling in the past four weeks, (c) dollars spent gambling in the past four weeks and (d) gambling symptom severity as measured by G-SAS.**
- 3. Study the experiences of problem gamblers seeking treatment throughout the course of the treatment and following its cessation.**

A pragmatic trial design was used in the present study. The purpose of the pragmatic trial approach is to attempt to ensure that the study results are “good to go” for use in clinical settings and for public policy decisions without the need for extensive additional translation research. The design advantages associated with pragmatic trials have attracted substantial discussions in the clinical trials literature (Tunis, Stryer, Clancy, 2003; Roland & Torgerson, 1998; Patsopoulos, 2011; Hotopf, 2002). The CONSORT group’s (Zwarenstein, Treweek, Gagnier, 2008), revision to the CONSORT reporting standards for clinical trials reported in the BMJ makes a range of key pertinent points in their discussion of pragmatic trials.

The use of pragmatic trial methodology involves an increase in utility of the trial. Citing Schwartz and Lellouch the CONSORT group argues: *“Most trials done hitherto have adopted the explanatory approach without question; the pragmatic approach would often have been more justifiable”* (p.2).

In a pragmatic trial, the same key bias minimisation methods are employed as in a standard RCT. A key distinction between pragmatic trials and traditional RCT trials is in the area of efficacy and effectiveness. An efficacy trial determines whether interventions produce effects under ideal circumstances. So an efficacy trial may, for example, exclude all people with co-morbid disorders in order that a “pure” efficacy result is obtained. In the comorbidity review published in Addiction produced by the current research group and in the NHMRC clinical guideline, this point has been argued in detail (see Lorains, Cowlshaw, & Thomas, 2011; Problem Gambling Research and Treatment Centre, 2011). The use of highly biased and unrepresentative participant groups free from comorbidities while in one sense pursuing rigour also potentially provide very little useful data concerning the people presenting to clinical services who have high rates of comorbidity. Similarly, in psychological treatment RCTs extensive treatment regimens may be used that could never be realistically implemented in a real clinical setting. For example, trials involving 12 or 24 sessions of therapy may be academically interesting but if the funder is only prepared to support six sessions of therapy the results are of very limited use in that context. Effectiveness studies (pragmatic trials) measure intervention effects under “real world” clinical settings. And this was our approach.

Thus in the present study people with co-morbidities were not excluded. In the problem gambling study environment this could involve the potential exclusion of over 90 per cent of real clients leaving a highly un-representative residuum sample (Lorains, Cowlshaw, & Thomas, 2011). The results from this residual and highly biased study sample are of very limited use to clinicians and policy makers. Similarly, we used our benchmark of up to 6 treatment sessions knowing that a typical course of treatment in the jurisdiction in which this study was performed usually involves up to 4 sessions. (Crisp, Jackson, Thomas, et al 2001). If in designing the present trial it has been decided to opt for 12 sessions, for example, apart from the issue of poor generalizability this could encourage and perhaps mandate high dropout rates.

A detailed description of the study methodology now follows.

Study A: Pragmatic effectiveness trial – Research methods

Study design

The study design was a parallel group, pragmatic randomised controlled trial, as summarised in the figure below. Individuals interested in participating in the study contacted the research team, where they were assessed for eligibility. Eligible participants were sent an explanatory statement and informed consent form, to be returned to the research team. Once informed consent was obtained, trained research assistants conducted the baseline assessment and participants were then randomly allocated to one of the four interventions. These interventions were: Cognitive-Behaviour Therapy (CBT), Behaviour Therapy (BT), Motivational Interviewing (MI) and Client-Centred Therapy (CCT). Participants in each intervention received up to six individual face-to-face sessions of their allocated treatment, with a registered psychologist. Follow up assessments were conducted at the end of treatment and at six and 12 months post-treatment for all available participants.

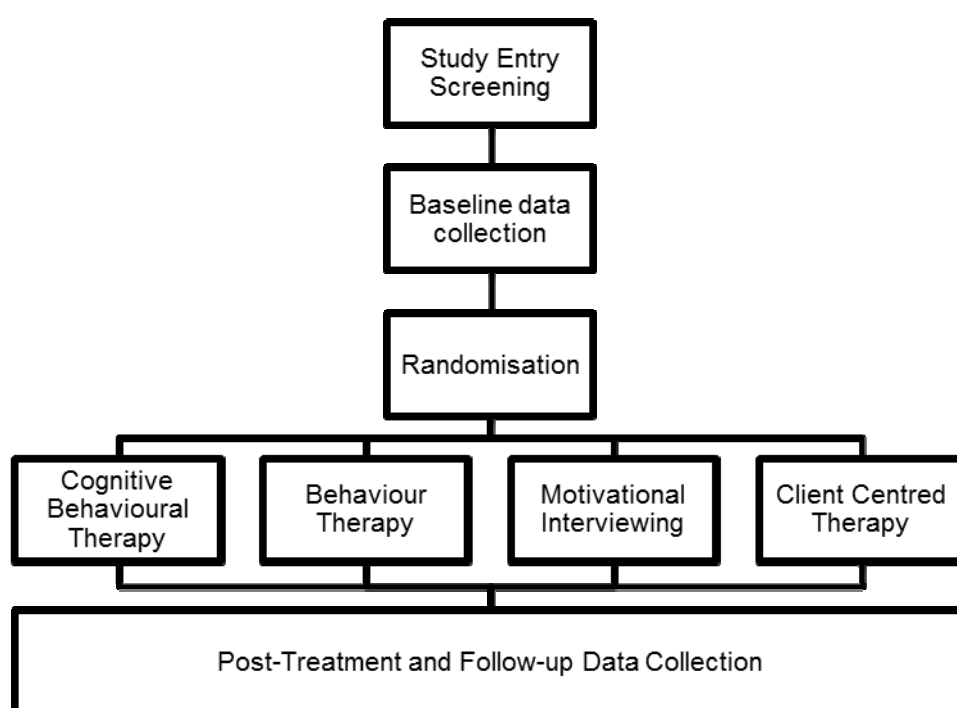


Figure 3 Study design

Ethics approval was obtained from the Department of Justice Human Research Ethics Committee (approval CF/11/22867), Monash University Human Research Ethics Committee (approval A1/2012) and the University of Melbourne Human Research Ethics Committee (CD/12/536402).

Participant recruitment and random assignment to treatment

Participants were recruited from the Greater Melbourne Metropolitan Region, Victoria, via advertisements in various media outlets, including newspapers, electronic media and university websites. Participant recruitment commenced in June 2012 and was finalised in February 2014. Individuals interested in participation contacted the research team via a free 1800 telephone number or email.

A screening and intake protocol was developed to respond to enquiries from individuals via telephone and email in a structured manner. During the screening and intake process, the research team were responsible for explaining the study, responding to questions, recording basic socio-demographic details (date of birth, sex, postcode of current residence, country of birth, where relevant, year of arrival in Australia, main language spoken at home and whether they identify themselves as Aboriginal, Torres Strait Islander or South Sea Islander) and assessing eligibility. Individuals were eligible to participate if they:

- were aged 18 years and over;
- wished to receive treatment for a self-identified gambling problem; and
- could communicate in English.

Individuals were not eligible to participate if they were:

- unable to understand and provide informed consent;
- at risk of self-harm; or
- currently receiving other treatments for their gambling problems from a counsellor or therapist, or had received such treatment in the past 12 months.

In keeping with the sampling principles suggested by a pragmatic trial, people with comorbid mental health and/or addiction disorders were not excluded from the trial.

Individuals eligible to participate then had their contact details recorded for the purpose of sending out the study information package which included the Explanatory Statement, the Informed Consent form and a reply paid envelope.

Once informed consent was received, participants completed a baseline assessment interview followed by random assignment to one of the four interventions. To ensure equal numbers across the four interventions, participants were randomised using a permuted block design. The block sizes randomly varied to reduce the chance of the research team recognising the assignment schedule (Schulz & Grimes, 2002). An external clinical trials unit, the NHMRC Clinical Trials Unit, independent

of the research team, was responsible for generating the randomisation schedule. All staff responsible for collecting the outcome data, at each time point, were blinded to the treatment condition of the participants i.e. full allocation concealment was employed.

Sample size considerations

Sample size calculations for this trial were based on a power level of 0.90 and an alpha level of $\alpha=0.01$. The Cochrane review of RCTs assessing psychological interventions for problem gambling was used to determine an appropriate effect size (Cowlshaw et al., 2012). For the primary outcome measure of gambling behaviour (assessed by frequency, amount and time spent gambling for this trial), this Cochrane review found an expected standardised effect size ranging from $d = 0.50$ and $d = 0.84$, for financial loss from gambling and frequency of gambling, respectively. We therefore powered the study to detect the smaller reported effect size of $d = 0.50$.

Given a power level of 0.90, an alpha of $\alpha = 0.01$, an effect size of $d = 0.05$, and a correlation of 0.8 between repeated measures, a sufficient sample size of $n= 136$ (34 participants per intervention group) was calculated using G*Power software and a priori repeated measures ANOVA.

However, taking in to account participant dropout for later longitudinal data collection a larger sample size of $n=276$ was chosen, representing 69 participants per intervention (i.e. effectively doubling the sample size). However it appears that this provision may have been excessive based upon the dropouts (loss to sample) actually experienced in the study. This means that the study is effectively powered to detect better than 0.50 effect sizes.

Study treatments

The interventions provided in this study were Cognitive-Behaviour Therapy (CBT), Behaviour Therapy (BT), Motivational Interviewing (MI) and Client-Centred Therapy (CCT). In all treatment groups, each participant received up to six individual, face-to-face sessions with a psychologist. The sessions were normally conducted on a weekly basis, ranging from 45 to 60 minutes a session. There was a 12-week limit for conclusion of all sessions to allow for clients to suspend treatment for work and other legitimate commitments. This design was implemented in order to support the pragmatic design philosophy of the trial. The psychologists providing treatment for this trial were required to have current registration with the Australian Health Practitioner Regulation Agency (AHPRA). Treatment was provided in the psychologists' places of usual practice to maximise the realism of the treatment episodes and the translation of the results to real clinic conditions.

For the purpose of this trial, a detailed treatment guide was developed for each of the four psychological interventions. As outlined in this report, the guides were subjected to extensive quality testing and review. Two Australian Psychological Society Fellows reviewed each of the manuals and

any recommended changes were implemented. A summary of the session structure for each intervention is provided in Table 11.

Table 11 Session Structure for the Four Interventions

Intervention	Session 1	Session 2	Session 3	Session 4	Session 5	Session 6
Cognitive-Behavioural Therapy (CBT)	History taking, assessment and goal formation.	Gambling education and self-management techniques.		Cognitive restructuring.	Challenging gambling specific erroneous cognitions.	Relapse prevention.
Behaviour Therapy (BT) Urge reduction	History taking, assessment and goal formation.	Gambling education and self-management techniques.		Imaginal exposure and reducing urges to gamble.		Relapse prevention.
Motivational Interviewing (MI)	Engaging with the participant, explaining the treatment, providing assessment feedback and history taking.	Check in with the participant and determine their goal for the session. The exact content of each session will differ depending on the participant's readiness to change and their ambivalence and resistance towards change. Underpinning each session will be the principles of MI including, expressing empathy, rolling with resistance, supporting self-efficacy and developing discrepancy.				
Client-Centred Therapy (CCT)	Engaging with the participant, explaining the treatment, providing assessment feedback and history taking.	Check in with the participant and determine what they hope to focus on in the session. Each session will be underpinned by the principles of unconditional positive regard, genuineness, empathic understanding, reflective listening, staying entirely within the participant's frame of reference and avoidance of volunteering leading questions, interpretations, suggestions or guidance.				

Study measures and data collection methods

As mentioned previously, basic socio-demographic characteristics, including those required to confirm eligibility, were collected during the screening and intake process (date of birth, sex, country of birth, year of arrival in Australia, language spoken at home, postcode of current residence and whether they identify themselves as Aboriginal, Torres Strait Islander, or South Sea Islander).

The baseline assessment included all other socio-demographic variables, including marital status, employment status, and highest education achieved. Questions relating to clinical history, such as, previous treatments for problem gambling or other mental health issues were collected during the baseline interview. Valid and reliable tools were used to assess all of the primary outcomes and additional measures.

Data collection interviews have been conducted at the end of treatment, 6 months follow up and further follow up was conducted at 12 months. These follow-up data collection interviews included all

of the primary outcomes and most of the additional measures. See Table 12 for an outline of the measures assessed at each assessment time point.

Table 12 Table showing the measures taken for each assessment time point

Measure	Screening and intake	Baseline (t ₀)	End of treatment (t ₁)	6 months (t ₂)	12 months (t ₃)
Socio-demographics	X	X			
Clinical history		X			
G-SAS		X	X	X	X
Gambling behaviours		X	X	X	X
DSM-IV		X		X	X
PGSI		X			X
Other gambling related measures – PG duration, family history, preferred gambling activity and gambling debt		X			
AUDIT		X	X	X	X
DASS-21		X	X	X	X
K6		X	X	X	X

All data collection interviews were conducted over the telephone by psychology trained research assistants, and took approximately 45 minutes to complete. The research assistants conducting the data collection interviews were blinded to the intervention that participants received. Participants were compensated for their time and efforts with a \$50 gift voucher for each follow-up data collection interview completed. The primary outcome measures are summarised below.

Primary outcomes

Gambling behaviours

One of the primary outcomes assessed was gambling behaviour. The questions used to measure gambling behaviours were based on Walker and colleagues (2006) framework for reporting outcomes in problem gambling treatment research. The gambling behaviour questions assessed past month frequency of gambling sessions (in days), time spent gambling (in hours) and amount of money spent gambling (in relation to net loss). These gambling behaviour questions were asked for each gambling activity the participant had gambled or played on in the past month and then summed.

Gambling symptom severity (G-SAS)

The Gambling Symptom Assessment Scale (G-SAS) (Kim, Grant, Potenza, Blanco, & Hollander, 2009) is a 12-item scale designed for the purpose of assessing change in gambling symptom severity

during treatment. This scale utilises a past week timeframe, and items are rated on a 5-point scale. The G-SAS has been shown to be a valid and reliable tool (Won, Grant, Potenza, 2009) for assessing gambling symptom severity and changes in symptoms during treatment.

