Qualitative methods in the context of treatment trials

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Outline

- Contribution of qualitative methods to treatment trials
- Developing & evaluating a complex intervention using quantitative and qualitative methods: the Upbeat study
- Mixed methods in process evaluation: SWAN study

Use of qualitative methods in evaluating complex interventions

- Review of 100 trials from Cochrane register
- 30 had qualitative component
- Most carried out before/during trial; few used to explain trial results
- Findings poorly integrated with trial findings
- Methodological shortcomings

Lewin et al (2009) BMJ

Before

- Explore issues related to healthcare questions/context
- Generating hypotheses
- Developing/refining intervention
- Developing/selecting outcome measures

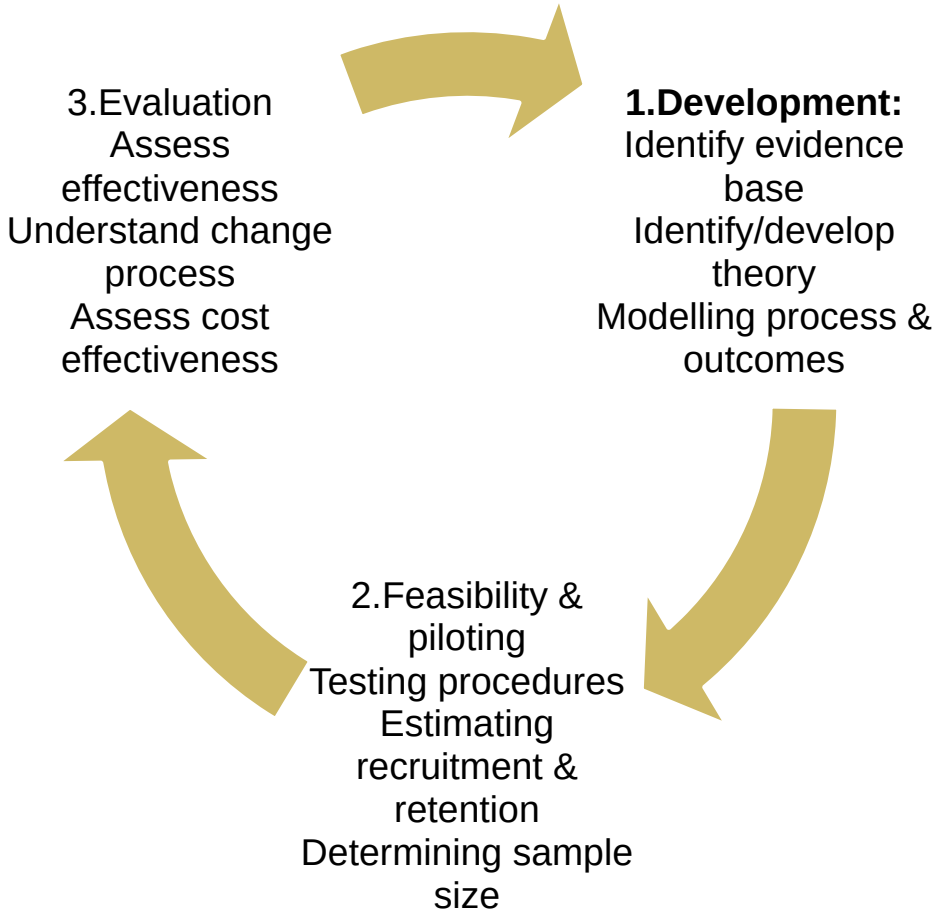
During

- Examining whether intervention was delivered as intended
- Unpack processes of implementation/change
- Explore deliverers and recipients response to intervention

After

- Explore reasons for findings
- Explain variations in effectiveness within sample
- Examine appropriateness of underlying theory
- Generating further questions/hypotheses

MRC guidelines on developing and evaluating complex interventions



Which qualitative methods can contribute to treatment trials?

