AUT UNIVERSITY GAMBLING AND ADDICTIONS RESEARCH CENTRE

Statistical Analysis Plan (SAP)

Effectiveness study of problem gambling standard and brief interventions

(NZMoH Ref: RM1013 Problem Gambling)

SAP Draft Date: 19 July 2012

SAP Version: 1.3

Revision History

Version	Date	Author(s)	Summary of Changes/Comments
1.0	18 May 2012	Alain C. Vandal	Initial version
1.1	13 June 2012	Alain C. Vandal	1. Inclusion of additional secondary Hypothesis C* to investigate changes between 3 and 12 months. 2. Removal of treatment-related heteroscedasticity checks and analysis adjustment 3. Specifications regarding baseline adjustment of primary outcomes, and PRIME-MD and NZDI secondary outcomes. 4. Restriction of list of adjustment covariates 5. Changes to the list of subgroup analyses 6. Expansion of PGSI-12-specific analyses 7. Inclusion of formal and informal assistance as test parameters in Hypothesis E 8. Other smaller changes
1.2	11 July 2012	Alain C. Vandal	1. Removal of adjustment for baseline in logistic regressions 2. Minor corrections
1.3	19 July 2012	Alain C. Vandal	1. Correction: inclusion of baseline in statements of Hypothesis D 2. Introduction of a test of random effects 3. Corrections on weighting 4. Corrections on baseline adjustments 5. Correction of “Goal met” analyses

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1 Amendments from previous versions

1.1 Version 1.0

The GEE analysis planned in the original proposal has been replaced by a mixed model analysis for normal and non-normal data. This change will yield very similar inference with normal outcomes and correct, individual- rather than population-based inference for non-normal outcomes.

1.2 Version 1.1

*1.2.1 Introduction of Hypothesis C**

Secondary Hypothesis C* with subhypotheses d, e and f (Section 3.2.3) was introduced to gauge the sustainability of the MI+W+B intervention as compared to the other three arms.

1.2.2 Removal of contingencies for heteroscedasticity across treatment arms

Testing for heteroscedasticity across treatment arms (section 7.7.2) and analytical contingencies for heteroscedasticity across treatment arms (in Section 7_4_3) were removed from the SAP. This decision was made for two reasons. The first was expediency. The second was the value of maintaining similar interpretability across the data analytical approaches for each outcome. Only statistical efficiency of the estimators, not their unbiasedness, can be affected by unchecked treatment arm heteroscedasticity.

1.2.3 Restriction of the list of potential confounders

The list of potential confounder is now displayed in Table 1, Section 7.2.2. This section also now specifies the process according to which potential confounders will be retained or not to adjust the treatment effect estimates, and the reporting policy on estimates related to confounders.

1.2.4 Baseline adjustment using outcome data collected post-randomisation

Baseline adjustment policy using post-randomisation data is described in Sections 7.2.1 and 7.7.6.

1.2.5 Change to the list of subgroup analyses

Subgroups for analyses were redefined and added. The changes are:

- Gambling severity: Median PGSI-12 used as cutpoint instead of value of 8
- Cutpoints for Mental health and Active alcohol abuse or dependence specified
- Problem gambling duration removed, as problem gambling severity is identified by PGSI.

- Inclusion of Goal and Belief in success at baseline as subgroup criteria.

1.2.6 Expansion of the PGSI-12 analyses

PGSI-12, although formally remaining a secondary outcome, will undergo the same analyses as primary outcomes. This includes analyses involving the equivalence hypothesis A in the ITT analysis set; primary hypotheses in the PP analysis set; and Hypothesis E.

1.2.7 Inclusion of formal and informal assistance as test parameters in Hypothesis E

The variables C5_6_Assist_informal and E3_7_Assist_formal, denoting assistance received by persons in an informal setting and by persons or institutions in a formal setting, respectively, have been included as potential replacement for the *A* variable in analyses involving Hypothesis E. A comment as to an alternative analysis for these is also included in Section 7.8.

1.2.8 Others

1. Inclusion of a protocol summary (Section 2).
2. References to the absence of time trend analyses have been clarified (p. 15).
3. The statement regarding effect modifiers was made more precise under Section 7.2.3.
4. Counsellor-specific random effects were included in the description of the variance-covariance structure (Section 7.3).
5. The phrase “univariate analyses” was replaced by “timepoint-specific analyses” under Section 7.3.
6. In Section 7.4.3, the phrase “with variance estimated in the full repeated measures setting” was added under the heading “Absence of repeated measures”.
7. Secondary outcome S2_8_SuicIdeation12 was removed from the outcomes and converted to covariate C9_3_SuicIdeation12, as its information was collected at baseline only.
8. Secondary outcome S2_4_4_PRIME-MD_Alc was removed. Sufficient information regarding alcohol-related comorbidities is collected through the AUDIT-C tool.
9. Secondary outcome S2_4_5_PRIME-MD_Bipolar was added.
10. Section 8 has been renamed *List of Planned Noninferential Outputs* from *List of Planned Outputs*.
11. Analyses in Appendix A were renumbered to correct errors in version 1.0 and to accommodate new analyses.

12. Covariates to be considered as potential confounders and covariates used to define subgroups for analyses are now identified in Appendix C as well as Sections 7.2.2 and 7.5.3.
13. Appendix B from version 1.0 is relabelled Appendix C in version 1.1.

1.3 Version 1.2

1.3.1 Clarification of variance structure in the absence of random effects

Analysis II (7.5.2) was separated into II.1 (individual random effects) and II.2 (no individual random effects). Adjustments were made elsewhere, most notably in Appendix B, to reflect this change.

1.3.2 Removal of baseline adjustment for regressions of categorical outcomes

Baseline adjustment in logistic and multinomial regressions has been removed. Both expediency for multiple imputation and the low improvements in efficiency expected from this adjustment justify this removal. In the case of S5_1_Goal_met3 this change rectifies an error as no baseline measure was available.

This change affects the analyses of S1_2_Control (41), S2_4_1_PRIME-MD_PHQ-9 (47), S2_4_2_PRIME-MD_Dysth (48), S2_4_3_PRIME-MD_MinorDep (49), S2_4_5_PRIME-MD_Bipolar (50), S2_5_1_Tob_current (51, 52), S2_5_2_Tob_freq (53, 54), S2_6_TxMH12 (55), S2_7_RxMH12 (56), S2_9_TxDrugAlcohol12 (57), S4_5_Legal_Probl (68, 69), S5_1_Goal_met3 (71, 72).

1.4 Version 1.3

1.4.1 Inclusion of baseline in statements of Hypothesis D

Correction of error and clarification of the treatment of P3_Gambling_QorI in the context of this hypothesis. The threshold in this case has been established at 5%. See Analysis 20.

1.4.2 Introduction of random effects testing

Random effects will be tested and possibly excluded from analysis as per 7.7.7. The description of analyses PGSI at 12 months (25, 31, 34), S2_3_DAST (46); S2_4_1_PRIME-MD_PHQ-9 (47); S2_4_2_PRIME-MD_Dysth (48); S2_4_3_PRIME-MD_MinorDep (49); S2_4_5_PRIME-MD_Bipolar (50); S2_6_TxMH12 (55); S2_7_RxMH12 (56); S2_9_TxDrugAlcohol12 (57); S4_6_NZDI (70).

1.4.3 Correction on weighting

The following analyses were identified as not requiring weighting: PGSI at 12 months (25, 31, 34); PGSI at 12 months dichotomised (35); S2_3_DAST (46); S2_4_1_PRIME-MD_PHQ-9 (47); S2_4_2_PRIME-

MD_Dysth (48); S2_4_3_PRIME-MD_MinorDep (49); S2_4_5_PRIME-MD_Bipolar (50); S2_6_TxMH12 (55); S2_7_RxMH12 (56); S2_9_TxDrugAlcohol12 (57); S4_6_NZDI (70).

1.4.4 Correction on baseline adjustment in Appendix B

The following analyses have further been identified as unadjusted for baseline: S1_1_3_PGSI-12-Dich (35); S1_1_4_PGSI-3-Dich (37, 39); S2_4_5_PRIME-MD_Bipolar (50).