Additional measures

Clinical history

Participants were asked questions relating to treatments they have previously received for problem gambling and other mental health issues and if they are currently taking any prescribed medication. More specifically, the participants were asked:

- the number of times they had ever participated in a treatment program for gambling problems
- whether they had ever, and in the past 12 months, attended Gamblers Anonymous meetings
- if they had ever sought professional treatment for any tobacco, alcohol, drug, other addiction or any mental health issues.
- if they were currently taking any prescribed medication for any mental health related issues.

Gambling-related measures

DSM-IV criteria (Stinchfield, Govoni, & Frisch, 2005)

Stinchfield and colleagues' ten-item questionnaire based on the DSM-IV criteria was used to determine if participants met the diagnosis for pathological gambling. Response options of yes or no are summed and a positive response on five or more items indicates a classification of pathological gambling (Hodgins & Stinchfield; 2008).

Problem Gambling Severity Index (PGSI) (Ferris & Wynne, 2001)

The PGSI is a nine-item scale designed to measure problem gambling. Using a 12-month time frame, responses are based on a 4-point Likert scale ranging from '0=never' to '3=almost always'. Scores on each item are summed and categorised as non-problem gambling (score of 0), low level of problem with few or no identified negative consequences (score of 1-2), moderate level of problems leading to some negative consequences (score of 3-7) or problem gambling with negative consequences and a possible loss of control (score of 8 or more). The original psychometric study reported by Ferris and Wynne was based on a General Canadian population sample of 3,120 people. Cronbach's alpha was found to be 0.84 and Test-retest reliability was 0.78.

Other gambling-related measures

- Family history of problem gambling
- Problem gambling duration, measured in years
- Current gambling related debts
- Preferred gambling activity

Psychological wellbeing measures

Kessler 6 (K6) (Kessler et al., 2002)

The K6 is a six-item scale that assesses non-specific psychological distress, over the previous month. Items are rated on a 5-point Likert scale, ranging from '0=none of the time' to '4=all of the time'. Scores for each item are summed and based on the overall scores participants are classified into low, moderate, high or very high risk. A score of 12 or greater constitutes a very high risk. The K6/ K10 tools are widely used and are recommended by the Australian Bureau of Statistics (2012). The K6 is now included in the US National Health Interview Survey and the National Household Survey on Drug Abuse.

Depression, Anxiety and Stress Scale – 21 (DASS-21) (Lovibond & Lovibond, 1995)

The DASS is a self-report questionnaire that measures the severity of a variety of symptoms, over the previous week, which is common to depression, anxiety and stress. For this trial, we used the 21-item version (DASS-21), as it takes less time to administer and it has excellent psychometric properties (Antony, 1998). Each of the three subscales (depression, anxiety and stress) contains seven items. These items are rated on a 4-point Likert scale, ranging from '0=did not apply to me at all' to '3=applied to me very much, or most of the time'. The scores for each subscale are calculated by summing the scores of the relevant items and then multiplying them by 2. The classifications according to degree of severity for the DASS-21 subscales include normal, mild, moderate, severe and extremely severe, with the cut-off points varying for each subscale. The DASS has excellent psychometric properties and is used widely (Brown, Chorpita, Korotitsch, 1997).

Other Addiction measures

Alcohol Use Disorders Identification Test (AUDIT) (Babor, Higgins-Biddle, Saunders, & Monteiro, 2001)

The AUDIT is a 10-item scale used as a screening tool for risky drinking behaviours. The AUDIT provides an overall score that indicates the level of risk associated with an individual's drinking and three sub-scores (consumption, dependence and alcohol-related problems) that also provides useful clinical information. The items are rated on a 5-point Likert scale. The alcohol dependence and alcohol-related problems subscales have a 12-month timeframe. An overall score on the AUDIT can be calculated by summing the scores for each item. Overall scores of eight or above indicate a level

risky or hazardous drinking, with a score of 20 or above indicating a high-risk level. Psychometric studies are indicative of a robust tool².

Substance Use

Participants were asked about their past year substance use, including tobacco products and illicit substances. Responses included daily (or almost daily), weekly, monthly, less than monthly or not at all in the past 12 months.

Clinical training and treatment integrity

In order to ensure high treatment integrity a number of actions were implemented. First the selection criteria for participating clinicians ensured that all clinicians were registered psychologist with the Australian Health Practitioner Regulation Agency (AHPRA) and hence had a significant level of professional attainment in their experience and training.

Manuals were developed for each of the four psychological interventions and each of these manuals were subjected to review by content specialists and two Fellows of the Australian Psychological Society.

Notwithstanding the quality of the practitioners and the preparation of the manuals a significant investment was also made in the training and supervision of clinician participants. Clinician participants attended at least three group meetings where the detail of the manuals were reviewed and discussed. The clinicians had input into the manuals before they were finalised. Many useful improvements were implemented.

All clinical sessions for all participants were recorded using a digital recorder supplied for this purpose and a recording protocol developed by the researchers was implemented. The client participants formally consented to these arrangements. This has generated a massive clinical interaction database.

For the purposes of the trial, a Fellow and a Member of the Australian Psychological Society conducted an audit of the recordings for all clinicians. Recordings were stratified randomly sampled from the first four sessions for each clinician. The assessors independently scored the sessions and a compliance measure was extracted from the analyses using a check sheet developed for the purpose. The same sheet was used for all sessions. All participating clinicians achieved more than the targeted

² Reinert D.F., Allen J.P. (2007). The alcohol use disorders identification test: an update of research findings. *Alcohol Clin Exp Res.* 31(2):185-99.

90 per cent adherence across their sessions. It was initially the intention in a later study to model the relationship between fidelity and treatment outcomes but this was discontinued because it is highly likely that such modelling would not reveal interesting results because of the low variability in intervention outcomes and a similarly low variability in (lack of) adherence.

Data analysis concepts and methods

Statistical analyses were conducted using IBM SPSS Statistics 21. For baseline demographics and clinical characteristics the mean and SD were used to summarise quantitative data. Where quantitative data was asymmetrically distributed the median and inter-quartile ranges are given. For categorical data, numbers and proportions are reported. Attrition in the study was actually very low as outlined in the study recruitment flowcharts. We took the following approach to various key analysis design questions.

Treatment of missing data

- Neither substitution nor synthetic estimation methods were used to replace missing data. Missing data was excluded on a pair wise rather than list wise method in order to maintain sample integrity.

Treatment of outliers

- No trimming or data modification was employed in order to preserve the integrity of data and the sample. However log (10) transformations were applied to skewed distributions in order to improve adherence to normality distribution assumptions.

Responders and non-responders

- No categorisation occurred of responders using any pre-specified clinical cut-off scores. The n and % of individuals that improved, deteriorated or stayed the same was reported.

Analysis methods for participants receiving fewer than six therapy sessions

The primary analysis was intention-to-treat (ITT) to investigate any statistically significant differences in primary outcomes over time for the sample as a whole, for each of the treatment arms, and whether there was an interaction between time and group. The ITT principle preserves the benefit of randomisation where all individuals are included in the analysis, in the groups to which they were randomised to avoid potential effects of participants having fewer than six treatment sessions. As previously outlined the great majority (84 per cent) of participants did not vary the number of sessions. This analytical approach is considered to be a central tenet of pragmatic trial methodology.

Statistical analysis methods

There is a considerable discussion in the clinical trials literature as to the most appropriate methods for statistical analysis of trials data. While it is generally accepted that Randomized Controlled Trials are the soundest design for assessing the effectiveness and efficacy of treatment interventions, there are quite varied approaches advocated for the analysis of RCT data.

The different approaches form the basis for an active technical discussion in the RCT Methodology literature. The choice of methods for the reporting of the findings of the current study were informed by this literature in terms of the necessity for the use of defensible and sound techniques as well as the necessity for accessible and clear presentation of the data. The users of the present report span a wide range of people including the general community, treatment professionals, scientists, funders and government. Thus while we have maintained high technical standards we have also been mindful of the need for clear and accessible presentation of the study findings.

Read, Kendall, Carper & Rausch (2013) in the Oxford Handbook of Research Strategies for Clinical Psychology reviewed alternative statistical analysis methods for Pretreatment, Post-treatment, Follow-up studies. They reviewed ANOVA, MANOVA, ANCOVA, MANCOVA and hierarchical linear modeling as alternative analysis methods for longitudinal clinical trial data. There was no clear “winner” as each technique has advantages and disadvantages. For example ANCOVA has attracted criticism over an extended period because of the risk of over estimation of effects sizes under certain conditions (see Egger et al, 1985) and it remains a very widely used analysis technique in trials. Yet in 2014, Egbewale, Lewis & Sim reviewed a range of different analytical approaches for RCTs including those with baseline imbalance (a common occurrence in small trials) by conducting extensive simulations and concluded:

"Across a range of correlations between pre- and post-treatment scores and at varying levels and direction of baseline imbalance, ANCOVA remains the optimum statistical method for the analysis of continuous outcomes in RCTs, in terms of bias, precision and statistical power".

We have opted to present ANOVA and ANCOVA based analyses in this report because of their robustness, simplicity and widespread use and their “fit” with the research objectives being considered in this report.

Outcome prediction study analyses

The study included consideration of two key study outcomes, relapse and dropout. **Relapse** was defined as:

“More than one episode of gambling after a period of abstinence or controlled gambling”

Dropout was defined at the three stages in the study as follows:

Pre-treatment

- *Provided informed consent and either withdrew before baseline data collection or before receiving any treatment sessions*

During treatment

- *Started treatment but did not finish the 6 sessions*

Follow-up dropout

- *Withdrew from the post-treatment data collection interview onwards*

A suite of statistical analyses was performed with the following aims:

1. Identify and examine the extent to which participant, treatment and therapist characteristics are predictive of relapse at post-treatment, 6 and 12 months follow-up.
2. Identify and examine the extent to which participant, treatment and therapist characteristics are predictive of dropout from psychological treatment for problem gambling.

The predictor variables utilized in the analyses were as follows:

Socio-demographic	Gambling-related	Psychological	Treatment or therapist
(Older) Age	Debt	Alcohol use	# of sessions attended
Gender	Erroneous cognitions	Anxiety	Treatment goal
Marital status	Family history of PG	Coping skills	Therapeutic alliance - participant
	Gambling behaviours	Depression	Therapeutic alliance - therapist
	Gambling symptom severity	Impulsivity	Years of counselling experience
	Self-efficacy (abstinence)	Psychological distress	Previous experience treating PGs
	Preferred gambling activity	Quality of life	
	Urges	Social support	
		Stage of change	
		Stress	
		Substance use	

Table 13: Predictor variables for outcome prediction study

The analysis approach was based on Fabricatore's two stage method namely:

- All variables were initially examined as uni-variate predictors while controlling for the effect of treatment
- Those approaching significance ($p < .10$) were included in the multivariate model

Thus in this method, the performance of potential predictor variables is examined using uni-variate methods and if they pass the criterion of $p < .10$ they are included in the multivariate modeling.

The relapse and dropout outcomes were distributed in the study sample as follows:

Table 14: Relapse and dropout outcomes in the study

Outcome	Pre-treatment	Post-treatment	6-months	12-months
Relapse, n (%)	NA	85 (70.8)	70 (77.8)	75 (79.8)
Outcome	During treatment	Follow-up		
Dropout, n (%)	56 (20.51)	43 (14.53)	NA	NA

At first glance relapse rates could be considered to be high but the definition of relapse being “*More than one episode of gambling after a period of abstinence or controlled gambling*” is very generously inclusive. The measures of gambling frequency, spend, time spent gambling and GSAS symptom scores provide a quite different picture of treatment outcomes.

In the analyses for predictors of post treatment relapse the following outcomes were obtained:

Table 15: Immediate post treatment outcome predictors analysis

Variable	OR	95% CI	p
(Older) Age	1.05	1.01-1.09	.01*
BCOPE Behavioural Disengagement	1.35	.86-2.10	.19
BCOPE Substance use	1.45	1.04-2.03	.03*
Gambling Frequency	1.06	1.01-1.12	.03*
GRCS Inability to stop gambling	1.13	.70-1.83	.62
GSAS total	.97	.83-1.13	.68
Gambling Urge	1.18	.83-1.67	.36
Treatment goal	5.56	1.63-18.95	.01*

- The full model was statistically significant $\chi^2(11, n=120) = 48.62, p<.01$.
- The model explained 33.3% - 47.5% of variance
- Correctly classified 79.2% of cases

Thus, (older) age, substance use, gambling frequency and the treatment goal were predictive of post treatment relapse.

For the predictors of relapse at 6 months the following results were obtained.

- The full model was statistically significant $\chi^2(8, n=90) = 33.15, p<.001$.
- The model explained 30.8% - 47.2% of variance
- The model correctly classified 86.7% of cases

Older age, substance use and treatment goal persisted as predictors at the 6 month follow up

Table 16: 6 Month outcome predictors analysis

Variable	OR	95% CI	p
(Older) Age	1.07	1.01-1.13	.02*
BCOPE Humour	1.29	.93 – 1.77	.12
BCOPE	1.43	1.01 – 2.05	.04*
Substance use			
Substance use	.47	.11 – 1.96	.30
Treatment goal	10.86	2.26-52.13	.00*

For the predictors of relapse at 12 months the following results were obtained.

- The full model was statistically significant $\chi^2(8, n=94) = 29.93, p<.001$.
- The model explained 27.3% - 43.0% of variance
- The model correctly classified 83.0% of cases

Table 17: 12 Month outcome predictors analysis

Variable	OR	95% CI	p
AUDIT	1.14	1.01 – 1.30	.14
BCOPE	.88	.62 – 1.25	.46
Instrumental Support			
DSM-IV total	.82	.59 – 1.14	.23
Gambling Frequency	1.08	.98 – 1.10	.24
Treatment goal	9.75	1.83 – 51.97	.01*

Treatment goal was the only significant predictor at the 12-month follow up data collection.

The analyses of dropout rates were conducted using the same stepped analytical framework and predictor set.

The analyses of pre-treatment dropout showed no socio-demographic differences in age, sex, country of origin, nor language.

