

SWAT 179: Impact of pre-notifications on retention in 17-year follow-up of very preterm born adolescents (PIPARI-SWAT)

Objective of this SWAT

This SWAT investigates whether sending a postal pre-notification to study participants would increase the response rate for the approval form and questionnaires and reduce the number of post-notifications. We hypothesized that participants randomized to be sent the pre-notification would have higher response rates and reduced post-notification rates than those allocated not to receive the pre-notification.

Study area: Follow-up, Retention, Randomisation

Sample type: Participants, Carer/Parent

Estimated funding level needed: Very Low

Background

Patient-reported outcome measures provide valuable insight into the impact of a condition or treatment on patients' lives. An appropriate method to collect these data is a postal or electronic questionnaire. Questionnaires are less prone to bias compared to data collected via interview. They can also be used to reach participants who live in a wide geographic area. Participant retention is essential to follow-up studies and low retention leads to missing data which can cause bias and limit the generalizability, validity and reliability of the results. For example, Walters et al. showed in 2017 that the median loss-to-follow-up in a sample of 151 trials was 11%.^[1] Studies within a trial (SWATs) are defined as "a self-contained study that has been embedded within a host trial with the aim of evaluating or exploring alternative ways of delivering or organizing a particular trial process",^[2] and several have been developed to investigate interventions to improve questionnaire response rates and retention.

Sending pre-notifications is a cheap way to try to increase retention. However, it may be difficult to obtain and maintain accurate postal or electronic addresses for participants in prospective follow-up studies. Although many different study protocols have evaluated methods to increase retention in follow-up studies, we are not aware of the publication of any protocol similar to ours. In the SWAT repository, SWAT 86 investigates the effect of pre-notification letters on questionnaire response rates and we have found five prior SWATs that investigated the effect of the pre-notification text message on the retention rate of questionnaires.^[4-8] None of these found a difference in response rates and none provided high certainly evidence as determined by a GRADE assessment.^[3] As examples, Sarathy et al. investigated the effect of electronic message timing on response rate and stated that post-notification was more effective than pre-notification,^[9] but Keding et al. found both pre-and post-notifications to be ineffective.^[8]

This SWAT was part of the prospective PIPARI study, which follows very preterm born children and their full-term born peers from infancy to adulthood. At 17 years of age, all study adolescents and their parents were invited to complete a survey. The questionnaires related to mental health, parenthood, language skills, executive functions, substance abuse, use of media and sexuality. Families chose to have contact and questionnaires by post or e-mail. Participants were assigned to one of the two SWAT groups using random permuted block randomization using SAS software, Version 9.4 of the SAS System for Windows (SAS Institute Inc., Cary, NC, USA) and block size of 12. Gender and sibling relationships were considered as stratification factors and a statistician not involved in the PIPARI-study was responsible for generating the allocation sequence and assignment to the intervention and control groups. A total of 132 adolescents were randomized to the pre-notification group and 137 adolescents to the control group. Children of the same family were in the same study group. Study participants were blinded to the set-up of the PIPARI-SWAT.

Interventions and comparators

Intervention 1: Pre-notification letter 2-3 weeks before the study approval form, which was sent 6-7 weeks before the study questionnaires. If the adolescent or parent has not returned the approval letter within 3 weeks, a post-notification phone call was made by the PIPARI-study researcher. In case of no answer to a phone call, a short message service (SMS) was sent.

Intervention 2: Control: no pre-notification.

Index Type: Method of Follow-up, Method of Invitation

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Response rate for the approval form.

Secondary: (1) Response rate of the follow-up questionnaires; and (2) rate of post-notifications (telephone calls, text-messages, e-mails).

Analysis plans

The normality of the distributions will be assessed both graphically and with the Shapiro-Wilk. Normally distributed variables will be described by means, standard deviations and minimum and maximum values. Continuous variables will be compared between study children and drop-outs using the independent sample t-test. Comparisons between two categorical variables will be done using the Pearson Chi Square or Fisher's exact test, as appropriate. Odds ratios and 95% confidence intervals will be computed using logistic regression to assess the impact of the pre-notification. Analyses will be adjusted for parents' education. Statistical analyses will be performed using SPSS version 27. A p-value <0.05 will be considered statistically significant.

Possible problems in implementing this SWAT

It might be challenging to get up-to-date addresses for the participants.

References

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2. Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? *Trials* 2018;19:139.
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4. Starr K, McPherson G, et al. SMS text pre-notification and delivery of reminder e-mails to increase response rates to postal questionnaires in the SUSPEND trial: a factorial design, randomised controlled trial. *Trials* 2015;16:295.
5. Bradshaw LE, Montgomery AA, Williams HC, et al. Two-by-two factorial randomised study within a trial (SWAT) to evaluate strategies for follow-up in a randomised prevention trial. *Trials* 2020;21:529.
6. Keding A, Brabyn S, MacPherson H, et al. Text message reminders to improve questionnaire response rates. *Journal of Clinical Epidemiology* 2016;79:90–5.
7. Man M-S, Tilbrook HE, Jayakody S, et al. Electronic reminders did not improve postal questionnaire response rates or response times: a randomized controlled trial. *Journal of Clinical Epidemiology* 2011;64:1001-4.
8. Ashby R, Turner G, Cross B, et al. A randomized trial of electronic reminders showed a reduction in the time to respond to postal questionnaires. *Journal of Clinical Epidemiology* 2011;64:208-12.
9. Partha Sarathy P, Kottam L, Parker A, et al. Timing of electronic reminders did not improve trial participant questionnaire response: a randomized trial and meta-analyses. *Journal of Clinical Epidemiology* 2020;122:70-7.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 14/MAY/2019

Revisions made by: not available

Date of revisions: