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RESEARCH

Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: methodological study

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ABSTRACT

Objective To examine the use of qualitative approaches alongside randomised trials of complex healthcare interventions.

Design Review of randomised controlled trials of interventions to change professional practice or the organisation of care.

Data sources Systematic sample of 100 trials published in English from the register of the Cochrane Effective Practice and Organisation of Care Review Group.

Methods Published and unpublished qualitative studies linked to the randomised controlled trials were identified through database searches and contact with authors. Data were extracted from each study by two reviewers using a standard form. We extracted data describing the randomised controlled trials and qualitative studies, the quality of these studies, and how, if at all, the qualitative and quantitative findings were combined. A narrative synthesis of the findings was done.

Results 30 of the 100 trials had associated qualitative work and 19 of these were published studies. 14 qualitative studies were done before the trial, nine during the trial, and four after the trial. 13 studies reported an explicit theoretical basis and 11 specified their methodological approach. Approaches to sampling and data analysis were poorly described. For most cases (n=20) we found no indication of integration of qualitative and quantitative findings at the level of either analysis or interpretation. The quality of the qualitative studies was highly variable.

Conclusions Qualitative studies alongside randomised controlled trials remain uncommon, even where relatively complex interventions are being evaluated. Most of the qualitative studies were carried out before or during the trials with few studies used to explain trial results. The findings of the qualitative studies seemed to be poorly integrated with those of the trials and often had major methodological shortcomings.

INTRODUCTION

Randomised controlled trials are used widely for showing causal relations in health and social care because their study design is the only one that is able to control for unknown or unmeasured confounders. Randomised controlled trials are sometimes used to evaluate "complex" interventions—that is, those "made up of various interconnecting parts"[1] that act both "independently and inter-dependently."[2 3] Qualitative approaches can contribute in several ways to the development and evaluation of both complex and other health interventions (box 1). Consequently, increasing numbers of randomised controlled trials of such interventions include qualitative components[4 5] and interest in this approach is growing. The use of multiple, integrated approaches may be particularly useful in the evaluation of the effects of complex health and social care interventions as these involve social or behavioural processes that are difficult to explore or capture using quantitative methods alone.[1]

The need for methodological research on the ways in which qualitative approaches should be used in randomised controlled trials has been discussed widely.[6-11] However, to our knowledge no studies have attempted to examine systematically current practice on the use of qualitative approaches in randomised controlled trials of complex healthcare interventions and how they could be used to improve the usefulness and policy relevance of the findings of a trial. By complex interventions we mean those including at least some of the following characteristics: several elements that "may act both independently and inter-dependently"[2]; complex systems or mechanisms for delivery of the intervention; an intervention that is difficult to describe and replicate; complex explanatory pathways, either physiological or psychosocial; and a degree of uncertainty about the mechanism of action of the intervention or its "active ingredient."[2]

We systematically examined the use of qualitative approaches alongside randomised controlled trials of complex healthcare interventions to provide an overview of current practice in this area and ways of identifying qualitative studies undertaken alongside randomised controlled trials. We also explored how trial teams could improve the quality of qualitative studies linked to randomised controlled trials and how synergies between qualitative approaches and randomised controlled trials can be maximised.

Box 1 Ways in which qualitative methods can be used alongside randomised controlled trials

Before a trial

- To explore issues related to the healthcare question of interest or context of the research
- To generate hypotheses for examination in the randomised controlled trial
- To develop and refine the intervention
- To develop or select appropriate outcome measures

During a trial

- To examine whether the intervention was delivered as intended, including describing the intervention as delivered
- To "unpack" processes of implementation and change
- To explore deliverers' and recipients' responses to the intervention

After a trial

- To explore reasons for the findings of the trial
- To explain variations in effectiveness within the sample
- To examine the appropriateness of the underlying theory
- To generate further questions or hypotheses

