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# METHODOLOGICAL CHALLENGES OF MIXED METHODS INTERVENTION EVALUATIONS

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**Abstract**

This paper addresses the methodological challenges that accompany the use of a combination of research methods to evaluate complex interventions. In evaluating complex interventions, the question about effectiveness is not the only question that needs to be answered. Of equal interest are questions about acceptability, feasibility and implementation of the intervention and the evaluation study itself. Using qualitative research in conjunction with trials enables us to address this diversity of questions. The combination of methods results in a mixed methods intervention evaluation (MMIE). In this article we demonstrate the relevance of mixed methods evaluation studies and provide case studies from health care. Methodological challenges that need our attention are, amongst others, choosing appropriate designs for MMIEs, determining realistic expectations of both components, and assigning adequate resources to both components. Solving these methodological issues will improve our research designs and provide further insights into complex interventions.

Key words (4-8): qualitative research, randomised controlled trials, mixed methods intervention evaluation, process evaluation

## Introduction

Randomised controlled trials (RCTs) are used to test whether interventions are effective. Increasingly researchers are using mixed methods intervention evaluations – which include a RCT - to address a range of questions related to understanding the effectiveness of an intervention (Creswell, Fetters, Plano Clark & Morales, 2009; Drabble & O'Cathain, 2015). In this article we address the methodological challenges involved in undertaking mixed methods intervention evaluations. We describe the benefits of using a mixed methods evaluation that includes quantitative and qualitative methods rather than only an RCT. We focus on the field of health research in which RCTs are common and we have some expertise.

In the field of health research a RCT is defined as "an experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. In most trials one intervention is assigned to each individual but sometimes assignment is to defined groups of individuals (for example, in a household) or interventions are assigned within individuals" (The Cochrane Collaboration, 2013, see definition of randomised controlled trial). Interventions can be drugs, devices or services in clinical settings, but can also be designed to impact on health behaviours in a range of settings such as schools and the community. Examples of public health interventions are peer support delivered in schools to aid smoking cessation amongst young people (Campbell et al., 2008; Munro & Bloor, 2010) or improving healthy eating in children (Thomas et al., 2003).

An industry has grown up around undertaking RCTs of drugs. Yet much of what is evaluated in health is more complex than a drug and is known as a 'complex intervention'. A complex intervention has many components or active ingredients (Oakley, Strange, Bonell, Allen, Stephenson, 2006; Campbell et al., 2007; Munro & Bloor, 2010), which combine independently and interdependently (Campbell et al., 2007), making the whole more than the sum of its parts (Hawe, Shiell & Riley, 2004; Oakley et al., 2006). The complexity of the intervention can take different

forms such as the variation in behaviours of the people delivering or receiving the intervention, the different groups or organisations affected by the intervention, and the variation in outcomes (Medical Research Council, 2008). Examples of complex interventions include the introduction of lifestyle interventions for people with obesity, or the reorganisation of the way in which a service is delivered to improve quality of care (Dixon-Woods, Bosk, Aveling, Goeschel & Pronovost, 2011).

Within health research, the question "is an intervention – be it a drug, service or technology – effective in improving health?" is very important and RCTs are an excellent way of addressing the effectiveness question. But increasingly this question is expanded to understand how an intervention is or is not effective and under what circumstances. This wider perspective requires methods that can address these issues, such as qualitative research (Pope & Mays, 1995; Britten, 2011). This is in line with arguments to move on from a focus on clinical interventions to encompass the arena of health care – stakeholders, e.g. insurance, professionals, hospitals, government – and the everyday world in which patients experience health and health care (Popay & Williams, 1998; Barbour, 1999).

A mixed methods intervention evaluation includes an RCT and qualitative research. A number of studies have identified examples of this combination of RCT and qualitative research (Lewin, Glenton & Oxman, 2009; Jansen, Foets & De Bont, 2009). In a systematic review of international journal articles reporting qualitative research undertaken with trials in health, 296 published articles were identified between 2008 and September 2010 (O'Cathain, Thomas, Drabble, Rudolph & Hewison, 2013). We draw on some of these examples, to explore methodological issues when undertaking mixed methods intervention evaluations.

**Important evaluation questions**

In this section we identify important questions relevant to evaluations of interventions which RCTs alone cannot address.

