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**Reflections on using the MRC guidance for developing and evaluating complex interventions as a guiding framework for a mixed methods, multiphase research study.**

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# Content

- Rationale for my research
- Research topic
- MRC guidance for Developing and Evaluating Complex Interventions
- Research methods
- Benefits, challenges and serendipitous discoveries

# The nature and size of the problem

- At least 20% of mothers experience mental health problems during pregnancy or the first postnatal year (the perinatal period). (O'Hara and Wisner, 2014)
- This leads to adverse consequences for the mother, her partner and her baby (O'Hara & McCabe 2013; Stein et al, 2014)
- The cost to the nation is £8.1 billion a year for every annual cohort of births (Bauer et al, 2014).
- This is 5x the cost of improving services.

# Current provision of care

- The most common MHPs are depression and anxiety.
- It is anticipated that 90% of mothers with MHPs can be identified and treated by primary care professionals(GP.s midwives, HVs, IAPT)(NICE, 2014).
- Up to 50% of mothers are not being identified and/or not receiving the help they need that will lead to sustained recovery (Henderson & Redshaw, 2013)

# The role of the health visitor

- In the UK, HVs are responsible for routinely assessing the health and well-being of all members of the family during the course of a number of universal mandated visits from pregnancy until the child is 2 (Department of Health (DoH) 2009).
- Maternal mental health is one of six high impact areas that describe aspects of practice where HVs can make a significant difference to health outcomes for pre-school children and their families (DoH 2014).
- Since 1989, HVs have been offering an intervention described as 'listening visits' (LVs) to mothers with postnatal depression (Holden et al, 1989)
- The 2007 NICE guideline for antenatal and postnatal mental health was updated in 2014 and LVs were not included as a recommended intervention (NICE, 2014).

# Disorienting Dilemma

(Mezirow 1978)

- HVs have a professional responsibility to identify and support mothers with mental health problems (DoH, 2014).
- The recommendations in the updated NICE guideline for antenatal and postnatal mental health have generated confusion about how that support should be provided (NICE, 2014).
- Such a dilemma can act as a catalyst for critical reflection of beliefs and assumptions and, potentially, consideration of alternative ways of working (Mezirow, 1978).

# Research

**Title:** Moving on from 'Listening Visits': a mixed methods, multi phase study exploring the support that health visitors provide to mothers with mental health problems.

## Aims

- To clarify the role of the health visitor (HV) in supporting mothers with mental health problems (MHPs).
- To find out how HVs approach 'listening visits' (LVs) in terms of their perceptions of the content, purpose, and challenges of delivering, the intervention.
- To update the intervention offered by HVs based on evidence of feasibility, acceptability, and effectiveness.

# Why use MRC Guidance for developing and evaluating complex interventions?

## A Complex problem

In an international position paper on mother-infant (perinatal) mental health Brockington et al (2017 p.114) refer to 'pregnancy and its aftermath' as 'the most complex event in human experience' and lament the fact that no country in the world makes adequate provision for the mental well-being of mothers and their infants.

