Process evaluations alongside trials: are we expecting too much?

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Introduction

- RCTs are becoming an increasingly common context for the use of qualitative methods

- Qualitative approaches can contribute in a number of ways to the development and evaluation of interventions

- But are there important methodological and practical limitations to the roles that qualitative process evaluations can play in the context of trials?
Presentation outline

- The roles that qualitative methods can play alongside RCTs
- How qualitative methods are *currently* being used within trials of complex health interventions – based on 2 methodological studies
- Debates on the methodological and practical consequences and limitations of mixing qualitative and quantitative approaches in the context of evaluation
- Ways to improve the quality and usefulness of process evaluations carried out alongside RCTs
What is a complex intervention?

Interventions may be complex in terms of:

- the number of discrete, active components and the interactions between them
- the number of behaviours to which the intervention is directed
- the number of organisational levels targeted by the intervention
- the degree of flexibility or tailoring permitted in intervention implementation
- the level of skill required by those delivering the intervention
- the extent of context dependency

From: Lewin 2006; Craig 2008
How might qualitative methods be used alongside trials?

<table>
<thead>
<tr>
<th>Pretrial</th>
<th>• Generating hypotheses for examination in the RCT</th>
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<td></td>
<td>• Developing the intervention</td>
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<td>• Developing and selecting outcomes measures</td>
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<td>During trial</td>
<td>• How the implementation process unfolds</td>
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<td>• Perceptions and contributions of participants</td>
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<td>• Whether the programme is implemented as intended</td>
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<td>• Whether the programme affects different sub-groups in different ways</td>
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<td>Post-trial</td>
<td>• Exploring the effects of a programme on outcomes that are difficult to measure</td>
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<td>• Looking at programme sustainability</td>
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<td>• Explaining variations in effectiveness</td>
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<td>• Theory building and testing</td>
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How are qualitative methods being used alongside complex health service RCTs?

- Few efforts to examine systematically:
  - How qualitative methods are currently used in RCTs
  - How they could be used to improve the usefulness and policy relevance of trial findings
Methodological study 1 - aims

To examine systematically the use of qualitative approaches alongside RCTs of complex health system interventions

- Is qualitative research being used?
- How and when is it used?
- How well is it conducted?
- How can it be improved?

Methodological study 1 - methods

- **EPOC**
  - Effective Practice and Organisation of Care Group

Random sample of 100 RCTs published in English from 2001-2003

- Databases + contact with authors

All published and unpublished qualitative studies linked to RCTs

- Data extraction by two reviewers

Descriptions and quality evaluation of RCTs and qualitative studies
Methodological study 1 - findings

Randomised controlled trials sampled (n=100)

Did not include qualitative research (n=70)

Included qualitative research (n=30)

Used qualitative methods (n=23):
- Before trial (n=10)
- Before and during trial (n=2)
- During trial (n=7)
- After trial (n=4)

Used qualitative forms of data collection only (n=7):
- Before trial (n=4)
- During trial (n=2)
- Unclear (n=1)
Methodological study 1 - When and why were qualitative studies used?

- 16 studies carried out pre trial
- 9 studies carried out during the trial
- 4 studies carried out post trial
- 1 unclear

Study objectives included:
- to explore knowledge, attitudes, practice of target groups
- to develop the intervention
- to develop measurement instruments
- to explore participant experiences of the intervention
- to explore issues influencing the effect of the intervention
Methodological study 1 - Quality of the qualitative studies

- Only possible to assess quality in 20 of the 30 studies
- Study quality was highly variable
- Key weaknesses in reporting:
  - No clear justification for the qualitative approach used
  - Inadequate descriptions of context, sampling, data collection and analysis methods
  - Insufficient evidence to support the claims made

<table>
<thead>
<tr>
<th>Qualitative Quality Assessment</th>
<th>1. Is this study qualitative research?</th>
<th>2. Are the research questions clearly stated?</th>
<th>3. Have ethical issues been taken into consideration?</th>
<th>4. Is the qualitative approach clearly justified?</th>
<th>5. Is the approach appropriate for the research question?</th>
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<tbody>
<tr>
<td>X</td>
<td>Yes</td>
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Methodological study 1 - Integrating the qualitative and RCT studies

- For most studies (67%): no integration found / not reported / unclear
- For 30% of studies: analyses conducted separately, some integration in interpretation
- No studies reported integration of both analysis and interpretation
- Only 2 studies stated explicitly that they had used a ‘mixed method’ approach
Methodological study 2

Focus: the use of qualitative methods alongside trial included in a Cochrane review on the effects of using lay health workers on maternal and child health and infectious disease control
Methodological study 2 - methods

Objective: To use qualitative studies conducted alongside the trials to explore factors and processes that might have influenced intervention outcomes.

