MRC START

Developing the science of recruitment

Developing a science of recruitment to RCTs

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Background: Why it matters

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[a] 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 idea

Systematic Techniques for Assisting Recruitment to Trials (START) is an MRC funded feasibility study.

We aim to:

- ❑ test the feasibility of ***nested RCTs*** as a methodology
- ❑ test innovative recruitment methods across multiple host trials, using nested RCT methodology
- ❑ rapidly expand the evidence base on recruitment, and
- ❑ explore the effects of recruitment interventions in different contexts.

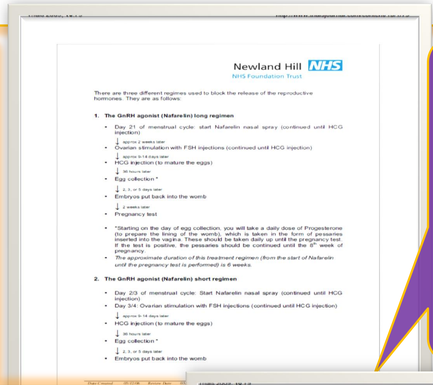
The interventions

- ❑ **Enhanced participant information sheets** (PISs) employ a system of user testing and graphic design to achieve a demonstrable improvement in patient understanding of, and information retrieval from PISs. 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.

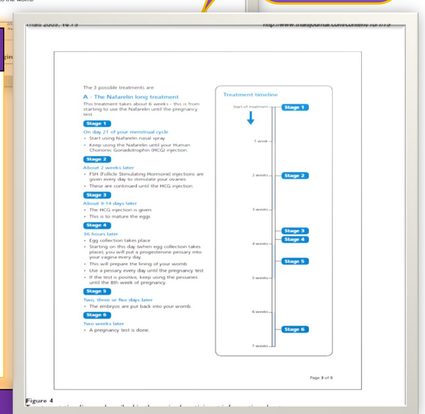


From: Knapp et al. 2009, Trials, 10:79 Doi:10.1186/1745-6215-10-79

Risks

Recent research[b] 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

[a]Treweek S et al. Strategies to improve recruitment to RCTs. *Cochrane Database of Systematic Reviews* 2010;Issue 1 Art. No.:MR000013.

[b]Graffy J et al. Trials within trials? Researcher, funder and ethical perspectives on the practicality and acceptability of nesting trials of recruitment methods in existing primary care trials *BMC Medical Research Methodology* 2010, 10:38
http://www.biomedcentral.com/1471-2288/10/38

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