1) *"*If the intervention was effective in the trial, will it b*e effective in the real world?"*

Policy makers, clinicians and patients want to implement evidence from RCTs in the real world. Implementing findings from interventions shown to be effective under experimental conditions requires information about which aspects of the intervention are essential for effectiveness (mechanisms of action) and the relevance of the context that the intervention was tested in to other circumstances (transferability of evidence) (Dixon-Woods et al., 2011; Greenhalgh, Kristjansson & Robinson, 2007; Pawson & Tilley, 2004; Newnham & Page, 2010). The need to address questions related to how and why interventions work through understanding mechanisms of action and the transferability of the evidence, has led to the inclusion of qualitative methods within these evaluative designs.

2) *"Why was* the intervention *not effective?"*

It can be time consuming and expensive to undertake RCTs. In theory, valuable evidence comes from RCTs which produce null results i.e. which show that an intervention was not effective. However, in practice, null RCTs, can feel like a waste of resources unless researchers can understand why the intervention was not effective so that other researchers refrain from evaluating similar types of interventions and move towards those that have a more likelihood of being effective. Researchers use qualitative and quantitative methods to facilitate understanding of why interventions do not work by exploring whether interventions have been delivered as planned or encountered barriers to successful implementation. For an example see Box 1.

Box 1: Case study Breastfeeding In Groups (BIG) study

Hoddinott, Britten and Pill (2010) evaluated an intervention to assess how effective an intervention was to improve breastfeeding rates using an approach called 'prospective mixed method embedded case studies' (p.777). The breastfeeding in groups (BIG) trial was a cluster trial of 14 sites in

Scotland in which 7 intervention sites increased group activities related to breastfeeding and 7 control localities retained their existing group activities. The research team utilised an ethnographic, realist evaluative methodology (Pawson & Tilley, 2004) to their trial design and conduct, which involved writing reflective diaries regarding meetings, telephone conversations, emails, and their thoughts and opinions about their experiences during the trial. They reflected on their backgrounds as a general practitioner and a former breastfeeding volunteer and how this affected their research roles. They hypothesised that the local environment in which the intervention took place would lead to differences between the intervention and control clusters. They conducted focus groups, interviews, and breastfeeding group observations during the study. Before analysing the trial outcomes, they utilised the qualitative research to devise an explanatory model of factors contributing to the success or failure of the sites' ability to deliver the intervention. The trial itself had a null outcome, with a reduction in breastfeeding rates in three of the seven intervention sites. The model constructed from the qualitative data identified problems with leadership, less resources, and issues with the rooms where group sessions were held, which helped researchers to explain differences in outcomes between clusters.

3) *"What is the optimal intervention to test?"*

It is important to understand an intervention so that large and expensive RCTs are not undertaken when it is not feasible for health professionals to deliver the intervention or the intervention is unacceptable to patients. For example, the intervention being tested in the RCT may be delivered in busy health service clinics which require health professionals to change their work practices. Qualitative methods such as interviews and focus groups with potential patients and those who will deliver the intervention can explore issues around feasibility and acceptability of interventions prior to an RCT, for example identifying how the intervention can be adapted to

operate well in the context in which it will be tested and/or delivered in the real world. Thus an intervention and / or its implementation can be optimised before undergoing expensive evaluation.

4) *"Will the RCT work?"*

RCTs can be challenging to run. For example, RCTs can struggle to recruit enough participants leading to low statistical power, or they can only recruit a narrow profile of the population that will actually use the intervention in the real world so they lack external validity (Bird, Arthur & Cox, 2011). Questions about how to improve the conduct of the RCT can be important, and qualitative research has addressed this issue. For example, research has identified misunderstandings that lead to non-participation in the trial by interviewing health professionals recruiting patients for RCTs and patients approached for participation (Dixon-Woods, Jackson, Windridge & Kenyon, 2006; Donovan et al., 2002). Observations of recruitment practices can identify reasons for misunderstanding such as poor communication.

5) *"Have we really understood the complexities of what we are researching?"*

The multifaceted nature and dependence on social context make complex interventions particularly challenging and costly to evaluate. The nature of complex interventions create methodological challenges for the RCT (Oakley et al., 2006; Campbell et al., 2007) such as difficulties in standardising the design and delivery of the intervention and understanding aspects of the local context in which the intervention is delivered (Medical Research Council, 2008). Whilst an RCT may remain the most rigorous way to evaluate the effectiveness of an intervention, there is increasing acknowledgement of the contribution that qualitative methods can make to understanding the complexity of interventions (Glenton, Lewin & Scheel, 2011).

