

SWAT 102: Addition of a pictorial aid to the patient information leaflet to improve recruitment in a randomised trial.

Objective of this SWAT

To determine whether the addition of a pictorial aid to the patient information leaflet (PIL) will improve recruitment in the POSNOC trial.

Study area: Recruitment

Sample type: Patients

Estimated funding level needed:

Background

Recruitment is one of the most important challenges for multi-centre trials. Various techniques have been developed and tested over the years and new methodologies are continuing to be developed. Enhanced PIL may help with patients understanding of the trial and therefore boost recruitment. This is being tested in this SWAT, embedded in the POSNOC trial of auxiliary treatment for women with breast cancer (NCT02401685), with participating sites randomised to use one of the PIL for all potentially eligible women.

Interventions and comparators

Intervention 1: A clearly illustrated pictorial aid at the end of the PIL to depict the randomisation process and crucial information about the two treatment arms in the POSNOC trial.

Intervention 2: Standard PIL.

Index Type: Method of Recruitment, Participant Information

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of women randomised to the POSNOC trial.

Secondary:

Analysis plans

Data analysis for the SWAT will firstly describe number and proportion of women randomised in each of the two intervention groups (enhanced PIL versus standard PIL). The distribution of recruitment fraction among participating sites is expected to be approximately log-normal. We will compare mean log-recruitment fraction between the groups using a multivariable regression model that will include stratification variables and be weighted according to number of women screened. The exponential of the difference in mean log-recruitment fraction represents the ratio of geometric means, which we will present with its 95% confidence interval and exact p-value. No interim analyses are planned.

Possible problems in implementing this SWAT

The current version of the PIL will need to be updated with the pictorial aid and submitted for approval as a substantial amendment. Some additional training on the use of the pictorial aid will need to be provided to sites randomised to use the enhanced PIL, but this is expected to be minimal.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Alan Montgomery, Clare Brittain, Shabina Khan, Mickey Lewis, Wei Tan, Amit Goyal, Clare Upton

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