SWAT 81: A Telephone Reminder to Enhance Adherence to Interventions in Randomised Trials

Objective of this SWAT
To evaluate the effects of a telephone reminder to enhance the adherence of participants to interventions in randomised trials.

Study area: Adherence, Retention
Sample type: Patients
Estimated funding level needed: Low

Background
A great deal of effort is expended in recruiting participants to randomised trials.[1] Following this, there is the problem of ensuring that they remain in the trial and adhere to the allocated intervention.[2] Adherence is the extent to which the participant's behaviour corresponds with the trial protocol in terms of, for example, taking medications as prescribed, attending clinical appointments and executing lifestyle modifications.[3] Poor adherence is particularly problematic in trials which seek to treat or prevent cardiovascular disease. A Cochrane Review of strategies to promote patient participation and adherence in cardiac programmes found that, although the benefits of such programmes are well documented, patients do not always agree to take part and many of those who do participate do not adhere to the recommended programme; concluding that there is a need to devise and evaluate strategies to improve adherence in such programmes.[4]

Non-adherence to the trial intervention has serious implications because it can decrease the statistical power of the study, impact negatively on the trial outcomes and increase the risk of attrition bias due to incomplete data.[5,6] Low adherence rates can also waste research resources, increasing the costs of trials and extending the time required to complete them. Therefore, research is needed to develop rigorous strategies for improving adherence to interventions in clinical trials.[6,7] One such strategy may be telephone reminders to non-responders, which have been shown to be effective in increasing recruitment to trials,[1] but have not been tested as a means to improve adherence to trial interventions.

This SWAT will do this in the intervention group of the randomised trial: Intensive Lifestyle Modification Programme versus Standard Care for Risk Factor Reduction and Stroke Prevention in Patients with Asymptomatic Carotid Artery Stenosis, which will take place at the Vascular Department, University Hospital College Galway, in collaboration with Croi Heart and Stroke Centre, Galway, Ireland. This host trial evaluates the effectiveness of an intensive lifestyle modification programme on cardiovascular disease risk factors and stroke in patients with asymptomatic carotid artery stenosis and the SWAT will evaluate the effectiveness of telephone reminders on participant's adherence to the intervention.

Interventions and comparators
Intervention 1: Telephone reminder (maximum three attempts with no messages left on voicemail to protect privacy) the day before their appointment to attend the intervention programme. The telephone reminder will be a scripted text to remind the participant is reminded of their study visit date and time and asking them to confirm their attendance the next day.
Intervention 2: No telephone reminder.

Index Type: Adherence to interventions

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Adherence to trial intervention (defined as 100% attendance)
Secondary: Number of dropouts, and time to drop out from the host trial.

Analysis plans
Analyses will be done on an intention-to-treat basis, using two-sided statistical significance at the 5% level and including appropriate descriptive analyses and between-group comparisons. The primary analysis will use the chi-square test to assess the difference in adherence rate between those receiving the telephone reminder and those not receiving the reminder. Odds ratios and 95% confidence intervals will be calculated. Time to drop out will be analysed using Kaplan-Meier curves and the log-rank test to compare the groups.

Data will be presented as proportions and percentages (adherence) and as the median, standard error and interquartile range (time to drop out).

Possible problems in implementing this SWAT
Ethical approvals for the host trial and SWAT have been sought and granted, therefore we do not anticipate any ethical issues arising.

References
1. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013.
2. Matsui D. Strategies to measure and improve patient adherence in clinical trials. Pharmaceutical Medicine 2009;23:289-97.
3. Sabaté E. Adherence to long-term therapies: evidence for action. World Health Organization, 2003.
4. Davies P, Taylor F, Beswick A, et al. Promoting patient uptake and adherence in cardiac rehabilitation. Cochrane Database of Systematic Reviews 2010: CD007131.
5. Hewitt CE, Kumaravel B, Dumville JC, et al. Assessing the impact of attrition on randomized controlled trials. Journal of Clinical Epidemiology 2010;63:1264-70.
6. Adamson J, Hewitt CE, Torgerson DJ. Producing better evidence on how to improve randomised controlled trials. BMJ 2015;351:h4923.
7. 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.

Publications or presentations of this SWAT design
BenSaaud A, Tawfick W, Jordan F, The Effectiveness of a Telephone Reminder to Enhance Adherence to Interventions in Randomised Trials, A Study within a Trial (SWAT), Vascular Journal Club 2018, UCHG.
Bensaaud A, Gibson I, Jones J, Flaherty G, Sultan S, Tawfick W, Jordan F. A telephone reminder to enhance adherence to interventions in cardiovascular randomized trials: A protocol for a study within a trial (SWAT). Journal of Evidence Based Medicine 2020; 13(1): 81-84.

Examples of the implementation of this SWAT

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