

SWAT 48: Effects of a £10 note on trial retention

Objective of this SWAT

To evaluate the effectiveness of providing trial participants with a contingent £10 note at a face-to-face appointment to increase retention at a subsequent follow-up study visit.

Study area: Follow-up, Retention, Outcomes

Sample type: Participants

Estimated funding level needed: Medium

Background

Attrition is experienced in most randomised trials with approximately a quarter of trials experiencing attrition resulting in greater than 10% of primary outcome data being unavailable for analysis [1]. This threatens the internal and external validity of the study and impacts on the statistical power and generalisability of study findings [2]. Every effort should therefore be made to limit attrition to reduce the risk of attrition bias, arising from differential attrition in the study groups.

Despite the importance of minimising attrition, there is limited available literature on appropriate methods to achieve this. A review by Bower et al identified three systematic reviews assessing retention methods [3] with limited findings. Much of the research had focused on follow-up questionnaires and the most effective retention strategy for increasing postal questionnaire return was the use of monetary incentives (risk ratio (RR): 1.18; 95% CI 1.09 to 1.28) [4]. The effect of incentives increased to RR 1.25 (95% CI 1.14 to 1.38) when the incentive was provided upon receipt of a completed questionnaire [4]. Bailey et al identified that response rates could also be increased through variation of the amount of incentive provided; £20 incentive vs a £10 incentive was found to increase response rates by 6-10% [5].

In their review, Brueton et al noted how most interventions tested in trials were concerned with improving postal questionnaire response rates as opposed to, for instance, participant return to clinic for face-to-face follow up visits [4]. Therefore, because many randomised trials use this method of follow up, further investigation of ways to improve retention for such visits is warranted. The most robust way to assess retention methods is through a randomised trial, nested within an ongoing host trial enabling a less biased, externally valid assessment of the effects of a strategy in a real world scenario [3]. With this in mind, this SWAT is being undertaken in a randomised trial of a smoking cessation intervention for people with severe mental illness, which is being conducted in the UK (SCIMITAR Plus) [6].

Interventions and comparators

Intervention 1: Participants will be given a £10 note, contingent on completion of the CO breath measure, as part of the 6 month face to face study appointment. This will be provided in addition to the £10 gift voucher currently provided as a gesture of thanks.

Intervention 2: Participants will not receive a contingent £10 note following completion of their CO breath measure as part of the 6 month face to face study appointment, but will however continue to receive the £10 gift voucher currently provided as a gesture of thanks.

Index Type: Incentive

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of participants completing a CO breath measurement at the SCIMITAR Plus 6 month appointment.

Secondary: - Proximity of visit completion to visit due date.

- Proportion of patients withdrawing from follow up (after contact is made to arrange the visit).

Analysis plans

Analyses will be conducted on an intention to treat basis, including all randomised participants on the basis of the groups to which they were randomised.

The primary outcome is the proportion of participants completing a CO breath measurement at the 6 month SCIMITAR Plus outcome time point. A chi squared test and odds ratios will be used to compare differences in proportions between the two groups.

The secondary outcome of proximity of visit completion date to visit due date will be presented as means and associated standard deviation. A Cox proportional hazards model will be used to compare the two groups.

The secondary outcome of proportion of patients withdrawing from follow up (after contact is made to arrange the visit) will be presented as numbers and percentages. These will be compared using a chi squared test and odds ratios.

Possible problems in implementing this SWAT

References

1. Hewitt CE, Kumaravel B, Dumville JC, Torgerson DJ. Assessing the impact of attrition in randomised controlled trials. *Journal of Clinical Epidemiology* 2010; 63: 1264-70.
2. Robinson KA, Dennison CR, Wayman DM, et al. Systematic review identifies number of strategies important for retaining study participants. *Journal of Clinical Epidemiology* 2007; 60: 757-65.
3. Bower P, Brueton V, Gamble C, et al. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials* 2014; 15: 399.
4. Brueton VC, Tierney J, Stenning S, et al. Strategies to improve retention in randomised trials. *Cochrane Database of Systematic Reviews* 2013; (12): MR000032.
5. Bailey JV, Pavlou M, Copas A, et al. The Sexunzipped Trial: Optimising the design of online randomized controlled trials. *Journal of Medical Internet Research* 2013; 15: e278.
6. Gilbody S, Peckham E, Man M, et al. Bespoke smoking cessation for people with severe mental ill health (SCIMITAR): a pilot randomised controlled trial. *The Lancet Psychiatry* 2015; 2(5): 395-402.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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