1.4.5 Correction of "Goal met" analyses

S5_1_Goal_met3 type was incorrectly identified in earlier versions. It is a polytomous variable. The correction was made in Appendix B and, in Appendix A, affects analyses 26, 32, 71 and 72.

2 Protocol summary

(Extracted from original Research Proposal, June 2008)

Background

Problem gambling is a significant public health issue, contributing to a broad spectrum of morbidity and harm to individuals, families and communities. Maori, Pacific peoples and populations in areas of high deprivation are disproportionately impacted. The Ministry of Health accords high priority to the prevention and reduction of gambling-related harm and funds intervention services including the Gambling Helpline and face-to-face counselling. It is not known how effective these services are, in general, or for particular groups. A weak evidence base internationally further impedes service improvement. Only three forms of psychological intervention can be considered 'possibly efficacious' and none have been demonstrated to be effective when conducted in every day clinical or community settings.

One of the 'possibly efficacious' approaches is a brief intervention involving a motivational interview and self-help workbook. It appears to produce outcomes comparable to more intensive therapies.

Aim

The objective of the proposed study is conduct research to inform policy and practice, leading to better outcomes for problem gamblers and a reduction in gambling harms. The main aim is to evaluate the effectiveness of a well developed and documented brief intervention for problem gambling and extensions of it. The study breaks new ground by moving evaluation from efficacy testing with volunteers to an assessment of effectiveness with problem gamblers who seek help. In addition to evaluating three well-defined models relative to standard care in New Zealand, it will identify which are more effective for a variety of client groups, including the major minority ethnic and other high-risk groups. A further aim is to describe what 'standard care' actually is and evaluate its

effectiveness relative to a defined intervention assessed previously in a well conducted randomised controlled trial (RCT). The study will also form the first module of a multi-site international clinical trial.

Design

This is a pragmatic randomised controlled trial of three interventions or usual care. One hundred and ten participants will be randomly allocated to each of four conditions embedded within the current operations of the Gambling Helpline. The three 'experimental' conditions are: (1) a motivational telephone interview, (2) a motivational telephone interview with follow-up self-instructional workbook, and (3) an extension of (2) involving motivational 'booster sessions'. The control group is standard care that clients receive during and following contact with the Helpline.

Participants

Four hundred and forty participants who consent to the study will be recruited from Helpline callers aged 18 years and above, and who seek information or assistance for their own gambling problem during a specified six-month period. Callers judged by counsellors to be experiencing acute psychotic symptoms or to be a serious risk to themselves or others will be excluded.

Main outcome measures

A range of measures (including standardised psychometric instruments) will be administered at intake and at one month, three months and one year. The main outcome measures are self-reports of days gambled, money lost and treatment goal success. Other outcome measures include control over gambling, gambling impacts, problem gambling severity (Lie-Bet screen and PGSI1), psychiatric comorbidity and substance use (PRIME-MD, DAST), tobacco and psychotropic medication use, general psychological distress (Kessler 10) and quality of life (WHOQol-8). Collateral assessment (at three months and one year) from people nominated by participants will include participant's gambling over past month, observed changes and confidence in accuracy of their (collateral) reports.

3 Study hypotheses

3.1 Notation

Notation

The outcome as a function of time t from baseline assessment will be denoted $Y(t)$. The subscript g =0,1,2,3 denotes the TAU, MI, MI+W and MI+W+B groups.; the subscript j=0,1,2,3 denotes the baseline, 3-month, 6-month and 12-month timepoints[1]; the subscript k=1,…,K_g identifies the

[1] Note that Y_{kg0} is treated as an independent covariate, systematically included in all models when available, within this analysis plan. Thus the subscript j=0 does not enter hypotheses below.

participant in group g, that has size K_g. The quantities t_{kgj} are the actual assessment times elapsed for participant k in arm g since baseline assessment. We define $Y_{kgj} = Y(t_{kgj})$, with common expectation μ_{gj}. A single subscript present refers to the treatment arm, and indicates that a common mean for the outcome involved is posited across the three non-baseline timepoints.

Averaging over post-randomisation timepoints is represented by ",●". This can correspond to the use of time-averaged endpoints or of suitable repeated measures models.

Averaging over groups is represented by "●,".

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

Parameters identified by subscripted letters are understood to represent the effect of the level in the category identified by the subscript. Thus $\mu_{g,\bullet}$ is the true mean time-averaged outcome associated with the gth treatment group.

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

Interactions are indicated by a colon (:).

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

The hypotheses are not fully spelled out below. The analysis plan spells out, often implicitly, what underlying distribution and other adjustments may enter into defining the hypotheses. Whatever these additional aspects are, they appear in the null and alternative hypotheses simultaneously.

3.2 Efficacy hypotheses

With $Y_{g,j,k}$ an efficacy outcome, the basic model is either $E(Y_{g,j,k}) = \mu_{g,\bullet}$, or $E(Y_{g,j,k}) = \mu_{g,j}$, where E(.) represents expectation. Adjustments may be added to these models as per this analysis plan; adjustments for baseline, when available, are systematic: the interpretation of the treatment effects are therefore as an average change from baseline in these cases. In some cases (e.g. Gambling Quit or Improved), a link function may need to be used and/or the inequalities presented may need reversing to correctly reflect superiority.

3.2.1 Equivalence hypothesis

A. (*Primary – lower is better)* The Motivational Interview (MI) group will show similar improvement to Treatment as Usual (TAU).

$$H_{A0}: |\mu_{1,\bullet} - \mu_{0,\bullet}| \leq \delta \quad \text{vs.} \quad H_{A1}: |\mu_{1,\bullet} - \mu_{0,\bullet}| > \delta$$

where δ is a present equivalence threshold for each outcome.

3.2.2 Superiority hypotheses

B. (*Primary – lower is better)*

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

$$H_{Ba0}: \mu_{2,\bullet} \geq \mu_{0,\bullet} \quad \text{vs.} \quad H_{Ba1}: \mu_{2,\bullet} < \mu_{0,\bullet}$$

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

$$H_{Bb0}: \mu_{2,\bullet} \geq \mu_{1,\bullet} \quad \text{vs.} \quad H_{Bb1}: \mu_{2,\bullet} < \mu_{1,\bullet}$$

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

$$H_{Bc0}: \mu_{3,\bullet} \geq \mu_{0,\bullet} \quad \text{vs.} \quad H_{Bc1}: \mu_{3,\bullet} < \mu_{0,\bullet}$$

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

$$H_{Bd0}: \mu_{3,\bullet} \geq \mu_{1,\bullet} \quad \text{vs.} \quad H_{Bd1}: \mu_{3,\bullet} < \mu_{1,\bullet}$$

C. (*Primary – lower is better*)

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

$$H_{Ca0}: \mu_{3,3} \geq \mu_{0,3} \quad \text{vs.} \quad H_{Ca1}: \mu_{3,3} < \mu_{0,3}$$

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

$$H_{Cb0}: \mu_{3,3} \geq \mu_{1,3} \quad \text{vs.} \quad H_{Cb1}: \mu_{3,3} < \mu_{1,3}$$

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

$$H_{Cc0}: \mu_{3,3} \geq \mu_{2,3} \quad \text{vs.} \quad H_{Cc1}: \mu_{3,3} < \mu_{2,3}$$

3.2.3 Secondary efficacy hypotheses

C*. (*Secondary –lower is better)*

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

$$H_{Cd0}: \mu_{3,3} - \mu_{3,1} \geq \mu_{0,3} - \mu_{0,1} \quad \text{vs.}$$

$$H_{Cd1}: \mu_{3,3} - \mu_{3,1} < \mu_{0,3} - \mu_{0,1}$$

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

H_{Ce0}: $\mu_{3,3} - \mu_{3,1} \geq \mu_{1,3} - \mu_{1,1}$ vs.

H_{Ce1}: $\mu_{3,3} - \mu_{3,1} < \mu_{1,3} - \mu_{1,1}$

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

H_{Cf0}: $\mu_{3,3} - \mu_{3,1} \geq \mu_{1,3} - \mu_{1,1}$ vs.

H_{Cf1}: $\mu_{3,3} - \mu_{3,1} < \mu_{1,3} - \mu_{1,1}$

D. (*Lower is better*)

a. The TAU group will evince significant reduction in gambling.

H_{Da0}: $\mu_{0,\bullet} \geq \mu_{0,0}$ vs. H_{Da1}: $\mu_{0,\bullet} < \mu_{0,0}$

b. The MI group will evince significant reduction in gambling.

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

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

H_{Dc0}: $\mu_{2,\bullet} \geq \mu_{2,0}$ vs. H_{Dc1}: $\mu_{2,\bullet} < \mu_{2,0}$

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

H_{Dd0}: $\mu_{3,\bullet} \geq \mu_{3,0}$ vs. H_{Dd1}: $\mu_{3,\bullet} < \mu_{3,0}$

Note that in the case of P3_Gambling_QorI, the hypotheses are defined differently.

E. (*Lower is better*)

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

In the model, $E(Y_{g,j,k}) = \mu_{g,j} + \alpha A_{g,j,k}$, where $A_{g,k}$ represents the level of engagement of participant k in group g=0,2,3, to which other adjustments may be added as per this analysis plan:

H_{E0}: $\alpha \geq 0$ vs. H_{E1}: $\alpha < 0$.

3.3 Engagement hypotheses

F. (*Secondary – Engagement outcomes - higher is better*)

With $V_{g,j,k}$ the level of engagement in other treatment services, the basic model is $E(V_{g,j,k}) = \nu_{g,j}$, to which other adjustments may be brought as per this analysis plan.

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

$$H_{Fa0}: v_{3,\bullet} u\leq v_{2,\bullet} \text{ vs. } H_{Fa1}: v_{3,\bullet} > v_{2,\bullet}$$

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

$$H_{Fb0}: v_{2,\bullet} \leq v_{0,\bullet} \text{ vs. } H_{Fb1}: v_{2,\bullet} > v_{0,\bullet}$$

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

G. (*Secondary - Engagement outcomes – higher is better*)

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

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

a. $H_{Ga0}: \mu_{3,\bullet} + \mu_{2,\bullet} \leq \mu_{1,\bullet} + \mu_{0,\bullet}$ vs. $H_{Ga1}: \mu_{3,\bullet} + \mu_{2,\bullet} > \mu_{1,\bullet} + \mu_{0,\bullet}$

b. $H_{Ga0}: \mu_{3,1} + \mu_{2,1} \leq \mu_{1,1} + \mu_{0,1}$ vs. $H_{Ga1}: \mu_{3,1} + \mu_{2,1} > \mu_{1,1} + \mu_{0,1}$

3.4 Safety and tolerability hypotheses

None.

4 Study design

Refer to protocol.

5 Study endpoints

5.1 Efficacy Endpoints

The primary efficacy endpoints are the primary efficacy outcomes P01.x to P03.x (self-reported average monthly numbers of days gambled, average monthly amount of money lost and Gambling Quit or Improved [GQI] indicator), time-averaged over the three assessments points. In the case of the number of days gambled in one month and amount of money spent gambling in one month, these endpoints correspond to an annual average of monthly values over the 12 months post-randomization. The GQI is defined as 1 if either the average number of days in the previous three months of follow-back is zero (quit) or the average amount of money spent in the previous three months of follow-back is less than half the

declared 12 month average at baseline. It has value zero otherwise. The time-averaged GQI is thus a value between 0 and 1 inclusively.

Secondary efficacy endpoints (Sx) consist of the primary outcomes at the individual assessment timepoints, as well as the endpoints listed under the appropriate tab of the *Effectiveness Trial – Final analysis - SAP v1_2 data dictionary.xlsx.*

5.2 Engagement Endpoints

The trial introduces engagement endpoints. The engagement endpoints covered by this analysis plan are E2_1_1, E2_2_1 and E2_3_1, the time-averaged versions of the workbook usage variables in the relevant arms, and (see *3. Engagement* tab of the *Effectiveness – SAP v1_1 Data dictionary.xlsx* worksheet).

5.3 Safety and Tolerability Endpoints

None.

6 Analysis sets

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

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

6.1 Intention to Treat

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

6.2 Per Protocol

Participants will be included in the per protocol (PP) analysis set if they fulfil the criteria of the ITT set, have complete at least one primary endpoint measurements and do not present any major protocol violation. Participants in the PP set will be assigned to the treatment arm corresponding to the treatment they actually received.

The following describes the major protocol deviations that will exclude patients from the PP population (minor deviations will not do so):

- Eligibility violation;
- Absence of any efficacy data.

Other major violations will be identified by the Steering Committee. All other protocol deviations will be considered as minor and will not lead to excluding patients from the PP population for analysis.

6.3 Workbook Engagement

Participants will be included in the Workbook Engagement (WE) analysis set if they fulfil the criteria of the ITT set and have received the workbook.

7 Statistical methodology

We categorise the types of analyses of treatment effects as outcomes into primary and secondary efficacy and engagement analyses (section 7.5), confirmatory analyses (section 7.7) and exploratory (section 7.8) analyses. Primary and secondary analyses relate to the reported treatment effects on all primary and secondary efficacy endpoints respectively. Confirmatory analyses are focused on ancillary statistics and may inform methodological choices in the primary and secondary analyses. Exploratory analyses include all other analyses, for the essential planned and unplanned variations on the primary and secondary analyses.

7.1 Descriptive statistics

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

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

7.2 Covariates

We distinguish between [independent] predictors, related to outcome and unrelated to the allocation; potential confounders, related to outcome and imbalanced by chance across the treatment arms; and potential effect modifiers, that may moderate the treatment arm effect.

7.2.1 Independent predictors

Generalities

Independent predictors are covariates that may be included in the model for interpretive purposes. The baseline value of the outcome being modelled is an independent predictor. The timepoint, seen as a ordered factor or as a (continuous) time since baseline is another. Independent predictors may be included in the model as a result of a specific hypothesis being tested. They are identified as such in Appendix A.

The baseline outcome value will be included in all models when available.

Baseline data collected post-randomisation

Due to feasibility considerations, some baseline data were collected 7 days post-randomisation, post-intervention. These concern the primary efficacy outcomes P1_Days_Gambled and P2_Money_Lost, and the secondary efficacy outcomes S2_4.x_PRIME-MD_yyy (x=1,2,3, 5, yyy=PHQ-9, Dysth, MinorDep, Bipolar) and S4_6_NZDI. These values will be used as baseline adjustments. See 7.7.6.

7.2.2 Potential confounders

Prior selection of potential confounders

Potential confounders will be selected from amongst baseline outcomes and demographic and personal history covariates as detailed below and identified in context in Appendix C. Comparisons of important and known potential confounders will be conducted at baseline to ensure that distributions are approximately equal between groups. If baseline separation between arms in some covariates emerge, outcome differences will be adjusted for these covariates should they prove significant (but all potential confounders will be assessed if the model retained does not involve an identity or exponential link - see 7.4.4). Baseline separation between arms in a covariate occurs for this purpose if any two mean estimates amongst the arms differ by one or more pooled standard deviations. In the case of the age group (C2_3_Age_group), this criterion will be applied to the continuous age covariate instead (

Significance testing of potential confounders

All potential confounders will be assessed for significance first as a single block, the significance of which will be assessed using an appropriate F or x^2 test. Should the block be retained as a result of this test, the individual covariates will be tested using backward selection based on the appropriate t, z, F or x^2 tests. The significance threshold for retention of potential confounders for adjustment purposes will be 0.1 for all tests (see Section 7.4.1). **The estimates associated with the retained confounders will not be reported** but the retained confounders will be reported by name.

Table 1: Potential confounders

Name	Full name	Name	Full name
C2_1_Gender	Gender	S1_1_1_PGSI-12	PGSI-12 (at baseline only)
C2_2_1_Marital_dich	Marital status, dichotomised	C3_2_1_EGM	Electronic Gaming Machines as primary gambling type
C2_3_Age_group	Age group at enrolment	C6_1_1_Current_goal_dich	Current goal, dichotomised

			(Quit vs. Control)
C2_4_Prim_eth	Primary ethnicity	C8_1_3_Prosp_succ_dich	Dichotomised level of belief in success within 12 months
C2_7_1_Fam_income_dich	Gross family income in last 12 months, dichotomised		

7.2.3 Effect modifiers

Effect modifiers are covariates that may affect the treatment arm effect (interactions involving treatment). Some analyses involve the timepoint as a treatment effect modifier. The subgroup analyses detailed in Section 7.5.3 implicitly define variables that may modify the treatment effect.

There are no other considerations of effect modification in this analysis plan.

7.3 Variance-covariance structure

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

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

7.4 Inferential framework

See also Section 3.

7.4.1 Significance threshold

All tests of significance of hypotheses concerning treatment effect parameters will be carried out using a level of significance of 5% and two-sided alternatives. The significance threshold of potential confounders (7.2.2) will be set at 10%, to promote unbiased and conservative inference. All estimates will be produced as point estimates and as 95% confidence intervals. Unless otherwise noted, model selection when required will be performed using backward selection from the largest model dictated by the situation.

7.4.2 Family-wise error rate adjustment

Each composite hypothesis (Hypotheses B, C, D, F, G in section 3) will be assessed by controlling False Discovery Rate at the stated significance threshold, in accordance with the procedure outlines in Benjamini &

Hochberg (*JRSSB*, 1995). Sub-hypotheses thus retained will be deemed statistically significant. The composite hypothesis will be deemed statistically significant if all subhypotheses are retained. No FWER adjustment will be carried out across outcomes.

7.4.3 Analytical framework for continuous endpoint analysis

Normality assumption

The analysis described below assumes that normality of residuals is a reasonable assumption (see 7.7.1). Contingencies for non-normality are described in 7.4.4.

Regression model

Repeated measures analyses will fit available endpoints as repeated measures over the 3 assessment time points (excluding baseline) to an appropriate normal mixed effects generalised least squares regression model.

Baseline outcome value will be included as an independent predictor in all models when available.

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

As per 7.2.2, models may **potentially** adjust for baseline covariates listed in Appendices, subject to achieving significance as per 7.4.1.

Inclusion of treatment arm; univariate and multivariate settings

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

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

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

Variance structure

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

A nested, zero-mean, participant-specific normally distributed random effect will be assigned to observations from a single participant to account for within-participant correlation in a simple compound-symmetry structure. **This random effect must only be used when there is more than one measurement per participant (e.g. not in the case of S_1_1_1_PGSI-12).**

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

Results

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

Trend models

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

Absence of repeated measures

When outcome data are collected only at 12 months (e.g. S1_1_1_PGSI-12), the above framework reduces to a baseline-adjusted ANCOVA, with variance estimated in the full repeated measures setting across the counsellors. For such analyses the individual random effects must be removed from the model, althought the counsellor-specific random effects should be retained.

Contingency for heteroscedasticity across treatment arms

This section was removed in version 1_1.

7.4.4 Alternative analytical frameworks for continuous endpoints under non-normality I: alternative family and transformation

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

If non-normality of residuals is evinced (see 7.7.1) or a non-normal family and/or non-identity link are called for, analyses equivalent to 7.4.3 using an alternative generalised linear model as a first choice, a data transformation as a second choice, or both as a third choice, will be investigated based on the estimated variance function from the residuals.

If a generalised linear model is selected, potential confounders will automatically be assessed for significance in the model, without verification of baseline separation (7.2.2)

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

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

Should the provisions of 7.4.4 fail to apply satisfactorily, the outcomes will be dichotomised based on thresholds commonly held in the literature, or failing the existence of such a threshold on the basis of the approximate median of the outcome in the TAU group, without consideration of the timepoint. The analyses will then proceed according to 7.4.4 using a binomial family and logit link, i.e. using mixed effects logistic regression.

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

7.4.6 Analytical framework for dichotomous (polytomous) endpoint analysis

The analyses will proceed according to 7.4.4 using a binomial (respectively, multinomial) family and logit (respectively, cumulative logit) link, i.e. using mixed effects logistic regression. Participant-level random effects must only be used in the presence of repeated measures.

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

7.4.7 Software

Analyses will be undertaken with R version 13.0 or higher, SAS version 9,2 or higher and SPSS (PASW) version 16.0 or higher.

7.5 Detail of the efficacy and engagement analyses

7.5.1 Primary vs. secondary analyses

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

The secondary analyses consist in the following:

- PGSI-12 and hypothesis A in the ITT analysis set;
- Primary outcomes and PGSI-12 within primary hypotheses in the PP analysis set;
- Primary outcomes and PGSI-12 within secondary hypotheses in the ITT analysis set;
- Primary and selected secondary outcomes (PGSI-12, attainment of goal and control) and Hypothesis E;

- Secondary outcomes and primary superiority hypotheses in the ITT analysis set;
- Engagement outcomes and engagement hypotheses in the ITT analysis set.

7.5.2 Description of the main analyses

I: Time-averaged continuous endpoints

Time-averaged analysis, as per 7.4.3, of a continuous primary outcome.

II.1: Timepoint-specific continuous endpoint, in the presence of repeated measures

Timepoint-specific analysis, as per 7.4.3, of a continuous primary outcome in the ITT analysis set. (Use participant-specific random effects).

II.2: Timepoint-specific continuous endpoint, in the absence of repeated measures

Timepoint-specific analysis, as per 7.4.3, of a continuous primary outcome in the ITT analysis set. (Do not use participant-specific random effects).

III: Time-averaged dichotomous endpoints

Time-averaged analysis, as per 7.4.6, of a dichotomous primary outcome in the ITT analysis set.

IV.1: Timepoint-specific dichotomous endpoint, in the presence of repeated measures

Timepoint-specific analysis, as per 7.4.6, of a dichotomous primary outcome in the ITT analysis set. (Use participant-specific random effects).

IV.2: Timepoint-specific dichotomous endpoint, in the presence of repeated measures

Timepoint-specific analysis, as per 7.4.6, of a dichotomous primary outcome in the ITT analysis set. (Do not use participant-specific random effects).

V: Time-averaged multinomial endpoint

Time-averaged analysis, as per 7.4.6, of a multinomial family random variable with cumulative logit link and weight variable corresponding to the number of valid responses over which the response is computed.

VI: Timepoint-specific multinomial endpoint

Timepoint-specific analysis, as per 7.4.6, of a multinomial family random variable with cumulative logit link and weight variable corresponding to the number of valid responses over which the response is computed.

VII: Time-averaged binomial endpoint

Time-averaged analysis, as per 7.4.6, of a binomial family random variable with logit link and weight variable corresponding to the number of valid responses over which the response is computed.

VIII: Timepoint-specific binomial endpoint

Timepoint-specific analysis, as per 7.4.6, of a binomial family random variable with logit link and weight variable corresponding to the number of valid responses over which the response is computed.

7.5.3 Subgroup analyses

The primary analyses will be repeated by considering possible interaction of the treatment arm with the following subgroups defined at baseline:

1. Gender: C2_1_Gender
2. Ethnicity: "Yes" responses only to each of:
    a. C2_4_1_Eth_NZEur
    b. C2_4_2_Eth_Maori
    c. C2_4_3_Eth_Pasifika
    d. C2_4_5_Eth_Asian_or_Other.

    Ethnicity subgroups will be defined according to response, so that participants may contribute data to more than one subgroup.
3. Gambling problem severity based on PGSI: C4_6_PGSI_12_dich
4. EGM anywhere or any other as primary gambling type : C3_2_1_EGM
5. Mental health comorbidities based on Kessler-10 score, cut point of 20: C9_1_K10MH_dich
6. Alcohol abuse based on AUDIT-C score, cut point of 4 for males and 3 for females: C9_2_AUDITC_dich
7. Goal (Quit or Control): C6_1_1_Current_goal_dich
8. Belief level: C8_1_3_Prosp_succ_dich

7.5.4 Analyses involving Hypothesis E

The assistance- and engagement-related variables in the analyses involving Hypothesis E are collected at the post-randomisation timepoints. As such their status as covariates is questionable. An exploratory structural equations model including treatment and baseline as exogenous variables, assistance and engagement variables, simultaneously or not, as endogenous mediators and outcomes as endogenous variables may be a more appropriate analysis.

