

# What works?

**Exploring how the implementation of Valuing Voices principles can improve the design phase of randomised controlled trials and reduce research waste: A qualitative study, Andrew Mott**

## Project summary:

The project explored a range of stakeholders' thoughts on how we better design randomised control trials (RCTs). The project undertook qualitative interviews with participants discussing the problems they already face which result in changes. They identified what changes already align with the Valuing Voices principles and barriers to aligning. Through identifying these elements, we designed guidance and support to address the barriers.

## What challenge did this project set out to address?

Prior to this project, we had identified that the methods of many randomised controlled trials change throughout the course of the project. Changing methods can be a lot of work, expensive, and delay trials. This project aimed to explore what causes the need for such changes and what could be done at the design and planning stages to reduce the need to change methods. To do this we undertook qualitative interviews with a range of stakeholders including healthcare professionals, patients and public representatives, trial management and support staff, statisticians, and regulatory staff and ethics committee members.

## What worked, for who and why?

The following key findings were identified by participants:

- Feasibility work ahead of a trial is essential. This included surveying relevant healthcare staff or patients, auditing records, modelling data, and risk assessment.
- Ensuring all relevant groups were involved in developing the study. Involving them early and equitably was noted as being key to a successful project. One group often noted as being missed from this stage was trial delivery staff.
- Using simple, clear, and broad definitions in study protocols was identified as a common reason for changes and incorporating these into study plans from the start would benefit projects in terms of generalisability and recruitment.
- Keeping study designs as flexible as possible. Often trials were designed to follow the process of a one or two centres and did not consider the differences between centres. This may be picked up with better feasibility work and involving a wider range of staff.
- Having time to reflect upon and learn from where things had not gone to plan was identified as currently lacking but considered crucial to avoiding future issues. Linked to this was the need for better methods of sharing such learning with others.

## What didn't work and why?

We had hoped to engage as many stakeholders in randomised controlled trials as possible. One specific group we approached but were unable to involve was research funders who may have a unique perspective on this topic, but there were none that were able to participate.

## What changed as a result of your project?

We have now identified several factors where the planning and design of randomised controlled

trials can potentially be improved. This includes how we undertake study feasibility, how we make design choices, and how we undertake shared reflection and learning.

## What next?

We will now be able to look at the planning and design process of randomised controlled trials and focus on improving the key elements raised by participants in this work. We will aim to investigate the impact of these factors and how practices surrounding them might be improved.

## Progress towards equitable and responsible research practices

We purposefully involved stakeholders at all levels of trials, working in different areas, with a variety of experiences and perspectives in this work. Some had led trials and had many years of experience, some had only been involved in one randomised controlled trial in a supporting role. The views of all the participants were considered equally, and we identified where different groups agreed or disagreed on topics. The topics of hierarchy and equity were discussed by many participants. Participants identified the way in which a team worked and how equitable it was as essential to the project being designed and managed well.