

# Process evaluations alongside trials: are we expecting too much?

Simon Lewin, Norwegian Knowledge Centre for the Health Services,  
and

Cochrane Effective Practice and Organisation of Care (EPOC) Group

21 November 2012



# 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

# How might qualitative methods be used alongside trials?

Pretrial	<ul style="list-style-type: none"><li>• Generating hypotheses for examination in the RCT</li><li>• Developing the intervention</li><li>• Developing and selecting outcomes measures</li></ul>
During trial	<ul style="list-style-type: none"><li>• How the implementation process unfolds</li><li>• Perceptions and contributions of participants</li><li>• Whether the programme is implemented as intended</li><li>• Whether the programme affects different sub-groups in different ways</li></ul>
Post-trial	<ul style="list-style-type: none"><li>• Exploring the effects of a programme on outcomes that are difficult to measure</li><li>• Looking at programme sustainability</li><li>• Explaining variations in effectiveness</li><li>• Theory building and testing</li></ul>

# 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

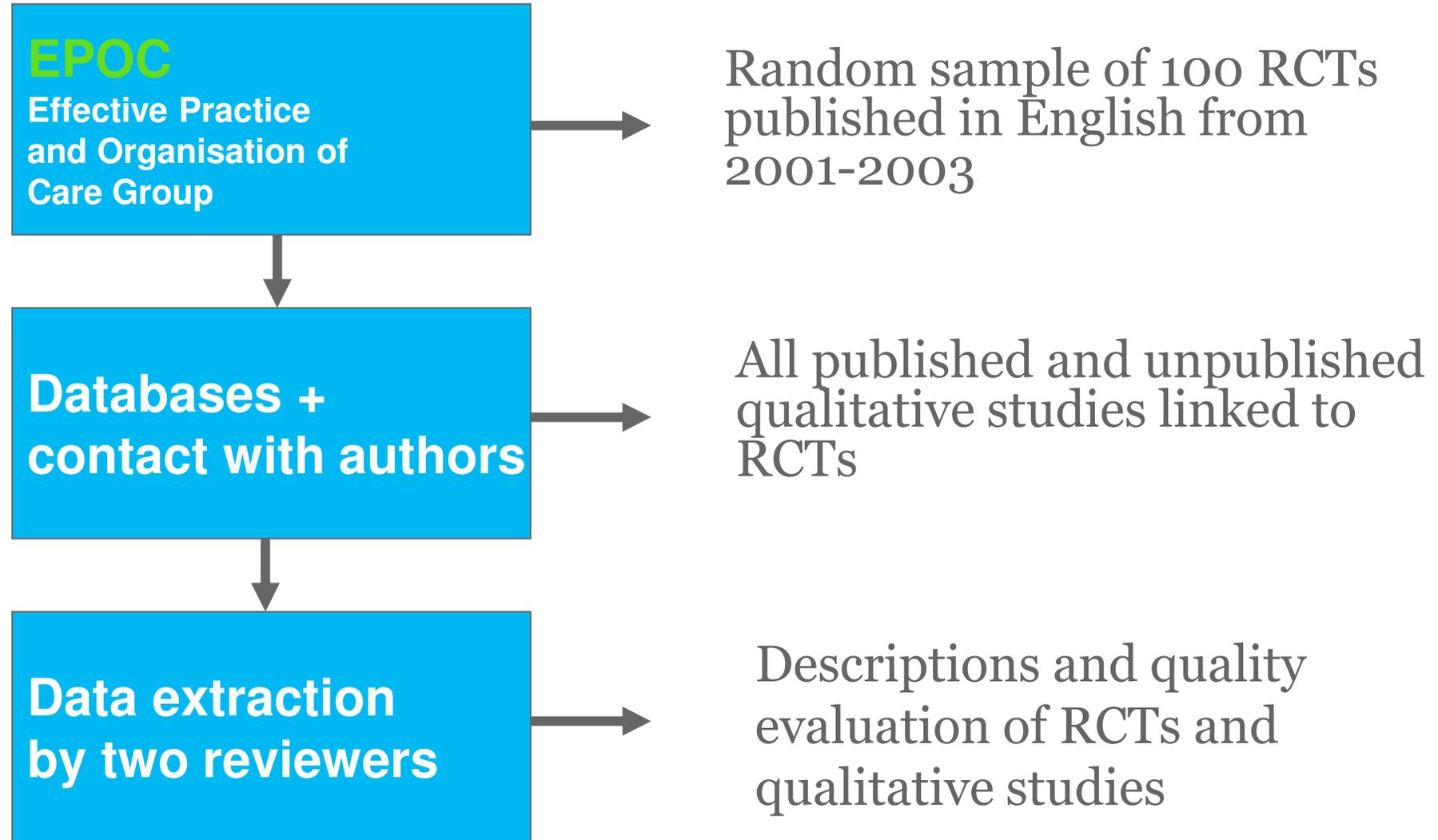
## Methodological study 1 - aims

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

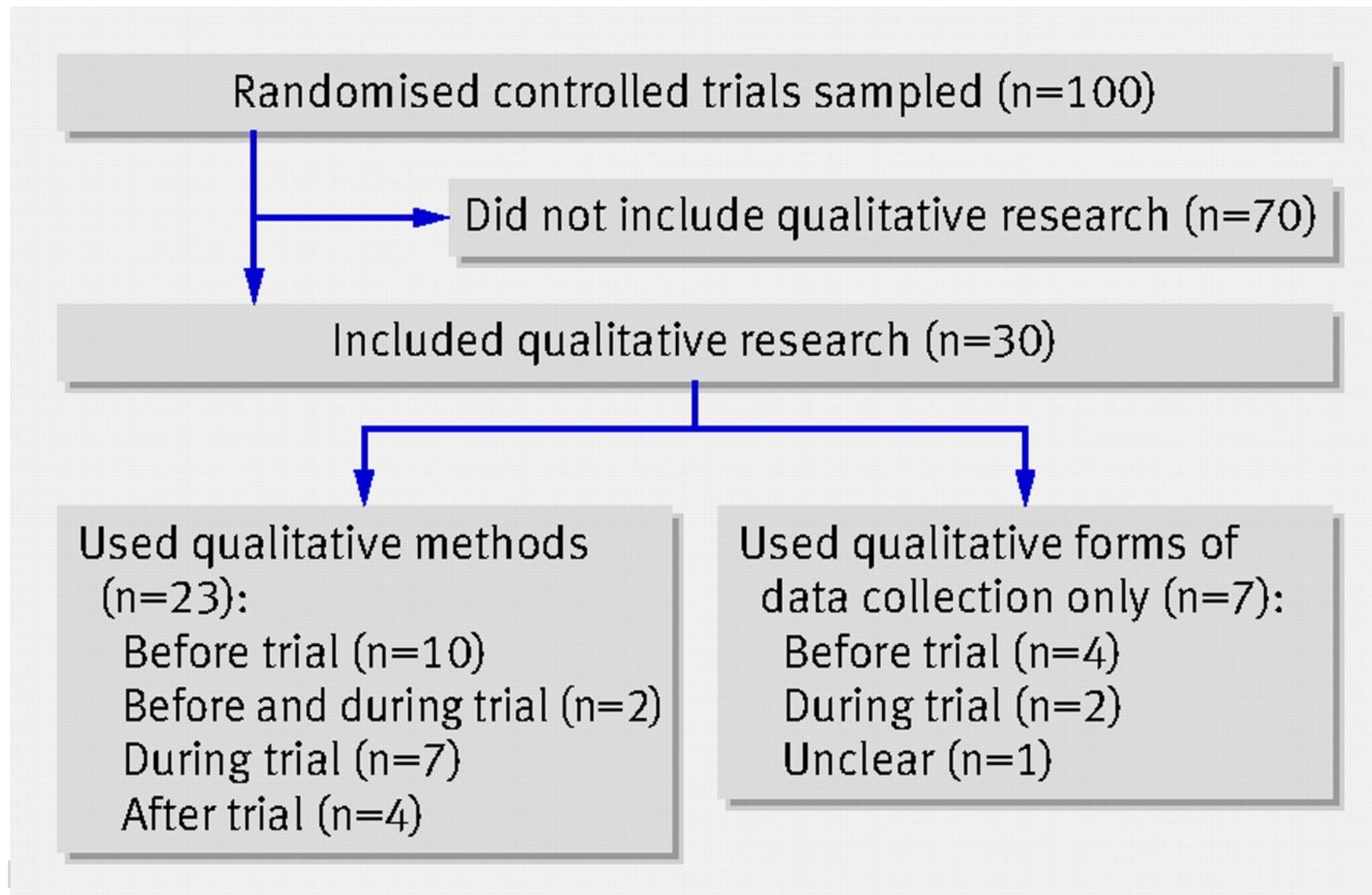
- Is qualitative research being used?
- How and when is it used?
- How well is it conducted?
- How can it be improved?

Lewin S, Glenton C, Oxman A. How are qualitative methods being used alongside complex health service RCTs? A systematic review. *BMJ*. 2009; 339:b3496.

# Methodological study 1 - methods



# Methodological study 1 - findings



## 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 - Integrating the qualitative and RCT studies

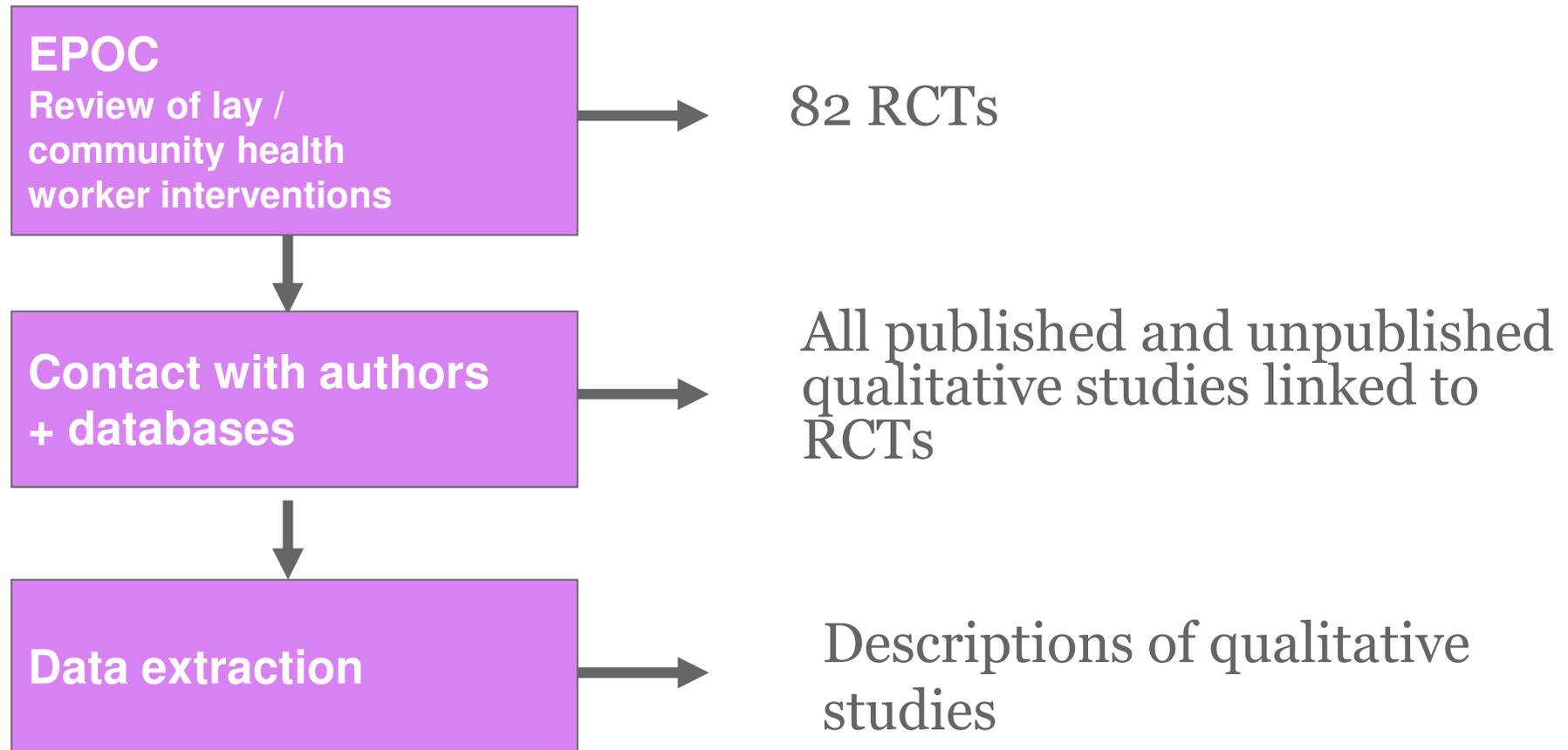
- For most studies (67%): no integration found / not reported / unclear
- For 30% of studies: analyses conducted separately, some integration in interpretation
- No studies reported integration of both analysis and interpretation
- Only 2 studies stated explicitly that they had used a 'mixed method'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

