

Investigating the effect of providing monetary incentives to participants on completion rates of referred co-respondents: An embedded randomised controlled trial


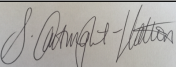
(Parenting with Anxiety SWAT) Statistical Analysis Plan

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1. SAP revision history

Version updated	Updated version number	Summary of changes	Author of changes	Date
Pre-1.0	1.0	Authorisation by study CI and senior statistician for SWAT interim analysis.	Chris Jones Abby Dunn Amy Arbon	19/01/2022
1.0	2.0	SAP updated to include details of final SWAT analysis. Authorisation by study CI and senior statistician.	Chris Jones	

2. Abbreviations

Abbreviation	Meaning
CPBQ	Challenging Parental Behaviour Questionnaire
EQ-5D-Y Proxy	EuroQol 5-dimension proxy measure for young persons
GAD7	Generalised Anxiety Disorder assessment
PWA	Parenting with Anxiety
SCAS	Spence Children's Anxiety Scale
SCARED-A	Screen for Child Anxiety Related Emotional Disorders (Adult)
SWAT	Study within a trial
SWEMWBS	Short Warwick and Edinburgh Mental Wellbeing Scale

3. Introduction

Version 1.0 of this SAP was prepared for the SWAT interim analysis. This was updated to version 2.0 to include the final analyses outlined in the protocol paper.

3.1 Background and rationale

See protocol paper.

3.2 Study objectives

The study will examine the impact of paying participants to refer a co-respondent to complete measures on the co-respondent response rate.

3.2.1 Objective

To investigate the hypothesis that payment to a participant to refer a co-respondent will improve the co-respondent completion rate. The completion rates of co-respondents who were referred by a participant who was paid will be compared to those who were referred by a participant who was not paid.

The specific SWAT hypotheses are:

1. Higher rates of nomination of a co-respondent in the payment arm, compared to the control arm (secondary objective).
2. Higher rates of consented co-respondents in the payment arm, compared to the control arm (secondary objective).
3. Higher rates of completion of co-respondent baseline measures in the payment arm, compared to the control arm (primary objective).
4. Higher rates of completion of co-respondent 6-month follow-up measures in the payment arm, compared to the control arm (primary objective).

Additionally, to investigate the effect of payment to a participant to refer a co-respondent on the quality of data provided to the study. As this is exploratory, no hypothesis has been generated for this objective.

4. Study methods

4.1 Study design

A parallel group embedded RCT to investigate the impact on co-respondent response rates of paying participants to refer a co-respondent to complete measures.

4.2 Randomisation

Participants for the main study are randomised into one of four groups: 1. Intervention and incentive, 2. Intervention and no incentive, 3. Control and incentive, 4. Control and no incentive. For the purposes of the SWAT, groups 1 & 3 combined will be compared to groups 2 & 4 combined.

4.3 Sample size

The sample size for this SWAT has been calculated to provide adequate power for the key objective of the host trial (N=1754). Given the weighting of index participants into the two arms (50% payment v 50% non-payment) and assuming 55% of co-respondents complete questionnaires in the group without financial incentives at baseline and 65% with baseline incentives, we would have in excess of 95% power to detect this difference in completion given our planned sample size. This sample size allows for 40% attrition (typical for online psychotherapeutic studies).

4.4 Framework

Superiority.

4.5 Outcome definitions

4.5.1 Primary outcome

1. Completion of co-respondent outcomes (No/Yes), where “completion” is defined as non-missing data for at least 80% of the primary outcome for the main trial (SCAS or SCAS-P), after “Prefer not to answer” responses have been set to missing.

4.5.2 Secondary outcomes

1. Nomination of co-respondents (No/Yes)
2. Consent of co-respondents (No/Yes)
3. Agreement between measures.
4. Time taken to complete measures.

5. Interim analyses

To investigate the quality of co-respondent’s referrals - i.e. that they are suitable candidates who have been appropriately nominated, an interim evaluation of the quality of data will be run after 120 participants have completed baseline data collection (60 in no-payment arm and 60 in the payment arm). If there does prove to be an inconsistency in the quality of data from the co-respondents in the two arms, the study team may amend the criteria and screening for co-respondents.

5.1 Outcomes for interim analyses

Data quality outcomes will be examined for the interim analysis.

These are:

Proportion of each scale completed by co-respondent

Whether or not the nominated co-respondent is deemed eligible

Amount of time (mins.) taken for co-respondent to complete all measures at baseline

Variability in scale measure responses

Agreement between respondent and co-respondent measures at baseline

5.2 Interim analyses

Data quality outcomes will be compared between the incentive/no incentive groups descriptively using summary statistics and plots appropriate to variable distributions. Means and standard deviations will be used to describe normally distributed variables, medians and interquartile ranges for skewed continuous variables and frequencies and percentages for categorical variables.

Bland-Altman plots

The difference between respondent and co-respondent/co-parent scale measures will be plotted against the average, by SWAT arm. The bias (mean of differences) will also be plotted as well as the 95% limits of agreement and their 95% confidence intervals. Plots will be produced for the following scales:

1. SCAS-P
2. SCAS-Pre

Results will be discussed with the Trial Steering Committee.

5.2.1 Early stopping or study continuation guidelines

N/A.