Requires a complex solution

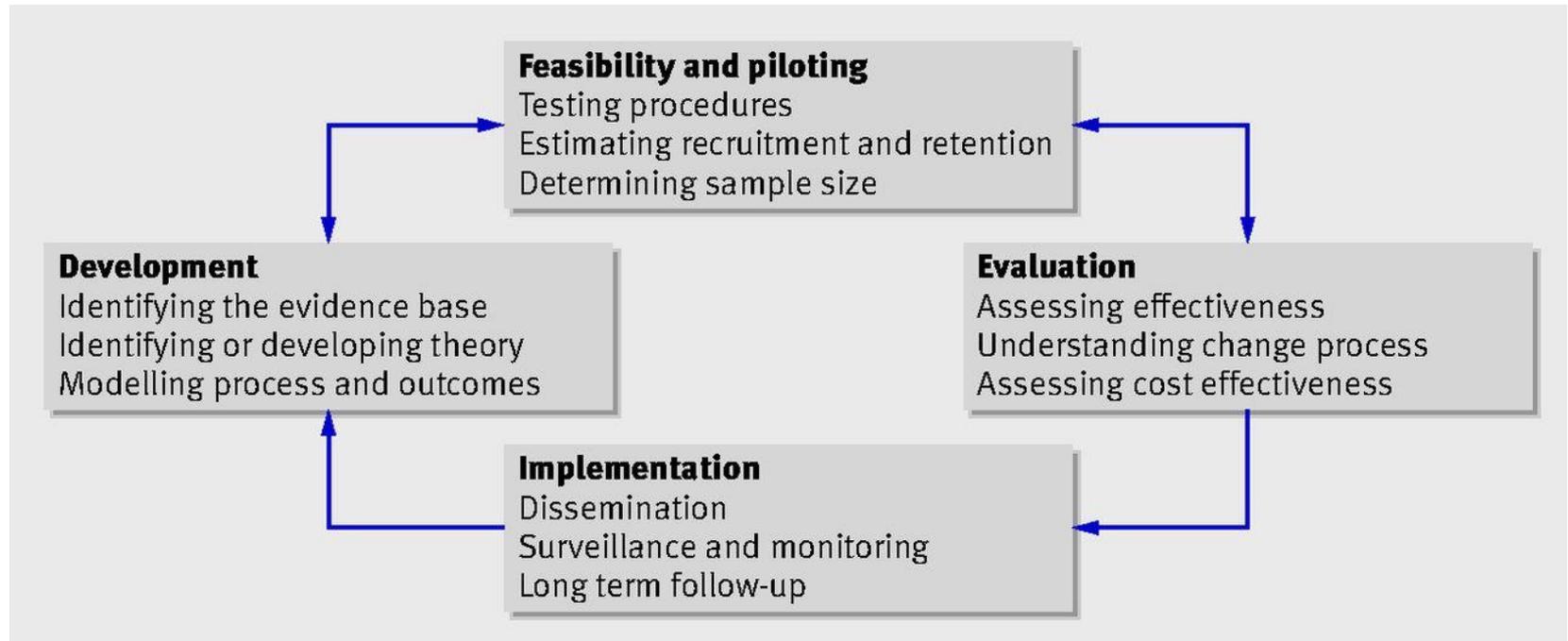
## **MRC guidance definition of a complex intervention**

- Number of interacting components within the experimental and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted.

(Craig et al, 2008)

3. MRC guidance provides a systematic approach to inform the steps necessary to move from the identification of a problem to the development of an appropriate solution.

# Key elements of the MRC development and evaluation



Peter Craig et al. BMJ 2008;337:bmj.a1655



# Not only, but also...

## Development phase of MRC guidance

- Identifying the evidence base;
- Identifying or developing theory;
- Modifying process and outcomes
  
- Craig et al, 2008

## Missing ingredients

- Information is needed about:
- the causal mechanism between the intervention ingredients and outcomes;
- the interactions between the proposed intervention ingredients;
- how the context i.e. the recipient and provider interact with the intervention.
  
- Bleijenberg et al, 2018

Enhanced development phase of MRC guidance (Bleijenberg et al, 2018)	Methods used in this programme of research
Problem identification and definition	Literature reviews :definition, prevalence, aetiology and impact of perinatal MHPs; evolution of LVs. Critical appraisal of NICE guideline.
<b>Identifying the evidence base (MRC)</b>	Systematic literature review to facilitate identification of core components of effective interventions.
<b>Identifying or developing theory (MRC)</b>	Literature review guided by BeHEMoTH mnemonic.
Determining the needs	Qualitative metasyntheses of the views of mothers and the views of health professionals
Examining current practice	Web-based survey (Theoretical Domains Framework; TIDieR cecklist)
<b>Modelling process and outcomes (MRC)</b>	Modified, real-time, technological, Delphi study
Intervention design	Development of a draft integrated assessment and intervention framework to guide the support that HVs provide to mothers with MHPs

# Step One

Are we all talking about the same thing?

- What do we mean by MHPs?
  - UH-OH!
- What is the size and impact of the problem
- What are LVs, where did they come from and how have they evolved?
- What evidence is available regarding their effectiveness?

# Step Two

- Why have LVs been excluded from the NICE guideline as an evidence-based intervention?
- (Should I carry on thinking about LVs or should I be thinking about something else)
- YES / NO /MAYBE
- UH-OH!