**Methodological challenges of mixed methods intervention evaluations**

Although the indications for using a mixed methods intervention evaluation might be clear to researchers, it might be difficult to undertake one in practice. Lewin et al. (2009) examined 30 trials

of complex interventions designed to change the organisation of care where qualitative research was also used. In a systematic mapping review, O'Cathain et al. (2013) identified 296 articles published between January 2008 and September 2010 that reported the qualitative research undertaken with an RCT and mapped the focus of the qualitative research in relation to the RCT in practice. Based on these outcomes, and a study of interviews with researchers undertaking mixed methods intervention evaluations (O'Cathain et al., 2014) we formulate methodological challenges in undertaking and reporting mixed methods evaluations.

## Choosing an appropriate design

A common approach to describing the use of qualitative research with RCTs is a temporal framework, which considers how qualitative research can be used before, during, or after a trial (Creswell et al., 2009; Jansen et al., 2009; Lewin et al., 2009; Sandelowski, 1996). What design is appropriate depends on the questions that need to be addressed with both strands in the mixed methods evaluation design (Boeije, Slagt & Van Wesel, 2013). In a before-trial design qualitative data is collected and analysed before the trial with the purpose of improving it. The focus of the qualitative research can be on the intervention, the trial conduct, or both. For an example, see Box 2.

Box 2: Adherence to treatment of cystic fibrosis in adolescents

Marciel et al. (2010) used mixed methods (focus groups, interviews, survey) before an RCT in the United States to adapt a peer support group intervention for adolescents, which had previously been tested on pre-school and school-age children. The intervention aimed to improve adherence to treatment for cystic fibrosis. Focus groups were conducted with health care professionals and interviews undertaken with adolescent patients, adult patients, and parents. The qualitative research identified that feelings of invincibility and lack of knowledge about the consequences of non-adherence made adherence in this age group particularly difficult. It also identified unanticipated

benefits of the mobile phone technology used in the intervention which allowed adolescents to have direct contact with their healthcare team. In the interviews, parents identified time constraints, lack of motivation, and forgetting treatments as barriers to facilitating adherence. Interviews with adolescents confirmed the acceptability of the proposed intervention to them which facilitated confidence in the proposed intervention prior to testing in an RCT.

A during-trial design involves the collection of qualitative data during the definitive trial to understand how the intervention is implemented in practice. A typical during-trial design is the process-outcome evaluation where the process evaluation aims to explain the trial results by understanding how the intervention was implemented in practice. See Box 1 for an example. Researchers have argued that process evaluations should be an integral part of trials of complex interventions, exploring why and how interventions work or do not work (e.g., Linnan & Steckler, 2002; Munro & Bloor, 2010; Oakley et al., 2006; Siu, Shek & Poon, 2009). A particular strength of process evaluations is the ability to distinguish between what is planned in a particular setting and what is actually done in practice (Aro, Smith & Decker, 2008). Specifically, process evaluations can distinguish between "interventions that are inherently faulty (failure of intervention concept or theory) and those that are badly delivered (implementation failure)" (Oakley et al., 2006: 413). This can help to avoid what has been termed 'type III errors' (Audrey, Holliday, Parry-Langdon & Campbell, 2006), that is, where a trial has a null result due to inadequate implementation of the intervention rather than a failure in the intervention design itself. Process evaluations may be particularly useful in cluster or multisite trials to understand how the context influences the same intervention being delivered at different sites (Oakley et al., 2006) and when an intervention attempts to change the organisation of healthcare delivery (Glenton et al., 2011). The UK MRC has recently issued guidance to help researchers design and implement good process evaluations (Moore et al., 2014).

An after-trial design involves collecting qualitative data after the trial has ended. Qualitative data collected after the trial can explore the longer term implementation of an intervention (MRC 2000; 2008) or may help researchers to explain the results of the trial if process evaluation data collected during the trial are unable to achieve this. When the trial is over the question remains how the trial findings can be used in daily practice. Qualitative research can help to translate the outcomes in the real world by studying relevant outcomes from the participants' point of view, studying how new practices are implemented, and how results are disseminated in the media and translated into policy and practice.

### Being clear about the expectations for the qualitative research

There may be tension around expectations for the qualitative research and what can be delivered in practice. Although the qualitative research may enrich understanding of the trial findings, this understanding 'will always be nuanced and qualified and rarely determinate' (Munro & Bloor, 2010: 710) and researchers must always remain open to the possibility of other interpretations of the data. Expectations also pertain to the resources that are spent on the qualitative component: no unreasonable limits should be placed on the time, skill and money required to complete an in-depth analysis which has quality and credibility (O'Cathain et al., 2014).

