SWAT 166: Effects on trial recruitment and retention of including a picture book with the participant information sheet

Objective of this SWAT
To establish if the number of patients recruited and retained in a clinical trial is improved by the use of an illustrated, narrative based participant information sheet (PIS) in addition to a standard PIS compared with presentation of the study using a standard PIS.

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

Background
During the recruitment process for clinical trials, potential participants are usually given a written patient information sheet (PIS) about the study. These are often long, complex and visually unappealing documents, which may have a negative impact on recruitment. Improving their readability using an alternative format, such as an illustrated narrative (picture book), may improve patient understanding and boost recruitment. Patients will also retain the picture book so that they can refer to it after recruitment. This may help them to understand what will happen throughout the study and act as a reminder of the importance of their participation, and thereby may also improve retention. This SWAT will be embedded in the EXTEND trial of antibiotics for patients with complicated intra-abdominal infection (ISRCTN72819021).

Interventions and comparators
Intervention 1: Illustrated, narrative based PIS, and a standard PIS.
Intervention 2: Standard PIS.

Index Type: Participant information

Method for allocating to intervention or comparator
Cluster randomisation of sites

Outcome measures
Primary: Recruitment into the host trial (proportion of eligible patients randomised into the host trial)
Secondary: Retention (proportion of patients who return the final questionnaire for the host trial)

Analysis plans
The primary outcome will be analysed at the individual level using a hierarchical logistic regression model with a single binary indicator for SWAT allocation, and correlation within site modelled using an appropriate correlation structure. The odds ratio will be reported together with a 95% confidence interval and p-value obtained using an appropriate small-sample adjustment. The fitted model will also be used to estimate the effect of SWAT allocation on the risk difference for recruitment to the host trial. Further exploratory analyses will look at differences in retention between SWAT groups among patients who join the host trial.

Possible problems in implementing this SWAT
No significant potential problems are likely.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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