

Sub study registration template

Sub-study title

Systematic Techniques for Assisting Recruitment to Trials in MRC START in [host trial name].

Study aims

1. To establish if the numbers of patients recruited in to the [host trial name] are increased by the use of a participant information sheet and covering letter developed through a process of 'User Testing', compared to a routine participant information sheet.
2. To explore whether user testing of the PIS and covering letter improves retention in the [host trial name] host studies.

Study design

The MRC START sub-study sits within the existing [host trial name] study design. MRC START in [host trial name] trial is a 'nested' RCT. Potential participants in the [host trial name] trials will be randomised to MRC START to receive either the standard or the user tested versions of the participant [host trial name] information sheets and covering letters.

Interventions

Patients who are being invited to participate in the [host trial name] trial will be randomly allocated to one of two interventions:

- sent the original [host trial name] trial participant information sheet and covering letter;
- sent the user tested participant information sheet and covering letter.

Inclusion/exclusion criteria

The recruitment trial will include all patients identified as potentially eligible for the [host trial name] Trial.

Outcome measures

The primary outcome will be the number of patients consenting to participate in the [host trial name] Trials. A secondary outcome will be retention in the [host trial name] studies. We will keep a record of all patients who were identified as potential participants and which intervention group they were in.