In the currently planned analyses, we can expect the effect of treatment on primary and secondary outcomes to be biased towards the null if

engagement and assistance variables are in the causal pathway from treatment to outcome.

7.6 Missing data

Assessment of the significance of potential confounders and effect modifiers will be based on complete-case analysis. If any confounder or effect modifier is retained based on the complete-case analysis, the final model will rely on multiple imputation to produce adjusted treatment effect estimates. Confounders or effect modifiers with significance beyond the stated threshold (see 3.1) after the multiple imputation stage will be removed from the model.

Missing outcome values will be accommodated without further adjustment in mixed effects models, under an assumption of missingness completely at random or missingness at random. Modelling of missingness and outcomes will be performed in confirmatory analyses (section 7.7)

7.7 Confirmatory Analyses

7.7.1 Normality assessment

Normality of continuous outcomes will be assessed using q-q plots, Kolmogorov-Smirnov and Shapiro-Wilks tests on the residuals of the mixed effects models involving treatment and timepoint interaction, as well as baseline outcome value when available. Should the normal family prove unsuitable, visual assessment of the estimated variance function will be used to determine whether a transformation of the data or a different generalised linear model is required. All analyses (univariate at each time point and repeated measures) associated with an outcome will be effected using the same transformation and/or generalised linear model.

7.7.2 This section removed in version 1.1

7.7.3 Influence and outlier analyses

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

Influence and outlier analyses may be carried out but in accordance with the ITT and PP population definitions no case will be removed from the analyses should they prove overly influential or to be outliers.

7.7.4 Collateral data

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

7.7.5 Missingness

Confirmatory analyses regarding missingness will include survival analysis of attrition (drop-outs) based on treatment arm, baseline primary

outcomes and demographic covariates. It is not expected that pattern-mixture analysis will be used but the possibility of doing so is retained. The purpose of these analyses will be to identify or discount possible links between treatment assignment and attrition.

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

7.7.6 Baseline data collected post-randomisation

In the case of primary outcomes P1_Days_Gambled and P2_Money_Lost, partial pre-randomisation baseline data are available to potentially identify bias in the baseline data collected post-randomisation that will be used for baseline adjustment. The correlation between pre- and post-randomisation data will be reported, as well as the estimate of their difference and their respective variances, pooled and by treatment group. These results will serve to inform the discussion.

7.7.7 Testing of random effects

Random effects associated with counsellors and participants will be tested using likelihood ratio tests against equivalent null models not involving the target random effect (but involving the remaining random effect) in the main analyses 01 and 03, concerning the non-composite primary outcomes P1_Days_Gambled and P2_Money_Lost under the time-averaged scheme. The random effects will be tested based on a likelihood ratio test, with models fitted using maximum likelihood only (not REML). The resulting p-value will be based on a null distribution of $(\chi^2_1 + \chi^2_2)/2$ distribution.

Random effects that do not appear significant will be removed from the model. If a random effect is removed from both models it will be removed from all analyses.

7.8 Exploratory Analyses

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

8 List of Planned Noninferential Outputs

The following lists the planned tables and list in the Trial Report, excluding the results of statistical analyses.

Reference	Title
Section 1: Screening, randomisation, intervention onset	
Table 1.1	Summary of overall screening
Table 1.2	Summary of reasons for ineligibility
Table 1.4	Summary of reasons for refusal
Table 1.5	Randomisation by accrual month
Table 1.6	Randomisation by treatment arm and block randomisation stratum
Table 1.7	Days between randomisation and protocol implementation by treatment arm
Section 2: Data completeness	
Table 2.0	Number of completed assessments at each time point and treatment arm
Section 3: Demographics and medical history at baseline	
Table 3.1	Demographic information by treatment arm
Table 3.2	Other covariate information by treatment arm
Section 4: Efficacy data by timepoint and treatment arm	
Table 4.1	Primary outcomes
Table 4.2	Secondary outcomes
Table 4.3	Engagement outcomes
Section 5: Adherence to intervention schedule	
Table 5.1	List of intervention interruptions by treatment arm, including reason and duration
Section 6: List of Adverse Events by Centre	
Table 6.1	List of Adverse Events by Centre and treatment arm (includes SAE and SUSAR status)
Section 7: Eligibility violations and protocol deviations	
Table 7.1	Listing of eligibility violations and protocol deviations, with investigator comments by treatment arm
Table 7.2	Participants excluded from ITT analysis set by treatment arm
Table 7.3	Participants excluded from PP analysis set by treatment arm

A APPENDIX: Summary table of analyses

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

2) Timepoints entered as covariates are entered as categorical covariates unless otherwise indicated.

Code	Endpoint	An. ID	Set	Focus	Statistical model	Hypotheses	Comment
Primary analyses (Primary analyses must also be carried out in the 18 subgroups defined in Section 7.5.3)							
01	P1_Days_Gambled, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted No timepoint covariate	A, δ=1 Ba,b,c,d	Report A with 95% CI FWER adjustment for B
02	P1_Days_Gambled at 12 months	II.1	ITT	Tx: (C1_2_Timepoint=12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
03	P2_Money_Lost, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted No timepoint covariate	A, δ=20 Ba,b,c,d	FWER adjustment for B
04	P2_Money_Lost at 12 months	II.1	ITT	Tx: (C1_2_Timepoin	Linear mixed effects, weighted Baseline-adjusted	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12)

				t=12)	Timepoint-adjusted Timepoint-treatment interaction		interaction
05	P3_Gambling_QorI, time-averaged	III	ITT	Tx	Logistic mixed effects, weighted No timepoint covariate	A, δ=0_13 Ba,b,c,d	FWER adjustment for B
06	P3_Gambling_QorI, at 12 months	IV.1	ITT	Tx: (C1_2_Timepoint=12)	Logistic mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
Secondary analyses							
Equivalence hypothesis for PGSI-12							
07	S1_1_1_PGSI-12, at 12 months	I	ITT	Tx	Linear regression, unweighted Baseline-adjusted	A, δ=1	Report A with 95% CI
Primary outcomes and PGSI-12 and primary hypotheses in the PP analysis set							
08	P1_Days_Gambled, time-averaged	I	PP	Tx	Linear mixed effects, weighted Baseline-adjusted No timepoint covariate	A, δ=1 Ba,b,c,d	FWER adjustment for B
09	P1_Days_Gambled	II.1	PP	Tx:	Linear mixed effects,	Ca,b,c	FWER adjustment

	at 12 months			(C1_2_Timepoint=12)	weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction		Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
10	P2_Money_Lost, time-averaged	I	PP	Tx	Linear mixed effects, weighted Baseline-adjusted No timepoint covariate	A, δ=20 Ba,b,c,d	FWER adjustment for B
11	P2_Money_Lost at 12 months	II.1	PP	Tx:(C1_2_Timepoint=12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
12	P3_Gambling_QorI, time-averaged	III	PP	Tx	Logistic mixed effects, weighted No timepoint covariate	A, δ=0_13 Ba,b,c,d	FWER adjustment for B
13	P3_Gambling_QorI, at 12 months	IV.1	PP	Tx: (C1_2_Timepoint=12)	Logistic mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
14	S1_1_1_PGSI-12, at	II.2	PP	Tx (no repeated	Linear mixed effects, counsellor-specific	Ca,b,c	FWER adjustment