- Systematic review & meta-synthesis of qualitative research (the evidence base)
- Individual in depth interviews
- Focus group discussions
- Ethnography/ observation in natural setting
- Documentary methods (diaries, letters, blogs)
- Triangulation (multiple methods & sources)

Individual depth interviews

- To identify beliefs & understand behaviours relevant to selecting an intervention
- To investigate perspectives of those who will be involved (patient, carer, clinician) in the trial & to identify desirable outcomes
- Pre and post intervention testing of trial procedures & outcomes in different groups

Focus Group Discussions

- Method for exploring shared experiences of potential trial participants (e.g. people with poorly controlled epilepsy) & to help model complex interventions
- Insight into social processes & environments likely to affect the trial procedures & outcomes (e.g. staff values & work practices at different sites)
- To test validity & acceptability of outcome measures
- To investigate acceptability of potential new treatments (e.g. in planning trials of high risk therapies)

Management of depression in patients on primary care coronary heart disease registers

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The problem

- Prevalence of depression estimated around 35% post myocardial infarction or coronary artery bypass graft (15% major depression)

  (Lett HS et al in Depression and Physical Illness (Ed A Steptoe) CUP 2006)

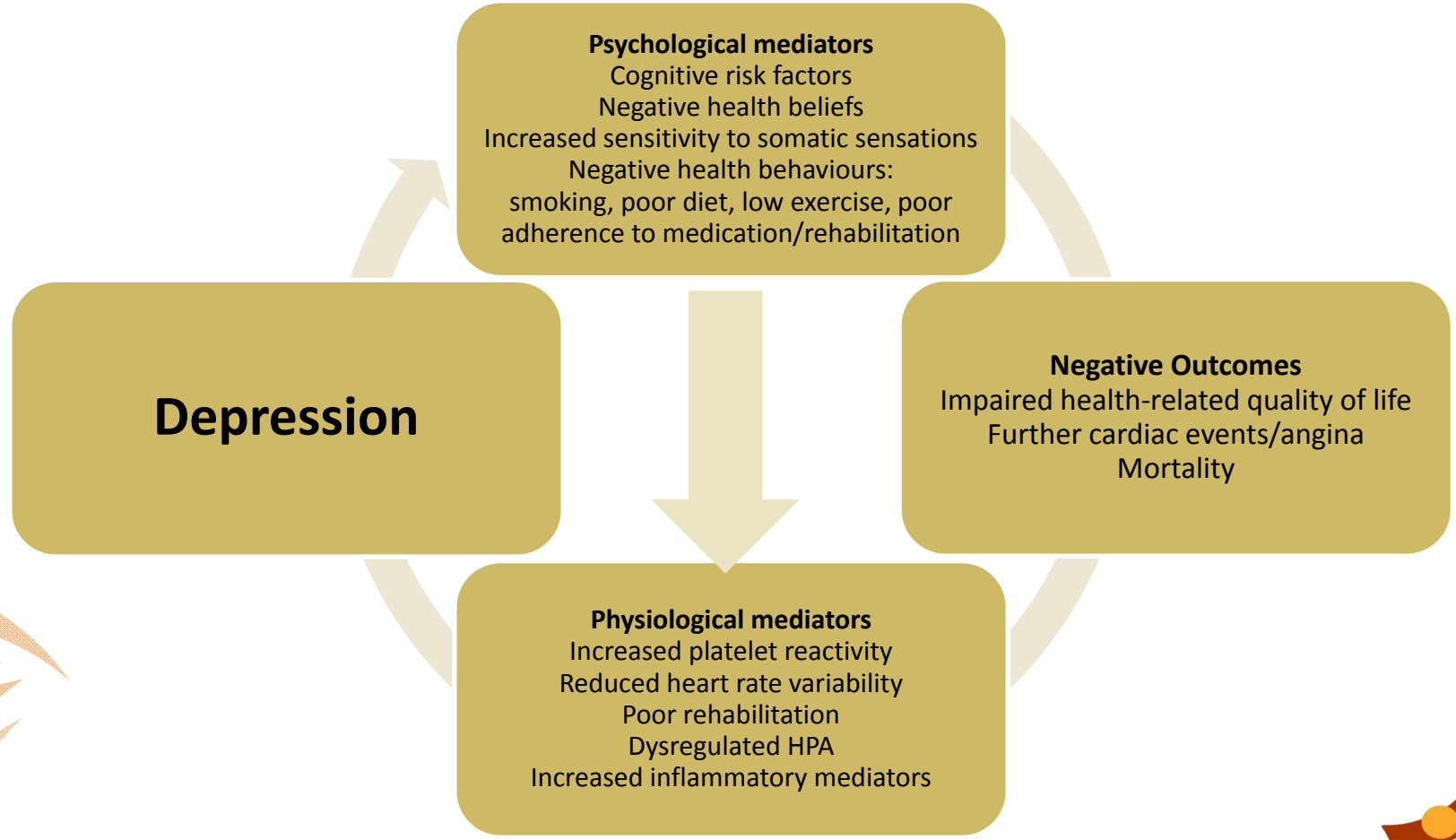
- Depression worsens cardiac prognosis:
  - further coronary events (OR=2.0)
  - death (OR=2.6)

Barth J, et al. *Psychosom Med*. 2004;66:802–813.

van Melle JP, et al. *Psychosom Med*. 2004;66:814–822.