Table 18: Analysis of demographic factors impact upon pre-treatment dropout

Variable	Pre-treatment dropout	Did not dropout before treatment	p value
(Older) Age M (SD)	44.59 (15.51)	49.88 (14.13)	.06
Male gender n (%)	20 (68.97)	147 (53.85)	.12
Born in Australia n(%)	18 (60.00)	154 (56.41)	.71
English main language n (%)	29 (96.67)	255 (93.41)	.48

The analyses of during treatment dropout provided the following results:

- The full model was statistically significant $\chi^2(8, n=272) = 20.02, p<.01$.
- The model explained 7.1% - 11.1% of variance
- The model correctly classified 80.1% of cases

Substance use was the only statistically significant predictor of during treatment dropout.

Table 19 Analysis of predictors of during treatment dropout

Variable	OR	95% CI	p
(Older) Age	.99	.97 – 1.01	.36
BCOPE Substance use	.81	.68 - .95	.01*
Substance use	2.38	1.19 – 4.78	.01*
Stage of change ^a			
Preparation stage of change	1.61	.77 – 3.37	.21
Action/ maintenance stage of change	.77	.33 – 1.80	.55

Analyses of follow up dropout revealed:

- The full model was statistically significant $\chi^2(19, n=296) = 89.74, p<.001$.
- The model explained 26.2% - 46.4% of variance
- The model correctly classified 91.2% of cases

Table 20: Analysis of predictors of follow up dropout

Variable	OR	95% CI	p
Age	.99	.97 – 1.03	.90
Number of sessions attended	.51	.43 - .61	.00*
Gender	.66	.26 – 1.71	.40
Expenditure	1.00	1.00-1.00	.27
BCOPE self-blame	.80	.64 – 1.01	.06
DASS-21 Anxiety scale	1.04	.99 – 1.09	.17

The number of sessions attended was the only statistically significant predictor of follow up dropout.

All of the models achieved statistical significance, with slightly different results across the different time frames. BCOPE substance use was the most frequently identified predictor and it is unsurprising that substance use may influence participation in a treatment study. However, notwithstanding the fact that all of the models reached statistical significance, one must also examine the magnitude of the effects revealed by the analyses. In sum, the odds ratios show that they were modest in effect size. Dropout and relapse were not strongly predictable from Socio-demographic, Gambling-related, Psychological nor Treatment or therapist variables.

Pilot study results

The pilot study was conducted as a separate exercise to the main data collection with the objective of determining the feasibility of the study methodology and protocols. 23 participants took part in the pilot and completed the intake, baseline interview, assignment, treatment and post treatment interview components of the study. The results of the pilot study are reported in the following section of this report.

23 participants completed the base line intake interview. The psychology trained Research Assistants for the Project undertook the screening interviews and the baseline interviews. The intake interview was the same as that used in the full study.

No difficulties were reported with comprehension or completion of the interviews. Two respondents reported some perceived degree of repetition of items (which is actually the case because we were using several tools designed to measure Problem Gambling acuity and diagnosis) but this was not cause for complaint from the participants. The interviews ranged from 30 to 40 minutes in length and were conducted by our psychology trained research staff.

The data file involves some 329 data fields and was programmed in SPSS. The data were entered first into a Microsoft Access database for error-checking and validation capability and were then transferred to SPSS. Double and independent checking was implemented for all data to ensure accuracy. The psychology research assistants undertook the data entry and cleaning.

Pilot quantitative baseline data collection

The pilot baseline results were as follows:

- There was an equal distribution of males and females.
- The ages of participants ranged from 29 to 79
- The majority of participants wished to cease gambling altogether
- A range of triggers for seeking treatment was identified mostly centring on lack of money

- Half of the participants had never previously sought treatment for problem gambling
- Almost 2/3 of the respondents had been treated for other mental health problems
- Length of time for the gambling problem ranged from less than year to 43 years

Entry to treatment and quantitative post-treatment data collection

23 participants were randomly assigned to one of the four treatment groups- Cognitive Behaviour Therapy (CBT), Motivational Interviewing (MI), Behaviour Therapy (BT) and Client Centred Therapy (CCT)

Two participants dropped out of treatment. Both specified that difficulty travelling to treatment sessions was the reason for their dropout. One participant received 1 treatment session the other received 0. Therefore we had 21 active participants for the pilot.

Participants completed the End of Treatment interview after completing treatment for their problem gambling. The Research Assistants conducted the End of Treatment Interviews.

No difficulties were reported with comprehension or completion of the interviews. The interviews ranged from 30 to 40 minutes and were conducted by our trained research staff.

The End of Treatment data file involved 298 fields and was programmed in SPSS. The data were entered into a Microsoft Access database for error checking and validation.

The results for the end of treatment pilot were as follows:

- Most of the participants considered their amount of gambling over the treatment period to be completely acceptable given their current recovery goals.
- After being treated for gambling problems 37% of participants did not gamble again.
- More than half of the participants reported that they have a less severe gambling problem before beginning treatment.
- Overall gambling activity and spending reduced after treatment as well as gambling related symptoms

The qualitative component of the pilot study

Background to the qualitative study

This qualitative study aimed to add considerable depth and detail to our understanding of individuals' experiences with problem gambling treatment. This approach was intended to help to shed light on how individuals experience treatment, their outcomes, and the interactions between their treatment and the social contexts in which they live.

The qualitative study was intended to:

- Provide evidence on the subjective experience of receiving treatment;
- Provide insights into how change is achieved and the factors that may constrain or facilitate this change over time;
- Help to understand why there may be heterogeneity in outcomes.

Specifically the qualitative study was guided by three research questions:

1. How do problem gamblers experience treatment aimed to help treat and support them with their gambling problem?
2. What are the barriers and facilitators that individuals experience within treatment?
3. Is there any significant interplay between an individual's social and personal contexts, their experiences within the treatment, and their short and long-term outcomes after treatment?

Qualitative data analysis and reporting

A one page summary of each interview was written by the scribe immediately following each interview, reviewed by the interviewer, and amended as required. All qualitative interviews were audio-recorded. A professional transcription company transcribed the semi-structured interviews. NVivo 10 was used to manage the qualitative data. Demographic descriptives for each participant were also entered to enable future analysis according to different variables. Data were subjected to a preliminary thematic analysis.

Verbatim quotes were used to illustrate the findings. Data was de-identified where relevant and pseudonyms were used to protect the anonymity of the participants.

Training and fidelity

The interviewers involved in the qualitative component, were all part of the qualitative research team, and were fully briefed regarding the data collection process. The two members of the research team debriefed after each interview in relation to the content and process of the interview. The full qualitative research team convened twice, at the completion of both pre-treatment and post-treatment interviews, to discuss and critique the process.

Conclusions for the pilot study

The pilot was considered to be successful. No specific issues were identified relating to the smooth conduct of the ensuing study that would require change to the protocols. Accordingly both the quantitative and the qualitative study protocols were not amended and the study commenced as planned.

Study A: Pragmatic effectiveness trial – Results

Participant recruitment outcomes and attrition

The final study outcomes for the flow of participants through each stage of the study is shown in the figure below. 260 participants completed the treatments and provided post treatment data, 249 participants, completed the 6 months follow up and 235 participants completed the 12 months follow up data collection. A feature of this study is the very modest loss to sample at the 12 months follow up.

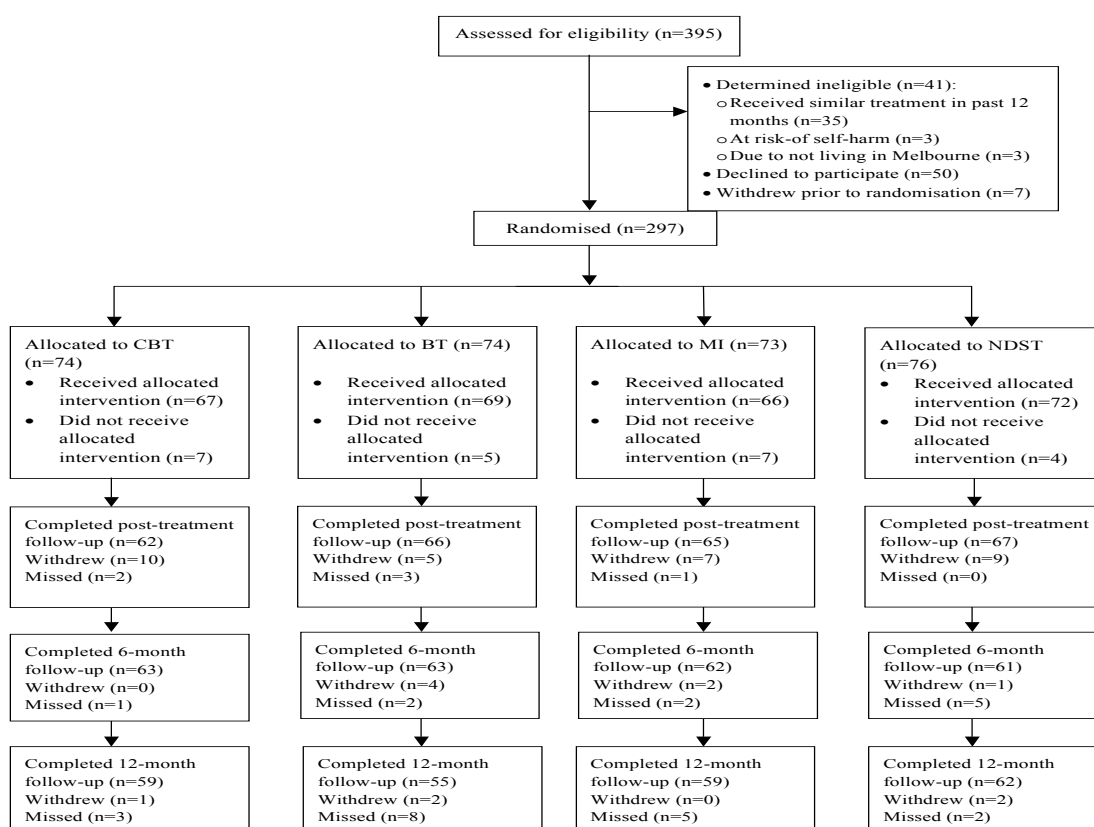


Figure 4 Participant flow chart for stages of the study

Enquiries were received from 442 people interested in taking part in the study. Just over half of participant enquiries were from advertisements placed in the Herald Sun newspaper. Google advertisements generated a further 67 participant enquiries. Figure 5, summarises the source of participant enquiries. The Herald Sun was by far the most effective recruitment channel.

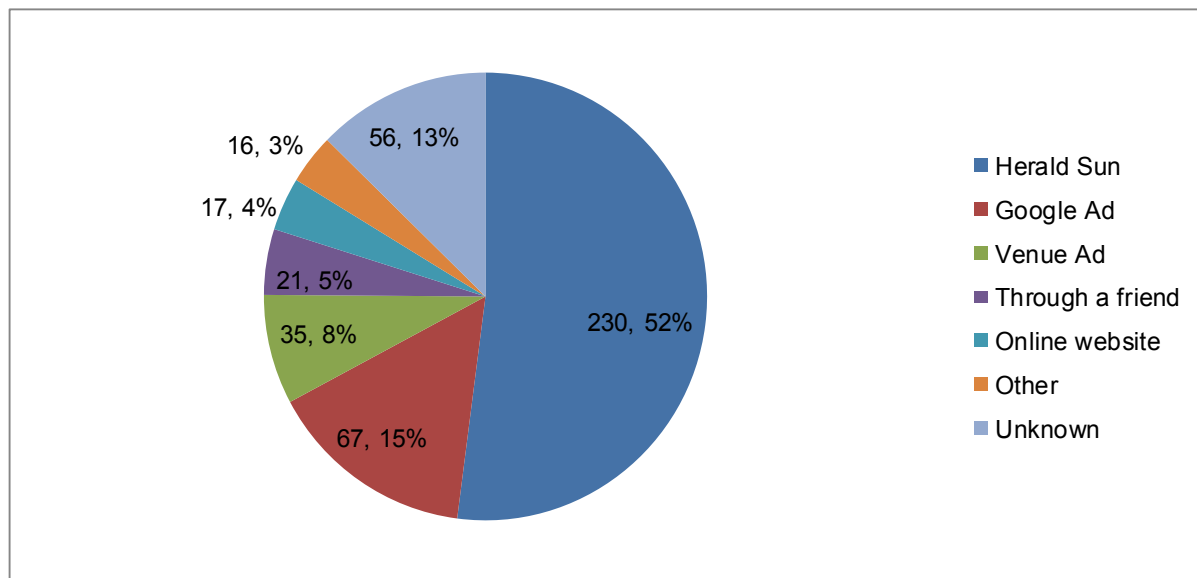


Figure 5 Recruitment source

The 442 participant enquiries were received between April 15th, 2012 and February 11th, 2014. Most enquiries were by telephone (n=304, 72%); the remainder were by email.

The main reason for exclusion from the PROGRESS study was receipt of psychological treatment for gambling problems within the past 12 months (n=35). This was not allowed under the study inclusion/exclusion criteria in order to avoid interaction effects with previous treatment. Three additional participants were excluded because they did not live in Victoria, and three participants were excluded because they were at current risk of self-harm.

Using permuted block randomisation, 74 participants were allocated to receive cognitive-behaviour therapy (CBT), 74 participants were allocated to receive Behaviour Therapy (BT), 73 participants were allocated to receive Motivational Interviewing (MI), and 77 participants were allocated to receive Client-Centred Therapy. Of the 297 participants randomised, 23 did not receive any treatment sessions. No significant differences were found between intervention starters and non-starters in terms of age ($p = .185$), gender ($p = .526$), treatment type ($p = 0.704$), instances of gambling in the past four weeks ($p = .776$), hours spent gambling in the past four weeks ($p = .402$), dollars spent gambling in the past four weeks ($p = .286$), or gambling symptom severity ($p = .890$).

Median time between baseline assessment and initial treatment session was 2.4 weeks, where 50% of participants had their initial treatment session between 1.6 weeks and 3.4 weeks after their baseline assessment. Most participants completed six treatment sessions (84%). Number of treatment sessions attended was not predicted by treatment type (chi-square = 14.10, $p = .518$). Overall, the median time for participants' involvement in treatment was 11.3 weeks, where 50% of participants had treatment duration between 5.4 weeks and 9.1 weeks (IQR = 3.7 weeks). The median time between sessions was 7 days, and 73% of sessions occurred between one and two weeks of the previous session. Eleven per cent of sessions occurred within a week of the previous session, and 17% of sessions occurred more than two weeks after the previous session. Median follow-up time was 1.4 weeks after the final treatment session for end-of-treatment assessment (50% between 0.7 and 2.7 weeks) and 26.1 weeks for six-month assessment (50% between 25.3 and 27.0 weeks). Thus the study timing adhered closely to the expected timing intervals.

Baseline data

Baseline characteristics for $n=297$ participants are shown in the following table.

The Productivity Commission Inquiry into Gambling (Productivity Commission, 2010) included a survey of clients of counselling agencies providing specialised gambling support services within each state and territory government. The data were based on responses from people who had sought assistance for problems with their problem gambling, and therefore represent a benchmark to determine the representativeness of the sample in the present study.

A chi-square goodness-of-fit test indicated there was no significant difference in the proportion of males identified in the current sample (55.0%) as compared with the value of 59% that was obtained in the previous nationwide survey, $\chi^2 (1, n=257) = 1.544$, $p = .214$. The PROGRESS sample tended to be older as compared with the sample in the previous nationwide survey, specifically we tended to have fewer participants in the 30-39 age group and more participants in the 60 years plus age group. This is likely because most of our participants were recruited through advertisements in the Herald Sun, a newspaper for which 31% of readers are Baby Boomers (News Australia, 2014). Using the DSM-IV criteria, 85.3% of the participants were diagnosed as pathological gamblers at baseline assessment. For the participants who did not meet problem or pathological gambling criteria, $n=1$ had a DSM-IV rating of one, $n=10$ had a DSM-IV rating of 2, $n=10$ had a DSM-IV rating of three and $n=12$ had a DSM-IV rating of four. Similarly, 88.3% of the participants scored in the problem gambling range based on the PGSI (score of 8 or more). There were no significant differences between treatment groups on any of the variables reported in the following table.

Table 21 Table of Baseline group socio-demographics and clinical characteristics (n=297)

Sociodemographic data	N (%)
Age (years) (mean, SD)	50.5(14.3)
Female	104(45.0)
<i>Relationship</i>	
Married/de facto	88(38.1)
Separated/divorced/never married	134(58.0)
Widowed	9(3.9)
<i>Education</i>	
University or college degree	70(30.3)
Trade/technical certificate/diploma	58(25.1)
Senior high school	42(18.2)
Junior high school	41(17.7)
Other	20(8.7)
<i>Employment</i>	
Full-time	102(44.2)
Part-time	26(11.3)
Casual/self-employed	23(10.0)
Full-time student	6(2.6)
Not working (full-time home duties/retired/pensioner/unemployed)	69(29.9)
Other	5(2.2)
<i>Income</i>	
Less than \$25,000	67(29.0)
\$25,000 to \$39,999	31(13.4)
\$40,000 to \$64,999	45(19.5)
\$65,000 to \$79,999	23(10.0)
\$80,000 to \$129,000	43(18.6)
\$130,000 or more	21(9.1)
Previous treatment	
Participation in a treatment program for gambling problems	96(46.6)
<i>Attendance at Gamblers Anonymous meetings</i>	
In the past 12 months	16(6.9)
More than 12 months ago	56(24.2)
Never	159(68.9)
Participation in treatment for tobacco use	11(4.8)
Participation in treatment for alcohol use	19(8.2)
Participation in treatment for drug use	6(2.6)
Participation in treatment for other addictions	5(2.2)
Participation in treatment for mental health problems	108(46.8)
Gambling data	
Pathological gamblers (DSM-IV criteria)	197(85.3)
Problem gamblers (PGSI score of 8 or more)	204(88.3)
Family history of gambling problems	102(44.2)
Years with a gambling problem (mean, SD)	13.9(10.1)
Poker machines/EGMs as preferred mode of gambling	150(64.9)
Any gambling-related debt	114(49.4)
Psychological well-being	
Kessler-6 within normal limits	155(67.1)
DASS-21 Depression within normal limits	103(44.6)
DASS-21 Anxiety within normal limits	142(61.5)
DASS-21 Stress within normal limits	146(63.2)
Drug and Alcohol Use	
AUDIT score within normal limits	141(61.0)
Daily tobacco use	55(23.8)
Weekly recreational drug use	23(10.0)

Effects of treatment group and time on key outcomes

Tables of means for constructed for all four primary outcome measures. These were then subjected to ANOVA and ANCOVA repeated measures analyses to examine whether there were time effects i.e. statistically significant changes in outcome measures over time (pre-treatment (t_0), post treatment (t_1), 6 months post treatment (t_2), and 12 months post treatment (t_3) and whether there were differences across the four treatment groups (CBT, BT, MI, CCT) and whether there were interactions between these effects i.e. whether some treatments resulted in different patterns of change. The following table includes the means for the gambling frequency measures for the treatment groups across t_0 to t_3 .

Table 22 Table of raw means for gambling behaviour measures for all treatment groups for pre-treatment, post treatment, 6 months following treatment and 12 months following treatment

	Group	Gambling frequency (Occasions per 4 weeks)		Gambling time (hours per 4 weeks)		Amount Lost (AUD per 4 weeks)	
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Baseline ($t=0$)	CBT	74	18.67 (17.63)	74	31.55 (25.77)	73	\$3,577 (4,033)
	BT	74	17.81 (13.93)	74	38.74 (45.41)	74	\$4,648 (7,420)
	MI	73	18.74 (16.12)	73	42.73 (61.12)	73	\$4,667 (7,048)
	CCT	76	16.14 (18.94)	76	28.11 (31.86)	76	\$4,382 (6,808)
	Total	297	17.82 (16.73)	297	35.21 (43.26)	296	\$4,320 (6,457)
Post-treatment ($t=1$)	CBT	62	9.56 (10.83)	62	15.63 (21.81)	62	\$4,190 (22,792)
	BT	66	8.20 (7.28)	66	13.92 (18.9)	66	\$1,827 (4,651)
	MI	65	11.00 (11.97)	65	21.19(30.75)	65	\$1,690 (3,305)
	CCT	67	9.52 (12.30)	67	14.93(27.37)	67	\$1,859 (3,341)
	Total	260	9.57 (10.77)	260	16.41 (25.18)	260	\$2,365 (11,592)
Six month ($t=2$)	CBT	63	10.75 (14.74)	63	15.33 (19.95)	63	\$1,819 (3,371)
	BT	63	9.14 (8.48)	63	16.38 (21.67)	63	\$2,526 (8,072)
	MI	62	10.79 (11.59)	62	14.56 (20.06)	62	\$2,219 (6,413)
	CCT	61	10.51 (11.77)	61	15.53 (31.50)	61	\$1,419 (1,920)
	Total	249	10.29 (11.80)	249	15.46 (23.50)	249	\$2,000 (5,507)
12 month ($t=3$)	CBT	59	7.25 (9.80)	59	13.47 (18.13)	59	\$1,112 (1,579)
	BT	55	9.89 (10.70)	55	15.3 (19.06)	55	\$1,259 (2,329)

		Gambling frequency (Occasions per 4 weeks)		Gambling time (hours per 4 weeks)		Amount Lost (AUD per 4 weeks)	
	MI	59	12.27 (13.19)	59	20.93 (33.29)	59	\$3,220 (15,031)
	CCT	62	9.87 (11.44)	62	16.18 (27.36)	62	\$1,929 (4,073)
	Total	235	9.82 (11.43)	235	16.49 (23.35)	235	\$1,891 (7,943)

Thus the results show a robust post treatment drop in gambling behaviours across all treatment groups that is sustained up to the 12 month post treatment measurement point.

The following table includes the means for GSAS gambling symptom measures for all treatment groups for pre-treatment, post treatment, 6 months following treatment and 12 months following treatment.

Table 23 Table of raw means for GSAS symptom measures for all treatment groups for pre-treatment, post treatment, 6 months following treatment and 12 months following treatment

Gambling symptoms		GSAS total scores		GSAS urge scores		GSAS frequency scores	
	Group	n	Mean (SD)	n		Group	n
Baseline (t=0)	CBT	74	25.82 (7.01)	74	Baseline (t=0)	CBT	74
	BT	73	27.48 (8.17)	73		BT	73
	MI	72	26.14 (8.93)	72		MI	72
	CCT	76	26.14 (8.04)	76		CCT	76
	Total	295	26.40 (8.05)	295		Total	295
Post-treatment (t=1)	CBT	62	18.19 (8.86)	62	Post-treatment (t=1)	CBT	62
	BT	63	19.63 (9.11)	63		BT	63
	MI	65	17.37 (8.82)	65		MI	65
	CCT	66	18.48 (8.87)	66		CCT	66
	Total	256	18.41 (8.90)	256		Total	256

6 months (t=2)	CBT	63	18.10 (8.97)	63	6 months (t=2)	CBT	63
	BT	63	18.65 (9.18)	63		BT	63
	MI	62	16.65 (9.29)	62		MI	62
	CCT	61	20.16 (9.91)	61		CCT	61
	Total	249	18.38 (9.37)	249		Total	249
12 months (t=3)	CBT	59	17.81 (9.14)	59	12 months (t=3)	CBT	59
	BT	55	17.78 (11.73)	55		BT	55
	MI	59	17.74 (9.33)	59		MI	59
	CCT	62	18.19 (10.85)	62		CCT	62
	Total	235	17.89 (10.24)	235		Total	235

For the GSAS scores a similar pattern of results was observed, i.e. post treatment means fell and the reductions were maintained at the 6 month and 12 month data collection points.

The data for all four primary outcome measures were then subjected to statistical analysis.

The outcome measures of 'frequency', 'time' and 'expenditure' all demonstrated positively skewed data distributions. This meant that the raw data bunched closer towards the zero measure and had data points that more lightly scattered towards a larger number. To improve the accuracy of the repeated measures ANOVA analyses, these data were first transformed using a log function (base 10) to improve normality of the distribution. The analyses included all data. The analyses appear in the following table.

Table 24 Table of ANOVA results for longitudinal analysis for the outcome measures gambling 'frequency', 'time' and 'expenditure,' by time of assessment and treatment group (n=249)

Dependent Measure	Factor	Repeated measures ANOVA	Effect size (partial eta squared)
Frequency	Time (t ₀ , t ₁ & t ₂)	F(2,350) = 45.4, p < 0.001	0.21**
	Treatment group (CBT, BT, MI, CCT)	F(3, 175) = 0.6, p = 0.59	0.01
Time	Time (t ₀ , t ₁ & t ₂)	F(2,346) = 53.5, p < 0.001	0.24**
	Treatment group (CBT, BT, MI, CCT)	F(3, 173) = 0.2, p = 0.87	0.004
Expenditure	Time (t ₀ , t ₁ & t ₂)	F(2,338) = 48.6, p < 0.001	0.22*
	Treatment group (CBT, BT, MI, CCT)	F(3,169) = 0.1, p = 0.95	0.002
*Large effect, **medium effect			

The repeated measures ANOVA analyses indicated medium to large effects occurring over time in these outcome measures. Post hoc examination of the means showed that there was a significant decrease in all measures after therapy and this was maintained at the 6-month time point. There was no effects resulting from the treatment group and all interactions between time and treatment group were non-significant.

Repeated measures ANOVAs were conducted to investigate the effects of time and treatment group on GSAS scores. The following table summarises the repeated measures results for the GSAS outcome measures.

Table 25 Table of ANOVA results for longitudinal analysis for the GSAS symptom measures gambling 'total', 'urge' and 'frequency,' by time of assessment and treatment group (n=249)

Dependent Measure	Factor	Repeated measures ANOVA	Effect size (partial eta squared)
GSAS total	Time (t ₀ , t ₁ & t ₂)	F(2,434) = 98.3, p < 0.001	0.31*
	Treatment group (CBT, BT, MI, CCT)	F(3,217) = 1.3, p = 0.26	0.02
GSAS urge	Time (t ₀ , t ₁ & t ₂)	F(2,436) = 66.9, p < 0.001	0.24**
	Treatment group (CBT, BT, MI, CCT)	F(3, 218) = 1.1, p = 0.35	0.02
GSAS frequency	Time (t ₀ , t ₁ & t ₂)	F(2,440) = 72.2, p < 0.001	0.26*
	Treatment group (CBT, BT, MI, CCT)	F(3,220) = 0.6, p = 0.77	0.01
*Large effect, **medium effect			

This analysis included all data. There was a significant effect of time on GSAS score (F(2,436) = 66.9, p < 0.001) and post hoc examination of the means showed that there was a significant decrease in GSAS score after therapy and this was maintained at the 6-month time point. The effect size indicated that the effect from time was a large effect. There was no effect of treatment group on GSAS score (F(3,217) = 1.3, p = 0.26) and the interaction between time and treatment group was also non-significant. Similar results were obtained for two GSAS sub-scores (GSAS-urge score and GSAS-frequency score). There were significant effects from time but not group.

Thus the results for this trial are simple. All four treatment groups have experienced significant reductions in the behavioural and symptom gambling measures and these reductions have been sustained for 12 months.

The absence of a statistically significant effect does not unequivocally mean that there is no effect. This is why the consideration of statistical power is an important consideration in the discussion of null results. In the present study, the statistical power has been set at relatively stringent levels and there is sufficient statistical power in the current 6-month data to be relatively confident of the outcomes.

The achieved study sample well exceeds those required to set stringent levels. In addition, threats to the validity of the study such as differential attrition have been well controlled in this study.

The study has shown that durable impacts upon gambling behaviour and gambling symptoms were achieved and these impacts were unrelated to the treatment used i.e. there was no statistically significant treatment group differences but that all treatments achieved large time effects with a strong reduction in gambling behaviour and symptoms that has been maintained for at least six months for the whole group of study participants. The study showed that manualised psychological treatments delivered by well-trained psychologists resulted in durable and significant reductions in gambling behaviour (frequency, time spent and losses) and gambling symptoms were achieved. In this study, the reductions were unrelated to the type of psychological treatment used. The reductions obtained in gambling behaviour and symptoms were statistically significant and clinically large as shown in the following table.