# Step three

- What are HVs doing at the moment to support mothers with MHPs?
- What do HVs think about what they are doing (including what do they think about LVs)?
- What are the barriers and facilitators that affect what they are doing?
- What do HVs think they should be doing in the future to support mothers with MHPs?
- What needs to happen to help them to do that?

# Step four

- What do HVs, in particular, and health professionals in general think about their role in supporting mothers with MHPs?
- What do mothers think about the support they receive from HVs in particular, and health professionals in general?
- What are the key messages to take on board from these analyses regarding the feasibility and acceptability of interventions.
- i.e. what women find helpful and what HVs feel is possible to deliver.

# Step five

- What are the core components and key clinical activities of effective perinatal mental health interventions, delivered by non-mental health specialists, that could be incorporated into a health visitor intervention?
- How are the interventions supposed to work?

# Step six

What do HVs think about the findings from step four and step five?

Which core components and key clinical activities do HVs think should be incorporated into a HV intervention?

# Step seven

- How can the identified components and activities be incorporated into a guide for practice?

# Literature Reviews

When investigating or developing complex interventions a series of literature reviews are needed to 'address questions of known effectiveness, contextual variation, intervention acceptability, feasibility and mechanisms of action.' (Richards, 2015 p.8)

Each question that is generated requires a different approach to a review of the literature (Petticrew et al, 2019).

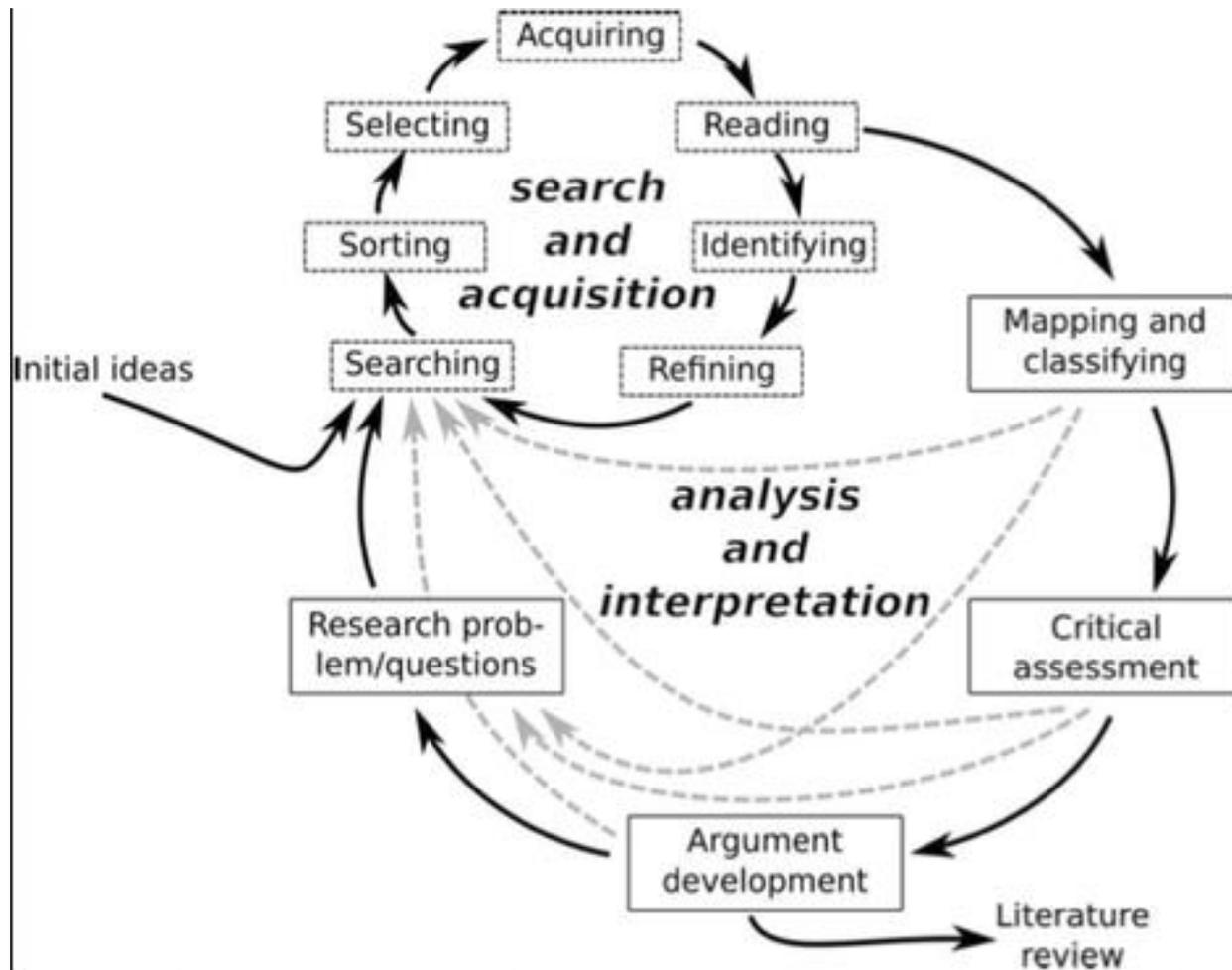
UH-OH!