METHODS

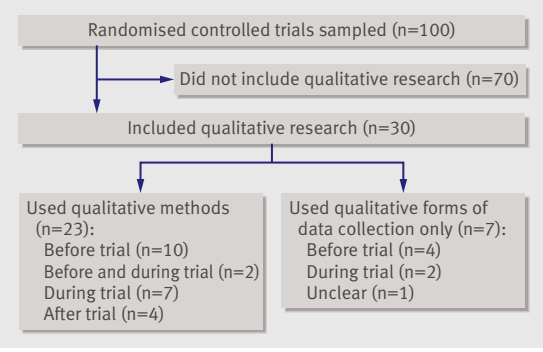
We obtained a list of all randomised controlled trials published in English during 2001-3 and included in the register of the Cochrane Effective Practice and Organisation of Care Review Group.[12] From the list for each year (492 randomised controlled trials in total) we sampled every fifth study to obtain a sample of 100 trials (33 or 34 trials from each year). We chose this approach for several reasons. Firstly, we wanted a sample of recently published trials of more complex interventions as we assumed that the use of qualitative methods alongside such trials has increased in recent years. Secondly, the randomised controlled trials needed to have been published sufficiently long ago to allow associated qualitative studies also to have been published. Thirdly, we thought the Cochrane Effective Practice and Organisation of Care Review Group register, with its specific focus on interventions to change professional practice and the organisation of care, more likely to include a higher proportion of relatively complex randomised controlled trials than databases such as Medline or Embase. Details on studies included in this register and the search strategies used to locate them are available elsewhere.[12]

Where the sampled report was not the primary paper for the randomised controlled trial, the primary report was located. We attempted to identify all published and unpublished qualitative studies linked to these randomised controlled trials. We defined a qualitative study as any study that used qualitative methods for data collection or analysis. We initially checked the primary randomised controlled trial for citations of qualitative studies. We then located the primary randomised controlled trial in PubMed and searched for related studies and other studies published by the authors of the randomised controlled trial. We also located the randomised controlled trial in the Science and Social Science Citation Index and checked the list of studies citing the paper. Any potentially relevant titles and abstracts were examined and full papers obtained where necessary. Finally, we contacted the authors of the randomised controlled trials for information on any published or unpublished qualitative studies linked to their trials. We received responses for 76 of the 100 papers.

Two reviewers used a standard form to extract data from each "case"—that is, the randomised controlled trial and any qualitative studies. This included descriptions of the randomised controlled trials and qualitative studies; the quality of the randomised controlled trials and the qualitative studies; and information on the approaches (if any) used by the authors to combine the findings of the randomised controlled trials and qualitative studies. The quality of the trials was assessed using the quality checklist of the Cochrane Effective Practice and Organisation of Care Review Group.[13] The quality of the qualitative studies was assessed using a modified checklist from the critical appraisal skills programme.[14] These modifications included further details on whether the qualitative approach was justified and appropriate to the research question, whether the research context was described adequately, and items to differentiate adequate reporting of methods from the appropriateness of those methods, in relation to the research question. We summarised the findings of the study narratively.

RESULTS

Thirty of the 100 included randomised controlled trials had qualitative work associated with them. Nineteen of these qualitative studies were published, either as stand alone papers or within another paper. In 23 (77%) of the 30 cases in which qualitative approaches were used, the researchers employed qualitative methods for both data collection and analysis. In the remaining seven cases some form of qualitative data collection (for example, group discussions or individual interviews) was used, but no formal analysis of these data using qualitative approaches was reported. Most of the qualitative studies (n=25) were carried out before or during the randomised controlled trial (figure). An explicit



Use of qualitative studies in sampled randomised controlled trials

Table 1 | **Characteristics of qualitative studies included in this review and their level of integration with accompanying randomised controlled trials (studies that used only qualitative methods of data collection are not described)**

