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Flinders Human Behaviour & Health Research Unit

Naltrexone Feasibility, Acceptability and Preliminary Effectiveness Study

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Executive Summary

The goal of the study was to evaluate the feasibility, acceptability and tolerability of naltrexone therapy in treating problem gambling in treatment resistant gamblers registered with the Statewide Gambling Therapy Service (SGTS) through a pilot study.

An audit of the database revealed 524 clients registered in the last year. Fifty-nine of these were identified as suitable for the project by SGTS therapists. From this group, 11 were un-contactable, 29 declined study involvement, 6 were excluded, 2 withdrew before commencing medication, 4 withdrew early from the project and 7 completed the study.

The majority of participants were male (male = 8, female = 3) ranging in age from 31-60 years (M = 49, SD =10). Most people considered their principal gambling problem to be related to Electronic Gaming Machines (Pokies = 8; TAB = 2; Lotto = 1). The duration of their gambling problem ranged from 3 to 15 years (M = 7, SD = 4.1).

Most people had tried two or more types of support or therapy service and all people had tried at least 4 sessions of SGTS behavioural therapy, yet still had a high gambling urge. No-one had severe co-morbid condition or axis-2 disorder and everyone had normal liver and kidney function at baseline and through-out the study.

The stable dose of naltrexone used ranged from 50mg to 150mg (50mg = 5, 100mg = 4, 150mg = 2). Time spent in the study ranged from 1 to 7 months, with 4 people withdrawing early.

Outcome measures were case studies, Gambling Urge and Gambling Activities. Measures used were; The Victorian Gambling Screen (VGS) Harm to Self Scale; The Work & Social Adjustment Scale (WSAS); The Kessler Psychological Distress Scale (K10); The Information Biases Scale; The Gambling Related Cognitions Scale; The Canadian Problem Gambling Index (CPGI); The Alcohol Use Disorders Test (AUDIT); Goldney Suicidal Ideation Scale.

Feasibility was examined in terms of the relative ease of providing naltrexone treatment to SGTS clients. Naltrexone therapy would be feasible if there were clinicians available to provide on-going medical care and if people could afford the cost of naltrexone or the cost was subsidised.

Naltrexone treatment appears to be acceptable to a small group of treatment resistant SGTS clients. Of the 59 people approached to be involved in the study, 15 accepted the invitation to participate. Of the 11 that commenced medication, 8 stayed in the project at for least 4 months. Approximately half of people experienced side effects during the first two weeks while only one person reported side effects at the end of their time in the study. Three of eleven participants moved from being classed as pathological to non-pathological gamblers on the key measure the Victorian Gambling Screen (VGS).

Preliminary findings suggest naltrexone is tolerable, acceptable and feasible, and can be expected to provide limited clinical benefit to a small number of patients.

1. Rationale

1.1 Background

Problem gambling is a significant and growing social problem. Studies estimate that in Australia approximately 1-3% of the population experience gambling problems that impact their personal, social and working lives (Productivity Commission, 2009). The full extent of negative consequences caused by problem gambling are undocumented, however reports suggest problem gambling poses a serious issue for those involved and often results in social and family breakdown, unemployment, suicide, depression and other substance abuse disorders (Petry et al. 1999).

Pathological or problem gambling is recognised in the diagnostic manual DSM-IV as belonging to the category of impulse control disorders. Overall the diagnosis determines that the problem is having a significant impact on the individuals functioning, which is indicated by at least five of ten symptoms, including: repeated unsuccessful efforts to control, cut back, or stop gambling; a need to gamble with increasing amounts of money in order to achieve the desired excitement; or committing illegal acts, such as forgery, fraud, theft or embezzlement, in order to finance gambling (APA, 2004).

The Australian Government recognises the significance of gambling issues in the community and provides substantial funding for gambling services. It is estimated approximately $20 million a year is spent across the states and territories (Productivity Commission, 2009). Consequently, there are services to treat problem gambling in every state in Australia. The treatments available include: cognitive behavioural therapy, behavioural therapy, cognitive therapy, counselling, psycho-education, financial counselling, hypnotherapy and mindfulness techniques.

From the treatments available, cognitive or behavioural therapies appear to be the most effective interventions. For example, preliminary longitudinal research of 150 participants treated with the Flinders behavioural technique at baseline, treatment completion and follow-up at 6 months, revealed that there was a statistically significant drop in depression, anxiety and gambling behaviours following therapy (Battersby et al, 2010, in-submission). However few randomised trials have been conducted into treatment for problem gambling and the field lacks conclusive evidence (Toneatto, 2005; McConaghy et al., 1983; Ladouceur et al., 2001; Westphal & Abbott, 2006).

Despite the positive results for behavioural and/or cognitive treatment, a small percent of clients do not extinguish their urge to gamble through psychological therapy and can be defined as treatment resistant. An examination of data from the Break Even / Gambling Help Services database for Statewide Gambling Therapy Service indicates that just over one quarter of clients (27.3%) who received 4 or more treatment sessions from SGTS therapists concluded treatment with a significant urge to gamble remaining. Psychological services appear unable to cater for this group and an alternative approach is needed.

1.2 Pharmacotherapy and problem gambling

One alternative therapy option for these treatment resistant patients is pharmacotherapy. A small number of studies have shown promise in treating PG with pharmaceuticals, including opioid antagonists, selective serotonin re-uptake inhibitors and mood stabilizers (Hollander et al, 2005). Generally studies have shown that from these treatments opioid antagonists are the most effective in reducing the urge to gamble (Leung & Cottler, 2008).

Opioid antagonists act on the opioid receptors in the central nervous system and block neurotransmitter action. It is thought they are useful in treating addiction because they block the dopamine driven reward pathway in the brain which is responsible for producing positive feelings and craving in response to gambling.

Naltrexone is the most widely researched opioid antagonist in the treatment of problem gambling. The drug's effectiveness in treating problem gambling has been investigated in six studies: two case studies, one open label, one randomised double blind trial, one open label comparison with another drug and one 6-12 month follow-up study.

Two case studies published in 1998 reported information about patients taking naltrexone for nine months and four weeks respectively at a 100mg and 50mg dose. The case studies both relied on informal interviews and clinical notes to determine effectiveness, and both reported significant success in decreasing gambling urge However, it is not clear if the patient taking for one month was responding to non-specific treatment effects as they reduced their gambling almost immediately on a 50mg dose. The patient taking the medication for nine months didn't experience a decrease in gambling urge until they had increased the dose from 50mg to 100mg (Crockford & el-Guebaly, 1998; Kim, 1998).

Following these early case studies, naltrexone therapy for problem gambling was tested by an open-label trial where 17 people maintained a dose ranging from 25mg to 250mg (with an average of 157mg) for six weeks. The study recorded an average drop in money spent gambling, frequency of gambling and overall improved clinical global impressions. The project also noted that side effects were experienced by 47% of participants (Kim & Grant, 2001).

Later the same group of researchers conducted the only randomised double blind placebo controlled trial of naltrexone in treating problem gambling. In this project 83 people took a dose ranging between 25mg to 250mg (average 188mg) for three months. The main outcome measures were clinical global impressions rated by the clinician and patient and the gambling severity scale. The final results revealed that there was a significant different between the placebo and naltrexone groups with 75% of the naltrexone group much improved, compared to 24% in the placebo group. In addition 45% of the naltrexone group reported side effects compared to 24% of the placebo group. However results should be viewed with caution as there was a very high attrition rate and data from only 45 of 83 patients were analysed (Kim, Grant, Adson & Chul Shin, 2001).

More recently, naltrexone treatment for problem gambling was examined in a comparison to bupropion in a small open-label trial. Nineteen people (36 total) maintained a naltrexone dose ranging from 25mg to 150mg (average 100mg) for 3 months. Outcome measures included Hamilton rating scale for depression and anxiety, Yale obsessive compulsive scale, clinical global impression and self report frequency and length of gambling. Clinical improvement was considered to be abstinence from gambling for two weeks, which was achieved by 76% of the naltrexone group and 75% of the bupropion group. Consistent with other projects there was a significant attrition rate and 6 of the 19 naltrexone participants withdrew due to side effects (Dannon, Lowengrub, Musin, Gonopolski & Kotler, 2005). Six to twelve months after the completion of the naltrexone vs bupropion study, data was collected from 10 responders to naltrexone treatment. It was found that 4 of the 10 patients had relapsed during the six month drug-free period (Dannon, Lowengrub, Musin, Gonopolski & Kotler, 2007).

In conclusion, the limited results suggest that there is clear promise for naltrexone in the treatment of problem gambling. However, as many of the studies are limited by small sample sizes and lack of control for extraneous variables, further research is required to really understand the effect of naltrexone in treating this impulse control disorder/ addiction. Moreover research is needed to understand the effects of naltrexone therapy in treatment-resistant participants in an Australian setting.

Finally, given the lack of precedent in conducting pharmaceutical research in the local context, a pilot study is required to gather information about the feasibility, acceptability, tolerability of naltrexone in treating problem gambling before a larger-scale study can be undertaken or recommended.

2. Aims of study

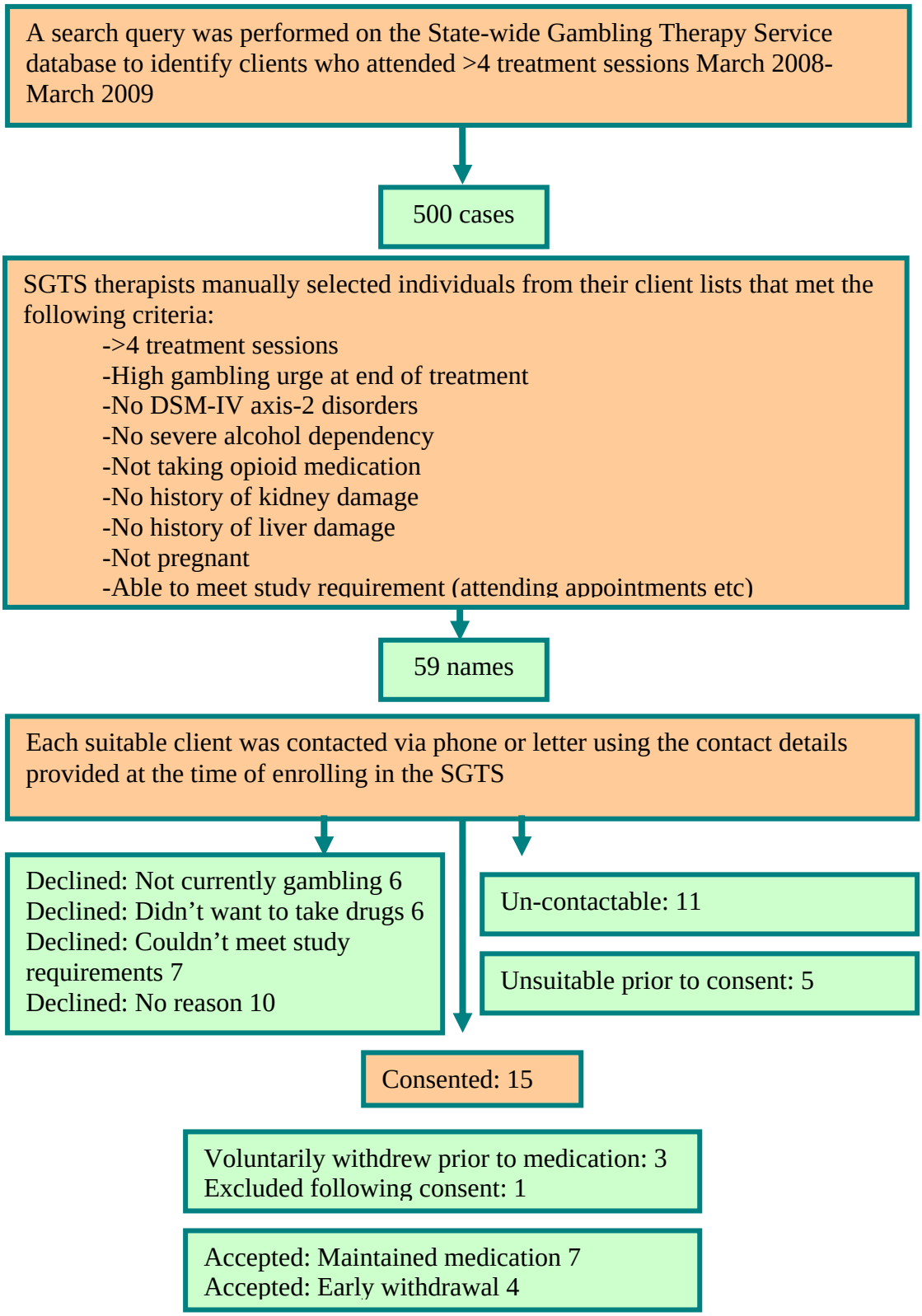
To record the feasibility, acceptability, tolerability, pilot effectiveness of naltrexone therapy in treating problem gambling in treatment resistant gamblers registered with the Statewide Gambling Therapy Service (SGTS).

