Tips to consider when optimising recruitment of patients to clinical trials

Recruitment is critical to a clinical trial's success.

This document briefly outlines some steps to help trial teams to plan a successful recruitment strategy or address recruitment difficulties if they arise. It does not give all the answers. Our aim was to give some tips on recruitment, draw your attention to key evidence and flag up resources that may be helpful. Recruitment can be very challenging and many trials recruit more slowly than expected [1].

1. Before initiating a trial, liaise with representatives from relevant stakeholder groups (e.g. Clinical Research Network Clinical Studies Groups, patient/carer representatives, potential recruiters, research nurses, pharmacists etc) to seek their input on the design and foster a sense of 'ownership' with the trial.

2. Undertake a feasibility study before the main trial, where possible, to ascertain likely numbers of eligible participants from each potential site [2]. Seek the views of recruiters and patients/carers to anticipate and address problems that could hinder recruitment [3]. Review patient information sheets, recruitment pathways and consent procedures to ensure they are as simple as possible for both patients and recruiters [3].

3. Consider using a screening log in study centres. This is helpful to keep everyone aware of the trial, ensure that all potential recruits are reviewed, enable a review of inclusion/exclusion criteria, and identify criteria that may be blocking recruitment.

4. Assess the relevance of interventions and strategies to improve trial recruitment that have been shown to be effective in a recent systematic review [4]:

    a. Where feasible, use opt-out procedures (where potential participants have to contact the trial team if they did not wish to be approached about the trial), rather than opt-in procedures for contacting potential trial participants.
    b. Use telephone reminders for non respondents.
    c. Consider financial incentives for patients (for example including £5 with the trial invitation) and SMS reminders for non respondents as they appear promising.

5. Focus attention on the recruiters and their experiences of the trial:

    a. Aspects of the design and conduct of trials can affect clinicians' willingness to invite patients to participate, for example, the availability of research nurse support, the timing of recruitment relative to difficult stages of the patient's illness, and fear that recruitment could have an adverse effect on the clinician-patient relationship [5-7]. An investigator's meeting at the design stage may be helpful to identify what is above and beyond clinical practice and how best the trial might fit into current practice.
    b. Recruiters may unwittingly be influencing potential recruits. Consider implementing a qualitative investigation alongside the trial to establish if the recruiters are truly committed to the trial, comfortable approaching potential participants [6], and at ease discussing equipoise and presenting

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treatments equally whilst avoiding terminology that may be misinterpreted [3].

c. Encourage recruiters to investigate patients' views of the trial and treatment preferences during the recruitment to trial consultation. Exploring and addressing such views in the context of evidence based treatment and study information can improve levels of informed decision making and facilitate trial participation [8].
d. Hold regular recruiter training sessions for all recruiting staff to: provide an opportunity for recruiters to air their views of the trial and their perceptions of how patients regard it; illustrate good and not so good practice in recruitment; address raised problems; and provide recruitment tips and advice documents [9]. Consult with less successful recruiters and centres and provide tailored support [9].

6. If recruitment is slower than expected consider if you should focus on recruiting new centres or practitioners, putting more effort into those that are recruiting poorly, or putting more effort into those that are recruiting well? This will depend on issues such as the difficulties of recruiting new centres or practitioners (e.g. in getting local NHS approval), recruiting prevalent or incident cases, and whether a well-recruiting centre or practitioner is at, or close to, saturation in their level of recruitment.

7. Maintain engagement with the trial among those involved with recruitment – circulate newsletters on progress and organise meetings to emphasise the ongoing need for the trial, based on the continuing uncertainty about the relative effects of the interventions being compared. If your Data Monitoring Committee has reviewed the accumulating results, it might be worth stressing that they are best placed to know the most up-to-date evidence and have not recommended that the trial should stop.

8. Be aware of the ethical and scientific challenges and opportunities of recruiting in multiethnic populations. Experience shows that written invitations are unlikely to attract ethnic minority populations, whereas oral communications are likely to succeed [10].

9. Consider drawing on approaches to trial management adapted from the world of business - a model using insights from marketing theory seems promising for planning and managing recruitment [11].

10. Evaluate any actions you take (for example by randomising centres, practitioners or potential participants to different approaches, interventions or strategies) and register this on the MRC START (Systematic Techniques for Assisting Recruitment to Trials) study website to contribute to the evidence base (www.medicine.manchester.ac.uk/mrcstart).

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