Randomised controlled trial, country	Qualitative study	Health service issue tackled by intervention	Trial stage during which qualitative research undertaken	Methodological approach to qualitative work	Reasons for including qualitative methods in trial	Nature and degree of qualitative and trial data integration in analysis and interpretation
Burns 2002,[w1] UK	Weaver 2003[w2]	Community based management of people with psychosis	During trial	"Thematic interview survey" and "critical incident approach"	6, 7, 8, 9, 11	B
Davies 2002,[w3] Canada	Davies 2002,[w4] Graham 2004[w5]	Uptake of obstetric guidelines	After trial	"Qualitative case study research methodology"	7, 8, 9	B
Faithfull 2001,[w6] UK	Faithfull 1995[w7]	Morbidity and satisfaction with care in men treated with radical radiotherapy for cancer of prostate and bladder	Before trial	Not stated	1, 4	A
Fretheim 2003,[w8] Norway	Fretheim 2004[w9]	Appropriate use of antihypertensive and cholesterol lowering drugs for prevention of cardiovascular disease	Before and during trial	Not stated	3	A
Jaatinen 2002,[w10] Finland	Jaatinen 2003[w11]	Managing doctor referrals to specialist	After trial	Action research	12	B (but hard to say as so little data)
Jibaja-Weiss 2003,[w12] USA	Jibaja-Weiss 2003[w12]	Breast and cervical cancer screening	Before trial	Not stated	3	F (No information)
Kaner 2003,[w13] UK	Lock 2002[w14]	Alcohol use	Before trial	Grounded theory	1, 3	A
Koniak-Griffen 2003,[w 15] USA	Lesser 2003[w16]	HIV prevention in adolescent mothers	During trial	Ethnography	1, 6	E
McKinstry 2002,[w17] UK	Unpublished	Telephone versus face to face consultations to manage requests for same day appointments	After trial	None specified	7	D
Miles 2002,[w18] UK	Miles 2002[w19]	Whether sexual health clinics for women led by specialist nurses are as effective as those led by senior house officers	Before and during trial	Focused ethnographic approach, grounded theory approach	1, 5, 6, 7, 8	B
Osganian 2002[w 20] (primary paper Luepker 2000), USA	Finnegan 2000,[w 21] Zapka 1999[w22]	Delay in presentation to hospital for acute myocardial infarction	Before trial	Not specified, but social cognitive theory and self regulatory model of health and illness behaviour both informed interview guide	1, 3	B
Robling et al 2002,[w23] UK	Robling 1998,[w24] Hale 1999[w25]	Use of direct access magnetic resonance imaging by general practitioners	Before trial	Critical incident technique in which each magnetic resonance imaging requested was regarded as a critical incident and was focus for interview	1, 4	A
Scheel 2002,[w26] Norway	Scheel 2002[w27]	Assisting people with lower back pain to return to work	Before trial	None specified	3	E
Stange 2003,[w28] USA	Goodwin 2001[w29]	Improving delivery of preventive services	During trial	Ethnography	12	D
Szmukler 2003,[w30] UK	Stern 1999[w31]	Support for carers of patients with psychosis	During trial	Narrative approach plus "relative influence questioning" for question guidance	13	D
Thapar 2002,[w32] UK	Unpublished	Primary care of people with epilepsy	Before trial	Not stated	3	D
Tijhuis 2002,[w33] Netherlands	Unpublished, Tijhuis 2003[w34]	Care for people with rheumatoid arthritis	Before trial	Not stated	4	D
Von Koch 2001,[w35] Sweden	Von Koch 1998,[w36] Von Koch 2000[w37]	Rehabilitation after acute stroke	During trial.	Study a: "qualitative case study"; study b: not stated	Study a: 5, 6, 7; study b: 5	A
Wallace 2002,[w38] UK	Unpublished, MacFarlane 2002[w39]	Communication between general practitioners, specialists, and patients about specialist consultations	During trial	Study a: none specified (called "qualitative evaluation"; study b: grounded theory approach	Study a: 7; study b: 6, 7	Study a: B; study b: F
Watson 2002,[w40] UK	Watson 2000[w41]	Evidence based prescribing by pharmacists	Before trial	Not stated, but used theory of planned behaviour to design interview guide	1, 3	A
Wheeler 2003,[w42] USA	Clark 1994[w43]	Management of heart disease in older women	Before trial	None specified. Implied to be loosely based on grounded theory	1, 3, 5	B
Young 2003,[w44] Canada	Young 2004[w45]	Care for patients after myocardial infarction	After trial	None specified (study notes that "qualitative design used"	7	B
Zermansky 2002,[w46] UK	Petty 2001[w47]	Appropriateness of repeat drugs prescribed to elderly patients	During trial	Not stated	12	A