Table 26 Table of findings for the PROGRESS trial outcome measures for the combined study sample at Baseline (t₀, n=297), Post treatment (t₁, n=260), 6 months (t₂, n=249) and 12 months (t₃, n=235)

Study Phase	Frequency (days gambled in a 4 week period)	Time (hours spent gambling in a 4 week period)	Spend (Net Loss AUD in a 4 week period)	GSAS Total
Baseline (t ₀ , n=297)	17.82 (16.73)	35.21 (43.26)	\$4,320 (6,457)	26.40 (8.05)
Post treatment (t ₁ , n=260)	9.57 (10.77)	16.41 (25.18)	\$2,365 (11,592)	18.41 (8.90)
6 months (t ₂ , n=249)	10.29 (11.80)	15.46 (23.50)	\$2,000 (5,507)	18.38 (9.37)
12 months (t ₃ , n=235)	9.82 (11.43)	16.49 (23.35)	\$1,891 (7,943)	17.89 (10.24)

From these data it can be inferred that over a 12-month period an “average” individual would gamble on 104 less days, spend 243 less hours gambling per year and they would save \$31,577 per year in losses. Of course there is high variability in the data so “average” losses certainly should not be construed to mean that all individuals would achieve those results. Some individuals would exceed these reductions and savings, whereas other individuals would achieve much less favourable results.

The interventions delivered in this study were manualised and delivered by experienced psychologists and hence caution should be exercised in generalizing the results to other clinician groups and also clinicians who are not using manualised interventions.

Notwithstanding these caveats, the magnitude and durability of the reductions in key outcome variables is a pleasing result. The interventions have achieved robust and sustainable reductions in gambling behaviours as measured by days gambled, time spent gambling, net losses and GSAS symptom scores.

Thus it has been found in this study that manualised psychological treatments specifically Behavioural Therapy; CCT: Client Centred Therapy; MI: Motivational Interviewing; CBT: Cognitive Behavioural Therapy, when administered by registered psychologists are effective in the treatment of problem

gambling and that the beneficial effects over the groups persist for at least 12 months.

Analysis of factors that may influence the therapeutic effects other than the treatments

One potential source of bias is individual differences in clinicians and in clinician client interactions.

Clinician Effects on Outcome Measures

In the present study the clinicians chose in conjunction with the researchers the type of treatment they were to deliver to their clients. The same treatment was delivered to all of their clients using the manuals supplied following briefings as to the specific treatments. The clinicians were experienced registered psychologists so the briefings were not primary “training” of the clinicians. 47 clinicians took part in the clinical delivery with contributions ranging from 1 client to 18 clients with an average of 6.6 and a median of 6 clients seen over the entire clinician group.

There were 47 therapists recorded in the data set and there were 26 (from 297) participants who had no therapist recorded. This preliminary analysis used a repeated-measures analysis of variance (ANOVA) to test whether effects differed between subgroups of therapists. For all four main outcome measures (GSAS, ‘frequency’, ‘time’ and ‘expenditure’) repeated measures ANOVA detected no effect from the therapist variable and no interaction effect with time. This was not unexpected given that therapists are clustered within treatment modalities and non-significant effects from treatment had already been seen.

For therapist, the time–subgroup interaction test on repeated measures ANOVAs was as shown for the following outcome measures:

- GSAS total, $F(76, 350) = 0.91, p=0.69$;
- ‘Gambling frequency’ outcome, $F(72, 272) = 0.98, p=0.54$;
- ‘Gambling time’ outcome, $F(72, 268) = 0.89, p=0.72$;
- ‘Gambling expenditure’ outcome, $F(72, 262) = 0.84, p=0.81$).

The gambling activity measures (frequency, time and expenditure) data were transformed using the log10 function to improve normality of the distributions. This simple analysis has very interesting implications because it suggests that whomever delivered the intervention the pattern of outcomes were not significantly affected.

Given the large numbers of clinicians in the study ($n=47$), the population variability of clinician skills is likely to be adequately represented in the study sample. But, notwithstanding this variability “clinician” is not a significant explanatory effect in the patterns of treatment outcomes in the simple analyses performed.

The impact of other psychological problems at baseline upon outcomes

Another factor that could potentially influence treatment progress is the existence of other psychological problems and addictions in the participant group especially if it is differentially distributed across different groups. There is strong evidence of comorbidities between problem gambling and psychological problems and addictions in the various epidemiological reviews that have been conducted concerning this link, some of which have been conducted by the present research group (e.g. Lorains, Cowlishaw, Thomas, 2011). However, because of the limited numbers of RCT studies that have been completed, there is little evidence of whether and how the existence of comorbidities might impact upon recovery from problem gambling as measured in this instance by outcome measures scores.

To address this issue, as outlined in the PROGRESS study methodology, various measures of psychological comorbidity were collected and then the four primary outcome measures were modelled using these measures as covariates. These analyses address the issue as to whether existence of comorbidities may impact upon treatment outcomes.

The measures that were included in this analysis were:

- The DASS three sub scales, depression, anxiety and stress.
 - A DASS sub-scale score of 10 and above indicated the presence of depression.
 - A sub-scale score of 8 and above indicated the presence of anxiety.
 - A sub score of 15 and above indicated the presence of stress.
- The AUDIT measures.
 - AUDIT score of 8 and above indicated a level of “risky” drinking.
 - A score of 20 and above indicated high risk drinking.
- Drug use reported occurring at least monthly during the previous 12 months before the baseline.
 - Yes drug use was reported
 - No drug use was not reported

The next table shows GSAS broken down by comorbidity status for psychological disturbance alcohol use and drug use at baseline, post treatment and at six months.

Table 27 GSAS total outcome measure broken down by comorbidity status for psychological disturbance alcohol use and drug use at baseline, post treatment and at six months

		GSAS mean (standard dev.)		
	N	Baseline (t ₀)	Post treatment (t ₁)	Six month (t ₂)
Total Sample	221	26.34 (7.95)	18.50 (8.99)	18.35 (9.35)
Depression_DASS				
No depression at baseline	98	23.43 (7.84)	15.86 (7.39)	16.81 (8.87)
Depression at baseline	123	28.66 (7.26)	20.60 (9.60)	19.58 (9.58)
Anxiety_DASS				
No anxiety at baseline	139	24.51 (7.59)	16.95 (8.10)	17.32 (8.71)
Anxiety at baseline	82	29.44 (7.61)	21.12 (9.83)	20.10 (10.17)
Stress_DASS				
No stress at baseline	128	24.20 (7.67)	16.91 (8.41)	17.10 (8.66)
Stress at baseline	93	29.28 (7.38)	20.68 (9.34)	20.06 (10.02)
Risk drinking AUDIT				
No risk at baseline	137	25.40 (7.86)	18.23 (9.28)	17.83 (9.42)
Risk at baseline	84	27.87 (7.89)	18.93 (8.52)	19.19 (9.24)
High risk drinking AUDIT				
No high risk at baseline	205	26.16 (7.90)	18.49 (8.99)	18.05 (9.32)
High risk at baseline	16	28.64 (8.44)	18.63 (9.19)	22.19 (9.20)
Drug use in previous year				
No drug use	196	26.38 (7.85)	18.40 (9.27)	18.11 (9.53)
Drug use	25	26.00 (8.83)	19.24 (6.42)	20.20 (7.77)

The same analyses were repeated for the three other primary outcome measures namely Gambling frequency (days gambled in a 4 week period), Gambling time (hours spent gambling in a 4 week period) and Spend (Net Loss expressed in AUD in a 4 week period). Tables of means for all the three measures were constructed and subjected to the same analyses. The results for all these analyses are summarised below.

Summary of results for comorbidity sub group interaction tests:

- For baseline depression, the time–subgroup interaction test on repeated measures ANCOVAs with outcomes of ‘gambling frequency’ i.e. $F(2, 354) = 0.86, p=0.42$; ‘time spent gambling’ i.e. $F(2, 350) = 0.83, p=0.44$; and ‘AUD loss expenditure’ i.e. $F(2, 342) = 0.94, p=0.39$.
- For baseline anxiety, the time–subgroup interaction test on repeated measures ANCOVAs with outcomes of ‘freq’ i.e. $F(2, 354) = 0.37, p=0.70$; ‘time’ i.e. $F(2, 350) = 0.54, p=0.58$; and ‘expenditure’ i.e. $F(2, 342) = 0.28, p=0.76$.

- For baseline stress, the time–subgroup interaction test on repeated measures ANCOVAs with outcomes of 'freq' i.e. $F(2, 354) = 0.53$, $p=0.604$.; 'time' i.e. $F(2, 350) = 0.35$, $p=0.70$.; and 'expenditure' i.e. $F(2, 342) = 1.5$, $p=0.23$.
- For baseline RISK, the time–subgroup interaction test on repeated measures ANCOVAs with outcomes of 'freq' i.e. $F(2, 354) = 1.4$, $p=0.26$.; 'time' i.e. $F(2, 350) = 1.6$, $p=0.20$.; and 'expenditure' i.e. $F(2, 342) = 3.03$, $p=0.05$.
- For baseline HIGH RISK, the time–subgroup interaction test on repeated measures ANCOVAs with outcomes of 'freq' i.e. $F(2, 354) = 2.8$, $p=0.07$.; 'time' i.e. $F(2, 350) = 1.3$, $p=0.28$; and 'expenditure' i.e. $F(2, 342) = 4.2$, $p=0.02$
- For baseline reported drug use as more than monthly in previous year, the time–subgroup interaction test on repeated measures ANCOVAs with outcomes of 'freq' i.e. $F(2, 354) = 0.56$, $p=0.57$.; 'time' i.e. $F(2, 350) = 0.87$, $p=0.51$; and 'expenditure' i.e. $F(2, 342) = 2.37$, $p=0.09$

These results indicate that the comorbidities used in this analysis did not provide additional statistical explanatory power tracking the progression of the participants over the time stages of the study. This does not suggest that comorbidity is not an important issue in the onset and treatment of problem gambling *but the data presented using the analysis model adopted show that there are not statistically significant effects in this study in terms of effects upon treatment outcomes.*

Thus two sets of factors that may impact upon the results obtained have been examined in this section. The first factor was "clinician" and the omnibus analyses demonstrate that there were not statistically detectable effects for clinician in this study. The second set of factors were comorbidities including depression, anxiety and stress as measured by the DASS, alcohol use as measured by the AUDIT and reports of drug use. These analyses also did not reveal significant effects upon the participant outcomes. Thus, these two major areas of potential impact upon outcomes were found to be not statistically significant in the reported analyses. Of course the absence of an effect may also be explained by a lack of statistical power to detect it or sample bias amongst other explanations. Nevertheless this is one of the largest (in terms of sample size) RCT studies of psychological treatments in problem gambling.

Study B: Qualitative study – Research methods

Study design

This qualitative study (Study B) was conducted alongside Study A, and was designed to provide a comprehensive picture of the variability and depth of individuals' experiences of psychological treatment for problem gambling. This qualitative approach provided participants with the opportunity to give a detailed and nuanced account of how they had experienced the treatment, and the outcomes, in the context of their own lives. The qualitative account also provided significant information regarding the participants' social, financial and health circumstances.

Aim of the qualitative study

The aim of the qualitative study was to explore and understand the perceptions of treatment by the participants, and in particular the barriers and facilitators that may have prevented or enabled change over time.

More specifically, the qualitative study aimed to:

- Provide evidence on the subjective experience of receiving treatment;
- Provide insights into how change is achieved and the factors that may constrain or facilitate change over time;
- Provide qualitative evidence for the diversity in treatment outcomes.

Recruitment and sampling

Interest for participation in the qualitative study was ascertained concurrently as participants were recruited for Study A. As people enquired about treatment, they were also informed, in addition to the plain language statement, that additional interviews would be conducted with a subgroup of participants. Hence, participants were self-selected. All participants who participated in the qualitative study signed a separate consent form.

In selecting participants for inclusion into the qualitative study, our primary aim was to ensure that the sample included a diverse range of participants with regard to four key participant characteristics: treatment arm, age, sex and gambling severity. It was not our aim to make comparisons according to these characteristics. A sampling matrix (Figure 6) was constructed to guide the recruitment according to these four characteristics so that the qualitative sample was broadly representative of the full treatment sample in Study A (25% from each treatment arm, 40% females, 40% aged 55 years and under, and 88% with a PGSI score of 8 or over). The total number of participants recruited into the

qualitative study was determined by the capacity of the research team to conduct interviews, as well as being deemed sufficient in number to capture a comprehensive picture taking into account potential attrition.

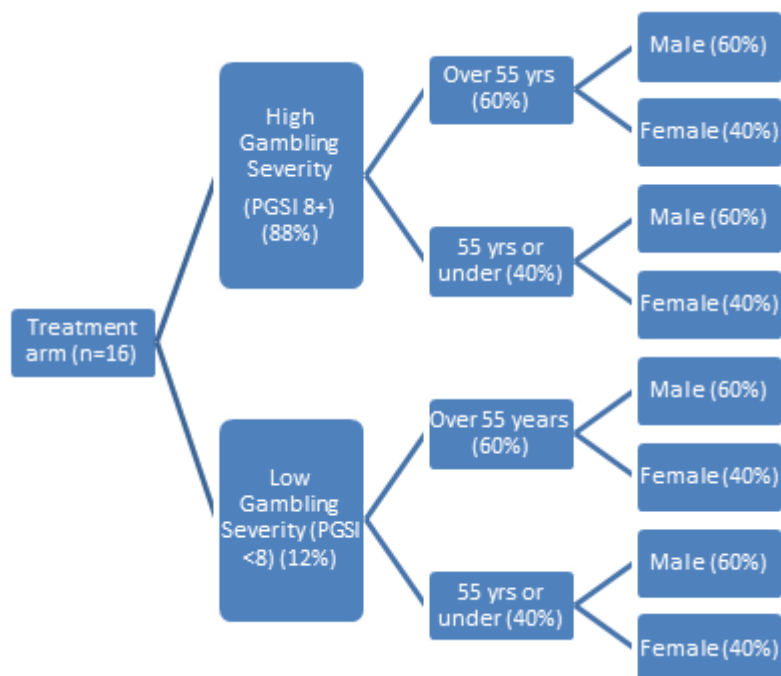


Figure 6 Sampling guide for Qualitative Study (B) recruitment for each treatment arm at pre-treatment

Data collection

The qualitative study comprised semi-structured interviews at 3 data collection points. Interviews were administered face to face, and took between 40 and 60 minutes to complete. The time points and number of participants are summarised in Table 28. Sixty-six participants were interviewed at pre-treatment, and 56 of them were interviewed immediately after treatment. Ten participants were not available for the post-treatment interview. If participants did not complete their treatment, they were still invited to participate in subsequent interviews. For the purpose of this report, which focuses on the experience of treatment, the analysis is primarily based on the post-treatment interview data.

