

SWAT 146: Adding 'Withdrawal Slips' within follow up reminders for questionnaires

Objective of this SWAT

To evaluate the effects on retention, questionnaire completion and trial efficiency of including withdrawal slips in follow-up reminders for questionnaires in a randomised trial, which allow participants to 'skip' that timepoint but remain in the study for further follow-up or to 'stop' any further follow-up questionnaires (i.e. to 'withdraw' from the study).

Study area: Follow-up, Retention

Sample type: Participants

Estimated funding level needed:

Background

The ROMIO study is comparing different types of surgery for patients with oesophageal cancer (ISRCTN10386621). It includes a set of reminder questionnaires, which are sent to participants who do not return their completed initial questionnaires within two weeks. These follow-up questionnaires are sent at multiple timepoints through the study.

The ROMIO patient and public involvement (PPI) group suggested that withdrawal slips should be sent to participants alongside their reminder questionnaire allowing them to skip that questionnaire but continue to receive subsequent follow-up questionnaires or to stop all questionnaires. As the potential impact of using such a slip was uncertain, this SWAT was designed to evaluate the effects of its introduction.

All ROMIO study participants are randomised to either receive a withdrawal slip or to not receive the withdrawal slip. However, only participants who require a reminder set of questionnaires will be included in this SWAT.

Interventions and comparators

Intervention 1: Inclusion of a withdrawal slip within the follow-up reminder sent to the participant by post.

Intervention 2: No withdrawal slip.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of questionnaires returned.

Secondary: Proportion of participants who missed one or more timepoints and proportion of participants withdrawing from the study.

Analysis plans

There is no formal sample size calculation for this SWAT because numbers are limited to the number of patients participating in the host ROMIO study. The ROMIO Study Executive Group (SEG) will periodically monitor this SWAT. Descriptive data analysis will take place at the end of the ROMIO follow-up period.

Possible problems in implementing this SWAT

Ensuring study staff at sites are adhering to this SWAT when their patients require reminders. The impact of the COVID-19 pandemic and its associated measures has added a challenge as more follow up is taking place over the telephone.

References

None

Publications or presentations of this SWAT design

None

Examples of the implementation of this SWAT

People to show as the source of this idea: ROMIO Study PPI Group

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Revisions made by:

Date of revisions: