

# **SWAT 157: Timing and value of participant vouchers to improve questionnaire return rates in the STADIA (STANDARDISED Diagnostic Assessment for children and adolescents with emotional difficulties) Trial.**

## **Objective of this SWAT**

To investigate the effects of the timing and value of participant vouchers on questionnaire return rates in a randomised trial involving children and young people and their parent/carers. Participants will be randomised to receive a single £20 voucher, conditional on completion of the 12-month questionnaires or up to two £10 vouchers, conditional on questionnaire completion at each of the 6- and 12-month time-points.

Study area: Retention, Follow-up

Sample type: Participants

Estimated funding level needed: Very Low

## **Background**

Missing outcome data as a result of losses to follow-up reduces study power and may introduce bias affecting the validity of a trial's results. Strategies to improve the retention of trial participants throughout the follow-up period can reduce missing data, improving research efficiency and minimising the risk of bias.[1]

This SWAT is embedded in the STADIA trial (ISRCTN15748675). Participant-reported outcome data are collected from participating parents/carers and/or children/young people at 6- and 12-months post-randomisation through online questionnaires. Participants are initially alerted to the need to complete these by email, text message or both. The parent/carer is the primary participant for all children/young people aged <16. Children/young people aged 11 to 15 years are also invited to participate alongside their parent/carer by completing their own questionnaires. Questionnaires for the child/young person aged 11 to 15 are sent via the parent/carer. Children/young people aged 16 and 17 are the primary participant and are sent follow-up questionnaires directly for completion. For young people aged 16 and 17, parent/carer participation is optional. If participating they are considered the secondary participant and are sent their questionnaires directly.

Originally, all participants taking part in the STADIA trial were offered a single £20 voucher, conditional upon completion of the 12-month questionnaires. The 12-month time-point was chosen to reflect the end of participants' involvement in the trial, with a single voucher payment selected for administrative simplicity and a higher value voucher considered to be preferable to participants. However, it is not known whether the offer of conditional voucher payments at both time-points may have an impact on the return of questionnaires, and consultation with the STADIA PPI (patient and public involvement) Advisory Panels indicated that offering voucher payments at both time-points may promote engagement with the trial throughout the follow-up period.

## **Interventions and comparators**

Intervention 1: A £10 voucher conditional on completion of the 6-month questionnaires plus another £10 voucher conditional on completion of the 12-month questionnaires. Participants will be informed of the conditional voucher at each follow-up time-point when the questionnaires are sent. Reminders to complete both 6- and 12-month questionnaires will also mention the voucher.

Intervention 2: A single £20 voucher conditional on completion of the 12-month questionnaires. Participants will be informed of the conditional voucher at the 12-month follow-up when the questionnaires are sent. Reminders to complete the 12-month questionnaires will also mention the voucher. The 6-month questionnaire emails and reminders will not mention the voucher available at 12-months.

Index Type: Incentive

## **Method for allocating to intervention or comparator**

Randomisation

## **Outcome measures**

Primary: A primary outcome has not been identified as the SWAT is not expected to have the power to detect significant differences.

Secondary: Return of at least one questionnaire during the follow-up period (yes/no); questionnaire return at the 12-month follow-up time-point (yes/no); questionnaire return at both follow-up time-points (yes/no); number of follow-up questionnaires returned (0/1/2); time from randomisation to return of the 6- and 12- month questionnaires.

### **Analysis plans**

It is estimated that approximately 500 participants will be randomised in the STADIA trial during the SWAT. The smallest detectable risk difference for a binary outcome with 80% power for each group of respondents is shown below. This is based on a conservative baseline response rate of 50% and 5% significance with no adjustment for multiplicity.

Respondent: Parent/carer, approximate number randomised\* 450 (90%), smallest detectable risk difference 13%

Respondent: Young people aged 11 to 15, approximate number randomised\* 124 (~25%), smallest detectable risk difference 26%

Respondent: Young people aged 16 or 17, approximate number randomised\* 74 (~15%) , smallest detectable risk difference 33%

\* Participants will be either a child/young person AND parent/carer dyad, or a parent/carer only (for young people aged 5 to 15) or young person only (aged 16 or 17).

For each group of respondents, outcomes will be analysed using mixed-effects regression models dependent on data type (binary, time-to-event, and ordinal). The models will adjust for trial allocation and will include a random effect for recruiting site. Comparisons of binary outcomes will be presented as both an absolute (risk difference) and relative (risk ratio) effect, along with 95% confidence intervals.

### **Possible problems in implementing this SWAT**

None anticipated

### **References**

1. Brueton VC, Tierney J, Stenning S, Harding S, Meredith S, Nazareth I, Rait G. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2013; 12: MR000032.

### **Publications or presentations of this SWAT design**

### **Examples of the implementation of this SWAT**

People to show as the source of this idea: Kapil Sayal, Florence Day, Kirsty Sprange, Kathryn Starr, Alan Montgomery, Chris Partlett, Laura Wyatt

Contact email address: stadia@nottingham.ac.uk

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Revisions made by: Kapil Sayal, Florence Day, Kirsty Sprange, Kathryn Starr, Alan Montgomery, Chris Partlett

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