5.3 Timing of final analysis

Final analysis will be conducted after completion of second follow up (m9-25 depending on sign up date) for the main study, although the SWAT ends six months and four weeks after the last co-respondent has consented. Analysis is expected to begin in May 2023.

5.4 Timing of outcome assessments

Outcomes were collected at baseline and following invitation to complete again 6 months post-consent.

6. Statistical principles

6.1 Confidence intervals and p values

95% confidence intervals will be reported. p-values will be interpreted in terms of strength of evidence against the null hypothesis of no difference between the arms.

6.2 Adherence and protocol deviations

N/A.

6.3 Analysis populations

Analyses will be performed following intention to treat principles. Co-respondents can be co-parents or others. Where relevant, co-respondents are referred to as “all co-respondents”, “co-parents only”, or “other co-respondents”.

6.4 Study population

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The study population is either co-parents or co-respondents to parents in the host trial (anxious male and female adults (aged 16+) who have children aged 2 to 11 years).

6.5 Eligibility criteria

Index participants (i.e. parents participating in the host trial) will be asked to nominate a co-respondent to complete a set of measures alongside them, primarily in order to examine agreement between parent and co-respondent ratings of child anxiety. To ensure that nominated co-respondents are suitable to participate in the study, we have included brief eligibility criteria. Co-respondents need to:

- Know the child well enough to answer a questionnaire about their feelings and behaviours.
- Be aged over 16 years.

6.6 Recruitment

Participant progress through the study will be summarised using a CONSORT flow diagram.

6.7 Withdrawal/follow up

Numbers withdrawing and reasons for withdrawal will be summarised by arm.

6.8 Baseline participant characteristics

For all consented co-respondents, the following characteristics will be summarised by arm:

- Birth gender (male/female/prefer not to say)
- Age (continuous)
- Ethnicity (ethnicitycp_cop and ethnicitycr_cor, multiple categories)
- Financial status (financialstatuscp_cop and financialstatuscr_cor, Comfortable/Managing/Struggling)
- Education (educationcp_cop and educationcr_cor, multiple categories)
- Relationship to parent (friend/grandparent/other/parent/relation)

Additionally, the following outcomes will be summarised where relevant:

- SCARED-A subscale and overall scores (co-parents only)
- GAD7 overall score (other co-respondents)

7. Final Analysis

7.1 Differences in outcomes for the final analysis compared to the interim analysis

SCAS and SCAS-P were treated separately in the interim analysis, but will be combined for the final analysis to correspond to the way SCAS will be analysed in the main trial analysis.

The SCAS and SCAS-P outcomes have different numbers of questions, response scales and overall scores. To allow them to be analysed together, standardised z-scores will be calculated for SCAS and SAP v2.0 04/05/2023

SCAS-P overall scores. z-scores will be calculated separately for SCAS and SCAS-P as $z=(x_{it}-m_t)/sd_t$ at each time point, where x_{it} is the value of SCAS/SCAS-P for the i th individual at time point t and m_t and sd_t are respectively the mean and SD of SCAS/SCAS-P at time point t . For the SWAT, this applies only to SCAS at baseline and m6 (this also applies to an additional time point in the main trial analysis) for the ICC and Bland-Altman secondary analyses.

For time to complete analyses, time per question will be presented so SCAS and SCAS-P results are directly comparable.

7.2 Analysis methods

All co-respondents nominated, consented and completed will be summarised by arm at baseline and m6 using frequencies and percentages.

7.2.1 Primary analysis (outcome completion, objectives 3 and 4)

Mixed effects multivariable log-binary regression models will be fitted for the primary outcome (completion) with a random effect for participant, and SWAT arm and time point (baseline/m6) as fixed effects. No other fixed effects will be included as no other variables are thought to be related to the outcome.

Treatment effects (between-group differences) will be reported as Relative Risk with 95% CI. Equivalent logistic regression models will also be fitted to report Odds Ratio with 95% CI.

7.2.2 Secondary analyses

Nomination and consent (objectives 1 and 2).

Data from all co-respondents nominated and consented will be modelled using equivalent models to the primary outcome and reported in the same way.

Data quality

Data quality will be evaluated in three ways:

1. Intraclass correlations on baseline co-respondent data for the two study arms.

ICCs will be calculated (separately for each arm) at baseline and m6 for outcomes completed by both parents and co-respondents (SCAS/SCAS-P (all co-respondents) PSC (co-parents only) and CBPQ (co-parents only)). ICCs for SCAS/SCAS-P will be calculated on the combined standardised SCAS scores.

2. Agreement between each parent and co-respondent's measures (all co-respondents) using Bland-Altman plots.

The difference between respondent and co-respondent scale measures will be plotted against the average, by SWAT arm, at baseline and at m6. The bias (mean of differences) will also be plotted as well as the 95% limits of agreement and their 95% confidence intervals. Plots will be produced for combined standardised SCAS scores.

3. Time taken per question to complete measures.

Time taken per question for SCAS/SCAS-Pre will be summarised at baseline and m6, by arm.

7.3 Missing data

Frequency and proportion of missing data/'prefer not to say' responses per variable will be tabulated.

7.4 Additional analyses

N/A.

7.5 Harms

N/A.

7.6 Statistical software

Stata version 17.0 or later will be used for analysis.

8. References

StataCorp. 2021. *Stata Statistical Software: Release 17*. College Station, TX: StataCorp LLC.