1=exploring issues related to healthcare question of interest or research context; 2=generating hypotheses for examination in randomised controlled trial; 3=developing and refining intervention; 4=development or selection of appropriate outcome measures; 5=examining fidelity or integrity of interventions delivered, including describing intervention as delivered; 6="unpacking" implementation and change processes; 7=exploring deliverers' and recipients' responses to intervention; 8=exploring reasons for trial findings; 9=explaining variations in effectiveness within sample; 10=examining appropriateness of underlying theory; 11=generating further questions or hypotheses; 12=other; 13=unclear; A=no integration (analyses and interpretation done separately); B=analyses done separately, with degrees of integration in interpretation; C=integration during both analysis and interpretation; D=not reported; E=other; F=unclear.[w48]

Box 2 Example of a qualitative study exploring how trial participants experienced the intervention (adapted from Harrison et al 2006[15])

Background

Researchers carried out a randomised controlled trial in the United Kingdom to evaluate the effects of joint teleconsultations on hospital follow-up appointments. They concluded that patients' overall satisfaction was higher for teleconsultations than for conventional outpatient appointments. A proportion of patients were, however, dissatisfied with their teleconsultation. It was not possible to determine from the trial findings the reasons for satisfaction or dissatisfaction or how satisfaction could be increased in other telemedicine programmes. The qualitative study aimed to answer these questions.

Qualitative methods used

Semistructured individual interviews were carried out with 24 patients within one month of their teleconsultations. The researchers used the framework approach to carry out a thematic analysis of these data.

Findings

Joint teleconsultations were, overall, highly acceptable to patients for several reasons. These included enhanced customer care, such as enhanced convenience, reduced cost, and increased punctuality. Most patients also appreciated the presence of the general practitioner in the consultation, feeling that this improved communication between the specialist and generalist and allowed the general practitioner to summarise and interpret the consultation for the patient. However, one patient stated that they had been excluded from the consultation. Other patients were dissatisfied with parts of the consultation because they would have preferred to be examined directly by the specialist. Some patients found that the technology interfered with their communication with the doctor—for instance, because of lack of synchronisation between sound and vision. The authors of the study discussed how some of these factors could be tackled in joint teleconsultations in the future.

theoretical basis for the intervention was reported in 12 of the 30 cases.

Randomised controlled trials that included qualitative research

The 30 trials that included qualitative research were carried out in a variety of settings, from general practices to communities and consumers' homes. Twenty four of the trials were carried out in primary care and the remaining six trials evaluated interventions in secondary care or across a mix of levels.

The trials dealt with a wide range of healthcare issues, the most common being mental health, the appropriate use of medicines, and sexual health. All the trials were carried out in high income countries. The methodological quality of the trials that included qualitative research was similar to those without such studies.

Box 3 Example of a qualitative study exploring why people declined to participate in a randomised controlled trial (adapted from Petty et al 2001[16])

Background

Researchers carried out a randomised controlled trial in the UK to evaluate the effectiveness of pharmacist run clinical drug reviews in patients aged 65 years or more from general practices. Eligible participants were contacted by post, sent one reminder, and contacted by telephone if no response had been made. Twenty six per cent (n=68) of those contacted by telephone did not wish to participate in the study. The aim of the qualitative study was to identify reasons for non-participation.