# Hermeneutic Systematic Literature Review

- Hermeneutics is the theory and methodology of interpretation.
- A hermeneutic systematic review seeks to synthesise and critique the existing literature on a topic of interest through a repetitive, cyclical process of accessing and interpreting all relevant sources of information to provide an integrative overview of issues relevant to practitioners and policymakers (Boell & Cecez-Kecmanovic 2014).

A hermeneutic framework for the literature review process consisting of two major hermeneutic circles.

*Reproduced with permission from Boell and Cecez-Kecmanovic 2019*

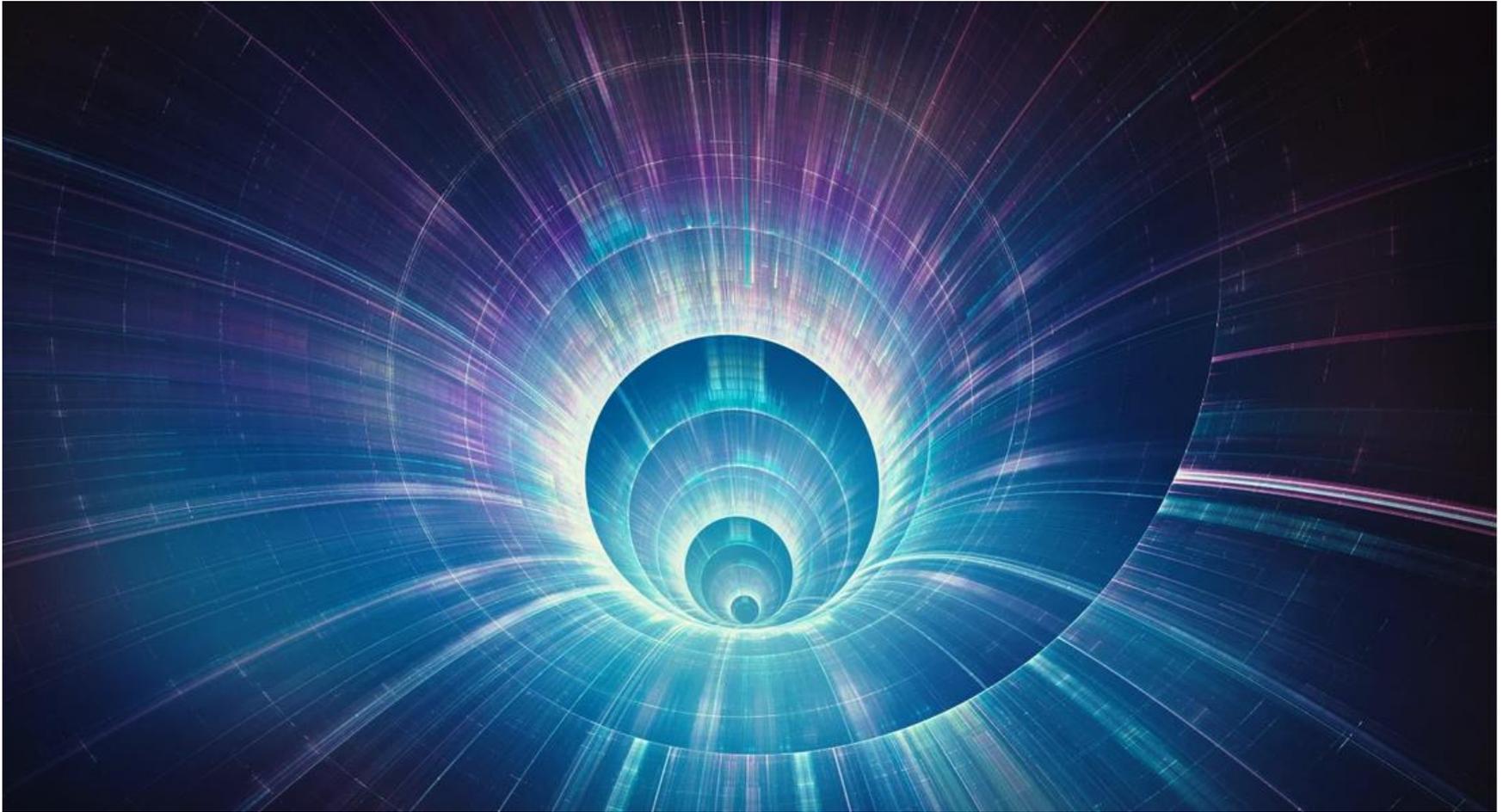


# Steps taken in hermeneutic systematic review (Greenhalgh et al, 2017\*)

- Generic search of Pubmed to identify highly cited review articles that seemed to answer the initial research questions posed.
- Citation tracking in Google scholar to identify additional articles.