	12 months			measures)	random effects only, if indicated (see 7.7.7), unweighted Baseline-adjusted		
Primary outcomes and PGSI-12 within secondary hypotheses in the ITT analysis set							
15	P1_Days_Gambled, contrast at 3 and 12 months	II.1	ITT	Tx:(C1_2_Timepoint=12) – Tx:(C1_2_Timepoint=3)	Linear mixed effects, weighted Baseline-adjusted Timepoint covariate Timepoint-treatment interaction	C*d,e,f	FWER adjustment Null is alternative less the interaction
16	P2_Money_Lost, time-averaged	II.1	ITT	Tx:(C1_2_Timepoint=12) – Tx:(C1_2_Timepoint=3)	Timepoint covariate Timepoint-treatment interaction	C*d,e,f	FWER adjustment Null is alternative less the interaction
17	P3_Gambling_QorI, time-averaged	III	ITT	Tx:(C1_2_Timepoint=12) – Tx:(C1_2_Timepoint=3)	Logistic mixed effects, weighted Timepoint covariate Timepoint-treatment interaction	C*d,e,f	FWER adjustment Null is alternative less the interaction
18	P1_Days_Gambled, time-averaged minus baseline	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted No timepoint covariate	Da,b,c, d	FWER adjustment Baseline subtraction not strictly necessary but indicated for ease of interpretation

19	P2_Money_Lost, time-averaged minus baseline	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted No timepoint covariate	Da,b,c, d	FWER adjustment Baseline subtraction not strictly necessary but indicated for ease of interpretation
20	P3_Gambling_QorI, time-averaged	III	ITT	Tx	Logistic mixed effects, weighted No timepoint covariate	Da,b,c, d	FWER adjustment H_{Dx0}: $p_{g,\bullet} \geq 0.05$ vs. H_{Dx1}: $p_{g,\bullet} < 0.05$
21	S1_1_1_PGSI-12, at 12 months minus baseline	I	ITT	Tx	Linear regression, unweighted Baseline-adjusted	Da,b,c, d	FWER adjustment Baseline subtraction not strictly necessary but indicated for ease of interpretation
Primary and selected secondary outcomes and Hypothesis E							
22	P1_Days_Gambled, time-averaged	II.1	WE	C7_1_Wkbk_Engagement	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
23	P2_Money_Lost, time-averaged	II.1	WE	C7_1_Wkbk_Engagement	Linear mixed effects, weighted Baseline-adjusted	E	Effect of workbook engagement; null is alternative less engagement term

					Timepoint-adjusted Timepoint-treatment interaction		
24	P3_Gambling_QorI, time-averaged	IV.1	WE	C7_1_Wkbk_Engagement	Logistic mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
25	S1_1_1_PGSI-12, at 12 months	II.2	WE	C7_1_Wkbk_Engagement	Linear mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted Baseline-adjusted	E	Effect of workbook engagement; null is alternative less engagement term
26	S5_1_Goal_met3, time-averaged	V	WE	C7_1_Wkbk_Engagement	Multinomial mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
27	S1_2_Control, time-averaged	II.1	WE	C7_1_Wkbk_Engagement	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term

28	P1_Days_Gambled, time-averaged	II.1	ITT	E3_7_Assist_formal, C5_6_Assist_informal (simultaneous inclusion of terms)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
29	P2_Money_Lost, time-averaged	II.1	ITT	E3_7_Assist_formal, C5_6_Assist_informal (simultaneous inclusion of terms)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
30	P3_Gambling_QorI, time-averaged	IV.1	ITT	E3_7_Assist_formal, C5_6_Assist_informal (simultaneous inclusion of terms)	Logistic mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
31	S1_1_1_PGSI-12, at 12 months	II.2	ITT	E3_7_Assist_formal, C5_6_Assist_i	Linear mixed effects, counsellor-specific random effects only, if	E	Effect of workbook engagement; null is alternative less

				nformal (simultaneous inclusion of terms)	indicated (see 7.7.7), unweighted Baseline-adjusted		engagement term
32	S5_1_Goal_met3, time-averaged	V	ITT	E3_7_Assist_formal, C5_6_Assist_informal (simultaneous inclusion of terms)	Multinomial mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
33	S1_2_Control, time-averaged	II.1	ITT	E3_7_Assist_formal, C5_6_Assist_informal (simultaneous inclusion of terms)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	E	Effect of workbook engagement; null is alternative less engagement term
Secondary outcomes and primary superiority hypotheses in the ITT analysis set							
34	S1_1_1_PGSI-12, at 12 months	II.2	ITT	Tx (no data collected at 3 and 6	Linear mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7),	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses

				months)	unweighted Baseline-adjusted		
35	S1_1_3_PGSI-12-Dich, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6 months)	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
36	S1_1_2_PGSI-3, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
37	S1_1_4_PGSI-3-Dich, time-averaged	III	ITT	Tx	Logistic mixed effects, weighted	Ba,b,c,d	FWER adjustment
38	S1_1_2_PGSI-3, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
39	S1_1_4_PGSI-3-Dich, at 12 months	IV.1	ITT	Tx: (C1_2_Timepoint =12)	Logistic mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
40	S1_2_Control, time-	I	ITT	Tx	Linear mixed effects,	Ba,b,c,d	FWER adjustment

	averaged				weighted Baseline-adjusted		
41	S1_2_Control, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
42	S2_1_Kessler-10, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
43	S2_1_Kessler-10, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
44	S2_2_AUDIT-C, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
45	S2_2_AUDIT-C, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction

					interaction		
46	S2_3_DAST, at 12 months	II.2	ITT	Tx (no data collected at 3 and 6 months)	Linear mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted Baseline-adjusted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
47	S2_4_1_PRIME-MD_PHQ-9, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6 months)	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
48	S2_4_2_PRIME-MD_Dysth, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6 months)	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
49	S2_4_3_PRIME-MD_MinorDep, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6 months)	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses

50	S2_4_5_PRIME-MD_Bipolar, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6 months)	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
51	S2_5_1_Tob_current, time-averaged	III	ITT	Tx	Logistic mixed effects, weighted	Ba,b,c,d	FWER adjustment
52	S2_5_1_Tob_current, at 12 months	IV.1	ITT	Tx: (C1_2_Timepoint =12)	Logistic mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
53	S2_5_2_Tob_freq, time-averaged	V	ITT	Tx	Multinomial mixed effects, weighted	Ba,b,c,d 2-sided alternatives	FWER adjustment
54	S2_5_2_Tob_freq, at 12 months	V	ITT	Tx: (C1_2_Timepoint =12)	Multinomial mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c 2-sided alternatives	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
55	S2_6_TxMH12, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7),	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses

				months)	unweighted		
56	S2_7_RxMH12, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6 months)	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
57	S2_9_TxDrugAlcohol 12, at 12 months	IV.2	ITT	Tx (no data collected at 3 and 6 months)	Logistic mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
58	S3_1_WHOQoL-8, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
59	S3_1_WHOQoL-8, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
60	S4_1_Affect_Work, time-averaged	I	ITT	Tx	Linear mixed effects, weighted	Ba,b,c,d	FWER adjustment

					Baseline-adjusted		
61	S4_1_Affect_Work, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
62	S4_2_Affect_Social, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
63	S4_2_Affect_Social, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
64	S4_3_Affect_Fam-Home, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
65	S4_3_Affect_Fam-Home, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction

66	S4_4_Affect_Health, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
67	S4_4_Affect_Health, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
68	S4_5_Legal_Probl, time-averaged	III	ITT	Tx	Logistic mixed effects, weighted	Ba,b,c,d	FWER adjustment
69	S4_5_Legal_Probl, at 12 months	IV.1	ITT	Tx: (C1_2_Timepoint =12)	Logistic mixed effects, weighted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
70	S4_6_NZDI, at 12 months	II.2	ITT	Tx (no data collected at 3 and 6 months)	Linear mixed effects, counsellor-specific random effects only, if indicated (see 7.7.7), unweighted Baseline-adjusted	Ba,b Ca,b,c	FWER adjustment across all 5 subhypotheses
71	S5_1_Goal_met3, time-averaged	V	ITT	Tx	Multinomial mixed effects, weighted	Ba,b,c,d	FWER adjustment
72	S5_1_Goal_met3, at	VI	ITT	Tx:	Multinomial mixed	Ca,b,c	FWER adjustment