Table 28 Data collection points for the qualitative interviews

Data collection point	Number of participants
Pre-treatment	66 (final)
Post-treatment	53 (final)
12 months post-treatment	47 (final)

The interviews were conducted by experienced members of the qualitative research team at a location convenient to both the participant and interviewer. Participants were allocated to the same interviewer for the duration of the study, a research strategy to promote rapport and continuity for the duration of the investigation. The three members of the qualitative team who conducted interviews took part in a training session and were fully briefed regarding the conduct of the interviews.

The broad aim and focus of each of the three interviews are outlined below.

The aim of the pre-treatment interview was to explore:

- The perceived impact that gambling has on the participant's life;
- Reasons for seeking treatment and their expectations of treatment;
- Their experiences with previous treatments;
- Their goals and expectations for treatment, and what constitutes a successful outcome; and
- Any foreseen barriers or enablers that may influence the treatment process.

The aim of the post-treatment interview was to explore:

- The participant's experience of the treatment and especially what was useful and/or not useful;
- Any changes (e.g. in gambling behaviour, quality of life) as a result of treatment; and
- How the current treatment compared with previous treatment they may have undertaken.

The aim of the 12-month post-treatment interview was to explore:

- Current attitudes to gambling and gambling participation post-treatment;
- Reflections of treatment and its impact on participants' lives; and
- Intentions to receive further treatment.

The interview schedules for all the interview interviews are included in the Appendices (Appendix 1-3). They include questions that were used as prompts for discussion.

Prior to conducting the interviews, participants were given an explanatory statement and had the qualitative research study explained to them by the interviewer. Participants were also given the opportunity to read and have any questions answered before they signed a consent form. All participants who took part in an interview were offered a \$50 voucher (which could be used at a well-known chain of retail stores) upon completion of each interview. The voucher was a means to compensate participants for their time and travel costs, and to engage them in long term follow up data collection post-treatment, in recognition that this is a hard to reach client and research population.

Data analysis and reporting

A one page summary and field notes were written-up immediately following the completion of each face-to-face interview. All qualitative interviews were audio-recorded and subsequently transcribed by a professional transcription service. NVivo 10 was used to manage and code the qualitative data (QSR International Pty Ltd, 2010).

Two analytical processes were used in the qualitative component of this study. First, is the well-established technique of thematic analysis. Systematic analysis of the post-treatment interview summaries and transcripts generated a wide range of both broad and more specific key themes in line with the central aims of the qualitative investigation (Lincoln & Guba, 1985).

The qualitative interviews also generated data for the identification and development of the second analytic process, in-depth case studies. Case studies better illustrate individual participant's trajectories through the experiences of treatment and post-treatment outcomes (Henderson, Holland, McGrellis, Sharpe, & Thomson, 2012). In this report the cases were not selected for generalisation or representativeness, but rather chosen to illustrate individual trajectories in relation to problem gambling over a period of time. The purpose of the case studies was to present in-depth information about each of the selected cases of interest, and drew on data from the pre- and post-treatment interviews.

While both of these analytical tools – thematic analysis and case studies - are valuable in their own right, the combination of these two analytical processes helped to reveal not only the rich descriptions provided by the participants, but also the complexity of social relationships and understandings in relation to the gambler's overall experiences of treatment. Qualitative research in this context was more than just an account of personal reflections and provided knowledge about gambling behaviours and the outcomes of treatment that may provide insights for future treatment of relevance to a broader population of people with gambling problems.

There is a potential for thematic analysis to fragment the interviews into their constituent elements and as such there is a risk of losing the overall coherence and richness of the participants' stories about

their experiences and expectations. The benefit of generating lengthy segments of talk that encapsulate concepts and themes is that they add a rich dimension to the research. The development of six case studies designed to pose the question 'what is going on' in this context (Bouma, 1996) illustrates the complexity of individual participants' experiences as well as placing the thematic analysis into context.

For consistency and accuracy, the same members of the research team who conducted the interviews also informed the analytic process. A training session was conducted with the research team to guide and streamline the coding and analytical processes. Further, two members of the research team independently coded a random selection of qualitative transcripts in order to validate themes and coding consistency (Braun & Clarke, 2006). Ongoing debriefing with the qualitative team occurred throughout the study to discuss any issues arising and to discuss any inconsistencies in coding and interpretation.

In reporting the data, participant's sex and age at pre-treatment are included to provide a context for participants' comments. While participants ranged according to a number of characteristics, these characteristics are not used to facilitate a comparison of individual participants' experiences.

Direct quotes are used and written verbatim to convey the essence of their words; three stops (...) are used to indicate where the discussion has been edited. Editing has been kept to a strict minimum.

Study B: Qualitative study – Thematic analysis

Interview participant characteristics at post treatment and 12 month follow up

66 Participants were interviewed at the baseline phase of the study. Of this initial qualitative participant group fifty-three participants in the study were interviewed at the completion of their 6-week treatment program. Of these 53, 47 were interviewed at 12 months following the completion of treatment. Thus the loss to the qualitative participant sample at 12 months was 6/53 or 11 per cent which is acceptable. Table 29 shows a breakdown of the sample characteristics by age, gender and baseline PGSI for the post treatment and 12 month follow up times. As these are essentially the same participants with modest drop-out rate it is unsurprising that they are closely similar. These data indicate that the post-treatment and 12-month follow-up qualitative study samples were representative of the full treatment sample. No statistically significant differences were detected across these variables.

Table 29 Qualitative Post-treatment and 12 month sample characteristics

Interview phase	Treatment arm#	PGSI at baseline	Age	Sex	
Post Treatment	<i>n</i>	Mean (SD)	Mean (SD)	%Female	
	CBT	12	14.7 (6.5)	46.3 (12.9)	50.0
	BT	13	15.8 (7.1)	44.6 (15.9)	38.5
	MI	15	14.3 (5.2)	51.9 (13.4)	46.7
	CCT	13	14.9 (5.9)	51.2 (12.5)	53.8
	ALL	53	14.9 (6.0)	48.7 (13.7)	47.2
12 month Follow-up	<i>n</i>	Mean (SD)	Mean (SD)	% Female	
	CBT	11	16.0 (6.3)	44.7 (12.6)	36.4
	BT	11	15.7 (6.4)	47.0 (16.2)	36.4
	MI	13	14.1 (5.8)	49.8 (15.0)	46.2
	CCT	12	14.3 (5.8)	53.3 (10.3)	58.3
	ALL	47	15.0 (5.9)	48.9 (13.7)	44.7

#BT: Behavioural Therapy; CCT: Client Centred Therapy; MI: Motivational Interviewing; CBT: Cognitive Behavioural Therapy.

Introduction and scope

The interview data from all of participants were subjected to thematic coding and analysed specifically for this qualitative report. This section presents predominantly the findings generated by the thematic analysis of the participants' experiences and reflections of their treatment program at 12 months post

treatment. The baseline and immediate post treatment data have been previously reported in detail in the 6 months report and are not repeated in detail in this report.

Individuals who participated in this qualitative study came from a wide range of backgrounds and differed on a range of demographic factors including: sex, age, ethnicity, marital status, level of education, income, years spent gambling, previous treatment experience, co-morbidities, gambling preferences etc. While they had a commonality in that all had sought treatment, their expectations of treatment varied enormously because of these very diverse backgrounds. Furthermore, some participants expressed the view that their expectations were met and surpassed, while for others, their expectations were not met.

Participants' expectations and preconceived ideas about treatment greatly influenced their experience of treatment, and therefore these will be briefly described to provide a context, prior to a description of the themes and sub-themes.

Participants who experienced the treatment as worthwhile and/or exceeding their expectations reported a range of benefits as indicated below:

- Participants gained greater insight in order to check self/behaviour when gambling;
- Participants benefitted from a professional face to face treatment as compared to previous experiences of telephone counsellors;
- Appreciated the opportunity for self-reflection;
- Gained a better understanding of gambling reduction as an ongoing process;
- Explored specific strategies during treatment to enable the reduction of problem gambling behaviour;
- Valued the simplicity of strategies in this treatment as compared to previous treatment attempts.

An example of how the treatment had exceeded the participant's expectations is illustrated by the following comment:

"I just thought that it was just going to be 'alright well you know tell me about your gambling' you know? And I thought it was just going to be very much possibly like maybe a therapist/client type relationship but it was much more than that because the psychologist was able to offer me cues and tips and ways of being able to see things differently in a different light and she gave me ways of being able to enrich and enhance my life and to become more of a participant in life rather than a spectator...So I'm becoming much more participatory in life and I'm relearning to enjoy life and all the wonderful things that life has to offer and gambling is certainly not a part of that." Male, 45 years

Participants who explicitly expressed disappointment with their treatment, as well as those whose expectations of treatment were not met, reported a range of experiences as indicated below:

- The need for more from treatment sessions than what participants received;
- Did not obtain any tools/strategies to facilitate change in their problem gambling behaviour;
- Felt they were repeating their gambling stories to yet another counsellor/psychologist;
- Perceived the treatment to be too narrowly focused on gambling problem given issue exists within wider life context;
- Perceived that the psychologist lacked in-depth insight into problem gambling;
- Expected treatment to be more gambling specific, not open ended;
- Treatment goals were not consistent between participant and psychologist (i.e., focus was on stopping gambling and not what triggers behaviour or why gambling began initially);
- Expected a miracle or expected too much;
- Expected something new from psychologist, given the numerous previous attempts at treatment.

An example of the treatment not meeting the participants' expectations, and their consequent disappointment, is illustrated by the following example:

"She just didn't offer me anything, anywhere along the line. In sort of there was a leading question and then - I just expected more from the other person, regardless of who the other - I expected guidance for me, I expected them to give me some stuff. And I felt that was - she was sort of curious about me and my story and how I got there or what were the drivers for me...But I don't know how to stop this and that's what I'm here for. But I just consistently felt there was nothing coming my way." Female, 59 years

It is apparent that participants' expectations and preconceived ideas about treatment greatly influenced their experience of treatment, and it is in this context that the major themes are identified and discussed. The figure below illustrates the major relevant themes that arose from the post-treatment interview data. The first major theme encompassed participants' direct experience of the delivery of treatment itself, which included their opinions about the number of sessions, the structure of the sessions, the therapeutic environment as well as their experiences of the psychologist. The second major theme related to the participants' perspectives about the immediate and tangible impact of the treatment. The third major theme encapsulated the factors that both facilitated and hindered the success of treatment.

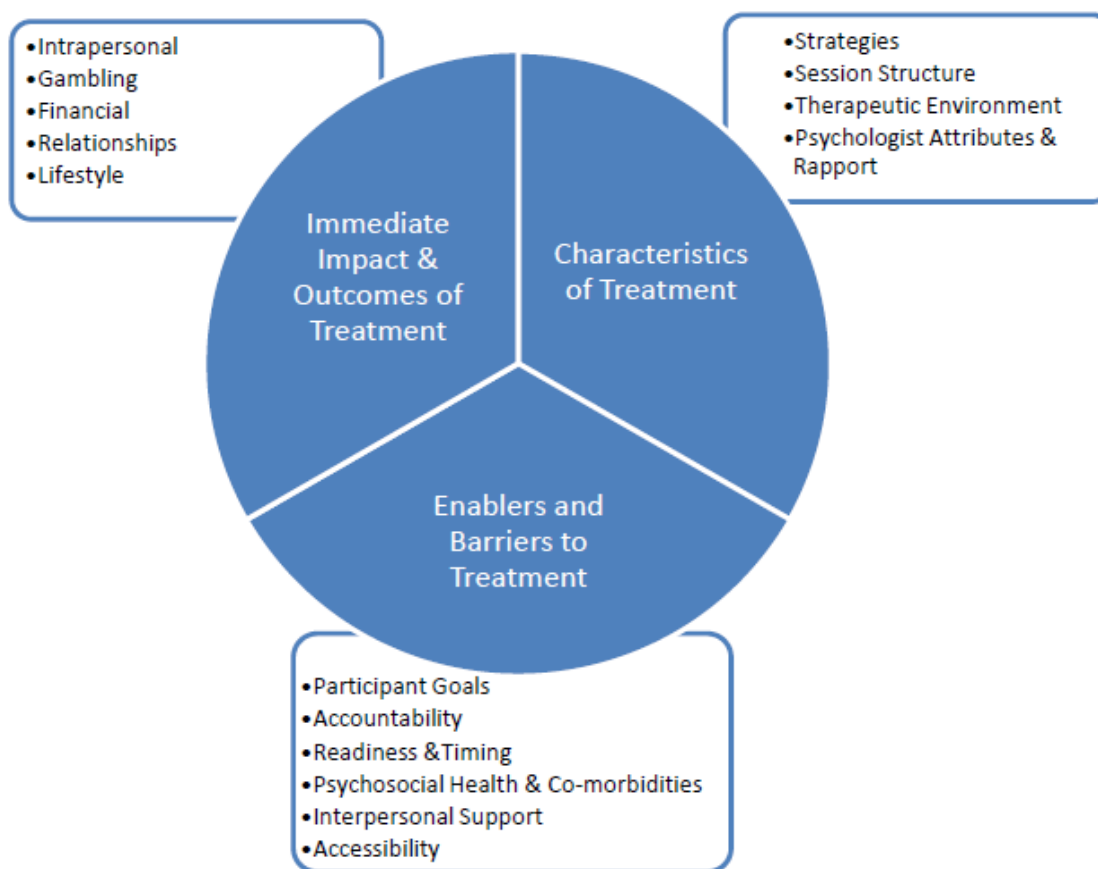


Figure 7 Major themes from post-treatment interviews

Longer term impacts and outcomes of treatment at 12 months

The 12-month follow up interviews provide a more mature and longer term reflection upon the outcomes of the treatment program. The high retention rate of participants in this aspect of the study was pleasing with a dropout rate of only 11 per cent from post treatment to a year later. 47 participants took part in the 12-month follow up interviews. This is a high retention rate over a year following treatment for people in a study who are frequently experiencing major difficulties and issues.

