



FOCUS ON RESEARCH

THE ACCEPTABILITY AND USEFULNESS OF A TRIAL PARTICIPATION DECISION AID: A MIXED METHODS STUDY INVOLVING STAKEHOLDERS

Researchers

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Aim

To investigate the acceptability and usefulness of a "trial participation decision aid" - a formal tool, which in this project was a booklet, to support people in their decision whether or not to take part in a randomised controlled trial.

Project Outline/Methodology

Five linked phases of research: a systematic review of the literature; a survey of UK Clinical Trial Units; a modified Delphi (a questionnaire based method) to investigate stakeholders (patients, trialists, research nurses, ethics committee chairs, decision-aid researchers) views on which items to include in a trial participation decision aid; and the development and assessment of two prototype trial participation decision aids.

Key Results

Informed by the literature, a list of possible items which could be included in a trial participation aid was developed. There was consensus across all stakeholder groups that the majority (60/66) of suggested items should be included in a trial participation decision aid. These included information about: trial participation and standard care; the likelihood of receiving different treatments; helping potential participants' determine what matters to them; ensuring information is balanced; guidance on how to make a decision; using plain language in the tool and guidance on development process. However, some areas of divergence between stakeholder groups emerged, particularly around the role of other trial participants experiences. The prototype decision aids were found to be generally well received by all stakeholder groups, with most agreeing these were an improvement on existing patient information leaflets for trials and recognising the potential to improve decision making in this context.

Conclusions

We successfully identified a range of information and procedural features that a variety of stakeholders

agree should be central to any decision aid. However, the place of trial participants' experiences is controversial and requires further research. This study has also shown that decision aids for trial participation are feasible to develop and broadly acceptable and useful to a wide range of stakeholders.

What does this study add to the field?

This is the first study to systematically explore the content of a decision aid for trial participation and assess the acceptability and usefulness of these tools with a range of stakeholders.

Implications for Practice or Policy

Whilst some aspects of trial participation decision aids still require research, this study has shown that researchers should give serious consideration to the potential of these tools to improve the trial consent process. This is further supported by the buy in from including a wide range of stakeholders.

Where to next?

The place of participants' experiences in trial participation decision aids requires further research. Additional development and testing of these decision aids in other trial settings is required. In addition, if these tools are to be used in practice, research around how their effectiveness should be assessed is required.

Further details from:

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