	12 months			(C1_2_Timepoint =12)	effects, weighted Timepoint-adjusted Timepoint-treatment interaction		Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
73	S5_2_Motivation, time-averaged	I	ITT	Tx	Linear mixed effects, weighted Baseline-adjusted	Ba,b,c,d	FWER adjustment
74	S5_2_Motivation, at 12 months	II.1	ITT	Tx: (C1_2_Timepoint =12)	Linear mixed effects, weighted Baseline-adjusted Timepoint-adjusted Timepoint-treatment interaction	Ca,b,c	FWER adjustment Null is alternative less only the Tx: (C1_2_Timepoint=12) interaction
Engagement outcomes and engagement hypotheses in the ITT analysis set							
75	E2_1_Wkbk_Read, time-averaged	V	WE	Tx	Multinomial mixed effects, weighted by number of valid responses	Fa,b With 2-sided alternative Ga	FWER of F adjustment based on whole contrasts between treatments Null is model of common mean.
76	E2_1_Wkbk_Read, at 3 months	VI	WE	Tx: (C1_2_Timepoint =3)	Multinomial mixed effects, weighted by number of valid responses	Gb	Null is alternative less only the Tx: (C1_2_Timepoint=3) interaction

					Timepoint-adjusted Timepoint-treatment interaction		
77	E2_2_Wkbk_Exercise, time-averaged	V	WE	Tx	Multinomial mixed effects, weighted by number of valid responses	Fa,b With 2-sided alternative Ga	FWER adjustment of F Null is model of common mean.
78	E2_2_Wkbk_Exercise, at 3 months	VI	WE	Tx: (C1_2_Timepoint=3)	Multinomial mixed effects, weighted by number of valid responses Timepoint-adjusted Timepoint-treatment interaction	Gb	Null is alternative less only the Tx: (C1_2_Timepoint=3) interaction
79	E2_3_Wkbk_Strategies, time-averaged	V	WE	Tx	Multinomial mixed effects, weighted by number of valid responses	Fa,b With 2-sided alternative Ga	FWER adjustment of F Null is model of common mean.
80	E2_3_Wkbk_Strategies, at 3 months	VI	WE	Tx: (C1_2_Timepoint	Multinomial mixed effects, weighted by number of valid	Gb	Null is alternative less only the Tx: (C1_2_Timepoint=3)

				=3)	responses Timepoint-adjusted Timepoint-treatment interaction		interaction
81	E3_7_AssistI_Any, time-averaged	VII	ITT	Tx	Binomial mixed effects, weighted	Fa,b Ga	FWER adjustment of F Null is model of common mean.
82	E3_7_AssistI_Any, at 3 months	VIII	ITT	Tx: (C1_2_Timepoint =3)	Binomial mixed effects, weighted by number of valid responses Timepoint-adjusted Timepoint-treatment interaction	Gb	Null is alternative less only the Tx: (C1_2_Timepoint=3) interaction

B APPENDIX: List of primary and secondary efficacy and engagement outcomes

B.1 *Primary outcomes*

Name	Full name	Description	Availability BL	3m	6m	12m
P1_Days_Gambled	Self-reported number of days when gambling occurred	Positive real, expressed as days per month	√	√	√	√
P2_Money_Lost	Self-reported amount of money lost per day	Positive real, expressed as dollars per day	√	√	√	√
P3_Gambling_QorI	Self-reported gambling	Dichotomous 0=no/1=yes	--	√	√	√

B.2 *Secondary outcomes*

Name	Full name	Description	Availability BL	3m	6m	12m
Gambling severity						

S1_1_1_PGSI-12	Problem Gambling Severity Index 12 months	Nine-item score	√	--	--	√
S1_1_2_PGSI-3	Problem Gambling Severity Index 3 months	Nine-item score	√	√	√	√
S1_1_3_PGSI-12-Dich	Problem Gambling Severity Index dichotomised (>=8 vs. <8) 12 months	Dichotomous 0=No/1=Yes	√	--	--	√
S1_1_4_PGSI-3-Dich	Problem Gambling Severity Index dichotomised (>=8 vs. <8) 3 months	Problem Gambling Severity Index dichotomised (>=8 vs. <8) 3 months	√	√	√	√
S1_2_Control	Control over gambling behaviour	Control over gambling behaviour	√	√	√	√
Comorbidity and substance use						
S2_1_Kessler-10	Mental Health Kessler -10, past 4 weeks	Score	√	√	√	√
S2_2_AUDIT-C	AUDIT-C	Score 0-12	√	√	√	√
S2_3_DAST	Drug Abuse Screening Test	Score, 10 items	√	√	√	√
S2_4_1_PRIME-MD_PHQ-9	PRIME-MD Major depressive disorder	Dichotomous 0=No/1=Yes	√	--	--	√

S2_4_2_PRIME-MD_Dysth	PRIME-MD Dysthimia	Dichotomous 0=No/1=Yes	√	--	--	√
S2_4_3_PRIME-MD_MinorDep	PRIME-MD Minor depressive disorder	Dichotomous 0=No/1=Yes	√	--	--	√
S2_4_5_PRIME-MD_Bipolar	PRIME-MD Bipolar disorder	Dichotomous 0=No/1=Yes	√	--	--	√
S2_5_1_Tob_current	Current smoking status	Dichotomous 0=No/1=Yes	√	√	√	√
S2_5_2_Tob_freq	Frequency of smoking	Categorical, 4 levels	√	√	√	√
S2_6_TxMH12	Treatment received for mental health problem in previous 12 months	Dichotomous 0=No/1=Yes	√	--	--	√
S2_7_RxMH12	Prescription received for mental health in previous 12 months	Dichotomous 0=No/1=Yes	√	--	--	√
S2_9_TxDrugAlcohol12	Treatment received for drugs or alcohol in previous 12 months	Dichotomous 0=No/1=Yes	√	--	--	√
Quality of life						
S3_1_WHOQoL-8	WHO Quality of Life	Score, 8 items	√	√	√	√
Gambling impact						

S4_1_Affect_Work	How was work affected in past 1 month	10-point Likert	√	√	√	√
S4_2_Affect_Social	How was social life affected in past 1 month?	10-point Likert	√	√	√	√
S4_3_Affect_Fam-Home	How were family & home affected in past 1 month?	10-point Likert	√	√	√	√
S4_4_Affect_Health	How was health affected in past 1 month?	10-point Likert	√	√	√	√
S4_5_Legal_Probl	Legal problems experienced in past 12 months (baseline)/3 months (follow-up)	Dichotomous 0=No/1=Yes	√	√	√	√
S4_6_NZDI	New Zealand Individual Deprivation Index	Score	√	--	--	√
Goal setting & motivation						
S5_1_Goal_met3	Goal met in the last 3 months	Categorical 4 levels 1=Not at all 2=Partially 3=Mostly 4=Completely	--	√	√	√
S5_2_Motivation	How motivated	10-point Likert	√	√	√	√

C APPENDIX: List of demographic and personal history covariates

C.1 *Demographic covariates*

Name	Full name	Description	Original variable name(s)	Potential confounder	Subgroup analysis
C2_1_Gender	Gender	Dichotomous, 1=Male/2=Female	BLQ5_2	Yes	Yes
C2_2_Marital	Marital status	Multinomial, 6 categories 1=Never Married/ 2=Married/ 3=De facto/ 4=Separated/ 5=Divorced/ 6=Widowed	BLQ5_3	No	No
C2_2_1_Marital_dich	Marital status, dichotomised	Dichotomous, 0=Not partnered/ 1=Partnered	BLQ5_3	Yes	Yes
C2_3_Age_group	Age group at enrolment	Multinomial, 5 categories 1=18-24/ 2=25-34/ 3=35-44/ 4=45-54/ 5=55+	BLQ5_4	Yes	No
C2_4_Prim_eth	Primary ethnicity	Multinomial, 4 categories 1=Maori\	BLQ5_6a-BLQ5_6d	Yes	No

		2=Pasifika\ 3=European\ 4=Other (including Asian)			
C2_4_1_Eth_NZEur	NZ European ethnicity	Dichotomous 0=No/1=Yes	BLQ5_6a-BLQ5_6d	No	Yes (only "Yes")
C2_4_2_Eth_Maori	Maori ethnicity	Dichotomous 0=No/1=Yes	BLQ5_6a-BLQ5_6d	No	Yes (only "Yes")
C2_4_3_Eth_Pasifika	Pasifika ethnicity	Dichotomous 0=No/1=Yes	BLQ5_6a-BLQ5_6d	No	Yes (only "Yes")
C2_4_4_Eth_Asian	Asian ethnicity	Dichotomous 0=No/1=Yes	BLQ5_6a-BLQ5_6d	No	No
C2_4_5_Eth_Other	Other ethnicity	Dichotomous 0=No/1=Yes	BLQ5_6a-BLQ5_6d	No	No
C2_4_6_Eth_Asian_or_other	Asian or other ethnicity	Dichotomous 0=No/1=Yes	BLQ5_6a-BLQ5_6d	No	Yes (only "Yes")
C2_5_Employed	Employment status	Multinomial, 10 categories	BLQ5_5a	No	No
C2_6_Education	Highest educational qualification achieved	Multinomial, 9 categories	BLQ5_7a	No	No

C2_7_Fam_income	Gross family income in last 12 months	Multinomial, x categories	BLQ5_8	No	No
C2_7_1_Fam_income_dich	Gross family income in last 12 months, dichotomised	Dichotomous, 0=below median\ 1=equal to or above median	BLQ5_8	Yes	No
C2_8_Area_resid	New Zealand area of residence	Multinomial, x categories	BLQ5_8	No	No

C.2 *Personal history covariates*

Note: Problem Gambling Severity Index (12 months) is a secondary outcome the baseline value of which is used as a covariate.

Name	Full name	Description	Original variable name(s)	Potential confounder	Subgroup analysis
Gambling severity					
S1_1_1_PGSI-12	PGSI-12 (at baseline only)	Problem Gambling Severity Index 12 months	BLQ1_15-BLQ1_23	Yes	Yes
Gambling characterisation					
C3_1_1 to C3_1_11_Gamb_Type_xxxxx	Gambling Type xxxxx=Type Cards=cards Casm=Casino gaming	Dichotomous 0=No/1=Yes	BLQ1_1a-BLQ1_1g	No	No

	machines CasTa=Casino tables ClubMa=Club Gaming Machines PubMe=Pub Gaming Machines Housi=housie Keno=Keno Lotto=lotto SpBet=sports betting Track=track Other=other				
C3_2_Gamb_Primary	Primary Gambling Type	1 Cards 2 Casino Gaming Machines 3 Casino Tables 4 Club Gaming Machines 5 Pub Gaming Machines 6 Housie 7 Keno 8 Lotto 9 Sports Betting 10 Track 11 Other	BLQ1_1rank1	No	No
C3_2_1_EGM	Electronic Gaming Machines as primary gambling type	Dichotomous, 0=No\ 1=Yes	BLQ1_1rank1	Yes	Yes
C3_3_Prob_duration	How long has gambling been a problem	Positive integer (months)	BLQ1_2	No	No
C3_4_Time_since	How long since the last time you gambled	Positive integer (days)	BLQ1_5	No	No

C3_5_1_Lie-Bet_More	Ever felt need to bet more	Dichotomous 0=No/1=Yes	BLQ1_3	No	No
C3_5_2_Lie-Bet_Lie	Ever felt need to lie	Dichotomous 0=No/1=Yes	BLQ1_4	No	No

Assistance, general					
C4_1_Assist_curr	Currently receiving assistance	Dichotomous 0=No/1=Yes	BLQ1_8	No	No
C4_3_Assist_prev	Previously received assistance	Dichotomous 0=No/1=Yes	BLQ1_11	No	No
C4_5_Assist_any	Received any assistance in past 3 months	Dichotomous 0=No/1=Yes	Asked at assessments only.	N/A	N/A
E3_7_Assist_formal	Received assistance from any treatment service in the past three months	Dichotomous 0=No/1=Yes	Asked at assessments only.	N/A	N/A
Assistance, personal					
C5_1_1_AssistP_Partner	Received assistance from Partner in past 3 months	Dichotomous 0=No/1=Yes	Asked at assessments only.	N/A	N/A
C5_1_2_APNum_Partner	# Times Received assistance from Partner in past 3 months	Integer	Asked at assessments only.	N/A	N/A
C5_1_3_APHful_Partner	Helpfulness of assistance from Partner in past 3 months	Categorical, 3 categories	Asked at assessments only.	N/A	N/A

C5_2_1_AssistP_Family	Received assistance from Family member in past 3 months	Dichotomous 0=No/1=Yes	Asked at assessments only.	N/A	N/A
C5_2_2_APNum_Family	# Times Received assistance from Family member in past 3 months	Integer	Asked at assessments only.	N/A	N/A
C5_2_3_APHful_Family	Helpfulness of assistance from Family member in past 3 months	Categorical, 3 categories	Asked at assessments only.	N/A	N/A
C5_3_1_AssistP_Friend	Received assistance from Friend in past 3 months	Dichotomous 0=No/1=Yes	Asked at assessments only.	N/A	N/A
C5_3_2_APNum_Friend	# Times Received assistance from Friend in past 3 months	Integer	Asked at assessments only.	N/A	N/A
C5_3_3_APHful_Friend	Helpfulness of assistance from Friend in past 3 months	Categorical, 3 categories	Asked at assessments only.	N/A	N/A
C5_4_1_AssistP_Other	Received assistance from Other person in past 3 months	Dichotomous 0=No/1=Yes	Asked at assessments only.	N/A	N/A
C5_4_2_APNum_Other	# Times Received assistance from Other person in past 3 months	Integer	Asked at assessments only.	N/A	N/A
C5_4_3_APHful_Other	Helpfulness of assistance from Other person in past 3 months	Categorical, 3 categories	Asked at assessments only.	N/A	N/A

C5_5_AssistP_Any	Received assistance from Any person in past 3 months	Dichotomous 0=No/1=Yes	Asked at assessments only.	N/A	N/A
C5_6_Assist_informal	Received assistance from any person in past 3 months	Dichotomous 0=No/1=Yes	Asked at assessments only	Hypothesis E	N/A
E3_7_Assist_formal	Received assistance from any treatment service in the past three months	Dichotomous 0=No/1=Yes	Asked at assessments only	Hypothesis E	N/A
Goal setting					
C6_1_Current_goal	Current goal	Categorical, 5 levels	BLQ3_1a	No	No
C6_1_1_Current_goal_dich	Current goal, dichotomised	Dichotomous, 0=Quit 1=Control	BLQ3_1a	Yes	Yes
Workbook engagement					
C7_1_Wkbk_Engagement	Composite	Multinomial, 3 categories	Asked at assessments only.	Hypothesis E	N/A
Prospective beliefs					
C8_1_1_Prosp_succ6	Level of belief in success within 6 months	10-point Likert	BLQ3_3	No	No

C8_1_2_Prosp_succ12	Level of belief in success within 12 months	10-point Likert	BLQ3_4	No	No
C8_1_3_Prosp_succ_dich	Dichotomised level of belief in success within 12 months	Dichotomised 0=Lower level of belief\ 1=Higher level of belief	BLQ3_3 and BLQ3_4	Yes	Yes
C8_2_Prosp_diffic	Level of difficulty expected in next 12 months	10-point Likert	BLQ3_5	No	No
Comorbidities at baseline					
C9_1_K10MH_dich	Mental Health Kessler - 10, past 4 weeks, dichotomised	Dichotomised 0=Well 1=Mental disorder	BLQ4_6-BLQ4_15	No	Yes
C9_2_AUDITC_dich	Active alcohol abuse or dependence	Dichotomised 0=No 1=Yes	BLQ3_4	No	Yes
C9_3_SuicIdeation12	Suicidal thoughts in the previous 12 months	Dichotomous 0=No/1=Yes	BLQ4_5	No	No