RCTs are critical to evidence-based practice, but recruitment problems pose challenges for funders, academics and research networks. There is little evidence to support recruitment. A recent Cochrane review identified only 14 studies where different recruitment methods had been tested by ‘nesting’ them in real RCTs. The review concluded: ‘It would be better if more researchers included an evaluation of recruitment strategies in real trials’.

The interventions

- Enhanced participant information sheets (PISSs) employ a system of user testing and graphic design to achieve a demonstrable improvement in patient understanding of, and information retrieval from PISSs. The test here is to establish whether improved comprehension leads to better recruitment and/or retention of participants and improved quality of informed consent.

- Multi-media participant information packages are currently in development. They will use a web-based platform to provide trial information via talking heads in an alternative format to the printed sheet. Potential participants will receive either a PIS alone or PIS and access to the multi-media package.

Next steps

Recruitment of host trials is underway and we are currently on schedule to meet our recruitment target of 12 RCTs in a variety of settings. We will ‘nest’ a rigorous test of recruitment methods in these trials by randomising patients within each trial to different recruitment interventions. The eventual aim of START is to make ‘nested’ trials of recruitment methods routine in the UK.

Risks

Recent research identified ‘a host of potential scientific, logistical and ethical obstacles’... to nested trial methodology. Concerns include:

- the nested study could jeopardize the host trial
- the results of single trials of nested recruitment interventions may not generalise
- implementation fidelity issues
- potential for confusion or increased burden for participants

References

1. Treweek S et al. Strategies to improve recruitment to RCTs. Cochrane Database of Systematic Reviews 2010; Issue 1 Art. No.:MR000013.
http://www.biomedcentral.com/1471-2288/10/38