When it is clear what qualitative research should achieve, it should be part of the research protocol. It is standard practice to publish a protocol for a RCT so that researchers can be held to account, for example in their choice of the primary outcome. Oakley et al. (2006) argue that process evaluations should prospectively specify a set of research questions and identify the processes to be studied, the methods to be used, and the procedures for integrating the findings of the process evaluation with the results of the trial. Such a practice encourages planning of the qualitative research and sharing of this plan with the whole team of researchers. In turn, this can facilitate integration between relevant components of the study. Process evaluations can be published within

trial protocols (e.g., Murphy et al., 2010) or as a standalone process evaluation protocol (e.g., Ellard, Taylor, Parsons & Thorogood, 2011; Grant, Dreischulte, Treweek & Guthrie, 2013). Guidance has been produced to help researchers write proposals for using qualitative research with RCTs (Drabble et al., 2014).

Clearly reporting how the qualitative research has enhanced the RCT

A key value of mixed methods research is that the whole is more than the sum of its parts (Barbour, 1999). For this to happen, one method must influence in some way the objectives, sampling, data collection, analysis, or interpretation of the other method within the study (O'Cathain, Murphy & Nicholl, 2007; Small, 2011). Within mixed methods intervention evaluations, the expectation is that the qualitative research will work to enhance the trial (O'Cathain et al., 2013; Popay & Williams, 1998; Song, Sandelowski & Happ, 2010). An example was given in Box 1, in which the integration of qualitative research explained how differences in staff attitudes and resources between clusters in a cluster RCT influenced differences in the primary outcome of breastfeeding rates between those clusters.

However, overview studies show that publications from mixed methods intervention evaluations often had no evidence of integration of the findings from the qualitative research and the trial (Lewin et al., 2009; O'Cathain et al., 2013). A challenge to all researchers engaged in mixed methods intervention evaluations is to explicitly report in journal articles the 'yield' or insights gained from undertaking qualitative research and RCTs within the same study (Boeije et al., 2013; O'Cathain et al., 2007).

Integration may be difficult because some evaluation team members may not feel able to act on findings generated from the qualitative research. This might be an issue in a before-trial design where the findings may not be available at the time they are needed, the findings may not have credibility amongst key team members such as the lead researcher, the trialists may be unwilling to

deviate from a particular path for their intervention and trial it, or the qualitative research may challenge established ways of thinking and practice. For example, Jansen et al. (2009) raised a concern that researchers actually focus on adapting the context to fit the intervention rather than considering how an intervention can be adapted to fit the context in which it will be delivered. Qualitative research that challenges such a mindset by suggesting a need to adapt the intervention to fit the context may be unacceptable to the wider team. To facilitate integration, the whole evaluation team may need to embrace a reflexive approach associated with qualitative research (Hesse-Biber, 2012). This happens best at an early stage of the study when teams can discuss how different values and beliefs shape their actions and reflect on their openness to different possibilities.

When a mixed methods intervention evaluation is complete, qualitative researchers and trialists may publish their findings in separate journals, each basing their articles solely on the findings from their part of the study. It is important that the timing of publication of articles allows for reporting of why the intervention was effective or not in the article reporting the trial.

## Trial governance

High quality RCTs are governed by external trial steering committees and data monitoring committees, are conducted according to standardised operating procedures, and are reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement (Schulz, Altman & Moher, 2009). This requires careful thought of the pros and cons of including the qualitative research in these practices and procedures (Cooper et al., 2014; Rapport et al., 2013) . Qualitative research should not be blindly subsumed within all these procedures with an accompanying loss of its key strengths – its flexibility - , nor blindly excluded. An example of the careful thought needed is that discussion about the whole study at trial steering committees, rather than only the trial, can ensure more opportunities for integration (Rapport et al., 2013). Yet when to reveal findings from the qualitative research to the wider team may need careful thought if negative

findings have the potential to demoralise the intervention deliverers or staff delivering the trial prior to the end of the trial (Cooper et al, 2014).

## Conclusions

Increasingly when researchers evaluate interventions they are likely to use mixed methods intervention evaluations where they combine qualitative research with an RCT. This is a positive move driven by researchers understanding the complexity of the interventions they evaluate, the trials they conduct, and the environments in which they research. Whilst this has become part of routine practice in some research communities, we have identified a number of methodological challenges with this approach in health research. None of the challenges presented are insurmountable and indeed reflecting on these challenges is likely to help research communities to understand how to maximise the benefits of mixed methods intervention evaluations.

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