SWAT 254: Pictorial enhanced written plus audiovisual information versus standard written information alone for disseminating trial results to trial participants

Objective of this SWAT
To determine the comparative effects of pictorial enhanced written plus audiovisual information versus standard written information alone for disseminating trial results to trial participants.

Additional SWAT Details
Primary Study Area: Dissemination
Secondary Study Area: PPI
Who does the SWAT intervention target: Participants
Estimated resources needed to conduct the SWAT: Medium
Estimated cost of the SWAT (£): 3500

Findings from Implementation of this SWAT
Reference(s) to publications of these findings:
Primary Outcome Findings:
Cost:

Background
Trial participants have repeatedly indicated that they would like to receive the results of the trials that they were enrolled in [1-4], but evidence suggests that trial teams are under performing in this area. In a survey of trial authors (n=1818), 33% indicated that they did not plan to disseminate their results to trial participants, and only 27% had already done so [5]. Reasons for not sharing trial results vary and include time lapses from the point of enrolment to when results become available and a lack of incentive and expectations to do so [5]. Nonetheless, sharing trial results is not only an ethical mandate of researchers [6] but also shows respect for participants, without whom trial conduct would not be possible [7].

Although guiding principles related to sharing results with trial participants have been proposed, including pro-actively offering overall the results to all trial participants, irrespective of what the results show, and managing participant expectations around when the results will become available [7], little is known about the most appropriate methods for doing so. We are aware of only three randomised trials that formally evaluated the effectiveness of different methods for sharing trial results with trial participants [3,6,8]. This apparent limited research on methods for disseminating trial results to trial participants highlights the need to expand the methodological evidence base for this essential trial process.

Host Trial Population: Adults
Host Trial Condition Area: Pregnancy & Childbirth

Interventions and Comparators
Intervention 1: Pictorial enhanced mailed written summary report complemented by an animated video with voice over of the host trial's results
Intervention 2: Standard mailed written summary report of the host trial's results

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures
Primary Outcome: Participant satisfaction with the dissemination method, measured using a 1-5-point Likert scale (from 1= very dissatisfied to 5 = very satisfied)
Secondary Outcomes: Participant satisfaction with the information provided, measured using a 1-5-point Likert scale (from 1 = very dissatisfied to 5 = very satisfied); Participant perception of their understanding of the summary results provided, measured using a 1-5-point Likert scale (from 1 = no understanding to 5 = full understanding); Participant rating of the usefulness of being provided with the results, measured using a 1-5-point Likert scale (from 1 = not at all useful to 5 =

very useful); Participants will be asked if they were glad to receive the results (Yes/No response option, with a free-text-box option to comment/expand on their response); Participants in the intervention 1 group will also be asked if they accessed the audiovisual link (Yes/No response option, with a free-text-box option to comment/expand on their response); Participant opinions for how trial results could be presented to participants taking part in future maternity care trials, using a series of options for different dissemination methods, informed by the literature, with a free-text option to suggest a method not presented in the list; and final direct costs incurred by the SWAT.

Analysis Plans
For the outcomes that use a Likert scale or yes/no response, descriptive statistics (frequencies and proportions) for each of the response options will be presented. For these outcomes, the numbers of participants who indicate 4 or 5 on each scale in the intervention 1 and intervention 2 groups will then be merged and the two groups, for each outcome, will be compared using odds ratios with 95% confidence intervals.

If more than 25% of intervention 1 participants indicate that they did not access the audiovisual summary, we will conduct sub-group analyses on all outcomes comparing those who answered i) intervention 1 yes accessed versus no did not access, ii) intervention 1 yes accessed versus intervention 2 group and iii) intervention 1 no did not access versus intervention 2 group.

The number of preferences for each option in the list of dissemination methods will be used to rank these options from most often to least often preferred. This will provide a preference-based list for how the results of future maternity care trials should be shared with trial participants.

Qualitative data (free-text responses) provided by participants will be analysed using content analysis to determine patterns in the data.

Possible Problems in Implementing This SWAT
None anticipated

References Cited in This Outline
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8. Mancini J, Genre D, Dalenc F, et al. Participants' uptake of clinical trial results: a randomised experiment. British Journal of Cancer 2010; 102: 1081-4. doi: 10.1038/sj.bjc.6605592

References to This SWAT

Source of This SWAT
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