Qualitative methods used

Researchers used unstructured questions to ask the 68 patients their reasons for not wishing to participate. The responses were recorded in writing. The researchers independently carried out a thematic analysis of these data, then agreed on a set of categories.

Results from the qualitative study

Ten broad categories of reasons for non-participation were identified. These included administrative categories such as difficulties in reading the invitation letter and not being available at the time suggested. Other categories were tied to behavioural factors such as confusion or lack of understanding of the trial, negative attitudes to health care, and mistrust of the objectives of the trial. The authors suggested that these factors needed to be addressed to increase the number of patients consenting to studies on drug review.

Qualitative studies

Objectives of the studies

The objectives of the qualitative studies varied widely (table 1). The 16 studies done either before the trial, or before and during the trial, had one or more of the following objectives: to explore the knowledge, attitudes, or practices of the target groups about the topic in question; to explore the illness experience of consumers; to develop the intervention; and to develop the instrument used to measure the effects of the intervention in the randomised controlled trial.

The nine qualitative studies done during the trials had a wide range of objectives. These included describing the intervention as delivered and exploring issues influencing the effects of the intervention, the illness experience of consumers, participants' experiences of the intervention (box 2), and reasons for refusal to participate in the trial (box 3).

Of the four qualitative studies carried out after the trial, two explored participants' experiences of the intervention, one explored factors influencing the effects of the intervention (box 4), and one analysed the process for development of the intervention.

Methodological approach, sampling, data collection, and data analysis

The methodological approaches of the included studies were heterogeneous. Whereas 19 of the qualitative studies did not refer to any specific methodological approach, 11 mentioned approaches such as grounded theory, ethnography, action research, and narrative approaches. Ten studies used several methods for data collection (most often combinations of individual interviews and group discussions), 10 utilised individual interviews only, five used focus groups only, and two used different forms of observation. The remaining three studies were unpublished and we were not able to obtain further information on data collection from the authors.

A number of studies inadequately reported several aspects of the methods: 13 did not describe their sampling approach and the remainder used a mix of purposive, convenience, and random sampling. In 14 studies we could find no information on the approach used to analyse data. Where such information was reported, thematic or content analysis or framework analysis was utilised (n=10) and, more rarely, a

Box 4 Example of a qualitative study exploring the reasons for the findings of the trial (adapted from Davies et al 2002[17] and Graham et al 2004[18])

Background

Researchers evaluated a strategy for implementing guidelines for nursing care during labour in hospital in Canada. The results of the trial were mixed. The researchers then carried out a qualitative study to explore why this guideline was introduced successfully in some settings but not in others.

Qualitative methods used

A case study approach was used, with individual interviews and group discussions done with nurses, nurse administrators, and nurse educators at the study sites. Interviews were audiorecorded and transcribed and a form of thematic analysis was applied.

Results from the qualitative study

A wide range of factors related to the study settings, the recipients of the guideline, and the characteristics of the guideline interacted to affect implementation of the guideline. Important factors included changes to the external environment of clinical practice; leadership and the availability of equipment in the study settings; concerns among the health professionals targeted; and strategies used to promote uptake of the guideline. The authors concluded that more attention was needed to identify organisational barriers to change and to address these using tailored implementation strategies.

grounded theory approach (n=2). Four studies used other approaches.

Links between qualitative studies and randomised controlled trials

Where the findings of the trial and qualitative studies were reported in separate papers, the link between the two was not always clear from the papers themselves. Sixteen of the qualitative studies shared authors with the report of the randomised controlled trial. Only nine papers explicitly described some level of linkage between the study teams.

In two of the studies the researchers stated that they had used a "mixed method" approach. Our review of the studies indicated some integration in the interpretation of the results from the trials and the qualitative research in eight cases although the analysis of the data was carried out separately. In most cases (n=13), however, we found no evidence of integration at the level of interpretation.