EPOC
Review of lay / community health worker interventions

82 RCTs

Contact with authors + databases

All published and unpublished qualitative studies linked to RCTs

Data extraction

Descriptions of qualitative studies

Methodological study 2 - findings

- 82 RCTs
  - 52 trials (63%): no qualitative data
  - 10 trials (12%): qualitative data collection referred to but not available
  - 6 trials (7%): qualitative data collection carried out pre-trial
  - 14 trials (17%): qualitative data collection carried out during or post-trial

Methodological study 2 - key themes across studies

- Participants’ appreciation of the lay health workers’ shared circumstances, e.g. with regard to social background or experience of the health condition
  - facilitated emotional and practical support

- Lay health workers also highlighted (6 studies):
  - need for regular supervision
  - support (or lack of support) from health professionals and communities

- *But*, descriptions of methods and results were often sparse
Methodological study 2 - example A

- Trial: evaluated the effect of lay health workers (LHWs) on tuberculosis control among farm workers in South Africa
- Trial findings: Tuberculosis treatment completion rates were significantly higher among participants in the LHW group

- Qualitative study:
  - Aimed to understand how the LHWs had experienced their role
  - Data collected through focus groups, and a thematic analysis was carried out
  - Trial main author also involved in the qualitative study

- Qualitative study findings: identified issues that could directly influence the success and sustainability of the programme:
  - The roles taken on by LHWs
  - LHWs’ perceptions of the incentives given
  - The problems they experienced
  - Importance of ongoing support
Methodological study 2 - example B

- Trial: evaluated the effect of family support workers on family functioning in families of children with cerebral palsy in the UK
- Trial findings: the support workers did not have any clinically significant effect on parental stress or family needs

- Qualitative study:
  - Aimed to examine how the intervention fitted into the context of families’ lives
  - Data collected through interviews with parents; parent and support worker diaries; observation of support workers-research team meetings
  - Thematic analysis

- Qualitative study findings:
  - Parents generally reported high satisfaction with the intervention
  - Parents liked the trusting relationship, the feeling of being supported and the provision of information

- Qualitative data and RCT published in same report and authors discussed the apparently contradictory results, including the choice of trial outcomes
Methodological study 2 - conclusions

- Wider inclusion of qualitative research alongside trials would have allowed exploration of factors influencing programme outcomes.
- But only 14 qualitative studies identified - often poorly reported.
- For interventions involving lay health workers, the potential of qualitative studies to provide insights into review findings cannot be realised at present.

Summary of findings from methodological studies

- Qualitative studies alongside RCTs remain relatively uncommon, but the picture may be changing slowly.

- More attention needs to be paid to the use of qualitative approaches for:
  - Intervention development
  - Process evaluation

- Qualitative study reporting quality is a key concern.

- Little explicit integration of qualitative and RCT data in the literature reviewed.
Are we expecting too much from qualitative process evaluations?

- Differing expectations of trialists and qualitative researchers regarding what qualitative methods can offer, and can achieve:
  - Intervention logic models / explanatory theories often inadequately developed
  - Range of views on the key / active ingredients of the intervention
  - Complexity of explanatory pathways, with a range of ’competing’ explanations
  - Specificity of some trialist questions not well suited to qualitative data

- Not always feasible to tailor the qualitative work to explore the trial findings

- Little guidance available on options for designing and conducting qualitative process evaluations in the context of trials
How can the quality and usefulness of qualitative studies conducted alongside RCTs be improved?

- Mixed method teams need to explore ways of working together to better maximise the synergies between different approaches in developing and evaluating interventions – guidance may be helpful
- More explicit and thoughtful use of theory to inform the development and evaluation of interventions
- Better reporting of qualitative findings alongside reports of RCTs in journals
- Better linking of qualitative studies and RCTs in medical databases

From: MRC guidance on developing and evaluating complex interventions.
Concluding points

- Qualitative and quantitative data provide different, but complementary, views

- Using qualitative methods in RCTs may ‘add value’ and create synergies

- Rigour is important for all methods

- Need to reflect on the benefits and problems which result from mixing methods

- It may be helpful develop guidance for researchers in the field
Thank you!

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