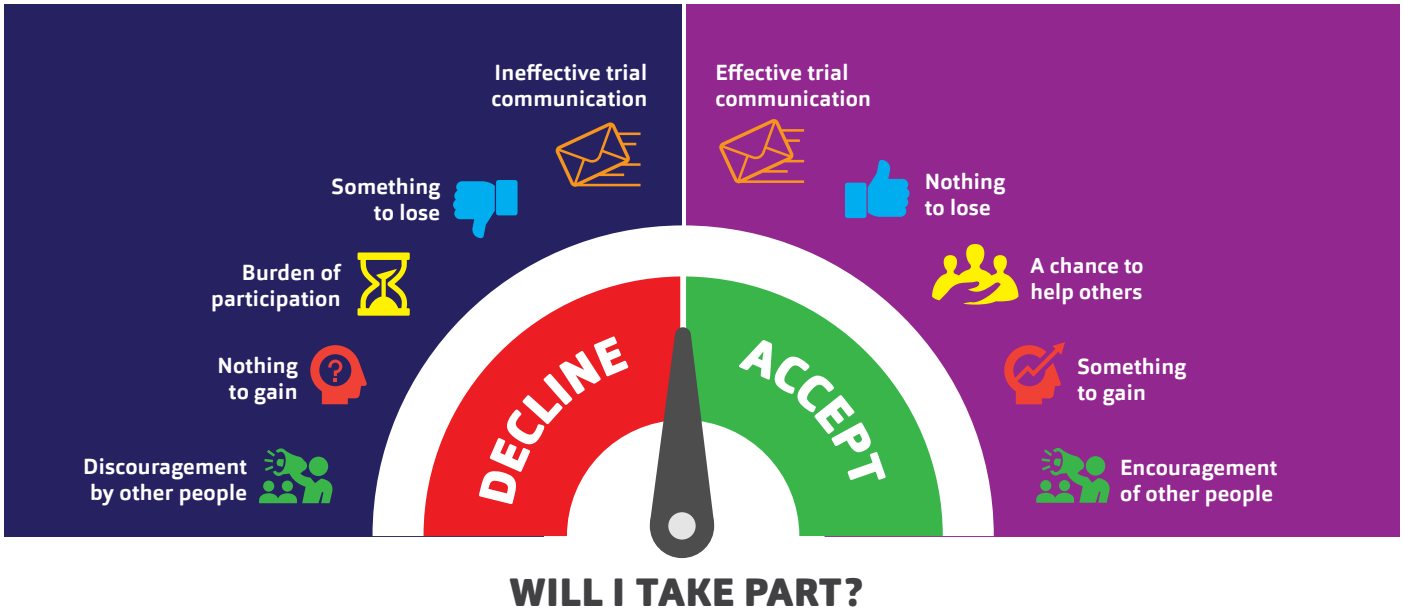
# Factors that impact on recruitment to randomised trials in health care: **a qualitative evidence synthesis**

## Implementation considerations

### Who is this summary for?

Below are a set of questions drawn from the findings in a Cochrane Review, which may help trialists plan, implement, or manage their recruitment strategies for randomised trials.




## About the review

A recent Cochrane Review of qualitative research explored the factors that impact recruitment to randomised trials in health care from the perspective of those invited to take part (Houghton et al. 2020). The review analysed 29 qualitative studies from around the world. We included people who had agreed to take part in a trial as well as those who declined. We included people who had been invited to participate in several oncology (cancer), pregnancy and childbirth, medicine and surgery, mental health and health promotion trials.

### How up-to-date was this review?

The review authors searched for studies that had been published up to 1 June 2017.

Randomised trials are the optimal way to minimise bias in evaluating the effects of competing treatments, therapies and innovations in health care. It is important to achieve the required sample size for a trial, otherwise trialists may not be able to draw firm conclusions which leads to research waste and raising ethical questions about trial participation. The reasons why potential participants may accept or decline participation are multifaceted. Yet, the evidence of effectiveness of interventions to improve recruitment to trials is limited and fails to recognise these individual decision-making processes. By learning more about what influences a person's decision to take part in a trial, we advise on how best to include people in trials.

