

SWAT 190: Identifying motivators of participation and key expectations of participants in randomised trials

Objective of this SWAT

To determine key motivators that influence participation in a randomised trial of melanoma early detection and participants' expectations from their involvement in the trial.

Study area: Recruitment, Retention, Intervention adherence

Sample type: Participants

Estimated funding level needed: Very Low

Background

There is a need to better understand the motivators and expectations of participants in clinical trials to identify areas and strategies to improve trial processes, particularly related to recruitment, retention, response to trial tasks and intervention adherence. The PRioRiTy study, a James Lind Alliance Priority Setting Partnership, concluded that one of the most pressing recruitment questions is to determine what motivates trial participation (1) and that the top retention priority is to understand what motivates participants to complete a clinical trial.(2)

This SWAT will be embedded in the MEL-SELF randomised trial of patient-led surveillance compared to clinician-led surveillance in people treated for early-stage melanoma (stage 0/I/II) (NCT03581188).(3) The host trial will assess whether patient-led surveillance (comprising: smartphone supported skin self-examination, teledermatology, fast-tracked unscheduled clinic visits in addition to routinely scheduled clinic visits) compared to clinician-led surveillance (usual care using treating doctor's usual processes for fast-tracked unscheduled and for routinely scheduled clinic visits) increases the proportion of participants who are diagnosed with a subsequent new primary or recurrent melanoma at a fast-tracked unscheduled clinic visit.

This SWAT would be straight-forward to run in any clinical trial. The evidence collected could then be used to guide the design of targeted strategies to improve recruitment, response to reminders to complete trial tasks, retention and adherence to trial interventions.

Interventions and comparators

Intervention 1: Two open-ended questions addressing participants' motivations for participation and expectations from trial involvement were included to an online questionnaire completed at baseline:

Please tell us why you decided to participate in this study?

Please tell us what you are hoping to get out of this study?

Index Type: Method of Recruitment, Method of Follow-up, Adherence

Method for allocating to intervention or comparator

Outcome measures

Primary: List of key motivators

Secondary: List of key expectations

Analysis plans

Data will be collected from the first 100 randomised participants in the host trial and analysed by content analysis. This will be an iterative process characterised by continual re-reading of the data, data coding and thematic identification (e.g. development of categories/themes and hierarchical ordering). Coding and analysis will be conducted in Excel.

Possible problems in implementing this SWAT

Collating useful information is dependent on sufficient response to the open-ended questions from participants in the host trial.

References

1. Healy P, Galvin S, Williamson PR, Treweek S, Whiting C, Maeso B, et al. Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership – the PRioRiT_y (Prioritising Recruitment in Randomised Trials) study. *Trials*. 2018;19(1):147.
2. Brunsdon D, Biesty L, Brocklehurst P, Brueton V, Devane D, Elliott J, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiT_y II (Prioritising Retention in Randomised Trials) study. *Trials*. 2019;20(1):593.
3. Ackermann DM, Smit AK, Janda M, van Kemenade CH, Dieng M, Morton RL, et al. Can patient-led surveillance detect subsequent new primary or recurrent melanomas and reduce the need for routinely scheduled follow-up? A protocol for the MEL-SELF randomised controlled trial. *Trials*. 2021;22(1):324.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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