Table 2 | Methodological quality of 20 of 30 included qualitative studies that had sufficient information to carry out a quality assessment

Quality criterion	Met criterion	Did not meet criterion	Unclear
Is this study qualitative research?	18	0	2
Are research questions clearly stated?	18	2	0
Have ethical issues been taken into consideration?	4	1	15
Is qualitative approach clearly justified?	4	10	6
Is approach appropriate for research question?	17	0	3
Is study context clearly described?	8	9	3
Is role of researcher clearly described?	2	17	1
Is sampling method clearly described?	11	6	3
Is sampling strategy appropriate for research question?	8	0	12
Is method of data collection clearly described?	12	4	4
Is data collection method appropriate to research question?	16*	0	4
Is method of analysis clearly described?	13	5	2
Is analysis appropriate for research question?	13	0	7
Are claims made supported by sufficient evidence?	11	6	3

*For five studies for which the details of methods of data collection were not clearly described or were unclear (for example, where and when data were collected), the data collection method itself, such as individual interviews or focus group discussions, was assessed as appropriate to research question.

Quality of the qualitative studies

Ten qualitative studies (including the seven with no formal analysis of the qualitative data) did not provide sufficient data to allow assessment of methodological quality. Quality assessment was therefore carried out on 20 studies (table 2). This showed high variability, with the most common weaknesses including lack of a clear justification for the qualitative approach used (no information in 16 studies); inadequate descriptions of context, sampling, data collection, and analysis methods; little reflection on the researcher's role in the research process (no information in 17 studies); lack of clarity on how ethical issues had been taken into consideration (no information in 15 studies), and insufficient evidence to support the claims made in the paper.

We did not identify any relation between interventions that reported using an explicit theoretical framework and the quality of qualitative studies carried out alongside trials of those interventions.

DISCUSSION

Qualitative studies undertaken alongside randomised controlled trials of interventions to change organisation and practice remain uncommon. Less than one third of recently completed trials of relatively complex interventions in the Cochrane Effective Practice and Organisation of Care register included some form of qualitative research. Of these, only about two thirds were published studies. This is surprising given the nature of these interventions and the growing awareness of the role that qualitative research can play in the design and evaluation of interventions.[5 8 19 20] Furthermore, contacts with authors suggested that many valued the findings of qualitative studies. Why then are qualitative approaches not used more extensively alongside trials? Constraints on resources and poor access to relevant expertise were mentioned by study authors in response to our requests for information on qualitative studies. It has also been suggested that linear models for evaluating interventions may impede the use of qualitative approaches. These models, it is suggested, view such evaluation as passing through a series of phases from the development of hypotheses to efficacy trials and then effectiveness trials. This may contribute to the view that earlier phases of research, such as efficacy trials, do not need to incorporate qualitative studies to explore the effects of contextual and other moderating factors. Such methods are seen as important only in the later phases of evaluation.[21]

Although much has been written on qualitative process evaluation alongside trials of complex interventions, the largest group of qualitative studies identified were those carried out before trials. Firstly, this suggests that reviewers who aim to understand better the effects of interventions through examining

Box 5 Improving the quality and usefulness of qualitative studies carried out alongside randomised controlled trials

- There is potential for far greater use of qualitative approaches alongside randomised controlled trials of complex interventions. In many randomised controlled trials, opportunities to understand better the effects of interventions and how they are experienced by recipients are not fully utilised. Funders, journals, and other stakeholders should encourage trial teams to use and report qualitative approaches alongside randomised controlled trials and to consider the implications of these qualitative findings for interpretation of the trial results
- Further efforts are needed to improve the reporting of qualitative studies, including the context of the research, the role of researchers, and the methods used
- Methods need to be developed for linking qualitative studies and randomised controlled trials in medical databases, including efforts to ensure that qualitative studies carried out alongside trials include a universal trial reference number (www.who.int/ictrp/utrn/en/index.html), so that the studies can be located more easily
- The ways in which quantitative and qualitative researchers work together in developing and evaluating interventions needs further exploration so as to understand better how to maximise the potential synergies between these different approaches

qualitative process evaluations may locate little data. Secondly, it indicates the need for more attention to this aspect of trial design.