## What are the implications of our findings?

On integrating our findings with previous intervention reviews by Treweek (2018) and Gardner (2018), we developed key questions that trialists can ask to guide their recruitment strategy. These questions below can practically guide recruitment. It is also important to use the conceptual model to enhance understanding of the complex factors that influence potential participant's decisions on whether to take part. Future development of recruitment strategies needs to adopt this individualised participant-centred approach to maximise recruitment, reduce research waste and ensure participants' ethical recruitment to randomised trials.

## Questions for trialists when planning their recruitment strategy

**These questions are:**

### *Communication of trial information:*

- Will trial information be delivered verbally with face-to-face contact?
- Will written information be offered as a supplement to / in addition to verbal information?
- Is the person delivering the trial information approachable, trustworthy, participant-centred and knowledgeable with a good ability to address queries?
- Has the recruitment strategy identified whether a clinician or a researcher is the most appropriate person to provide the trial information?
- Has time been provided to ensure that the potential participant can consider the trial information at their own individual pace?
- Is information clear and concise free of medical jargon, clearly identifying options, time commitment, randomisation process, treatment equivalence, intervention details, potential benefits and side effects?
- Has the timing of the delivery of trial information been considered in order to ensure potential participants have the opportunity to consider the trial information as distinct from their diagnosis and standard treatment?

### *Significant components of the trial itself:*

- Will trialists aim to minimise additional time commitment to the trial (beyond routine care)?
- Will trialists consider using incentives or reimbursements to acknowledge participants' time and effort?
- Will trialists, where appropriate, consider including health assessments and monitoring as incentives for participation?
- Will trialists consider how best to explain randomisation and freedom to withdraw from the study?

### *Influence of other people:*

- Will recruiters identify other people, such as family and friends, who influence potential participants' decision and, where appropriate, include them in information giving sessions?
- Will recruiters ensure HCPs who are involved in care, are knowledgeable about the study and able to answer questions in a non-biased way?
- Will recruiters consider sourcing useful internet links and media sources with information on the intervention, to recommend to potential participants?

### *Weighing up the risks and benefits:*

- Will recruiters be very clear when communicating risks to potential participants?
- Are the recruiters effective in communicating information, particularly when recruiting potential participants who are concerned about risks or feel that they have “nothing to gain” from trial participation?

### *Personal benefits of trial participation:*

- Will recruiters, where appropriate, highlight quicker access to services, better follow up care, increased contact time with physicians and an opportunity to learn more about their condition as potential benefits to trial participation?
- Will recruiters, demonstrate empathy to potential participants who may be managing symptoms and feelings of desperation or isolation for some time?

### *Making a difference: benefits for others:*

- Will recruiters highlight possible benefits of altruism and contribution to science as key potential benefits of trial participation?
- Will recruiters demonstrate their gratitude to potential participants for their contribution to the trial?

***The questions presented in this summary are from a Cochrane Review. The review authors have searched for, assessed and summarised relevant qualitative studies using a systematic and predefined approach. They have then used the review findings to develop a set of questions for implementers. It is also important to use the conceptual model to enhance understanding of the complex factors that influence potential participants’ decisions on whether to take part.***

## Reference

The information for this summary is taken from the following Cochrane Review: Houghton C, Dowling M, Meskell P, Hunter A, Gardner H, Conway A, Treweek S, Sutcliffe K, Noyes J, Devane D, Nicholas JR, Biesty LM. Factors that impact on recruitment to randomised trials in healthcare: a qualitative evidence synthesis. Cochrane Database of Systematic Reviews 2020, Issue10. Art. No.: MR000045. DOI:10.1002/14651858. MR000045.pub2.

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000045.pub2/full

When preparing this summary, we used a template developed by Cochrane Norway/The Norwegian Satellite of the Effective Practice and Organisation of Care (EPOC) Group.

Health Research Board TMRN Trials Methodology Research Network

QUESTS QUALITATIVE RESEARCH IN TRIALS CENTRE

TRIAL FORGE