3. Methods

3.1 Recruitment

Participants were recruited via an audit of the State-wide Gambling Therapy Service client database. The following flow-chart describes the recruitment process.

Flow chart of recruitment



3.2 Participants

Participants consisted of 11 people who satisfied the inclusion and exclusion requirements (see flow-chart above) and commenced medication. The group contained men and women range in age from 31 to 60 years (see Table 3 below).

Table 3: Demographic information of participants (n=11)

Gender: Male = 8 Female = 3		
Gambling type: Pokies = 8 TAB = 2 Lotto = 1		
	Range	**Mean (SD)**
Age	31-60	49 (10)
Problem Gambling Severity (CPGI) clinical cut-off 8+	7-34	18.7 (8.4)
Problem Gambling Severity (VGS) clinical cut-off 21+	15-56	41 (12)
Duration of gambling problem (yrs)	3-15	7 (4.1)

3.3 Procedure

The project employed a naturalistic design which monitored patient progress as participants received standard medical and psychological attention in conjunction with naltrexone medication.

Medication

Participants took a daily dose of naltrexone for 1-7 months. The dose began at 50mg and was increased fortnightly in 50mg increments until: the dose reached a maximum of 250mg; the participant experienced undesirable side effects or the participants gambling urge was reduced 50% from baseline (according to subjective report and/or GUS score).

Medical Care

Prior to commencing naltrexone all participants underwent a thorough medical examination and participants only commenced medication if liver and kidney function test results fell within the normal range. In addition, throughout the duration of the study participants had fortnightly or monthly consultations with project doctors or their GPs to monitor side effects, drug efficacy and liver and kidney function.

Psychological Care

For the first 1-3 months of participation in the study, patients were encouraged to maintain contact with a SGTS therapist. Over this period clients had the option of engaging with any kind of therapy offered by the SGTS or other service providers. The types of concurrent therapy and support people experienced included: financial counselling, psycho-educational therapy, general counselling, cognitive therapy, behavioural therapy and support groups.

Research Monitoring

In conjunction with decisions about dose increase, the gambling urge scale was administered at every medical appointment. In addition, for the duration of the study a suite of questionnaires monitoring psychological changes were administered to participants at baseline, 1 month, 3 months and at the end of the project.

Questionnaires

Gambling Urge Scale: The Gambling Urge Scale (GUS) is a self-report questionnaire measuring the extent of gambling urge. The scale consists of six items rated on a likert (1-7) scale including statements such as 'I crave a gamble right now' and 'All I want to do is gamble'. A final score is generated as a total of the response to each item and higher scores indicate greater urges to gamble. Research into concurrent, predictive and criterion-related validity of the GUS suggest the GUS is a valid and reliable instrument for assessing gambling urges among non-clinical gamblers (Raylu & Opei, 2004a).

The Victorian Gambling Screen (VGS) Harm to Self Sub-Scale: The Victorian Gambling Screen is a self reported questionnaire. The harm to self sub-scale is comprised of items 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 19, 20 and 21 from the complete scale. The questions ask the client to rate on a four point scale (ranging from never to always) how frequently they have experienced symptoms of problem gambling in the last month. Questions include items such as 'Has your need to gamble been too strong to control?'. The final score ranges from 0 = no harm to self to 60 = high harm to self. Concurrent validity indicates that this scale correlates very highly with the South Oaks Gambling Screen (SOGS) (R = 0.97), but extends the score range. The scale has been validated for use in Australia by Ben-Tovim, Esterman, Tolchard, Battersby and Flinders Technologies (2001).

The Work & Social Adjustment Scale (WSAS): The Work and Social Adjustment Scale is a self-report questionnaire used to measure patient's perspective of their functional ability/ impairment. The scale contains five items which enquire the degree the clients gambling problem affects their ability to function in the following areas: work, home management, social leisure, private leisure and family and relationships. Each question is answered using a 1-7 likert scale ('not at all' to 'very severely') with higher scores corresponding to a higher degree of severity. Research into the validity of the scale suggests that WSAS correlates closely with the severity of depression and obsessive-compulsive disorder symptoms at 0.76 and 0.61 and is sensitive to patient differences and change following treatment (Mundt, Marks, Shear & Griest, 2002).

The Kessler Psychological Distress Scale (K10): The K10 is a ten item self report questionnaire that asks the client to rate on a five point scale (ranging from 'never' to 'most of the time') items regarding distress in the previous four week period. Questions include items such as 'in the last 30 days, about how often did you feel tired out for no good reason?' Final score ranges from under 20 = likely to be well, 30+ likely to have a severe mental disorder.

The Gambling Related Cognitions Scale: The Gambling Related Cognition Scale (GRC) is a 23 item self report questionnaire that records common thoughts associated with problem gambling. Statements include items such as 'Praying helps me win' and 'I will never be able to stop gambling'. Clients use a seven-point likert scale (1 = strongly disagree, 2 = moderately disagree, 3 = mildly disagree, 4 = neither agree nor disagree, 5 = mildly agree, 6 = moderately agree, 7 = strongly agree) to indicate how much they agree with each of the statements. The final score is created by adding the values gained from the items, with the higher score reflected more gambling related cognitions. A comparison with the South Oakes Gambling screen indicated the scale has good psycho-metric properties in measuring gambling cognitions in a non-clinical sample (Raylu & Oei, 2004b).

The Canadian Problem Gambling Index (CPGI): The CPGI is a 27 item self report measure designed to record severity of problem gambling in previous 12 months. Examples of questions include: 'Thinking about the last 12 month, have you needed to gamble with larger amounts of money to get the same feeling of excitement?' Responses are recorded on a four-point scale (Never=0, Sometimes=1, Most of the time=2, Almost always=3). Questions 1-9 form a total score that ranges from 0=no problem gambling, 1-2=low level problem gambling, 3-7=moderate level problem gambling and 8=problem gambling with negative consequences.

The Alcohol Use Disorders Test (AUDIT): The Alcohol Use Disorders Identification Test: Self Report Version is a non-diagnostic ten item questionnaire indicating hazardous alcohol use. Individuals are required to rate how frequently they engage in certain activities on a scale of 1-5. Questions 1 to 3 measure quantity and frequency of alcohol use, questions 4 to 6 measure possible dependence on alcohol and questions 7 to 10 measure alcohol-related problems. Final scores range from 0 indicating abstainer, >8 indicating low risk alcohol use, 8+ indicating risky or harmful alcohol use, 13+ indicating alcohol dependence is likely. According to a recent review of studies reporting the psycho-metric properties of the AUDIT, the scale reveals specifics and sensitivities superior, to those of other self-report screening measures and good test-retest reliability and internal consistency (Reinert & Allen 2002).

Goldney Suicidal Ideation Scale: The Goldney Suicide Ideation Scale is a four item self-report measure that records suicide ideation at face value. The questions include items such as 'Have you recently felt that life wasn't worth living?' and 'Have you recently found yourself wishing you were dead and away from it all?'. Responses are recorded on a four point scale ranging from 'not at all' to 'much more than usual'. A final score is generated by summing responses (0 or 1).

4. Case Studies

4.1 Patient One

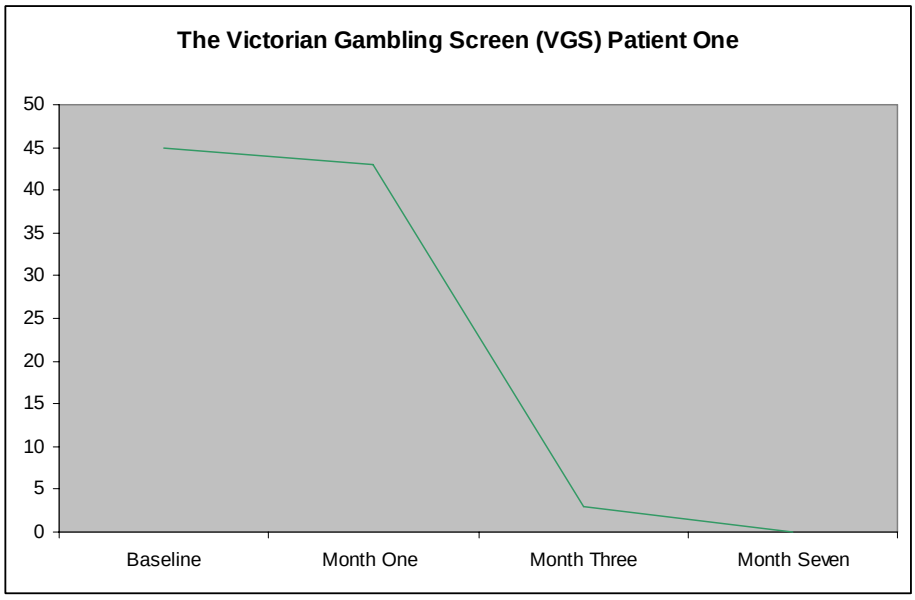
Patient one has gambled excessively on the pokies for around 12 years. She has tried cue exposure therapy at the SGTS including inpatient program with some success and continued to see a therapist and undergo therapy during the study. At the start of the project she experienced strong gambling urges and gambled all her available cash once a fortnight. A dose of 50mg was maintained for 7 months. After one month, the dose was increased to 100mg following a gambling binge, but was reduced again when she

experienced side effects. During the first three months Patient one gambled sporadically, despite feeling that the medication was reducing her urge. After three months she felt there was a dramatic decrease in the urge to gamble and claimed she only gambled small amounts, even when she had access to significant amounts of money. Patient one reported side effects at the start of the project and when the dose was increased these effects included sweating, drowsiness, difficulty sleeping, nausea, migraine and nightmares. By month three the side effects had subsided. As Patient one lives in a rural town, the cost of travel to Adelaide was difficult, but worth the journey for the medication. She requested a referral to her GP to find a method of continuing to take naltrexone. She was not gambling at all at the end of the study and wrote in an email to her therapist "I have put all your suggestions into play and with the naltrexone find myself a happy person. …. I have way too much to do without racing off to gamble my last few dollars on those dratted machines".