The rigour of qualitative studies undertaken alongside randomised controlled trials, or at least the reporting of methods used, is an important concern. We identified major shortcomings in many of these studies, particularly issues of sampling, analysis, and critical analysis of the researchers' roles. Interestingly an explicit theoretical basis for the intervention was reported in over a third of cases—a higher proportion than reported in recent reviews on the use of theory in implementation research.[22 23] Twice as many of the randomised controlled trials that included qualitative work also had a clearly specified theoretical basis (40%) compared with randomised controlled trials without any qualitative work (20%). However, the use of theory is by no means the norm in studies in this specialty (only 27% of randomised controlled trials did so explicitly) and it remains unclear whether interventions based explicitly on a particular theoretical approach are more likely to be effective than those designed using pragmatic processes.[24-26]

In our sample we found little evidence of explicit integration of data from qualitative studies and randomised controlled trials and few cases discussed mixed methods approaches. Such data could be integrated in several ways. Discussion of the trial findings could draw on both the qualitative and quantitative data in, for example, exploring reasons for success or failure of the intervention or for variation in effects across sites or individuals. Description of the intervention could also make explicit how qualitative approaches contributed, for example, to identifying barriers to change and developing the intervention. The extent of collaboration within trial teams between researchers from different disciplines, such as social scientists and epidemiologists, is another important aspect. The reported data did not, however, allow us to explore this adequately, and further work on the basis of case studies of trial teams is needed.

Limitations of the study

This study has several possible limitations. Firstly, we may not have identified all qualitative studies linked to the index randomised controlled trials. However, we did receive a high response rate from the authors of randomised controlled trials, and other reviews have indicated that this approach identifies the largest number of additional studies.[23] All methods of identifying studies were resource intensive—a potential barrier to examining qualitative work done alongside trials. Secondly, trials sampled from the Cochrane Effective Practice and Organisation of Care database may not be representative of all randomised controlled trials evaluating interventions to change professional practice and the organisation of care. The sampled trials are unlikely to be representative of randomised controlled trials more widely but are likely to be similar, in terms of their use of qualitative methods, to other randomised controlled trials of complex interventions. Finally, our analysis is based largely on study reports. These may not reflect the extent of integration of qualitative and quantitative findings.

Conclusions

Although well conducted qualitative studies can support trial design and improve our understanding of the effects of complex interventions and the mechanisms through which changes occur, qualitative studies remain relatively uncommon alongside trials of complex interventions. Most of the qualitative studies were carried out before the trial, had important methodological shortcomings, and the findings were poorly integrated with those of the trials. This study highlights ways in which the quality and usefulness of qualitative studies carried out alongside randomised controlled trials can be improved (box 5). Further work is needed to develop further methodological and practical guidance for trial teams who plan to utilise qualitative approaches.[8 27]

WHAT IS ALREADY KNOWN ON THIS TOPIC

Complex healthcare interventions involve social processes that can be difficult to explore using quantitative methods alone

Qualitative research can support the design of interventions and improve understanding of the mechanisms and effects of complex healthcare interventions

Increasing numbers of randomised trials of complex interventions are now thought to include qualitative components

WHAT THIS STUDY ADDS

Qualitative studies remain relatively uncommon alongside trials of complex healthcare interventions

Most of the qualitative studies identified were carried out before the trial so opportunities to understand better the effects of interventions and how they are experienced by recipients are not being fully utilised

Most of the qualitative studies had important methodological shortcomings and their findings were often poorly integrated with those of the trial in which they were nested

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Competing interests: ADO was an investigator for two of the included trials and CG worked in the unit in which these trials were coordinated.

Ethical approval: Not required.

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