As has been reported in the quantitative component of this study the overall impacts of the treatments were quite positive within the study sample. The fact that the impacts were broadly positive probably

assisted the high retention rate. However this should not be confused with an inability for participants to reflect upon their treatment experiences with vigour. Many participants were prepared to share tough insights about their own strengths and weaknesses and their issues with the program and the clinicians who were treating them. Indeed in the qualitative responses gave a much richer picture of their experiences and the study outcomes.

Participants were asked to reflect upon whether, and how, their treatment had an impact on their lives and whether they felt differently compared to when they entered the program and as they progressed through it. Central to the discussions with all participants was whether participating in treatment did or did not have an impact on them and if so whether the impact was positive or negative. Given that the interviews were conducted one year after the completion of treatment, as would be expected the focus of the discussion was more on the long term impact for participants.

Consistent with the post treatment data collection the clear majority of participants reported that their treatment had a significant impact on a variety of areas of their life, and that it was positive.

As with the post treatment study outcomes, the interviews also revealed that not all participants uniformly found that their treatment had led to a positive outcome. Some had significant reservations about aspects of the treatment program and their clinicians which squarely at odds with their actual quantitative outcomes.

The same five subthemes were found as in the post treatment data collection. These were:

- Intrapersonal issues
- Gambling activity
- Financial impacts
- Impact on relationships
- Lifestyle changes

Once again the outcomes while based upon more mature reflections concerning the impact of the treatments reflected those in the earlier interviews. An additional theme emerged in the analysis of the 12-month follow up interviews and this was reflections upon the therapeutic process and the associated interactions with their clinician. The participants were much more inclined than in their previous interviews to reflect upon these issues. This is understandable because in the immediate post treatment interview, the long term prospects were unknown. 12 months following treatment it is clear whether the treatment has been a success and there is the opportunity for more mature

reflection upon the strengths and weaknesses of the process and the participants. Thus the additional theme was identified:

- Therapeutic process

This theme was important for many participants and frequently mentioned.

It must be remembered that the interpretation of the responses involve extraction of separate sub-themes five key subthemes that co-exist and interrelate as many participants reported multiple impacts on many aspects of their life as a result of their treatment. These subthemes are now discussed in more detail.

Therapeutic process (12 months reflections)

Within the therapeutic process sub-theme many participants reflected upon the process and the role of the clinician within it.

Some participants gave a highly positive account of their interactions with their clinician.

“It is a huge shift, I didn't think a psychologist would help me in any way, but she actually has helped me. Because I can remember the first interview I went - oh I went in with her. I was so negative, um but she turned it around, which was a - which is a positive thing”. (Female, 58)

Others framed their perceptions in terms of the behavioural outcomes they achieved and the family responses to the changes.

“Well, even says I have improved greatly. I, I - the thing is, I don't need to go to the pokies around - locally anymore, which I, I used to do three, four or five times a week”. (Female, 74)

However balancing the highly positive comments were comments that had a more negative or measured response.

“Let's just be honest like the treatment wasn't absolutely perfect. And it probably was a better fit for somebody else” (Male, 41)

Some mentioned their dislike of going for treatment

“And I didn't feel it was productive for me. I mean it had nothing to do with her but I didn't feel it was productive for me sort of and I got to the stage where I was dreading going”. (Male, 54)

Others pointed to specific skills and knowledge they had acquired during the course of the program.

"...it basically came down to a lot of different things within the treatment program that I did take things away from..." (Female 51)

"You know, like...and I think that it was helpful in that it -- it's a bit like teaching, you don't know the impact that you have on somebody until it comes back to you when the kids grown up and they say you were...you did this for me, and that's happened". (Female, 66)

Some participants noted the power imbalance in the relationship and the ascribed authority awarded to the clinician.

"I'd never been to a psychologist before and some people say whatever the psychologist tells you is gospel and if you're steadfast on it, you know, listen to every word she says or, you know, and then right you're cured you walk away. I'd think that would only be five percent, you know, maybe only two percent, you know, that a short course like that is going to cure you, you know". (Male, 45)

Other mentioned the role of other co-morbidities in the treatment and recovery process especially the role of alcohol.

"We addressed - yeah we addressed a few things, um the gambling, um obviously that's the obvious one. Alcohol which contributed to it, um, um smoking marijuana which I've done before um, you know which contributes to it as well. Because you know with the alcohol and that, um it does you know, just... Yeah, and the good thing about it, she made me realise that you know, whatever you do think, it's only a thought. A thoughts not right or wrong, it's just a thought and an urge, your urges can last - you know she taught me, your urges can last from 60 seconds to hours, to urge to gamble. And um yeah which is a good thing, so you know, a lot of times when I think about gambling, you know I think about it. Then I try to distract myself, so then I don't think about it. Which is you know, a tool that she's taught me to do, which I've never even thought of. Then when you think about it logically it's a good thing, so yeah, no it was good". (Male, 45)

Intrapersonal issues (12 months reflections)

This category was retained from the post treatment analysis but interestingly this was not an area of active reflection for many participants in this stage of the study. Perhaps they had moved on from this in their analysis of their progress and situation from a more mature perspective.

"Yeah, yeah, and I mean look you know, it's not the end of the world, some of the issues that I have. I know that I just need to work on my own self-esteem and build that up myself" (Male, 42)

Two participants spoke of being "healed" by their treatment.

"I'm still being, the debts incurred, the good thing is my whole family's supporting me so it's hard, but what it important is – I feel like I'm healed". (Female 45)

Gambling activity (12 months reflections)

Many participants spoke at length about the impact of the program upon their gambling activity. A common theme was that significant progress had been made but they now desired more progress.

"And now I have trimmed it down but ah ah I'm still gambling more than I should. ... there's certainly been a change in my attitude". (Male, 65)

"Yeah good, good, it's not um, yeah I've been sort of pretty, yeah pretty good at it actually, that's why I've improved a lot, like in terms of I'm not, you know it's just every now and then, it's not, and it's not big, it's you know. Depending on you know like it's <laughs> yeah it's not big at all actually. I mean it's I bet on the horses occasionally and maybe one, you know once or twice, you know like small bets on the machines. It's not you know, not big huge like I was doing before yeah, yeah so certainly notice the difference in terms of yeah that sort of stuff". (Male, 49)

Some reported that their process was still ongoing after a year since their treatment.

"I've started to gamble less... um lucky to go maybe once a fortnight or once every three or four weeks now, which is really good for me, and life's sort of picking up. We could be moving to a three or four bedroom home, with my son moving back in home. He's got a job now, he's working back on his apprenticeship, so that's really good. He's been doing that for about two months now. I've nearly finished my warehouse course, which means I'll have my um fitters and packing and um forklift licence, so that will help me get back into the workforce hopefully. So I'm just having trouble; I still have urges to go gambling but I manage to distract myself from doing, like going". (Female, 41)

"...so it's a positive thing. On the gambling front, I've been... a bit um... well I've been-well-I-I-I think I'm happy with... to a degree - I'll add that in "to a degree" on how I've been gambling.... There have been – there've been many periods when I haven't gambled for like four or five weeks, which is a really good sign, obviously". (Male, 50)

Others reported strong results:

"I strictly reduced, um, previously I used to lose two or \$3,000. Now, it's maybe two, \$300, so ..."
(Male 45)

These results are consistent with the major reductions reported in spend and frequency of gambling in the quantitative data collection.

However, some reported some lack of progress

"...probably not much changed full stop to be honest in the 12 months um, still betting a lot. I remember telling my friend, he asked me because I seen him one week, I told him I haven't had a bet for 30 days and then I seen him later and he goes, "still going?" and I said, "Yeah, yeah 40 days." But then when I think...when the floodgates did open I think it was yeah pretty bad there for a while, you know, I was betting a bit more heavier and a bit more often..... Some people, you know, are probably a bit mentally tougher or the gambling might not be as ingrained, you know, in your makeup as other people are. But I think um, yeah it was a benefit but then again yeah it wasn't, so it's hard to say. It helped me short-term but, you know, I sort of that soon- that soon dissipated and just back to the old ways, the old habits". (Male, 45)

Variability (ups and downs) were also commonly reported.

"Oh, its been a really interesting year, and kind of weird. So I have my good periods and bad periods, I can be off, I can stop for two or three months and then I have a binge. And I had stopped for a good two months up until December". (Male, 43)

Many used the terminology of lapses to describe their gambling behaviour.

"I do have lapses still um. But they're looking up you know I, when I walk in there now, unless I'm affected by alcohol or anything else..." (Male, 45)

Variability in outcomes (individual differences) and across time within the same individuals (up and down) sit within a strong quantitative study trend downwards in spend, frequency and clinical symptoms.

Financial impacts (12 months reflections)

The participants were clear and succinct in their descriptions of the financial consequences of their participation in the treatment.

"I can actually walk out with still having money in the bank and still having money for...to live till next pension day whereas in the past I would probably blow everything". (Female, 66)

The magnitude of the impact reported varied widely. One participant reported:

"I'm not borrowing, I don't owe anyone a cent". (Male, 50)

Whereas others reported important but more modest gains financially.

"....because we've had a bit more money to do things. I've managed to save \$150 cash for us to go away on the weekend so..." (Female, 41)

The ability to take holidays as a positive outcome was frequently mentioned by the participants.

"That is a strategy that I've had anyway and that's how we've saved for the holiday. So I've had to put the money in that account um and yeah, but just yeah having things paid up front first. You know I have direct debits come out and things like that yeah, so I do that, so that what's left that is my money and then yeah.....So and then with my money I would find the capacity to pay off debts, or to do something correct with that money". (Male, 44)

Inability to pay off debt before the treatment was a commonly reported problem and many participants were pleased to report that they were able to address their debt better.

"Um but, but really um she made me reflect...okay...there were lots of times. I was thinking back to when I would pop down from work to the Tattsлото place and I think I told you if I thought there was somebody from work, if no they were also playing Tattsлото, I would ask for the gift. Pretend it was—which I did still, genuinely would be using at certain times and I realised then that was a time in my life when I was spending. My income wasn't working with my spending; I wasn't prepared to cut back on a lot of activities I'd do, you know...I don't mean overseas trips, I mean um, um, just...oh...I mentioned to somebody. Somebody said "gosh you are a member of a lot of things." And I thought yeah, that's what I find interesting in life to be and they all cost money and this and that...so I should have been cutting back. One key point for me was I wasn't paying off my credit card in full every month". (Female, 58)

Many participants also commented on the impact of their gambling upon their nest eggs. The participants who were of superannuation age mentioned their concerns about its management into the future.

"I just feel, look I've been crazy, I know that, but I think... I think at this moment of my life with my friend needing me a lot, and James, and, and I think, you know, sometimes - and not having a lot of -

like my money's in super, and, and yes I have brought some over, but sort of trying to realise well that's all I've got, and I've got to live off that, um... and I don't want to touch my, like nest egg for when I'm, you know, old, older, um I'm sort of trying to - I am, I'm, I'm just going to try and stay away from there. Um because at the end of the day it doesn't matter what help you get, unless you're going to have something that's going to - unless it's going to make you violently sick when you see a poker machine, I don't know how it could stop you. It's usually when you, you know? Um... I know people have had good success, but that's usually when they've lost everything, and they're - where I'm hoping I'm not going to get to that point". (Female, 54)

The better control of financial matters reported by some of the participants is consistent with the quantitative data reported earlier in this study. These interviews support this view that lack of money due to problem gambling in families and for individuals are very significant and frequently quite injurious.

Impact on relationships (12 months reflections)

In commenting on relationships many participants mentioned gambling friends that had a negative impact upon their recovery. For example, one participant mentioned:

"We used to go together and he used to encourage me to go with him because he didn't want to go by himself [beep] and I used to go with him and that's how I started, and-and to this day, I still blame him for my gambling problem". (Male, 50)

Others mentioned how they avoided some of their associates now and went with non gambling friends as a way of managing triggers for gambling.

"And so I make sure I go to that pub and I make sure I'm with him, um and when- when sort of the opportunity arises I do sort of...I don't like to associate... work's very busy. I don't like to associate too much, but when we do go I try to ensure that I'm with someone else so that it takes the temptation away for me. Um, so I- I- have definitely tried to- to do those little things". (Male, 38)

Many participants mentioned issues about their non-disclosure of their gambling problem to friends and relatives and the impact they feared this may have on the relationships.

"Because my wife doesn't know that, so she has – she lives a normal life, like she has to get things which everyone has and she – she has to go to her parents' place in once in a year and I can't stop that otherwise it will be a big shock and the whole house of cards that I have set up will come falling down". (Male, 33)

Others reflected upon the negative impacts of their gambling upon their relationships.

“When you're not working, um, and you're at home and you're left to your own devices, um, and, you know, in terms of sort of, um, yeah, just, you know, um, personal relationships and things like that, in terms of not being, um, ah, you know, when you already been drinking at sort of five o'clock or something and, you know, and you've been doing – but yeah, just the whole thing about sort of being at home and being on – on – not having that work, um, and those other distractions and interactions and stuff, and your mind goes, you know, um, and it gets into that more depressive bit, space of, you know, what are you doing?” (Male, 48)

The qualitative data show clearly that problem gambling has significant impact upon personal relationships and that some relationships with other gambling friends may impede control.

Lifestyle changes (12 months reflections)

Cessation or moderation of gambling has a major impact upon the lifestyle of former problem gamblers. Some participants reflected upon this issue. One participant noted the need to change her lifestyle.

“You know, I have...I just have to find another outlet in my life. And unfortunately I'm not a joining person, I'm not...people say oh you should join this and you should join that but I'm- I'm, I either have to force myself to do something, I have to do something, you know. I've got myself a - where my husband before he went to the nursing home lived in um a retirement village so I got quite friendly with those people and I've actually got myself a little casual job in there. And that's only been two weeks ago that I started there, I work in the dining room”. (Female, 66)

Some reported positive consequences of their management of their problem gambling.