Table 4.1 Questionnaire results for Patient one

Tool	**Month**			
	0	**1**	**3**	**7**
Gambling Activities	41	44	14	0
The Victorian Gambling Screen (VGS)	45	43	3	0
Gambling Related Cognitions Scale (GRC)	86	70	38	27
The Kessler Psychological Distress Scale (K10)	4	4	1	10
The Information Biases Scale	109	95	47	33
The Canadian Problem Gambling Index (CPGI)	24	22	13	6
The Alcohol Use Disorders Test (AUDIT)	4	2	3	1
Goldney Suicidal Ideation Scale	0	0	0	0

Figure 4.1 Victorian Gambling Screen results for Patient one



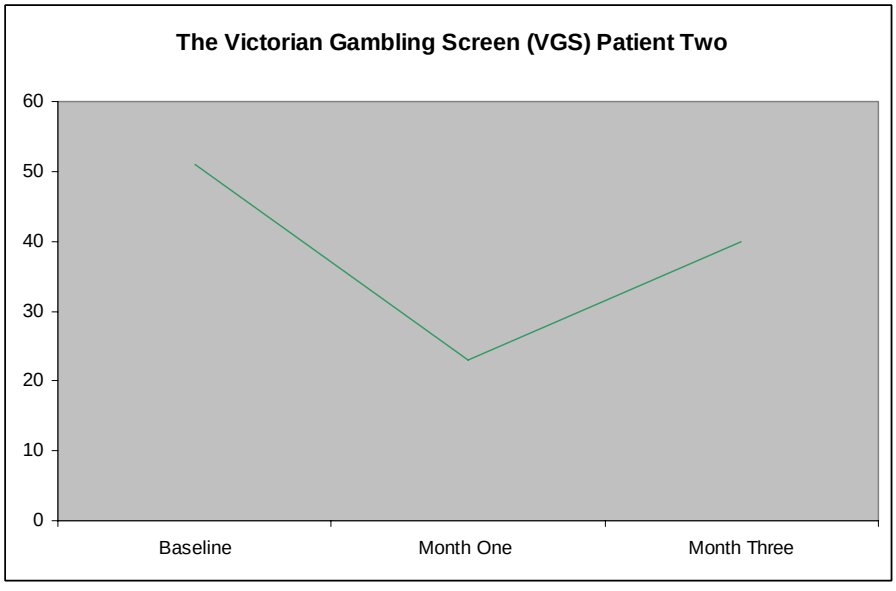
4.2 Patient two

Patient two has experienced problem gambling with the pokies for around six years. She has tried cue exposure therapy at the SGTS, Pokies Anonymous, Private Counselling, Acupuncture and Self-barring. During the project she continued to see a therapist and undergo exposure therapy. At the start of the naltrexone trial Patient two felt a strong urge to gamble most days and spent approximately 90% of her income on gambling and spent on average 70 hours a month in gaming venues. A dose ranging from 50mg-150mg was maintained for five months. Almost immediately Patient two felt her gambling urge reduce (around 10-30%), which allowed her to resist the urge to gamble for the first three months. After three months, Patient two lapsed (won $600) and felt an on-going very strong gambling urge. Despite the dose being increased to 150mg she continued gambling several times a week for another month. At this point, her gambling urge remained high but she was able to resist or only gamble moderate amounts for the remainder of the study. Patient two noticed side effects that lasted approximately six weeks that included: drowsiness, increased eating and frustration. After five months, she found the logistics of the study (blood tests, collecting medication from the hospital) overbearing and withdrew, despite noticing benefits. She was gambling at a reduced rate at the end of the project compared to the start.

Table 4.2 Questionnaire results for Patient two

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	62	31	46	
The Victorian Gambling Screen (VGS)	51	23	40	
Gambling Related Cognitions Scale (GRC)	115	83	74	
The Kessler Psychological Distress Scale (K10)	44	25	40	
The Information Biases Scale	123	137	131	
The Canadian Problem Gambling Index (CPGI)	24	11	34	
The Alcohol Use Disorders Test (AUDIT)	1	1	1	
Goldney Suicidal Ideation Scale	1	0	1	

Figure 4.2 Victorian Gambling Screen results for Patient two



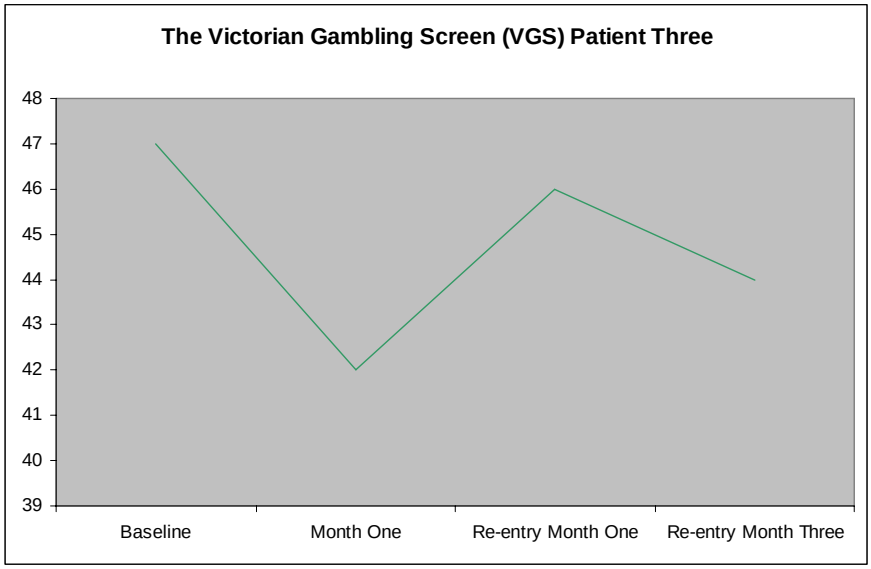
4.3 Patient three

Patient three has been a problem gambler for the last 7-10 years. At the start of the trial he gambled at least once a week and spent approximately $500-$1000 and around 10-20 hours a month in a gaming venue. His gambling behaviour was normally accompanied by socialising and drinking alcohol and in this context he considered himself to be a binge drinker. He has tried cue exposure therapy, counselling at the Wesley Uniting Mission, counselling from a private practice and psychiatric care as an out-patient at a hospital. During the trial a dose ranging from 50mg-150mg was maintained. In the first six weeks Patient three felt his urge to gamble did not reduce at all and he still gambled in excess of $1000 per week, although his drinking reduced considerably. At six weeks (on a dose of 150mg) Patient three withdrew from the study as he experienced headaches, dizziness, nausea and he was still gambling. Three months later Patient three re-entered the study as gambling continued to be a problem and he revealed that he had previously been unwilling to cut-down on drinking. At this point, on 100mg, he reduced drinking and smoking and was able to reduce the amount he spent gambling. However, after three weeks of abstinence, he found he was able to drink alcohol again (despite taking 100mg) and this acted as a trigger to resume gambling. At the end of the study he felt the medication only had minor effect on gambling urge, and actually encouraged him to neglect behavioural strategies. At the end of the project he was gambling excessively and claimed "I feel like I'm relying on naltrexone rather than making an effort with my behaviour".

Table 4.3 Questionnaire results for Patient three

Tool	**Month**			
	0	**1**	**Re-entry**	**3**
Gambling Activities	45	48	46	46
The Victorian Gambling Screen (VGS)	47	42	46	44
Gambling Related Cognitions Scale (GRC)	93	79	83	62
The Kessler Psychological Distress Scale (K10)	32	29	34	28
The Information Biases Scale	114	121	127	123
The Canadian Problem Gambling Index (CPGI)	21	30	31	31
The Alcohol Use Disorders Test (AUDIT)	17	17	23	8
Goldney Suicidal Ideation Scale	2	1	2	0

Figure 4.3 Victorian Gambling Screen results for Patient three



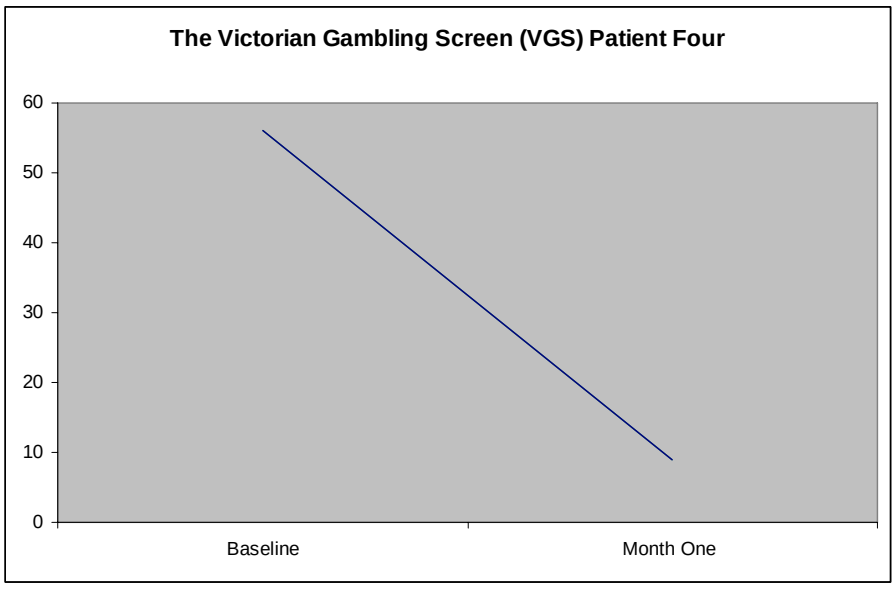
4.4 Patient four

Patient four has gambled excessively on the pokies for the last three years. She was unsuccessful reducing the urge to gamble through cue exposure therapy at the SGTS. She maintained irregular contact with a therapist during the trial and did not undergo exposure therapy again. At the start of the trial she gambled on the pokies almost every day. It was estimated that she would spend at least 100 hours and over $1500 playing the pokies in a month. A dose of 100mg was maintained for approximately two months. During this time Patient four reported a dramatic drop in gambling. Her partner corroborated her report by explaining he had noticed a significant change and that they were able to sit in a venue without gambling. He also felt she was far less distracted by thoughts of gambling. However, the logistics of the study became difficult and Patient four withdrew from the project at two months. She relapsed into gambling behaviour without the medication but declined to enter back into the project, despite her early success. It is not clear how much she is gambling now as she declines all contact.