- Papers were selected for full-text analysis based on the likelihood that they would add 'meaning' to the overview.
- Additional sources were added using forward and backward tracking of selected articles combined with the authors' professional knowledge and advice from experts in the field regarding relevant articles, conference abstracts, unpublished studies etc.
- A narrative synthesis was iteratively generated, as more papers were included, that reflected 'the key questions, theories, methods, findings and scholarly arguments relevant to the research questions'

\*Hermeneutic systematic review of the relative merits of telehealth for the management of cardiac failure (Greenhalgh et al, 2017. p.3).

# Lost in the internet!



UH-OH!

# Listening Visits

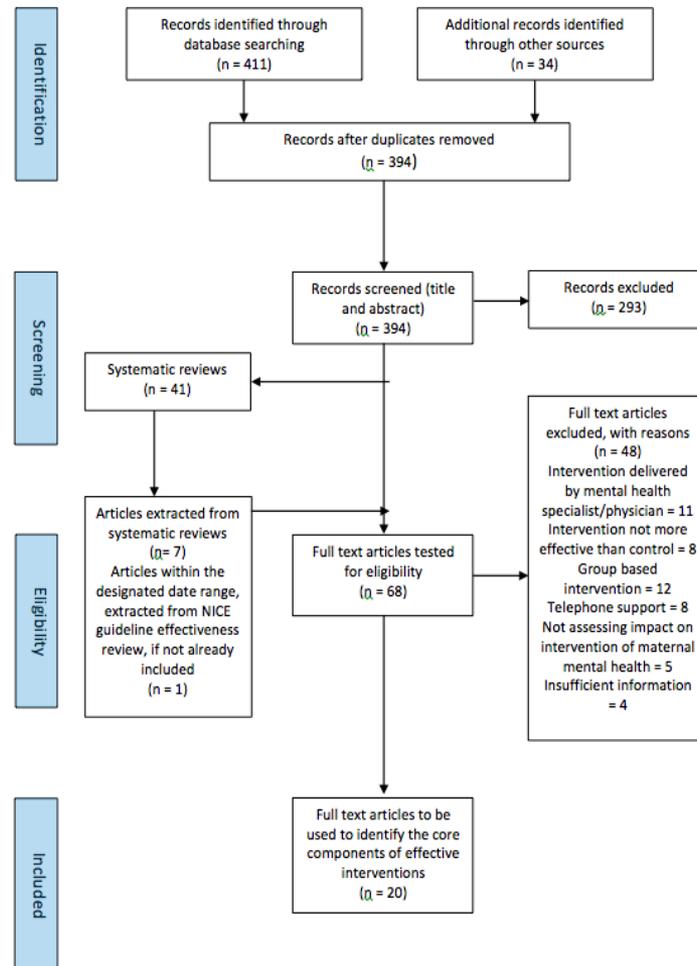
- Pearl citation
- Holden J, Sagovsky R, Cox J (1989) Counselling in the general practice setting: controlled study of health visitor intervention in the treatment of postnatal depression. *Br Med J* **298**: 223 - 226

