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A systematic review of process evaluations of primary care interventions addressing chronic disease

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ABSTRACT

Objective: Process evaluations (PE) alongside randomized controlled trials of complex interventions are valuable because they examine implementation fidelity, and address questions of for whom, how and why the interventions had an impact. We used the UK Medical Research Council guidance for PE as a guide to provide a synthesis and appraisal of the methods used in PEs of primary care interventions, and their main findings on implementation barriers and facilitators.

Design: Systematic review

Setting: Primary health care

Participants: Patients with non-communicable diseases, and their health providers

Findings: 69 studies were included. There was an overall lack of consistency in how PEs were conducted and reported. The main weakness is that only 30 studies were underpinned by a clear intervention theory often facilitated by the use of existing theoretical frameworks. The main strengths were robust sampling strategies, and the triangulation of qualitative and quantitative data to understand intervention's mechanisms. Findings were synthesized into 3 key themes: 1) a fundamental mismatch between what the intervention was designed to achieve and local needs, 2) the required roles and responsibilities of key actors were often not clearly understood and; 3) the health system context – factors such as governance, financing structures and workforce- if unanticipated could adversely impact implementation.

Conclusion: Greater consistency is needed in the reporting, and the methods of PEs. In particular, greater use of theoretical frameworks to inform intervention theory. More emphasis on formative research in designing interventions is needed to align the intervention with the needs of local stakeholders; and to minimise unanticipated consequences due to context-specific barriers.

Registration with PROSPERO Registry: registration number is CRD42016035572

Keywords: process evaluations, primary health care, complex interventions, systematic review, chronic disease, non-communicable disease, qualitative

Strengths and Limitations of the study

- A study limitation is appraising the studies using a tool which we developed based on the UK Medical Research Council's guidance on process evaluations, which has not been tested elsewhere.

- A strength of this review is having a multidisciplinary team of authors with vast experience in clinical trials and process evaluations to enable a reflexive thematic synthesis and interpretation of the papers.

INTRODUCTION

An accessible, effective and affordable primary health care (PHC) system is needed to equitably reduce the rising non-communicable disease burden. (1-3) Complex interventions comprising of "multiple interacting components (although additional dimensions of complexity include the difficulty in their implementation and the number of organisational levels they target)" are often used to reduce this burden. (4) Such interventions addressing chronic disease often require individual and organisational behaviour change within dynamic policy, local environment and health system contexts. (5) (6) Randomised controlled trials (RCTs) of complex primary care interventions have been conducted but there is often ambiguity as to what was actually implemented. (7-9) Process evaluations (PE) are conducted alongside trials examine if a complex intervention was implemented as intended, and to explore if, for whom, how and why the intervention had an impact. (4)

A process evaluation is defined by the United Kingdom Medical Research Council (MRC) as a study to '*understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors'*. (4) The MRC process evaluation framework and guidance published in 2015 is based on the synthesis of influential frameworks and theories in public health research and informed by the authors' process evaluations. (4) Implementation concepts of reach, fidelity, and adoption were made explicit, as was the need for the intervention theory i.e. the hypothesis relating to how the complex intervention may interact with contextual factors to produce variation in outcomes (10, 11) Ideally the intervention theory would determine the process (qualitative and quantitative) data to be collected and analysed before the RCT outcomes are known. PE findings could potentially help explain variation in RCT outcome, refine the intervention theory and inform future research priorities. Recognising the need to facilitate implementation of evidence into practice and policy- the MRC guidance also expands on the importance for process evaluations to be conducted across all stages of research i.e. feasibility/piloting, evaluation of effectiveness, and post-evaluation stages. While the guidance was well-received, outstanding questions remain in this developing field. For example, what is the role of other theories and frameworks for process evaluations? What methods can be used and how?(12-14) Synthesising the collective 'experience' described in published process evaluations may answer some of these questions.

This review has two primary objectives. First, to review the methods used in published process evaluations and their alignment with the MRC guidance, and second to identify the key implementation barriers and facilitators reported in these process evaluations.

METHODS

The systematic review protocol has been prespecified, and described in detail elsewhere. (15) A summary is presented here according the PRISMA guidelines.(16)

Eligibility Criteria for the randomised controlled trials with the included process evaluation

Population: Patients with non-communicable diseases(Diabetes, Depression, Cardiovascular Disease, Chronic Obstructive Pulmonary Disease, Chronic Kidney Disease, Type 2 Diabetes Mellitus), and their primary care providers. (5)

Intervention: complex interventions which comprise "*multiple interacting components although additional dimensions of complexity include the difficulty of their implementation and the number of organisational levels they target*" within PHC.(4)

Comparator: the control condition may include treatment as usual, active control or placebo control.

Outcomes for this systematic review: (1) Strengths and limitations of each process evaluation using the MRC guidance as a reference point. (2) Identification of implementation barriers and facilitators for the complex interventions.

Timing: published data from 1998.

Design: process evaluation of the included randomised controlled trials (RCTs) as defined by the MRC as 'a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors'. (4) Given that process evaluations are often not explicitly labelled as such (11), we included studies with comparable aims.

Exclusion criteria: not a journal article, not a report based on empirical research, not reported in English, reviews and not human research.

Search strategy and data extraction: Standard systematic review methods were followed for searching (1998 till June 2018), screening and extracting data from eligible studies. (15) Two reviewers (HL, AM) conducted most of the data extraction, with a third reviewer (MN) assisting in data extraction with some papers and as part of quality assurance, checked on the data extraction for a 10% sample of the identified papers. Given that a key aim of this study was about process evaluation methodology- we deviated from the published systematic review protocol, by including our interpretation in addition to the study's strengths and limitations posited by the authors of those papers.

Data analysis and synthesis

Descriptive items (e.g. number of positive RCTs) were tallied and synthesised into 3 tables. (1) Overall characteristics: presenting the studies grouped into different diseases and ordered by year of publication. (Appendix 1); (2) Methods table: grouping studies by the stages of the process evaluation (i.e. feasibility/ piloting, effectiveness, post-evaluation) (Appendix 2); (3) Quality assessment. (Appendix 3).

Extracted qualitative data were coded by HL, and grouped into categories of context, mechanisms and implementation. Inductive derivation of the key themes was done through constant comparison between the findings from the papers within each category and examining the relationships between them. Appendix 4 provides illustrative quotations. The methodological and implementation findings were triangulated using a modified MRC PE framework to examine how the process evaluations elicited the implementation findings.

Patient and Public Involvement

While patient and public perspectives were synthesised from published papers, no public and patients were directly involved in this study.

FINDINGS

(1) Characteristics of included studies

We identified 69 studies. The PRISMA flowchart is presented in Figure 1. In summary, 66 studies were conducted in high income countries, 1 study in Zambia, 1 in Malaysia and 1 in India. Cardiovascular disease, diabetes mellitus, and depression were the conditions most often investigated, with only six studies on chronic obstructive pulmonary disease and one

study on chronic kidney disease. Overall, the complex primary care interventions fit within the general categories of facilitating patient self-management (13 studies), organisational change to include collaborative care (15 studies), facilitating better case management using clinical information systems (e.g. tele-health) (15 studies), and the use of decision support and guideline implementation (e.g. referral systems) (22 studies). In addition, 5 studies explored the challenges when conducting trials in primary care e.g. the recruitment of patients.

Only 22 studies were labelled clearly as process evaluations, though this was more common in recent years. Twenty studies were conducted at the feasibility stage with five labelled as PEs, 43 studies at the effectiveness stage with 17 labelled as PEs, and six studies at the post-evaluation stage with none labelled as process evaluations. In thirty-five studies the degree of separation between the process and outcome evaluation researchers was explicit. The cost considerations for the system and stakeholders was mentioned in 10 papers (see Table 1 for more detail). In Figure 2 the context of the studies and an overview of the main methodological and implementation findings are diagrammatically presented in a PE framework.

Table 1: Summary of the characteristics of the included studies

Disease Condition	interventions	Setting	RCT Outcomes	Cost Considerations (Y/N/NA)
20 studies on depression.	Interventions mostly around collaborative care through increasing expertise of different roles (e.g. lay worker, nurse for pro-active care, GP for PHC) (16 studies), times to implement practice guidelines (4 studies), and trialling specific interventions such as physical exercise and cognitive behaviour therapy. (2 studies).	9 UK, 7 USA, 1 Sweden, 1 Germany, 1 Australia 1 India.	11 positive RCTs, 5 Negative, 4 N/A	4/19 Y, 14 N, 2 N/A
17 studies on diabetes	The interventions included improving guideline-based referral and treatment (7 studies), patient self-management, community support (7 studies) and tele-health (3 studies).	3 Ireland, 3 UK, 1 Norway, 2 USA, 2 Canada (1 of the First Nations), 2 Australia, 1 New Zealand, 1 Malaysia	6 Positive, 10 Negative, 1 N/A	3/16 Y, 13/16 N, 1/16 N/A
25 studies on CVD.	10 studies were about improving the screening and management of CVD using best-practice guidelines. (e.g. educational materials to improve referral, or decision analysis). 10 studies were about organisational change with models of care that incorporated new roles such as a nurse-led clinic, or the use of a lay worker for angina management, and technology (e.g. tele-monitoring, point of	9 UK, 6 Australia, 3 Canada, 2 New Zealand, 2 Netherlands, 1 Ireland, 1 USA, 1 Zambia	15 Positive, 5 Negative, 5 N/A	3 Y, 15 N, 6 N/A