Table 4.4 Questionnaire results for Patient four

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	53	10		
The Victorian Gambling Screen (VGS)	56	9		
Gambling Related Cognitions Scale (GRC)	123	23		
The Kessler Psychological Distress Scale (K10)	38	12		
The Information Biases Scale	150	25		
The Canadian Problem Gambling Index (CPGI)	26	0		
The Alcohol Use Disorders Test (AUDIT)	0	0		
Goldney Suicidal Ideation Scale	1	0		

Figure 4.4 Victorian Gambling Screen results for Patient four



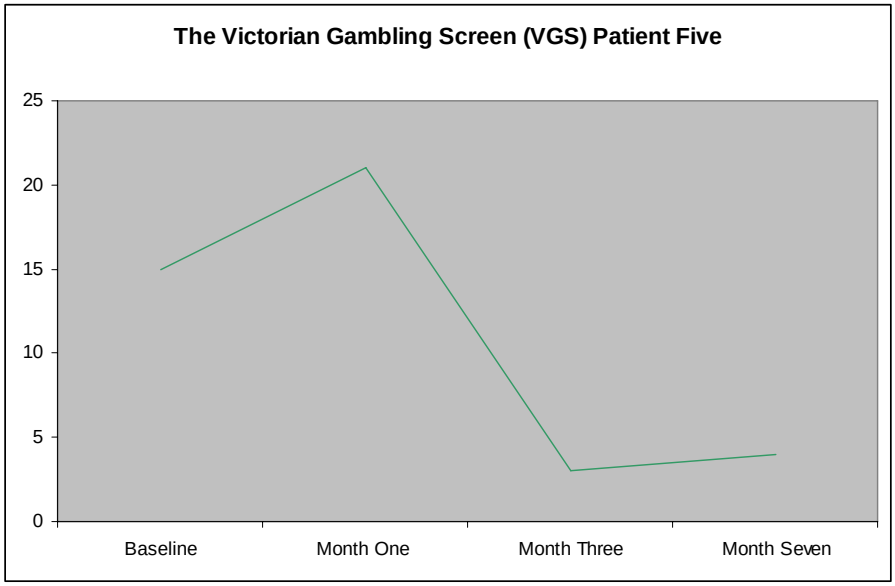
4.5 Patient five

Patient five began the study with a long history of problem gambling, including excessive gambling on the pokies and lotto. He has registered with SGTS, but never properly engaged with the cue exposure therapy. At the start of the project his gambling urge was fairly low, his behaviour was stable and he wasn't gambling on the pokies at all (partly as his money was managed and he had little spare income). However, he was drinking excessively and regularly consumed 22 standard drinks in one night. A dose of 50mg was maintained for 6 months with no breaks in medication. During this time, Patient fives drinking reduced substantially (although he still categorised as alcohol dependant on the AUDIT). He gambled small managed amounts on lotto during the study, with no significant lapses into problem gambling, even when he had access to large amounts of money (e.g. when he won $20,000). He reported few side effects – nausea and drowsiness when drinking. Patient five maintained contact with a therapist at the SGTS, but did not re-engage with cue exposure therapy. He was happy to be involved in the project and had no issues with the logistics of reporting regularly to the hospital (and found the visits helpful). However he would have difficulty paying for the cost of naltrexone. At the end of the study he was only gambling very small amounts.

Table 4.5 Questionnaire results for Patient five

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	31	27	13	12
The Victorian Gambling Screen (VGS)	15	21	3	4
Gambling Related Cognitions Scale (GRC)	37	53	31	23
The Kessler Psychological Distress Scale (K10)	11	16	10	10
The Information Biases Scale	100	82	25	25
The Canadian Problem Gambling Index (CPGI)	7	9	12	11
The Alcohol Use Disorders Test (AUDIT)	18	19	9	10
Goldney Suicidal Ideation Scale	0	0	0	0

Figure 4.5 Victorian Gambling Screen results for Patient five



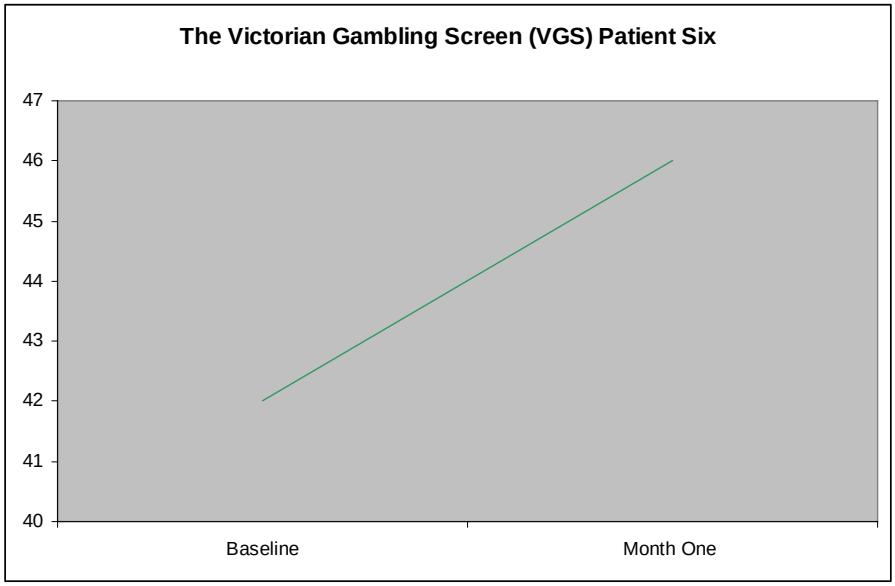
4.6 Patient six

Patient six has had a gambling problem for 5 years, mainly with the pokies. At the start of the project he gambled around 3 times a week spending approximately $150-300 a week. He maintained a dose ranging from 50mg-150mg for four months. During this time his gambling behaviour fluctuated, generally with a continued strong gambling urge and frequent gambling episodes. Until around month three, at which point he had been taking 150mg for two months, and experienced a drop in urge and behaviour. Patient six consistently claimed through-out the project that he felt no effect at all from the medication. He felt like his eventual control over gambling was related to realising the repercussions of excessive gambling. At this point he withdrew from the project. Over the course of the study, Patient six maintained semi-regular contact with a therapist at the SGTS, but did not re-engage with cue exposure therapy. Travelling to the hospital was a significant distance from his home and work-place, but was worth it to try the medication. As he does not attribute the reduced gambling urge to naltrexone, he would not be willing to pay for the treatment. At the end of the project he was in a period of abstinence but claimed "it's related to realising the consequences of gambling…I haven't noticed any effect from naltrexone".

Table 4.6 Questionnaire results for Patient six

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	34	39		
The Victorian Gambling Screen (VGS) Harm to Self Scale	42	46		
Gambling Related Cognitions Scale (GRC)	68	64		
The Kessler Psychological Distress Scale (K10)	28	30		
The Information Biases Scale	115	95		
The Canadian Problem Gambling Index (CPGI)	13	17		
The Alcohol Use Disorders Test (AUDIT)	16	18		
Goldney Suicidal Ideation Scale	0	0		

Figure 4.6 Victorian Gambling Screen results for Patient six



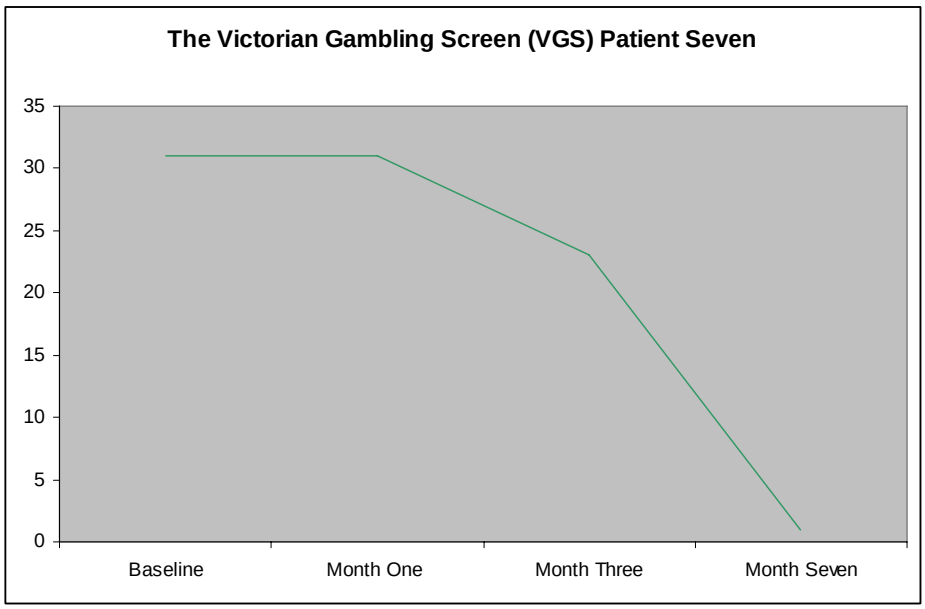
4.7 Patient seven

Patient seven has had gambling problem with the pokies for 8 years. He has registered with SGTS, but never properly engaged with the cue exposure therapy. At the start of the project he had a moderate to strong gambling urge and gambled a few times each month ($1500). A dose of 50mg was maintained for 5.5 months. During this time he abstained completely from gambling. He did feel a moderate gambling urge at times – but he talked himself out of it each time. He experienced side effects including headaches, poor circulation and nausea, although these reduced with time. He attributed this outcome to the medication as he was not undergoing any other therapy. He maintained contact with a therapist at the SGTS, but did not re-engage with cue exposure therapy. He was happy to be involved with the project and had no issues with the project logistics. He requested a referral letter to continue taking the medication and would be happy to pay the cost of naltrexone. At the end of the trial he was not gambling at all and stated "the medication is very helpful".

Table 4.7 Questionnaire results for Patient seven

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	41	27	14	4
The Victorian Gambling Screen (VGS) Harm to Self Scale	31	31	23	1
Gambling Related Cognitions Scale (GRC)	64	42	25	28
The Kessler Psychological Distress Scale (K10)	24	14	11	10
The Information Biases Scale	131	54	86	35
The Canadian Problem Gambling Index (CPGI)	14	20	5	6
The Alcohol Use Disorders Test (AUDIT)	1	1	1	1
Goldney Suicidal Ideation Scale	0	0	0	0

Figure 4.7 Victorian Gambling Screen results for Patient seven



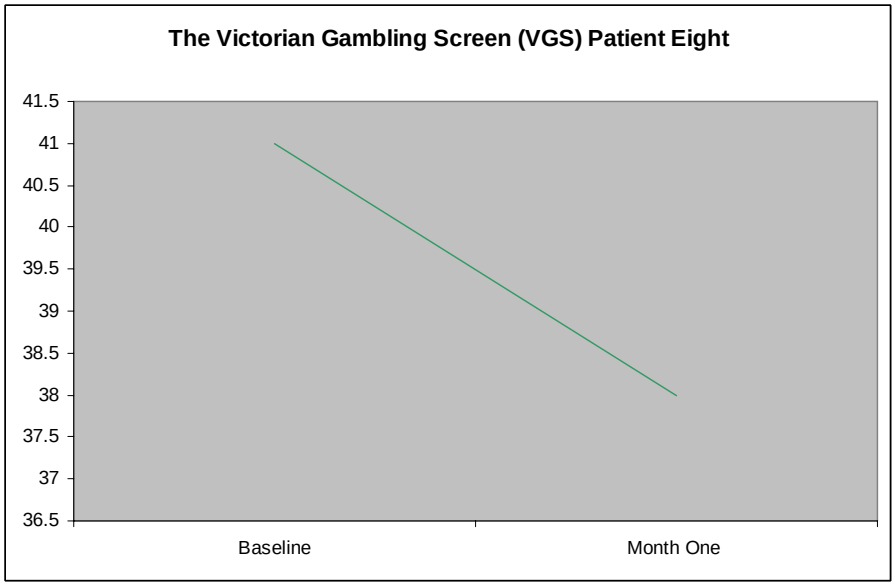
4.8 Patient eight

Patient eight has had a gambling problem for 2-5 years. He first sought help from the SGTS in 2008 but dropped out of the program after completing only four sessions. He had not accessed any other gambling help services. Patient eight mainly gambled on the TAB after work at a hotel or club before going home. His usual pattern is to spend around 1.5 hrs a day and 2 hrs on the weekend and use 60-70% of his income on gambling. A dose of 50-100mg was maintained for five months. For the first month his urge and behaviour decreased, until he stopped the medication for several days, gambled and spent $600. After this time he continued to have a strong gambling urge and to spend around $200 a week (less than prior to naltreoxne study) for the rest of the trial. During the first weeks he experienced drowsiness. At the end of the trial he was gambling moderate amounts.