Stafford L, et al. *J Psychosom Res*. 2007;62:401–410.

Theoretical model of possible mechanisms for depression in CHD



Carney RM, et al. *J Psychosom Res.* 2002;53:897–902.
Rozanski A, et al. *Circulation.* 1999;99:2192–2217.

Treatment: the evidence base

Antidepressants and CBT have been shown to reduce depression with only modest effect in people with CHD, and these treatments are not associated with improvement in cardiac outcome or survival

Thombs BD, De JP, Coyne JC et al. Depression screening and patient outcomes in cardiovascular care: a systematic review. JAMA 2008; 300(18):2161-2171

UPBEAT

Objectives

- To describe the relationship between depression and CHD in primary care
- To develop and pilot an intervention for patients with CHD and depression

Objective 1: descriptive cohort

- Prevalence, incidence, and risk factors for depression in patients on CHD registers in general practice
- Course, prognosis, and current management of CHD with and without depression
- Effect of depression on mortality, cardiac symptom severity, health related quality of life, disability, service use and costs

Objective 2: modelling intervention, process and outcome

1. What is the evidence for management of depression in CHD in primary care?
2. What are the candidate interventions?
3. How might these be delivered in an RCT? By whom?
4. What are the likely barriers & facilitators?

Qualitative studies to develop intervention & method of delivery

- Systematic review of quantitative & qualitative evidence
- Study of experiences & attitudes of primary care professionals
- Study of experiences & attitudes of primary care patients with CHD & depression
- Development of theoretical understanding of how the intervention causes change

Findings of systematic review

Understanding of depression: GPs & PNs unsure of relationship between mood & social problems & of their own role in managing it
Recognising depression: ambivalence re screening tools
Stigma and shame: diagnosis of depression is stigmatising
Management strategies: limited options
R**elationships between professionals:** role conflicts within PC & lack of interaction with specialist services
Managing depression: ambivalence re working with depressed people; lack of confidence
Training needs: more training wanted, but not prioritised compared with physical health

Qualitative study of General Practitioners & Practice Nurses

Aims

- Understand GPs' and PNs' views and experience of managing depression in CHD
- Identify issues to be addressed when developing a CHD depression intervention

Methods

- Individual in depth interviews in participating practices

Understandings of depression

Depression in CHD is similar to that in other groups

Distress post event is natural; only severe or chronic requires management

Social problems e.g. loneliness & debt identified as important in CHD depression

Confidence or perceived responsibility to address these varied

Current management

Talking therapies favoured; lack of access a barrier

Reluctance to accept antidepressants observed

Exercise was commonly recommended

Level of informal counselling varied

Local resources useful but difficult to identify

Qualitative study of patients

Aims

- explore patients' perceptions of links between their physical & mental health

- understand experiences of living with depression & CHD, coping strategies & attitudes to current management

Methods: individual interviews & FGDs

CHD and depression link – **patient** themes

Emasculation: unemployment, no longer breadwinner, impotence, feeling ‘useless’

Negative life events: relationship breakdown, bereavement, ‘hard’ life

Ill health & ageing: fear of the future, pain, loss of function, isolation

Attitudes to management –patient themes

Liked: talking therapy; cardiac rehab / exercise programmes (gained confidence, accessed social & professional support)

Disliked: antidepressants (not compatible with understanding of depression as a social/personal problem, stigma associated with disease model)

Barriers: not wanting to ‘bother’ GP, discomfort discussing emotions

Conclusions from both qualitative studies: implications for RCT

Range of options to address common problems in CHD – loneliness, debt, impotence, being housebound, relationship problems

Allow patient choice and clinical judgement
Clinicians need support to manage social problems

PNs may be willing to lead, but need training and convincing of effectiveness & time saving benefits

UPBEAT intervention: case management

Self management support through case management using a personalised health plan:

For? people with symptomatic CHD and depression
Delivered by? case manager
Where? patient's home or GP surgery
How? initial meeting (1 hour) face to face; follow up via telephone/email (15mins)
How long? 6 months; follow up weekly - fortnightly

Process evaluation and mixed methods

Evaluation of complex interventions

RCTs most rigorous way to evaluate effectiveness

But, if negative result, was intervention

- ineffective?
- inadequately applied?
- applied in an inappropriate context?

Or did trial use

- Inappropriate design?
- Inappropriate comparison groups?
- Inappropriate outcomes?

If positive result, can the results be applied to a different context?

- Increased recognition that evaluation of complex interventions more informative if mixed methods used
- Look inside 'black box'

Why evaluate processes?

Main question for RCT - Does it work?

Process evaluation can

1. address equally important questions:
   - Why does it work?
   - Why does it not work in some settings?
   - Who does it work for?
   - Which participants most likely to respond ?
   - What are the active ingredients?
2. examine external validity

MRC: recommends conducting a process evaluation to 'explain **discrepancies** between expected and observed outcomes, to understand how **context** influences out-comes, and to provide insights to aid **implementation**

Integrating process evaluation within trials (or other evaluations)

- Process evaluations are studies that help us understand the trial **processes** or **underlying mechanisms** in relation to context, setting, professionals and patients
- Provide **explanations** for results and enhance understanding on whether or how interventions could move **from research to practice**
- Process data should be collected from all intervention and control sites
- Qualitative and quantitative data
- Data should be analysed before outcome data to avoid bias in interpretation

Data collection

- Contextual information
  - Arrangements for each site
  - Nature of problem at each site
- Implementation
  - Mechanisms
  - Consistency
- Receipt
  - Opinions of participants re acceptability etc
  - Perceived impact

What should triallists report?

- Process evaluations should be clearly labelled
- Process evaluations should clearly state their purpose
- report if pre-specified or post hoc, and why selected timing chosen (eg to explore unanticipated findings)
- State and justify choice of methods
- summarise or refer to the main findings

Grant et al 2013

The SWAN study: A pragmatic RCT of supported employment in London

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Background

- 90% unemployment in Severe Mental Illness
- Traditional employment interventions based on ‘Train and Place’ models
- New ‘Place and Train’ model:

  Individual Placement and Support (IPS)

IPS

- Focus on Competitive Employment
- Rapid job search
- Client preferences important
- On-going support prn
- Work by IPS workers with employers
- Integration of IPS services with mental health services

Process measures

- Context
  - Local employment data
  - Deprivation scores
  - Labour market – benefits system, discrimination
  - Local vocational services (TAU) quantified
- Intervention implementation
  - Systematic review of evidence on mechanisms
  - IPS Fidelity Scale
  - Events records (IPS workers diaries)
- Receipt
  - Qualitative study of experiences of referring clinicians and participants

Summary of Findings

- Low rates of employment in both arms
- No significant differences between TAU and intervention
- Intervention arm less costly than TAU

Howard et al, Br J Psychiatry 2010

Qualitative study

- Interviews with trial and clinical staff
- Focus groups
- Hypothetical scenarios
- Data analyzed thematically using constant comparative techniques

Results – Themes

Misconceptions about RCTs (1)

CC2: *SWAN is still a study isn't it and it's still only fifty fifty and, and there was a little bit of misrepresentation when they first came out, um, because basically fifty percent of the guys were being told right no we can't do anything for you, um, whereas you'd sort of let us, they let us sort of think that it was you know, they were a, a, sort of a, a s- a grounded, um, established, er, service to, to provide, er, employment help… they said it was a trial this that and the other but they certainly didn't say that you know there's a good chance that, you know, your clients aren't going to get (the supported employment).* (Interview)

Results – Themes

Lack of Equipoise (1)

CC7: *The intervention arm is better and the reason why I believe is that it provides the extra support that the clients require to pass through the selection and interview and helpful in gaining a job. Also the clients believe that, apart from their employer, they have somebody that they can seek support from because the SWAN shall make them aware if they have problems and also the third one* (reason) *which I am about to* (say) *is that the employer also has prior knowledge about the individual, that if they are relapsing they can inform the SWAN*. (WS2)

Results – Themes

Misunderstanding the trial arms (1)

CI : *Until the last year or so, the question of real open market paid employment for people with more disabling conditions rarely came into the picture for clinical teams…Not only was it not really often discussed or any action taken, but rarely did the staff actually refer patients to this particular employment agency. Which they could have done, but they didn't. So it wasn't as if this was a sort of, you know, widely used option and it's a valuable resource and many people going that way. …I think it's two things, one is the trial sensitised staff to the question of work, but also that the wider health policy environment has changed*. (Interview)

Results – Themes

Eligibility (2)

CC7: *I wouldn't refer them. I wouldn't refer them.*

QR: *Really, why?*

CC11: *I wouldn't.*

CC12: *I wouldn't.*

QR: *Why?*

CC7: *…So with someone like this you get them a job and within two or three months they are relapsed, back in the hospital, the pressure is too much, its like they are not really well enough, because three months they are still having a good and bad day, they are still complaining about their current medication, they need to keep taking their medication.*

CC3: *But for me maybe the bad days are because she hasn't got anything to do, nothing meaningful to do during the day. I would be more likely to refer this lady because she is motivated, she is saying that she wants to go out…so you have to take that on, she would like to go out to work.* (WS 2)

Results – Themes

Paternalism (1)

CC8: *So say people come with umm very complex issues about rejection and umm this, you know this may feel like another rejection to them and we may have as clinicians, we may feel we don't want to put our clients through that*. (WS1)

Conclusions

- Equipoise, eligibility interpretation and research process misunderstandings were common problems in this RCT.
- Eligibility interpretation may lead to a lack of generalisability and recruitment.
- Paternalism meant that some individuals were denied access to the trial and not allowed to make an informed choice about participating in research.

