

# Maximising the value of combining qualitative research and randomised controlled trials in health research: the QUALitative Research in Trials (QUART) study – a mixed methods study

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## Scientific summary

### The QUALitative Research in Trials (QUART) study

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# Scientific summary

## Background

Researchers sometimes undertake qualitative research with randomised controlled trials (RCTs) of health interventions, particularly when evaluating the effectiveness of complex interventions.

## Objectives

To systematically explore how qualitative research is being used with trials and identify ways of maximising its value to the trial endeavour of providing evidence of effectiveness of health interventions.

## Design

A sequential mixed methods study with four components: a systematic mapping review of peer-reviewed journal articles reporting qualitative research undertaken with specific trials, a review of studies combining qualitative research and trials, a survey of lead investigators of trials which appeared not to use qualitative research and an interview study of researchers sampled from these articles and studies.

## Methods

1. Database search of peer-reviewed journals between January 2008 and September 2010 for articles reporting the qualitative research undertaken with specific trials: MEDLINE, PreMEDLINE, EMBASE, The Cochrane Library, Health Technology Assessment (HTA), PsycINFO, CINAHL, British Nursing Index, Social Sciences Citation Index and Applied Social Sciences Index and Abstracts. Full articles were assessed to identify the focus of the qualitative research in relation to the trial. Data extraction from a sample of articles was undertaken to identify its potential value to the trial endeavour, good practice and ways of maximising value.
2. Systematic search of the *metaRegister of Controlled Trials (mRCT)* database of registered trials to identify studies combining qualitative research and trials, followed by a review of the proposals and final reports of these studies to consider how qualitative research is presented in key study documentation.
3. Survey of 200 lead investigators of trials with no apparent qualitative research to identify 'invisible' qualitative research.
4. Semistructured telephone interviews with 18 researchers purposively sampled from the first three methods to explore their perceptions of undertaking this work and how to maximise its value for the specific trial.

## Results

Qualitative research was undertaken with at least 12% of trials on the *mRCT* database in the 2000s. A large number of articles reporting qualitative research undertaken with trials ( $n = 296$ ) were published between 2008 and 2010. These articles had a wide international authorship and a total of 28% (82/296) of articles reported qualitative research undertaken at the pre-trial stage, that is, as part of a pilot, feasibility or early-phase trial or study in preparation for the main trial. The majority related to trials of complex interventions and approximately one-quarter to trials of drugs or devices.

The articles focused on 22 aspects of the trial within five broad categories. Some articles focused on more than one aspect of the trial, totalling 356 examples. The qualitative research focused on the intervention being trialled (71%, 254/356), the design, process and conduct of the trial (15%, 54/356), the outcomes of the trial (1%, 5/356), the measures used in the trial (3%, 10/356), and the target condition for the trial (9%, 33/356). All the subcategories are described and illustrated with examples in the report. The largest subcategory focused on exploring the feasibility and acceptability of the intervention in practice (23%).

There were eight types of potential value of the qualitative research to the trial endeavour. These included making trials more efficient by improving recruitment rates, improving the ethics of trials by helping trialists to be sensitive to human beings participating in trials and improving informed consent procedures, improving the internal and external validity of trials, facilitating implementation of trial results by facilitating replicability of interventions in the real world and transferability of trial results to other settings, and facilitating interpretation of trial findings.

We identified a number of ways of maximising value to the trial endeavour, including by using qualitative research more at the pre-trial stage and reporting findings with explicit attention to the implications for the trial endeavour. We developed guidance to help researchers to improve how they report this work, QUALitative Research with Trials: Excellent Reporting (QUARTER), and guidance for researchers and commissioners on writing proposals for qualitative research and trials.

During interviews, three models of study were identified: qualitative research as peripheral to the trial, qualitative research as an 'add-on' to the trial and a study with qualitative research and trial as essential components, with the third model offering more opportunity to maximise the value of the qualitative research. Interviewees valued the use of qualitative research with trials and identified team structures and wider structural issues within health research as barriers to maximising the value of qualitative research. If impact on the trial was important to the research lead, this shaped the team structure, team communication, resources and dissemination strategy. There was also an indication that impact of the qualitative research on the trial occurred within some studies in ways that were invisible to others owing to structural constraints such as publishing norms, limiting its value to other researchers working on similar interventions or in similar environments.