Table 4.8 Questionnaire results for Patient eight

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	43	45		
The Victorian Gambling Screen (VGS) Harm to Self Scale	41	28		
Gambling Related Cognitions Scale (GRC)	75	104		
The Kessler Psychological Distress Scale (K10)	25	27		
The Information Biases Scale				
The Canadian Problem Gambling Index (CPGI)	14	20		
The Alcohol Use Disorders Test (AUDIT)	13	7		
Goldney Suicidal Ideation Scale	0	0		

Figure 4.8 Victorian Gambling Screen results for Patient eight



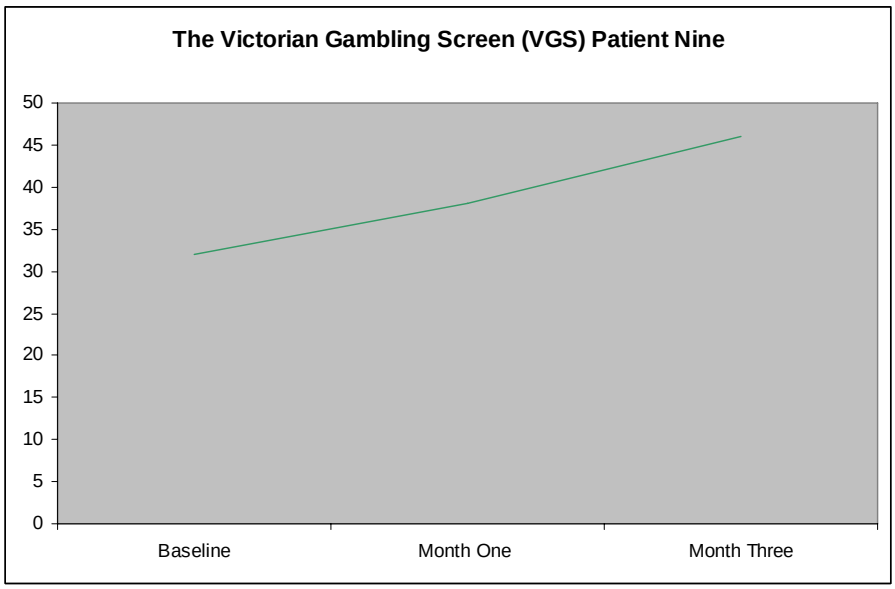
4.9 Patient nine

Patient nine has an 8 year history of problem gambling. At the start of the project he experienced a strong desire to gamble, and gambled a few times a week spending around $800 a month. He maintained a dose of 100mg for 5 months. During this time he experienced increased gambling urges and behaviour. In combination with significant life upheaval (relationship break-up, moving house and selling his house), Patient nine gambled everyday with an unknown total amount (approximately $300-500 a week). During this time he maintained contact with a therapist at the SGTS and saw a private counsellor, but did not re-engage with cue exposure therapy. He experienced night sweats and nausea at the start of the project, but these subsided after month one. He felt the medication had not helped at all, and may have made his gambling worse. As he did not feel the medication had helped, he was reluctant to continue and would not pay for naltrexone. At the end of the trial he was gambling excessively and stated "I don't think naltrexone has helped at all".

Table 4.9 Questionnaire results for Patient nine

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	30	40	45	
The Victorian Gambling Screen (VGS)	32	38	46	
Gambling Related Cognitions Scale (GRC)	62	63	61	
The Kessler Psychological Distress Scale (K10)	24	24	18	
The Information Biases Scale	73	69	86	
The Canadian Problem Gambling Index (CPGI)	10	20	26	
The Alcohol Use Disorders Test (AUDIT)	15	8	15	
Goldney Suicidal Ideation Scale	0	0	0	

Figure 4.9 Victorian Gambling Screen results for Patient nine



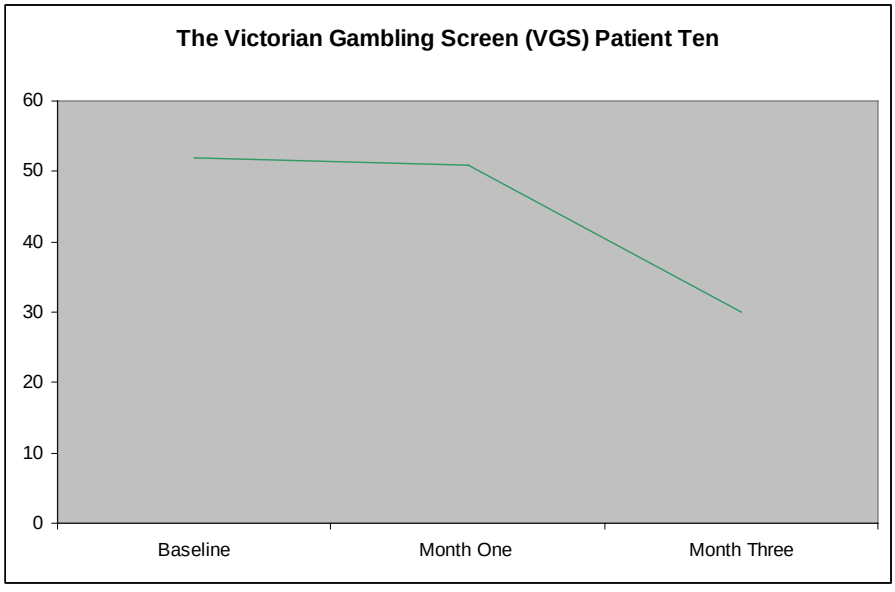
4.10 Patient Ten

Patient ten has a 20-30 year history of problem gambling, mostly on the pokies. In the month preceding the study he did not experience a strong desire to gamble and had only engaged in controlled gambling. However, he was keen to be involved in the study as gambling had been a re-occurring issue for a long time and he could for-see stressful events that may trigger another episode. He maintained a 50mg dose for four months. During this time he experienced little urge to gamble and only engaged in occasional social gambling with small amounts of money ($5). He had a break for one week from the project when he had an upset stomach, but did not experience any side effects. He reported he was happy to be involved in the study and found the contact with extra people around gambling helpful. He claimed he would be happy to pay the cost of naltrexone. At the end of the study he was only gambling small amounts and said "thankyou for allowing me to be involved, the whole project and the extra support has been very helpful".

Table 4.10 Questionnaire results for Patient ten

Tool	**Month**			
	0	**1**	**3**	**6**
Gambling Activities	48	40	24	
The Victorian Gambling Screen (VGS) Harm to Self Scale	52	51	30	
Gambling Related Cognitions Scale (GRC)		81	40	
The Kessler Psychological Distress Scale (K10)	43	39	39	
The Information Biases Scale	142	132	84	
The Canadian Problem Gambling Index (CPGI)	34	30	9	
The Alcohol Use Disorders Test (AUDIT)	18	9	6	
Goldney Suicidal Ideation Scale	4	1	4	

Figure 4.10 Victorian Gambling Screen results for Patient ten



4.11 Patient eleven

Commenced medication, but was unable to return questionnaires or be interviewed in time for the end of the study.

4.12 Group Summary

4.13 Very Improved Patients

Patient one is considered to have improved significantly because she dramatically reduced her gambling behaviour and urge over the course of the study and dropped into the non-pathological range on the VGS at the final assessment (stabled dose 50mg).

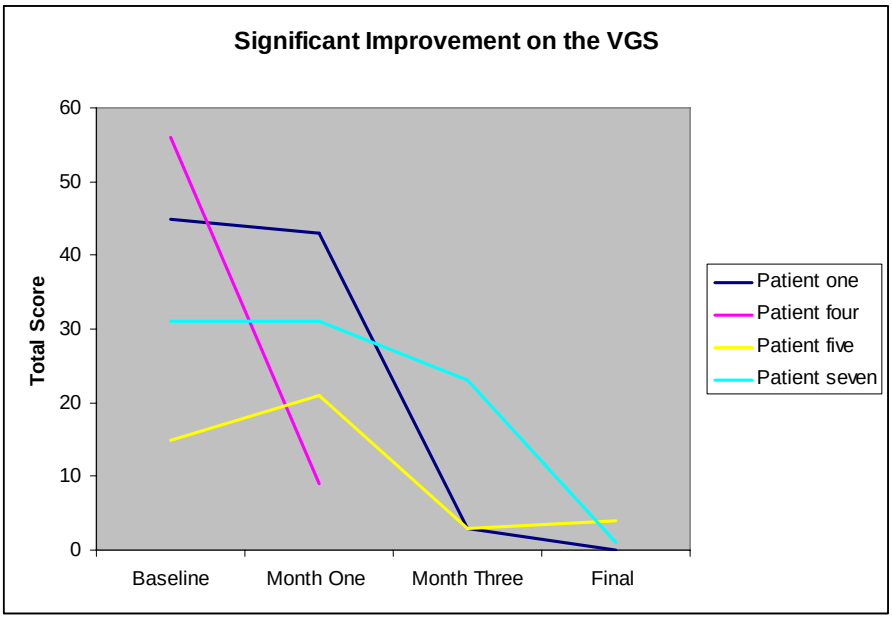
Patient four is also considered to have improved significantly as she also dramatically reduced her gambling behaviour and scores. However, as she dropped out of the study after six weeks, it is not clear if she maintained this improvement (stable dose 100mg).

Patient five is considered significantly improved as his final score was within the non-pathological range. However, it should be noted that his score was low to begin with so he would also fit into the moderately improved category (stable dose 50mg). Patient seven is considered significantly improved as he consistently reduced his gambling behaviour and urge over the course of the study and dropped into the non-pathological range on the VGS at the final assessment (stable dose 50mg).

Characteristics of group

By the end of the project, all patients in the 'very improved' group were classified as non-problem gamblers. As can be seen in figure 4.13, almost everyone in this group maintained the medication for longer than 3 months at a low dose (most 50mg). This level of medication compliance suggests that people found the medication acceptable and beneficial. The low dose suggests that either these people were sensitive to the medication and that it led to a reduction in urge with only a minimal done, or that they were susceptible to the placebo effect. There were no consistent patterns detected across the key outcome measures of age group, gender, time with a gambling problem, ethnicity, previous efforts to extinguish the gambling urge or social support. There were also no consistencies in undergoing cue exposure treatment during the trial (one person continued with cue exposure, while three did not). However, all people were committed to stopping gambling and maintained some kind of behaviour/ cognitive strategy to prevent gambling (money management, self-talk and cue exposure).

Figure 4.13 Victorian Gambling Screen results for Patient with significant improvement



4.14 Moderately Improved Patients

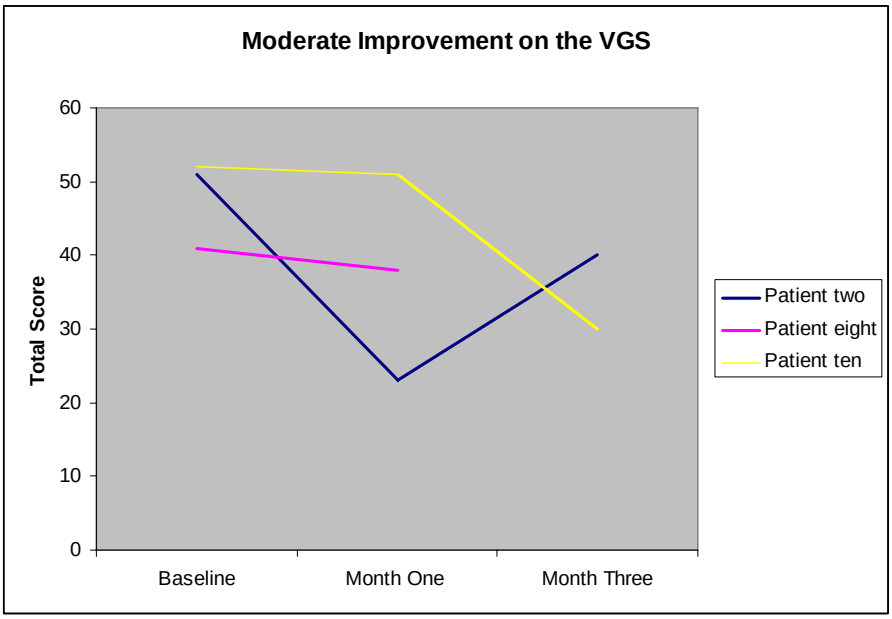
Patient two is considered moderately improved because at her final assessment she was gambling less than prior to the trial but still at a pathological level. It is worth noting that her behaviour and gambling urge fluctuated across the study, with a significantly improved period around month one (stable dose 100-150mg). Patient eight is considered moderately improved as he was gambling less than at the start in the final assessment, but still experienced a moderate urge and lapsed occasionally (stable dose 100mg). Patient ten is considered moderately improved as his gambling behaviour reduced over the study, but did not descend into the non-pathological range. It is worth noting that he had a reduced gambling urge one month prior to taking naltrexone (stable dose 50mg).

Characteristics of group

Everyone in the moderately improved group experienced some benefit from taking naltrexone, yet this was not consistent or could not be classified into non-clinical range on the VGS. As can be seen in figure 4.14 this group did not take naltrexone for as long as the significantly improved group. The people in this group had a higher dose range than the significantly improved, which reflects their struggle to find an effective dose (as the dose was increased until urge dropped 50%). Also, this group was not as consistent in taking the medication as the significantly improved group, as patients two and eight both had breaks in medication that coincided with significant lapses into gambling.

There were no consistent patterns in age group, gender, time with gambling problem, ethnicity, previous efforts to extinguish the gambling urge or social support for this group and, also, there were no consistencies in concurrent cue exposure therapy (patient two continued cue exposure, eight and ten did not feel it was necessary).

Figure 4.14 Victorian Gambling Screen results for Patient with moderate improvement



4.15 Minimally Improved Patients

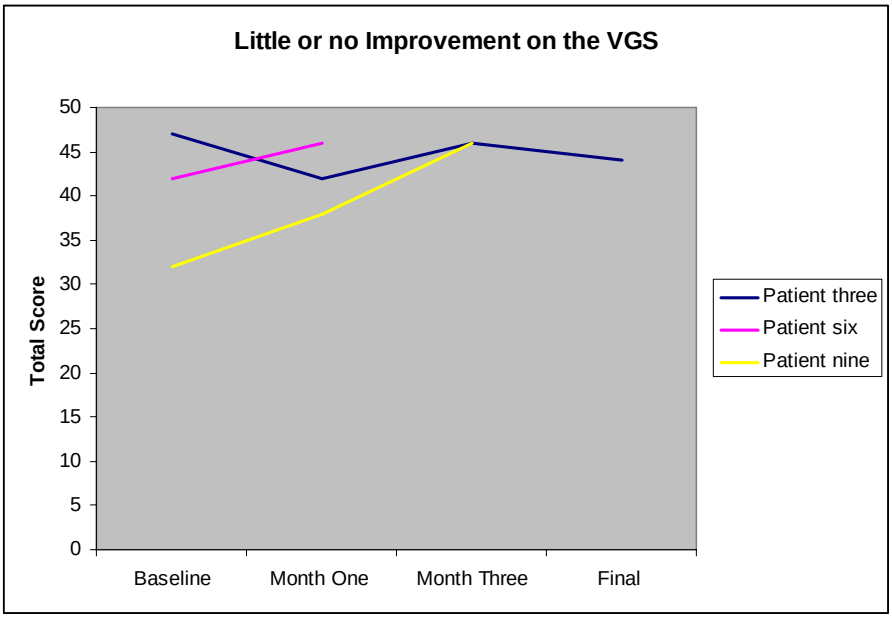
Patient three was categorised into the minimally improved category because although he spent considerable time taking naltrexone at a high dose he consistently experienced a strong gambling urge and gambling behaviour. However, he did note that naltrexone lessened the urge somewhat and his eventual decision to stop the medication was due to the nausea experienced while drinking alcohol (stable dose 150mg).

Patient six was considered minimally improved as his gambling behaviour was consistent across the project, and he consistently claimed that he did not notice any effect from naltreoxne (stable dose 150mg). Patient nine was considered not improved as his gambling behaviour and urge increased across the study (stable dose 100mg).

Characteristics

Everyone in this group experienced no or little benefit from taking naltrexone. This group maintained treatment for approximately the same length as the moderately improved group, at the highest dose level. The high dose reflects the lack of effect at a lower dose and continued gambling urge and behaviour. There are no consistencies in age, social support or previous attempts at therapy across this group, but all three members were Australian-born males. There may be a commonality that each member was sceptical about the ability of naltrexone to reduce their gambling urge, however it may be that as they felt no effect, they grew increasingly doubtful as the study progressed. None of the people in this group actively pursued cue exposure therapy during the trial, and two of the three members did not consistently apply behaviour or cognitive strategies to stop gambling. One member was only able to stop gambling when he stopped drinking alcohol, but was reluctant to do this. One member was going through considerable life turmoil and was actively self-destructive.

4.15 Minimally Improved Patients



5. Results/ Discussion

5.1 Feasibility of offering naltrexone treatment to SGTS clients

The main factors determining whether naltrexone is a feasible treatment option for SGTS clients were the practicability and cost of organising doctors to perform medical screens, monitor progress and prescribe medication and the cost of medication. It has been suggested that organising the psychiatry registrar to perform medical screens and on-going review to a small group each year would be acceptable and easy to facilitate. This significantly reduces the prospective cost of providing the treatment. The cost of providing naltrexone as an adjunct therapy to clients of the SGTS is outlined in table 5.1 below. The results indicate that naltrexone therapy is a relatively expensive option for gambling patients with moderate clinical benefits. However, for treatment-resistant patients who have few other viable treatment options, the cost may be warranted.

Table 5.1 Cost of providing medication to one person for 6 months

Item	**Unit**	**Cost**
Medical screen and review 1 p/month: Psychiatry registrar at FMC	1 hr per month	No cost
Organisation by SGTS reception		No cost
Medication 50-100mg dose	1 month	$150-300
	Total	**$150-300**

5.2 Acceptability of offering naltrexone treatment to SGTS clients

Naltrexone treatment offered through the naltrexone pilot study appears to be acceptable to a small group of treatment resistant SGTS clients. As can be seen from the flow chart on page 8, the majority of SGTS clients approached to participate in the study were not interested or did not find the treatment appealing (or acceptable). However, a select group of patients (15 of 59 targeted people approached), who had

been unsuccessful with previous attempts at therapy, were currently gambling and were not adverse to drug therapy found the idea of treatment attractive.

From the group who commenced medication it seems that the majority did find the therapy acceptable. Two participants withdrew at 6 weeks because they found either the logistics of the study (difficult to come into the hospital), or the medication (side effects from concurrent drinking) unacceptable. Two withdrew after four months because they stopped gambling, and it was no longer a priority to comply with the study requirements. The remaining participants completed the study.

Table 5.2 Length of time in the project

ID	**Time in study**	**Status**	**Break in medication**
1	7 months	Completed	1 week (side effects)
2	5 months	Withdrew	Several days (forgot)
3	6 weeks	Withdrew re-entered 3months	3 months (side effects)
4	6 weeks	Withdrew	None
5	6 months	Completed	None
6	4 months	Withdrew	1 week (illness)
7	5.5 months	Completed	None
8	5.5 months	Completed	1 week (illness)
9	5.25 months	Completed	None
10	4 months	Completed	None
11	1 month	Completed (no results available)	None

5.3 Tolerability

Tolerability can be measured through the prevalence of unpleasant side effects. As can be seen from table 5.3, almost all of the participants reported side effects at week two and approximately half at one month, yet by month three the majority of side effects had subsided. The most common side effect reported was nausea followed by drowsiness.

Table 5.3 Number of people experiencing side effects at each time point

	Time in project				
Side effects	**Week 2**	**Month 1**	**Month 3**	**Final**	**Total**
Nausea	4		1		5
Dizziness	2	1			2
Head ache	2	1	1		3
Poor vision	1	1			2
Poor circulation	2				2
Drowsiness	1	3	1	1	3
Wakefulness		1			1
Excessive eating	1	1			2
Suppressed appetite					
Excessive sweating	1	1			2
Moodiness	1	1			2
Frustration	1	1			2

5.4 Effectiveness

In summary, the effectiveness of naltrexone in reducing the severity of problem gambling can be measured using self-report questionnaires recording gambling behaviour, alcohol use, social functioning and suicidal tendencies. As discussed in the group summaries (page 21-23) the majority of participants (n=7) found the project helpful in reducing the urge to gamble and reported some reduction in gambling urge and gambling behaviour while taking naltrexone. For one group (n=4) of patients, this helped them to reduce their gambling activities into a non-pathological range. For other patients (n=3) the medication helped to 'take the edge off' their gambling urge, but they still continued to gamble at a problematic level. For a final group (n=3) the medication had little or no effect and participants engaged in significant gambling behaviour and would not repeat naltrexone treatment. Overall it is clear that the majority of people benefited from being involved in the study, however, until placebo controlled research is conducted it will not be clear if naltrexone is effective due to treatment non-specific effects (such as the placebo effect, social desirability etc) or through a biochemical process.

6. Future Directions

6.1 Treatment

a. Based on preliminary findings it is recommended that naltrexone treatment is made available to a small group of treatment resistant patients at the SGTS for a maximum period of 6 months, with a dose ranging from 50mg-150mg (depending on urge reduction). It is recommended the treatment should only be made available to people who meet criteria:

- pathological gambler
- confidence in effectiveness of medication
- tried at least four sessions of cue exposure therapy without success
- committed to re-engaging in cue exposure therapy
- committed to over-coming gambling behaviour
- normal liver/ kidney function

6.2 Research

a. It is recommended that research is conducted to follow-up patients from the current naltrexone pilot study 6 months and a year after ceasing medication.

b. It is recommended that research is conducted to follow the progress of future SGTS patients who take up the naltrexone treatment option.

c. It is recommended that a randomised controlled trial is conducted in order to understand the mechanisms underlying successful use of naltrexone. Until placebo controlled research is conducted it will not be clear if naltrexone is effective due to treatment non-specific effects (such as the placebo effect, social desirability etc) or through a biochemical process.