## Methodological study 2

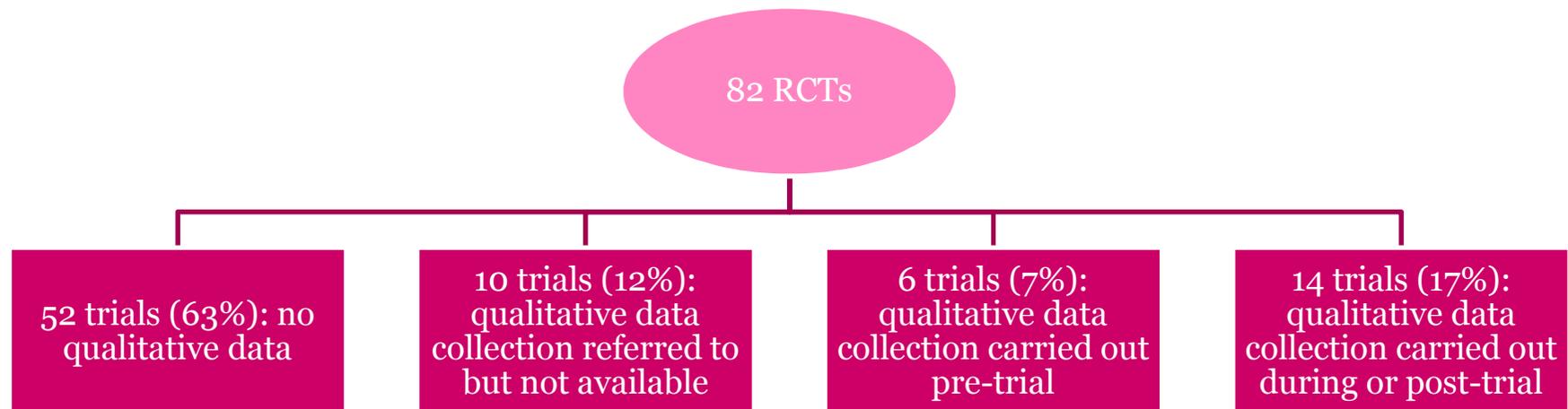
Focus: the use of qualitative methods alongside trial included in a Cochrane review on the effects of using lay health workers on maternal and child health and infectious disease control

## Methodological study 2 - methods

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



# Methodological study 2 - findings



## 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 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

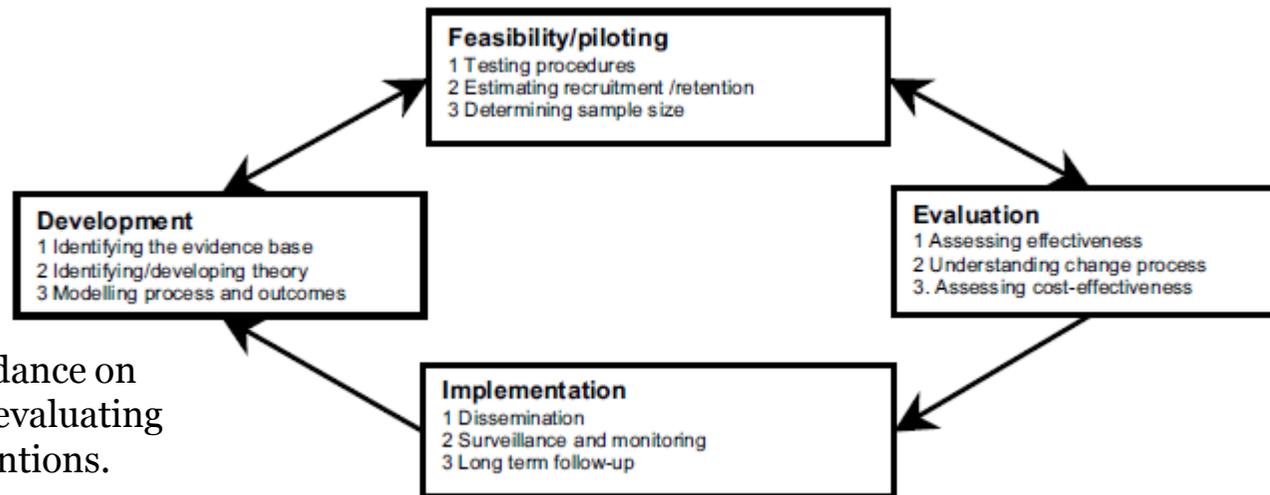
# Summary of findings from methodological studies

- 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



# 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!

For further information:

[simon.lewin@nokc.no](mailto:simon.lewin@nokc.no)

Norwegian Knowledge Centre for the Health Services