# Overview of 'Listening Visits'

## Results from review of title / abstracts of references citing 'pearl' citation, in Google scholar.

Main focus of the article	Number of articles (n = 581)
Listening visits / role of the HV in perinatal mental health care	57
Role of the HV (everything except perinatal mental health care)	26
Impact on the child	22
Mother-infant relationships / interaction	12
Prevalence, aetiology, symptoms	78
Prevention	19
Assessment	31
Treatments / Interventions (not delivered by HV)	152
Pathways / collaborative care	12
Views of women	33
Views of health professionals	7
Other (not about perinatal mental health)	69
Random or in another language	63

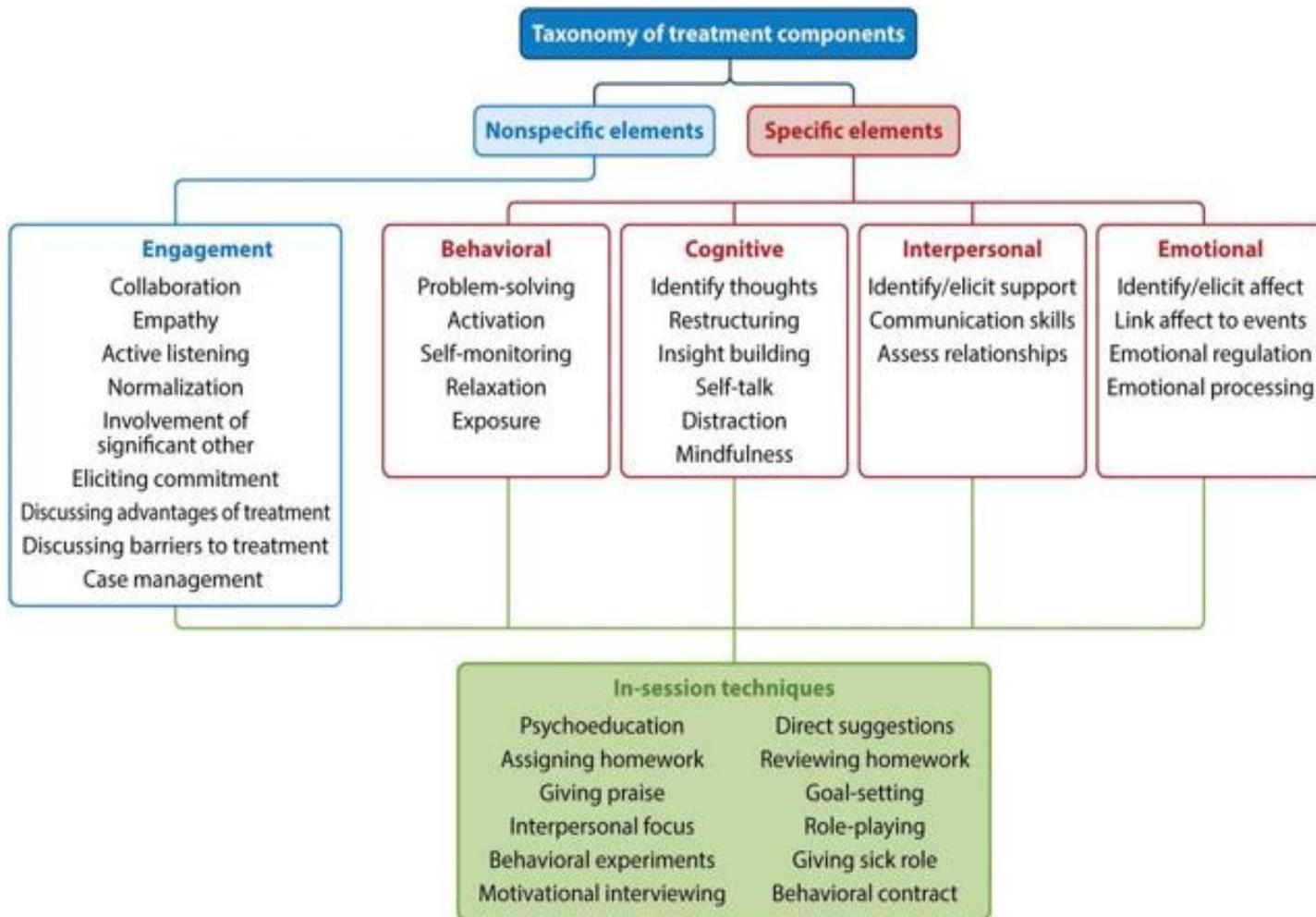
# PRISMA flow chart indicating selection of articles from literature review of effective interventions for mothers with mental health problems delivered by non-mental health specialists.