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Appendix

Appendices 1.	**Participant Information sheet and consent form**
Appendices 2.	**Naltrexone media fact-sheet**
Appendices 3.	**Alcohol Use Disorders Test** **Canadian Problem Gambling Index** **Gambling Activities** **Gambling Related Cognitions Scale** **Gambling Urge Scale** **Goldney Suicide Scale** **Informational Biases Scale** **Victorian Gambling Screen** **Kessler K10**
Appendices 4.	**Abbreviated MIMs entry for naltrexone**

Southern Adelaide Health Service / Flinders University

Flinders Clinical Research Ethics Committee

Flinders University and the Independent Gambling Authority

A feasibility, acceptability and preliminary effectiveness study of naltrexone in treatment-resistant problem gambling

Participant Information Sheet

Researchers: Prof Malcolm Battersby, Dr Peter Harvey, A/Prof Michael Baigent, Dr Rene Pols, Dr Carolyn Edmonds, Ms Jane Oakes, Ms Faye Forbes, Ms Sharon Harris, Ms Laufey (Faye) Thordardottir, Mr Ben Riley.

Dear sir/ madam,

The researchers listed above are contacting you in relation to a research project trialling a new treatment for problem gambling. We would like to invite you to participate in this research project but whether you wish to join or not is entirely up to you. Whether you take part or not, the services which you receive from the Statewide Gambling Therapy Service will not be affected in any way.

You have been selected as a potential participant for the study because of your involvement with the Statewide Gambling Therapy Service (SGTS). A treating therapist with the SGTS has referred you to our research team because they believe you may be suitable for the study.

Aim: The study aims to see if a medication normally used to treat alcohol dependency, Naltrexone Hydrochloride, is effective in reducing or eliminately the symptoms of problem gambling.

Involvement: Your involvement with the study will span around ten months. To start with, you will meet with one of our project staff to sign a consent form and complete some questionnaires. Then you will need to present for an initial medical screening session with a clinician at the Centre for Anxiety and Related Disorders (CARD) at Flinders Medical Centre, which will take up to an hour. During the medical appointment you will have a blood sample taken to check your liver and kidneys are performing correctly. If you are a woman and think you may be pregnant, the doctor will also give you a pregnancy test. The study cannot include anyone who is already pregnant, and any women who become pregnant during the project will have to withdraw from the study, and stop taking naltrexone.

If your liver and kidneys are functioning properly, you are not pregnant and you don't have any severe psychological disturbances or dependancies (such as alcohol or opiate dependancy), then the clinician will prescribe a month's supply of the medication naltrexone for you.

For the first 6-12 weeks of the project you will have weekly sessions with a therapist at the Statewide Gambling Therapy Service, which will take up to an hour. This gives the therapist a chance to monitor how the medication is impacting your gambling behaviour. You will also have fortnightly visits to the treating clinician in order to check your liver and

kidney function and receive a series of prescriptions for naltrexone (this will be managed via FMC pharmacy for ease of access etc).

The project doctor will gradually increase the dose of naltrexone that you take everyday (the daily dose will increase 50 mg every fortnight) until the gambling urge you experience when you are presented with a trigger specific to you, is reduced by at least 50%; or until the dose reaches 250 mg p/day; or until you experience side effects (such as gastrointestinal upset, dizziness, headaches). At the regular appointments with the treating clinician from CARD, the doctor will take a sample of urine and check you are taking the medication as agreed.

Before treatment and 1, 3, 6 and 7-10 months into the study you will be required to complete some questionnaires which will take around an hour to complete. The questionnaires might ask you to disclose some personal or sensetive information, for example information about the amount of money you have spent on gambling in the last week.

If you choose to partake in the naltrexone feasibility study, you will still have all the other elements of the Statewide Gambling Therapy program avalaible to you, including: financial counseling, education, problem solving, help addressing other dependencies, and the family and cognitive behaviour therapy program.

In clinical practice people are generally only prescribed naltrexone for a 3-12 month period. In this project, you will have access to naltrexone for approximately ten months. You will not be supplied naltrexone beyond the end of the project. However if you would like to continue taking the medication you will be able to access the drug by visiting a GP and receiving a private script.

Benefits: There is some evidence that suggests naltrexone hydrochloride is helpful in reducing the symptoms of pathological gambling. You may experience an improvement in your behaviours related to problem gambling.

Risks: Some people who have taken naltrexone have experienced nausea, headache, dizziness, nervousness, fatigue, insomnia, vomiting, anxiety and drowsiness. There is also some evidence that when people take naltrexone they might have difficulty experiencing pleasure from activities they normally enjoy, for example eating, sex and exercise. If you are severely troubled by side effects the doctor will cease prescribing naltrexone for you.

Naltrexone can cause liver injury in large doses taken over a long period. If you develop abdominal pain lasting more than a few days, white bowel movements, dark urine, or yellowing of your eyes, you should stop taking naltrexone immediately and see your doctor as soon as possible. We will be monitoring your liver function using a blood test and if liver injury is noted, the doctor will cease prescribing it.

You will need to be very clear with your doctor if you are taking any other medications, as studies looking at the possible interactions between naltrexone and drugs other than opiates have not been performed and the effect of mixing medications is not known.

Naltrexone blocks the action of opiate drugs and medications (such as cough and cold preparations, antidiarrheal preparations and strong painkillers eg morphine, heroin, codeine, methadone). If you do need pain relief you can take paracetamol, aspirin or antiinflammatories such as ibuprofen with good effect. In an emergency situation, if stronger painkillers are required your doctor or hospital will be able to provide this by giving you a larger than usual dose of opioid. As a result, your breathing may be particularly slow and will need to be monitored carefully during any medical procedures.

You will be given a medic-alert bracelet to wear in case you have an accident/injury or need opiate pain killers for some other reason as painkillers may not work properly until

the naltrexone wears off (this takes up to 72 hours). You will need to wear the bracelet at all times to alert medical personnel to the fact that you are taking naltrexone. Wearing the bracelet should help to ensure that you can obtain adequate treatment in an emergency. Also be sure to tell the treating physician that you are receiving naltrexone therapy.

If you take naltrexone and you are already regularly taking opioids (eg methadone, morphine or heroin) you are likely to get withdrawal symptoms and a return of the pain for which they were prescribed.

Compensation: If you suffer injury as a result of participation in this research or study, compensation might be paid without litigation. However, such compensation is not automatic and you may have to take legal action to determine whether you should be paid.

Confidentiality: All records containing personal information will remain confidential and no information which could lead to your identification will be released, except as required by law. This includes the blood samples taken during the course of the project.

Publication: The results of this study are the property of the sponsor and Flinders University and may be published in scientific journals at a later date. It is possible that the results may not be published for commercial, scientific or other reasons.

Withdrawal: You are free to participate or not to any extent and free to withdraw at any time. If participation is withdrawn then you have the option to withdraw your information.

Outcomes: As a Participant you will not be informed of the overall results of the study, except via published scientific reports.

Contact: If you would like further information about joining the study please contact our project staff on **(08) 8404 2607**. If you would like to contact the principal researcher please contact Prof Malcolm Battersby on malcolm.battersby@flinders.edu.au

FCREC

This study has been reviewed by the Flinders Clinical Research Ethics Committee. If you wish to discuss the study with someone not directly involved, you may contact the Executive Officer, FCREC at the Flinders Medical Centre (8204 4507) or email research.ethics@fmc.sa.gov.au.

Southern Adelaide Health Service / Flinders University

CONSENT TO PARTICIPATION IN RESEARCH

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

give consent to my involvement in the research project the **Naltrexone Feasibility Study**
I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect me, have been fully explained to my satisfaction by

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

and my consent is given voluntarily.

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

1. Medical Examination
2. Administration of Naltrexone Hydrochloride
3. Monitoring Therapy with a Trained Therapist
4. On-going Psychological Questionnaires and Interviews

- o I have understood and I am satisfied with the explanations that I have been given.
- o I have been provided with a written information sheet.
- o I understand that my involvement in this research project may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.
- o I declare that I am over the age of 18 years.
- o I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action to determine whether I should be paid.

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

I, ... have described to .....
the research project and nature and effects of procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

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

Status in Project: .....

Fact Sheet

Naltrexone Feasibility, Acceptability and Preliminary Effectiveness Study

Chief Researchers: M Battersby, R Pols, M Baigent and P Harvey

What is naltrexone?

Naltrexone (naltrexone hydrochloride) is an opioid receptor antagonist which operates by blocking the action of opiates in the brain. This includes manufactured opiates such as morphine and heroin and naturally occurring neurotransmitters such as dopamine.

Although there is still discussion about the precise mechanism of naltrexone, it probably has an effect on behaviour by acting on the dopamine driven reward pathways (Grant & Kim, 2002).

What is naltrexone used for?

Naltrexone is most commonly used to treat alcohol dependency, but it's also sometimes used as an adjunctive therapy in maintenance of former opioid dependent patients. These are approved uses of the medication and any GP is able to prescribe a course of naltrexone in these situations (MIMs).

In addition, there have been reports of using naltrexone to help patients overcome impulse control disorders such as problem gambling, kleptomania and shopping addiction (Crockford & el-Guebaly, 1998).

However, presently naltrexone is only approved for use in the treatment of alcohol dependency and as an adjunct treatment to maintain abstinence from opioid use. Further research is required before naltrexone can be considered a validated treatment for other conditions, such as overcoming impulse control disorders.

What are we using naltrexone for?

The current pilot study is using naltrexone to treat the urges associated with problem gambling in a small sample of people (10-15) who have been unsuccessful with behavioural therapy.

Is it likely to be effective in treating problem gambling?

There is limited previous research into the efficacy of naltrexone. However, previous reports (case studies, an open-label trial and a randomised controlled trial) all reported naltrexone was effective in reducing the urge to gamble (Kim, 1998, Kim & Grant 2001, Kim et al. 2002, Dannon et al, 2005).

What are the side effects of naltrexone?

The list of side effects associated with naltrexone includes: nausea, vomiting, diarrhoea, constipation, stomach pains, headache, drowsiness, nervousness, dizziness, chest pain, joint and muscle pain, rash, tiredness and anxiety. There is also debate in the research literature about whether naltrexone is associated with dysphoria (unpleasant mood). It is unclear what the true relationship is as the literature has evidence to support and refute the association (Crowley et al 1985, Malcolm et al 1987, Miotto et al, 2002).

What pre-cautions are undertaken to minimise risk in the study?

Liver and kidney function is monitored fortnightly or monthly by the project doctors. Psychological changes are monitored in fortnightly sessions with a gambling therapist.

Who is sponsoring the study?

The Independent Gambling Authority is sponsoring the study. The pharmaceutical company manufacturing naltrexone is not sponsoring the project through donations of money or medication.

What are some controversial issues?