Howard et al, Contemporary Clinical Trials 2009

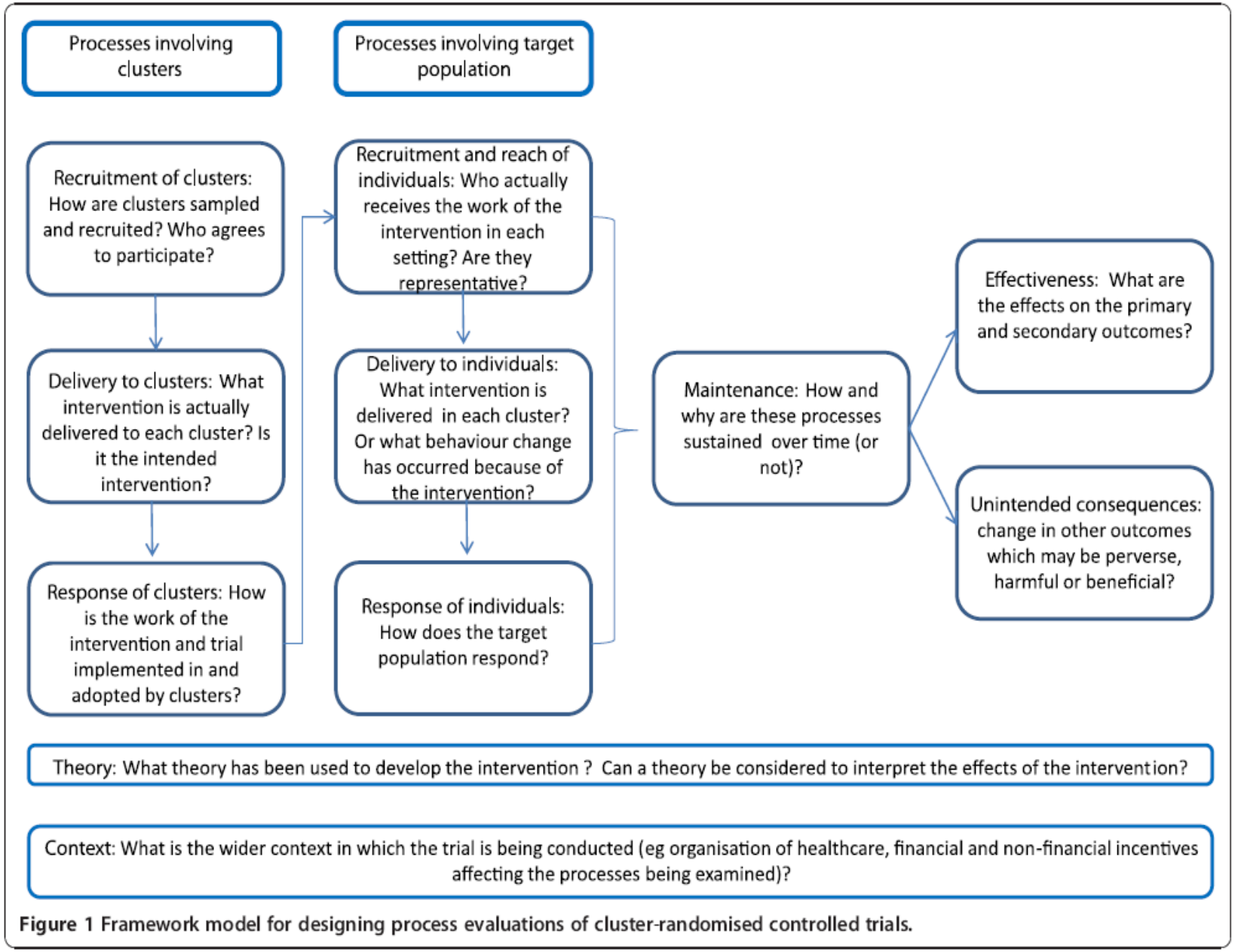

Figure 1 Framework model for designing process evaluations of cluster-randomised controlled trials.

Table 1 Example research questions and methods for evaluating each process

Domain	Example research questions	Research methods that could be applied	Probable best stage of study to collect data
Recruitment of clusters	How are clusters sampled and recruited?	Documentation of recruitment process by research team.	Pre-intervention
	Who agrees to participate?	Quantitative comparison of recruited and nonrecruited clusters.	
	Why do clusters agree to participate (or not)	Qualitative analysis of interviews with cluster gatekeepers or members.	
Delivery to clusters	What intervention is actually delivered for each cluster? Is it the one intended by the researchers?	Qualitative analysis of observational, interview and documentary data relating to the cluster-level intervention.	Pre-intervention and early intervention
Response of clusters	How is the intervention adopted by clusters?	Quantitative data measuring cluster members' perceptions of the intervention and uptake of trial components. Qualitative analysis of observational, interview and documentary data about how clusters adopt the intervention.	Pre-intervention and early intervention
Recruitment and reach in individuals	Who actually receives the intervention in each setting? Are they representative?	Measurement of receipt in target population. Quantitative comparison of those receiving vs. not receiving the intervention.	During intervention
	Why do clusters achieve the pattern of reach they do? Do they introduce selection bias?	Qualitative analysis of observational, interview and documentary data about how clusters achieve reach.	
Delivery to individuals	What intervention is actually delivered for each cluster?	Qualitative analysis of observational, interview and documentary data about what intervention is delivered and why.	During intervention
	Is the delivered intervention the one intended by the researchers?	Measurement of intervention fidelity across its components.	
Response of individuals	How does the target population respond?	Qualitative analysis of observational and interview data about target population's experience of and response to the intervention.	During intervention and post-intervention
Maintenance	How and why are these processes sustained over time (or not)?	Any of the above, but probably focused on processes identified as critical, or as likely to be difficult to sustain.	During intervention and post-intervention
Unintended consequences	Are there unintended changes in processes and outcomes, both related to the trial intervention and unrelated care?	Qualitative analysis of observational and interview data for identification. Quantitative data collection for potential unintended consequences during the trial, or use of routine datasets.	Intervention and post-intervention
Theory	What theory has been used to develop the intervention?	Quantitative process data analysis can assess whether predicted relationships and sequences of change happened during implementation.	Post-intervention
Context	What is the wider context in which the trial is being conducted?	Qualitative data collection from policy documents or interviews.	Pre-intervention and early intervention

Problems with process evaluation

- Resource intensive
- Needs significant funding

Summary points

- A detailed process evaluation should be **integral** to the design of many RCTs
- Process evaluations should specify **prospectively** a set of process research questions and identify the processes to be studied, the methods to be used, and procedures for integrating process and outcome data
- Expanding models of evaluation to **embed** process evaluations more securely in the design of RCTs is important to improve the science of testing approaches to health improvement

SUMMARY

Use of qualitative methods in treatment trials:

- provides insight into experiences of patients, carers & professionals
- Can enhance relevance of outcomes
- Can improve delivery of intervention
- Can improve engagement , adherence & retention
- Can help interpret findings & anomolies