“I recently got ...a little dog. I had a friend give me a pair of sneakers at the right time, so – and they're really good ones, so I just put them on and the dog takes me for a walk when my son comes over in the evening, or when the kids are at school”. (Female, 41)

Work changes were also mentioned by many participants.

“I've just been slogging it out and doing it tough until I get my forklift licence. I could have got a couple of different jobs in-between, but I really want to do forklift. I know that's good money. It's minimum \$28 an hour, forklift driving, and it's hours that I can do, it's the sort of job I can do Monday to Friday while the kids are at school”. (Female 42)

One participant clearly articulated to walk with a girl on the beach, resulting from his improvement.

"I just turned 40 the other month. Um about walking on the beach with a girl. That was the main aim. I love the beach, you know. I'm single and even – it's hard because I do recall some of the things he told me, it just doesn't stay. It- it's not there and it's understated. But every now and again I'll be doing something random and it'll pop in like that. Walking on the beach". (Male, 39)

The necessity to avoid triggers was identified by some as having an impact upon their lifestyle.

"I really have to get into a psychological process of, right, I'm, I'm going to visit my best friend, who lives 300 metres from Caulfield TAB, I really have to come up with a thought process of avoiding the TAB when I'm visiting my friends". (Male, 54)

One participant mentioned their love of singing as a distracting activity.

"Well, when I like singing. And both of the two places had karaoke – had pokie places right next door because it was a pub that had karaoke. Two different venues in and they both had pokies and I remember not going – specifically not going on purpose on the nights that I went and did karaoke". (Female, 36)

And as mentioned previously holidays figured prominently in discussions about the impacts of gambling less upon lifestyle.

"I go away....Oh, at least once every four or five weeks, at least, yeah. Really, there's not much physical things going on anymore that we can do long walks, so we love to go for a drive. We go, we like - the next trip is planned to Echuca, but it's not planned yet, but that's where we go. We love walking along the wharf and it's lovely". (Female, 74)

So, in sum, many participants reported positive improvements in their lifestyle and everyday life as a result of better control of their gambling.

Discussion of the 12 month follow up interviews

The interviews provided some interesting insights into the process and outcomes of the treatment program. The same themes as identified in the post treatment interviews emerged but with the addition of some discussion about the therapeutic process and the role of the clinician and the client-therapist relationship.

Many reported positive benefits of better control of their gambling. This included improvements in personal relationships, the ability to take holidays and an overall calmness in managing everyday life that had been denied to many for a long time.

There was a slight reluctance amongst some of the participants who had achieved individually very good results to talk expansively of what are obviously also very good group results. Perhaps this may be borne of a concern about “tempting fate” and the possibility of relapse. Although the results are strong and are durable for a year, many described in their interviews that their recovery was an ongoing process that required ongoing vigilance and effort. A handful of participants spoke of “cure” but most spoke in a more measured manner.

It would be very interesting to talk with this group again to gather their yet longer-term views of their progress. However, to control their gambling for a year following treatment is a fine achievement that deserves (cautious) celebration.

Discussion and conclusions

Research and clinical implications

This report describes the 12-month post treatment outcomes for the Psychological Treatments for Problem Gambling (PROGRESS) Study: A Pragmatic Randomised Controlled Trial and Qualitative Study. This was a longitudinal study of treatment outcomes for a sample of 297 Victorians who enrolled in a treatment program for problem gambling.

The objectives of this study were to:

1. Study the relative effectiveness of four manualised psychological interventions (Cognitive Behaviour Therapy, Motivational Interviewing, Behaviour Therapy and Client Centred Therapy) in the treatment of problem gambling.
2. Determine the durability of any therapeutic gains obtained by the four psychological interventions as measured by the key outcome variables (a) instances of gambling in the past four weeks, (b) hours spent gambling in the past four weeks, (c) dollars spent gambling in the past four weeks and (d) gambling symptom severity as measured by G-SAS.
3. Study the experiences of problem gamblers seeking treatment throughout the course of the treatment and following its cessation.

The major outcomes for the study are described in the body of the report and in the abstract to this paper so it is not proposed to repeat them ad nauseum in detail yet again. The focus in this discussion is on the clinical implications of the findings and whether they are credible.

If the findings are taken at face value, then there is good evidence that manualised psychological therapies “work” in the treatment of problem gambling. The somewhat unexpected result obtained in this study is that the exact content of the therapy used does not seem to affect the participant outcomes. Although there has not been strong previous empirical evidence to suggest that this might be the case, some commentators might be prepared to claim that, for example, in the case of CBT, because it has the greatest evidence base to date, it would be likely to be the most effective. However, absence of evidence for effect is not evidence for no effect. In the present study, the four types of psychological therapy have been compared using a rigorous research methodology in the context of a longitudinal study and now there is evidence, as opposed to speculation, that suggests the differences in outcome effectiveness are not statistically nor clinically significant. This is an interesting finding. It suggests that the therapeutic setting and goals and intents of the participants overcome differences in the technical content of the treatment. Of course, in any clinical study Hawthorne (expectancy) effects may be an explanatory factor in study outcomes (Polgar and Thomas, 2013). One of the inclusion criteria for this gambling trial was that we included people who had not

received treatment for the 12-month period prior to the commencement of the trial. Many had not previously received treatment. Thus, their expectations of success were high and the participants were ripe for commitment to the therapeutic endeavour. At the same time, some of the members of the research team have been conducting this large RCT, we (Browning, Thomas, Enticott) conducted in China an even larger RCT of the effects of motivational interviewing versus conventional care upon treatment outcomes for patients with diabetes (Browning et al 2016). We found large clinical effects for the treatments we implemented with evidence of strong Hawthorne effects.

The other finding of interest is that the effects seem to be durable. There is not the washout over time of effects that is sometimes experienced in studies treating behavioural addictions as illustrated in the results of our Cochrane review (see Cowlishaw, S., Merkouris, Dowling, Anderson, Jackson, & Thomas). These findings are remarkable and we reproduce them here once again.

Study Phase	Frequency (days gambled in a 4-week period)	Time (hours spent gambling in a 4-week period)	Spend (Net Loss AUD in a 4-week period)	GSAS Total
Baseline (t ₀ , n=297)	17.82 (16.73)	35.21 (43.26)	\$4,320 (6,457)	26.40 (8.05)
Post treatment (t ₁ , n=260)	9.57 (10.77)	16.41 (25.18)	\$2,365 (11,592)	18.41 (8.90)
6 months (t ₂ , n=249)	10.29 (11.80)	15.46 (23.50)	\$2,000 (5,507)	18.38 (9.37)
12 months (t ₃ , n=235)	9.82 (11.43)	16.49 (23.35)	\$1,891 (7,943)	17.89 (10.24)
Δ 12 months- baseline	-8 (-45%)	-18.72 (-53%)	-\$2429 (-56%)	-8.51 (-32%)

If the findings are taken at face value, then there are simple and clear implications for good practice in the treatment of problem gambling. Manualised psychological treatments implemented by well-trained psychologists appear to achieve robust and durable results. Thus treatment services should use this model in the design and delivery of their services. At this point there is no evidence to suggest differential effects for the different psychological treatment modalities.

Strengths and limitations of this study

As outlined in the introduction in this report, the study design was informed by a rigorous analysis of previous studies in the form of a published Cochrane review. Many actions were taken to address potential areas of bias in the study design and its execution and the analyses performed to address the study aims. These actions are discussed in detail in the study report.

Nevertheless some potential biases remain.

A major issue in the study is the use of predominantly self-report data. The best available measures were chosen and these measures are “industry-standard” in that they are used widely within the problem gambling literature, but they nevertheless are a source of potential bias through inadvertent errors in self report or intentional errors made with the intention of concealing the true situations for the participants. These intentional errors may be made because of embarrassment, symptom maximisation, hypochondriasis or other mechanisms. We share this problem with the rest of this field.

A second issue that affects all studies is the sample validity. However, our analyses of the study sample compared to previous studies and most notably the Australian Productivity Commission's shows no statistically significant differences in terms of gender composition and age profile with the present study sample. The representativeness issue is directly affected by the group to whom the study results are intended to be generalised. As is the ethical requirement with all studies, the participants in this study were volunteers so there is no suggestion that the high rate of durable and successful treatment outcomes would apply to a higher acuity group. These were volunteers responding to public advertisements sponsored by a university. It is possible that this may have induced some expectancy effects amongst the participants. Also because the treatment was free there may have been a cognitive dissonance effect where people are more affected by social desirability in their reporting of outcomes because they did not want to appear to be ungrateful. However, there is no firm evidence that any of these effects were in operation.

In this study, a non-treatment control group was not employed. This is consistent with rigorous pragmatic trial requirements. However, one has the issue of whether the treatment effects could be attributed to placebo or other effects. It is useful to note that the participants in this study were people with long standing gambling problems who had not had recent or any previous treatment. A spontaneous major reduction in symptoms for 300 people following treatment compared to pre-treatment is unlikely. However, aside from the methodological issues there are serious safety issues in using non-treatment or wait list controls. Suicide is common amongst people with problem gambling and a non-treatment or wait list control would attract significant negative focus in an ethics approval process. As a former HREC chair, the CI Professor Thomas would be unlikely to approve such a trial because of this unacceptable risk, especially because it is not methodologically necessary.

Further, while we have made every effort to ensure blinding through the separation of staff conducting assessments and those involved in group allocation, it is possible that expectancy effects may have been in evidence in the study. Of course, people's expectations may influence the reported outcomes. Nevertheless we used strong methodology to address this.

The main problematic issue in the project execution related to speed in recruitment. The study took much longer to complete than was originally planned. However, this was not a threat to study neither

integrity nor validity. The effects of timing of data collection for the participants has been modelled and has been found to be negligible.

However, at the end of the day, this study was directly informed by our rigorous Cochrane review and our NHMRC endorsed guidelines in which we identified many limitations in studies in this field and we used this knowledge to design our trial. Compared to previous studies this was a very large trial. There is little opportunity to attribute uncertainty to the results from power considerations. It is what it is.

We thank the many participants and staff who supported this study for their wonderful efforts and our reviewers for their insightful comments and improvements.

Appendices

APPENDIX 1 - Qualitative Pre-Treatment Interview Schedule

Part 1: Participant's perception of impact of gambling

- Can you tell me how gambling is/has affected your life? (*In the more recent past*)

Part 2: Reason for participating/seeking treatment

- What are your reasons for seeking treatment? What were the triggers for you seeking help?
- What are your reasons for participating in the study? (Prompt: What led you to respond to the advert to participate in this study?) *Enquire about qualitative sub-study as well.*

Part 3: Expectations of treatment

- You are about to start your treatment program. What are your goals and expectations of the treatment? (Compared to how you feel and act now, how do you think/hope/expect you will feel and act (1) immediately after your treatment, as well as (2) 12 months on?)
- How do you imagine your treatment to be?
- How do you think treatment will enable to achieve your goals/expectations? What do

Part 4: Previous experiences of treatment

- What are your previous experiences of treatment? (*List treatment types and when they took place, formal (e.g. involving a practitioner) and informal (e.g. GA)*)
- What worked well/not so well? Why do think it worked/didn't work?

Part 5: Understanding of recovery and change

- The aim of the treatment is to make you feel better. How will you know if you're better? How can you measure it?
- Please describe in your own words how you think you will act and feel when you are better. (Prompts: is it changes in behaviour, emotions, financial status, relationships etc.) - What does recovery look like to you?
- What do you think are the main barriers/enablers to change/recovery/improvement from your gambling problems?
- What factors do you think will enable/hinder your recovery?

Is there anything more you would like to say, or anything you think is important that we have not yet discussed?

APPENDIX 2 - Qualitative Post-Treatment Interview Schedule

(If participant did not complete all 6 sessions, confirm number of sessions completed and find out about their reasons for not completing the treatment program. Then proceed with the following interview schedule).

Part 1. Experiences of treatment

Now that you have completed your treatment program, what do you think about your treatment?

- Has the treatment helped you in any way?
- Do you feel that your problems were resolved when you finished treatment?
- How would you describe the help you received?
- What parts of the treatment did you find useful/not so useful? Why?
- What things enabled or prevented you from achieving your goals and expectations?
- Was the treatment what you expected?

Part 2. Life now compared to pre-treatment

- What's life like now compared to before your treatment (when we first interviewed you)?
- If you feel that you have changed, do you think this was due to your treatment or to other events in your life?

Part 3. Reflections on treatment

- How have you felt and thought about your treatment since commencing?
- Do you think your treatment should have been different in any way in order to have helped you more?

Part 4. Expectations over next 12 months

- We will contact you in 12 month's time to see how you are going. How do you think your life will be in the next 12 months in relation to your gambling and general health and well-being?
- Do you think you will seek further treatment?

Is there anything more you would like to say, or anything you think is important that we have not yet discussed?

APPENDIX 3 - Qualitative 12 Month Post-Treatment Interview Schedule

Part 1: Current life and management of gambling

Now that 12 months has passed since we spoke to you and your treatment finished, how are you going?

- How are you managing your gambling?
- Are you meeting your goals in terms of management of your gambling? If yes/no, please explain.
 - Reduced gambling participation, urges, expenditure
 - Better quality of life
 - Financial stability and security
 - Improved personal relationships
 - Self-efficacy (control, power, esteem)
 - Support from family, friends and community

Part 2: Reflections on treatment

- What are your thoughts about the treatment program which you took part in?
- If you experienced benefits as a result of the treatment, are you able to maintain them?
- What impact do you think that the treatment has had on your life?

Part 3: Search for additional support

- Have you sought additional support in the form of treatment or counselling since completion of this study's treatment program?
 - If so, what kind of support – give details. Why have you sought this support?
 - If not, why not? Is it because you feel better, no need for further treatment - or you haven't got around to it, and don't know where to go?

Part 4: Current/future beliefs about gambling

- Now that this study has finished what are your views on your gambling? Please describe.
- Have your views about gambling changed since you first became involved in the study? If so, what do you attribute this change to?
- How do you think your life will be in the future in relation to your gambling and general health and well-being?

Is there anything more you would like to say, or anything you think is important that we have not yet discussed?

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