-Drugs vs behavioural therapy for psychological issues

-Use of naltrexone to facilitate opiate withdrawal (rapid detox)

-Similarity to naloxone (reverses opiate overdose)

AUDIT

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

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

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

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

	0 No	2 Yes, but not in the last year	4 Yes, during the last year
9. Have you or someone else been injured because of your drinking?	○	○	○
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	○	○	○

Sum of all (10) item scores:	**TOTAL**

CPGI

Thinking about the past 12 months, please answer the following questions about your gambling:

	0 *Never*	1 *Sometimes*	2 *Most of the time*	3 *Almost always*
1. How often have you bet more than you could really afford to lose?	○	○	○	○
2. How often have you needed to gamble with larger amounts of money to get the same feeling of excitement?	○	○	○	○
3. When you gambled, did you go back another day to try to win back the money you lost?	○	○	○	○
4. Have you borrowed money or sold anything to get money to gamble?	○	○	○	○
5. Have you felt that you might have a problem with gambling?	○	○	○	○
6. Has gambling caused you any health problems, including stress or anxiety?	○	○	○	○
7. Have people criticised your betting or told you that you have a gambling problem, regardless of whether you thought it was true?	○	○	○	○
8. Has your gambling caused any financial problems for you or your household?	○	○	○	○
9. Have you felt guilty about the way you gamble or what happens when you gamble?	○	○	○	○

TOTAL

Sum of scores for items 1 – 9: ☐

Still thinking about the last 12 months:

	Never	*Sometimes*	*Most of the time*	*Almost always*
10. Have you lied to family members or others to hide your gambling?	○	○	○	○
11. Have you bet or spent more money than you wanted to on gambling?	○	○	○	○
12. Have you wanted to stop betting money or gambling but didn't think you could?	○	○	○	○

Next, we explore some of your beliefs about gambling, as well as any early experiences you have had with gambling or betting money. For each of the following, please indicate if you strongly agree, agree, disagree, or strongly disagree:

	Strongly agree	*Agree*	*Disagree*	*Strongly disagree*
13. After losing many times in a row you are more likely to win	○	○	○	○
14. You could win more if you used a certain system or strategy	○	○	○	○

Please answer Yes or No to the following questions:

	Yes	*No*
15. Do you remember a big win when you first started gambling?	○	○
16. Do you remember a big LOSS when you first started gambling?	○	○
17. Has anyone in your family EVER had a gambling problem?	○	○
18. Has anyone in your family EVER had a drug or alcohol problem?	○	○
19. In the last 12 months, have you used alcohol or drugs while gambling?	○	○
20. Have you gambled while drunk or high in the last 12 months?	○	○
21. In the last 12 months, have you felt that you might have an alcohol or drug problem?	○	○
22. If something painful happened in your life, did you have the urge to gamble?	○ *	○
23. If something painful happened in your life, did you have the urge to have a drink?	○ *	○
24. If something painful happened in your life, did you have the urge to use drugs? Or medication?	○ *	○
25. Have you been under a doctor's care in the last 12 months because of physical or emotional problems brought on by stress?	○	○
26. Have you felt seriously depressed in the last 12 months?	○	○
27. In the last 12 months have you seriously thought about or attempted suicide as a result of your gambling?	○	○

* This includes doing as well as having the urge

Gambling Activities

Please note: Questions 1 – 9 are for gamblers only, questions 10 – 12 are for all clients.

	0 Never	1 A few times	2 Weekly	3 A few times a week	4 Daily or more often
1. How often did you gamble on gaming machines during the last month?	○	○	○	○	○
2. How often did you gamble on other gambling activities during the last month?	○	○	○	○	○

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

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

	0 Never	1 Rarely	2 Some-times	3 Often	4 Always
7. How frequently do you spend more money than you planned in a gambling session?	○	○	○	○	○

8. How would you rate the strength of your urge to gamble during the past month on the scale below?

None at all		*Slight*		*Definite*		*Marked*		*Very severe*
○	○	○	○	○	○	○	○	○

9. How difficult would it have been to resist gambling during the past month if you had had money in your wallet or purse?

Not at all		*Slightly difficult*		*Moderately difficult*		*Very difficult*		*Extremely difficult*
○	○	○	○	○	○	○	○	○

10. How would you rate the present state of your financial problem on the scale below?

None at all		*Slight*		*Definite*		*Marked*		*Very severe*
○	○	○	○	○	○	○	○	○

11. How satisfied are you with the way you manage your finances?

Very satisfied		*Fairly satisfied*		*Neither satisfied nor dissatisfied*		*Fairly dissatis-fied*		*Very dissatis-fied*
○	○	○	○	○	○	○	○	○

12. How would your rate the present state of the gambling problem on the scale below?

None at all		*Slight*		*Definite*		*Marked*		*Very severe*
○	○	○	○	○	○	○	○	○

Gambling Related Cognitions Scale

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

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

(continues on next page)

	1 Strongly disagree	2 Moderately disagree	3 Mildly disagree	4 Neither agree / disagree	5 Mildly agree	6 Moderately agree	7 Strongly agree
13. I collect specific objects that help increase my chances of winning	○	○	○	○	○	○	○
14. When I have a win once, I will definitely win again	○	○	○	○	○	○	○
15. Relating my losses to probability makes me continue gambling	○	○	○	○	○	○	○
16. Having a gamble helps reduce tension and stress	○	○	○	○	○	○	○
17. I'm not strong enough to stop gambling	○	○	○	○	○	○	○
18. I have specific rituals and behaviours that increase my chances of winning	○	○	○	○	○	○	○
19. There are times that I feel lucky and thus, gamble those times only	○	○	○	○	○	○	○
20. Remembering how much money I won last time makes me continue gambling	○	○	○	○	○	○	○
21. I will never be able to stop gambling	○	○	○	○	○	○	○
22. I have some control over predicting my gambling wins	○	○	○	○	○	○	○
23. If I keep changing my numbers I have less chance of winning than if I keep the same numbers every time	○	○	○	○	○	○	○

TOTAL

Sum of all (23) item scores: ____

Gambling Urge Scale

Please rate on a scale of 0 (disagree) to 7 (agree) how you would respond to the following questions:

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

Goldney Suicide Scale

The following questions are about how your health has been for the past few weeks. Please respond to all of the following questions by ticking the answer which you think most nearly applies to you.

		0	0	1	1
		Not at all	***No more than usual***	***Rather more than usual***	***Much more than usual***
1.	Have you recently felt that life wasn't worth living?	○	○	○	○
2.	Have you recently thought of the possibility that you might do away with yourself?	○	○	○	○

		0	0	1	1
		Definitely not	***I don't think so***	***Has crossed my mind***	***Definitely has***
3.	Have you recently found yourself wishing you were dead and away from it all?	○	○	○	○
4.	Have you recently found that the idea of taking your own life kept coming into your mind?	○	○	○	○

TOTAL

Sum of all (4) item scores: _____

Informational Biases Scale

Note: If you don't play the pokies, please proceed to the next questionnaire – no need to fill this one in.

	Don't agree at all			*Partially agree*			*Strongly agree*
	1	*2*	*3*	*4*	*5*	*6*	*7*
1. I believe that some machines keep me from winning because they are programmed to produce fewer wins than normal	○	○	○	○	○	○	○
2. In some establishments the pokies are more likely to pay out than others	○	○	○	○	○	○	○
3. I would rather use a poker machine that I am familiar with than one that I have never used before	○	○	○	○	○	○	○
4. The longer a poker machine has gone without paying out a large sum of money, the more likely are the chances that it will pay out in the very near future	○	○	○	○	○	○	○
5. I have purposely avoided playing on poker machines that have recently paid out a lot of money	○	○	○	○	○	○	○
6. I know some poker machine users who are just plain lucky	○	○	○	○	○	○	○
7. I have a favourite poker machine that I use	○	○	○	○	○	○	○
8. One's chances of winning are better if he or she gambles on a machine that has not paid out in a long time	○	○	○	○	○	○	○
9. People win large amounts of money on pokies on a fairly frequent basis	○	○	○	○	○	○	○
10. Hearing about other people winning on the pokies encourages me to keep on playing	○	○	○	○	○	○	○
11. When I see others winning on poker machines, I feel that my turn is coming too	○	○	○	○	○	○	○
12. There are certain strategies (for example, betting all your credits at once) that one can use with poker machines to help him or her win	○	○	○	○	○	○	○

Victorian Gambling Scale

Please indicate how much you agree or disagree with the following statements by ticking the appropriate box:

	Don't agree at all			*Partially agree*			*Strongly agree*
	1	*2*	*3*	*4*	*5*	*6*	*7*
1. It makes me upset when I almost win on pokies	○	○	○	○	○	○	○
2. If I win on a certain machine, I am more likely to use that machine again at a later date	○	○	○	○	○	○	○
3. After a long string of wins on a poker machine, the chances of losing become greater	○	○	○	○	○	○	○
4. If I experience a long string of losses on a poker machine, a big win must be coming just around the corner	○	○	○	○	○	○	○
5. If I'm experiencing a losing streak, the thought that a win has to be coming soon keeps me gambling	○	○	○	○	○	○	○
6. I know some people who gamble that are just plain unlucky with pokies	○	○	○	○	○	○	○
7. Thinking about times that I have won on the pokies encourages me to keep playing	○	○	○	○	○	○	○
8. I sometimes find myself trying to win back money that I have lost on the pokies	○	○	○	○	○	○	○
9. Winning on the pokies makes me feel skilful	○	○	○	○	○	○	○
10. Sometimes, I'll keep on playing the pokies because I get a strong feeling that I'm about to win	○	○	○	○	○	○	○
11. I sometimes talk to the machine in order to make it do what I want. For example, I will sometimes mutter, "Come on! Come on!" under my breath	○	○	○	○	○	○	○
12. Winning on the pokies encourages me to keep on playing	○	○	○	○	○	○	○
13. I tend to think more about my wins than my losses on the pokies	○	○	○	○	○	○	○

Sum of all (25) item scores: **TOTAL** _____

Kessler K10

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

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

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

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

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

	5 *All of the time*	4 *Most of the time*	3 *Some of the time*	2 *A little of the time*	1 *None of the time*
19. In the past four weeks, about how often did you feel so restless that you could not sit still?	○	○	○	○	○
20. In the past four weeks, about how often did you feel depressed?	○	○	○	○	○
21. In the past four weeks, about how often did you feel that everything was an effort?	○	○	○	○	○
22. In the past four weeks, about how often did you feel so sad that nothing could cheer you up?	○	○	○	○	○
23. In the past four weeks, about how often did you feel worthless?	○	○	○	○	○
					TOTAL

Naltrexone hydrochloride

Bristol-Myers Squibb Pharmaceuticals

MIMS Abbreviated Prescribing Information

Section: 20(b) Agents used in drug dependence
Consumer Medicine Information: Available

Pregnancy Category: B3

Sport Category: Permitted in sport

Uses/Indications: Alcohol dependence (within treatment program); adjunctive therapy in maintenance of former opioid dependent patients

Contraindications: Patients receiving opioid analgesics; current opioid dependence; acute opioid withdrawal; failed Narcan challenge test, positive urine screen for opioids; acute hepatitis, hepatic failure

Precautions: Precipitation of abstinence; precipitated withdrawal; hepatic, renal impairment; ultrarapid detoxification; pregnancy, lactation, children

Adverse Reactions: Hepatotoxicity; GI upset; headache; dizziness; nervousness; fatigue; somnolence; anxiety; joint, muscle pain; others, see full PI

Drug Interactions: Thioridazine; opioid containing medicines; laboratory tests: enzymatic methods of opioid detection (possible interference), see full PI

REVIA (**Tablet**) Prescription required. S4
Naltrexone HCl; lactose; pale yellow, f-c, scored; gluten free;
Dose: Alcohol dependence: 50 mg once daily for up to 12 wks. Opioid dependence: 25 mg initial dose, 50 mg/day thereafter. Perform Narcan challenge
Pack: 50 mg [30] Brand substitution is permitted. : Authority - PBS/RPBS (Rp 1)
[Approved indication(s) for authority: For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.] PBS: $143.33