## Conclusion

A large number of articles were published between 2008 and 2010 reporting the findings of qualitative research undertaken with trials. They addressed a wide range of aspects of trials and there were examples of this research affecting the trial by facilitating interpretation of trial findings, developing and refining interventions for testing in the trial and changing the measures used in the trial. However, researchers are not necessarily maximising the value of qualitative research undertaken with trials. Researchers can maximise value by promoting its use at the pre-trial stage to ensure that the intervention and trial conduct is optimised at the main trial stage, being explicit about the conclusions for the trial endeavour in peer-reviewed journal articles reporting the qualitative research and valuing the contribution of the qualitative research as much as the trial, particularly for complex interventions and health interventions delivered in complex environments. Wider structural issues such as publishing norms will also need to be addressed. Future recommendations for researchers include: plan the qualitative research, design and implement studies not trials, use qualitative research at the feasibility and pilot stage of trials, be explicit in publications about the impact of the qualitative research on the trial and implications for the trial endeavour, undertake in-depth qualitative research, allow qualitative research to take a challenging role and develop a learning environment around the use of qualitative research and trials.

## Recommendations for different stakeholders

If qualitative research is undertaken with specific trials, we would expect that research to impact on that trial in some way by optimising the intervention or trial conduct, explaining trial findings or facilitating transferability of trial findings in the real world. This may not be occurring and we make the following recommendations to maximise the value of this endeavour:

### Researchers

#### Plan the qualitative research

It is not possible or necessary to use qualitative research to address all the aspects identified in our framework in the context of a single trial. Researchers will need to think about the problems and challenges their planned trial is likely to face and design the qualitative research to address these, while allowing for a degree of openness and flexibility to address possible emerging issues as the trial progresses.

#### Design and implement studies not trials

Some lead researchers we interviewed identified the qualitative research as essential to their desire to produce evidence relevant to the real world, whereas others described it as an addition to the trial and even as peripheral to the trial. If it was perceived as essential to the trial, the impact on the trial was central to the team's thinking.

#### Use qualitative research at the feasibility and pilot stage of randomised controlled trials

Qualitative research undertaken at the feasibility or pilot phases of a RCT can impact on the main trial by optimising the intervention, improving the conduct of the trial or identifying the appropriate outcomes and measures. This can result in successful and efficient trials, which, we would argue, would be more likely to have positive results if shown to be feasible. At the pre-trial stage, the research can be iterative, feeding into the feasibility trial and seeing improvements in recruitment or the intervention during this time.

#### Think about the impact on the trial and implications for the trial endeavour

One of the most problematic things we came across here was the lack of explicit articulation of the effect of the qualitative research on the trial or the lessons for that trial or future trials. We do not think that the qualitative research and the trial have to be published in the same article for this to happen. Some authors show that these lessons can be articulated in the qualitative article. There is an issue about the timing of the two components working against this and a related finding was researcher concern about the contamination of the experiment by the qualitative research, with concern that some intensive techniques such as diary keeping and interviews can offer a therapeutic effect. This requires thought at the planning stage so that intensive qualitative data collection on a large proportion of the trial participants can be undertaken after the collection of important outcome data. There is also the potential for bias for some endeavours, for example using qualitative research to study variation of outcomes when the outcomes are already known. Again, the potential for this bias can be considered at the planning stage. There is some evidence in the wider literature that the qualitative research can take on procedures associated with trials such as having a published protocol for the process evaluation or qualitative research, which would ensure planning and thinking about contamination and bias and how to minimise these in the context of a specific study.

#### Undertake in-depth qualitative research

Descriptive qualitative research has utility for health-care practice; however, some research questions required an explanatory approach with in-depth analysis (e.g. asking why the trial finding was null or positive) and this could be lacking. We found some undermining of the epistemological roots of qualitative research in which some researchers described implicit pressure to undertake large samples and structured interviews. We recommend that researchers engage expertise in qualitative research and resource the

qualitative research in terms of the time, money and staffing required. There is a lot of activity in this field yet researchers present their findings without necessarily building on learning in the field. The approach to building a conceptual framework from existing qualitative research can help learning from disparate qualitative research undertaken with trials and there may be other opportunities to develop such models or make use of existing ones.

### **Allow qualitative research to take a challenging role**

We identified qualitative research as describer, explainer and translator of evidence, with some evidence also as challenger of current practices.

### **Develop a learning environment about this issue**

Some researchers have developed considerable expertise in undertaking qualitative research with trials and could share this expertise by running training courses and writing about how to undertake this work well. Researchers new to the field of combining qualitative research and trials, both qualitative researchers and trialists, would benefit from attending these courses and reading some of the exemplars we identify in this report.

### **Funders**

Funding application forms could include requirements for the detail of the qualitative research, for example specifying the rationale for its use and detail of methods, sample size, analysis and resources required.

### **Ethics committees**

Ethics committees could recognise the need for qualitative research to evolve throughout studies without the need for submission of substantial amendments.

### **Journal editors**

Journal editors could consider the importance of applied qualitative research to their readership and, where it is undertaken with a trial, request that the lessons for trials are made explicit. Electronic publication, with its associated longer article length, may facilitate this.

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