# Extraction of core components of effective interventions

- The method for extracting core components was guided by the distillation and matching model (DMM) (Chorpita et al, 2005) and Intervention Components Analysis (ICA) (Sutcliffe et al, 2015)
- The DMM was used by Singla et al (2017) to identify the treatment components and implementation processes of effective interventions, for community based individuals with common MHPs, delivered by non-specialist providers in low and middle-income countries.

# The taxonomy of treatment components of psychological treatments for common mental disorders delivered to adults in low- and middle-income countries (Singla et al, 2017).



# Identifying the theories

- The MRC guidance emphasises the need for a comprehensive understanding of why a problem occurs (the predisposing factors), the interventions that might be appropriate, and how the interventions are supposed to work in the real world of clinical practice.
- This includes the use of formal and informal theories to explain how interactions between causes, symptoms, intervention components, providers, recipients and context culminate in both expected and unexpected outcomes (Moore & Evans, 2017).

## BeHEMoTH criteria (Booth & Carroll, 2015) used to inform search of the literature

<b>Behaviour of Interest</b>	<b>Interventions directed at the prevention, identification and management of perinatal mental health problems</b>
<b>Health context</b>	<b>Community or primary care</b>
<b>Exclusions</b>	<b>Statistical models</b>
<b>Models or Theories</b>	<b>Models, theories, frameworks, or concepts.</b>

Number of articles identified = 271

Number of theories identified = 144

UH-OH

# Critical Appraisal of NICE guideline

- Flottorp et al (2013) have developed a checklist to identify the determinants of health professional practice, based on a systematic review and consensus process.
- One of the 7 domains in the checklist is 'guideline factors'.
- The authors suggest the use of 7 questions to explore aspects of guidelines that might influence practice.
- These were used as the headings to ensure a systematic approach to the critical appraisal of the relevant recommendations in the NICE guideline for antenatal and postnatal mental health (NICE, 2014).

# Guideline factors checklist (Flottorp et al, 2013)

- What is the quality of the evidence supporting the recommendation and has it been assessed appropriately?
- What is the strength of the recommendation, has it been assessed appropriately, and are the implications of the strength of the recommendation clearly communicated?
- Is the recommended action (what to do) stated specifically and unambiguously? Is sufficient detail provided to allow the targeted healthcare professionals to perform the recommended action?
- Is the recommendation culturally appropriate?
- Is the guideline or recommendation accessible?
- Do the organisation(s) and people who made the recommendation have credibility with the targeted healthcare professionals?
- Is the recommendation consistent with recommendations in other guidelines with which the targeted healthcare professionals might be familiar?

# Benefits, challenges and serendipitous discoveries (of using the enhanced MRC Guidance)

- Systematic approach.
- The development phase
- Context (recipients and providers)
  - a complexity-Informed approach to health services research should be predicated on ‘rich theorizing, generative learning, and pragmatic adaptation to changing contexts’ rather than seeking to establish a singular, universal truth (Greenhalgh and Papoutsis, 2018 p.1.)
- Narrative
- Theory
- Bias
  - Once we create classification schemes we become enshrined in guidelines and protocols, ossify and reproduce our prejudices and make those assumptions appear scientific and channel our prejudices in particular directions (Greenhalgh, 2015 – Real v rubbish EBM)
  - Complexity
    - The edge of chaos – uncertainty, unpredictability
    - Small changes make a big difference

- Journey of 'thinking'
  - 'a commitment to 'thinking' which is willing to question, and open to trusting the resonance of understanding that 'comes' without expecting answers that are declared 'truth' for all time.'  
(Smythe 2007)

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