	care testing). 5 studies explored trial implementation such as recruitment of patients and providers, and were less about the intervention.			
6 studies on COPD (2 including other chronic disease), and 1 addressing CKD.	4 studies were about improving self-management of patients through educational materials, or use of monitoring, with support from health providers. 2 studies were about stimulating physical activity through the use of technology. 1 study was about implementing management guidelines in CKD in primary health care.	3 Netherlands, 1 Ireland, 1 UK (Scotland), 1 USA, 1 Australia	2 Positive, 1 Negative, 4 N/A	0 Y, 5 N, 2 N/A.
Overall Synthesis of 69 studies in total. 20 Depression, 17 Diabetes, 25 CVD, 6 COPD and 1 CKD.	**Overall, the complex primary care interventions fit within the general categories of facilitating patient self-management (13 studies), organisational change to include collaborative care (16 studies), facilitating better case management using clinical information systems (e.g. tele-health) (15 studies), and the use of decision support and guideline implementation (e.g. referral systems) (22 studies). In addition, 5 studies were exploring the conduct of trials in primary health care e.g. the recruitment of patients.**	**22 UK, 10 Australia, 9 USA, 5 Ireland, 5 Netherlands, 3 Canada, 3 New Zealand, 1 Sweden, 1 Germany, 1 India, 1 Norway, 1 Malaysia, 1 Zambia In addition, 2 studies focused on First Nations peoples in Australia and in Canada. 3 studies were focused on the populations living in disadvantage.**	**33 Positive, 21 Negative 14 N/A**	**10 Y*, 47 N, 11 N/A**

Abbreviations: COPD: Chronic Obstructive Pulmonary Disease; CKD: Chronic Kidney Disease; CVD: Cardiovascular Disease; GP: General Practices; N: No; N/A: Not Applicable; RCT: Randomised Controlled Trial; UK: United Kingdom; USA: United States of America; Y: Yes.

* Of note two were full evaluation reports (outcome, process and economic evaluations) in the UK journal of Health Technological Assessments in addressing the question of whether an innovation with limited evidence base in a pragmatic setting (e.g. introducing cognitive behaviour therapy in schools) should be scaled up. Eight papers included descriptions of the how costs considerations such as financing incentives/ government subsidies impacted on intervention implementation.

(2) Process evaluations' strengths and limitations

Description of Intervention theory- clear intervention description and clarification of causal assumptions

Thirty papers were assessed as having clear intervention descriptions and clarification of causal assumptions, and in sixteen it was unclear because despite clear intervention descriptions, the causal assumptions were not described explicitly. An example of a paper that explicitly describes intervention theory is Grant et al who uses the Template for

Intervention Description and Replication (TIDieR) checklist to clearly describe the researchers' assumptions of the intervention's mechanism as compared to the stakeholders' perspectives. (17)

Use of existing theories and frameworks: A strength of 22 studies was the use of existing theoretical frameworks to inform their intervention development and/or evaluation. (See Table 2) Theories and frameworks used are grouped according to Nilsen's proposed categories. (18) This is depicted in Box 1, with illustrative examples from the identified studies. In essence, eleven studies used classic theory to inform the development of the intervention theory. In eight studies determinant, implementation theories and evaluation frameworks were used to assist in the synthesis and analysis of qualitative data. The authors of two studies also used their findings and implementation theories to iteratively inform their implementation strategies. The evaluation frameworks were used by study authors to comprehensively evaluate and synthesise their process evaluation data. The MRC framework for complex interventions was used to inform the approach to intervention development in three studies.

Box 1: Illustrative Examples of the use of Theories and Frameworks

Classic Theories

Theory of Planned behaviour-. "*Using the theory of planned behaviour (TPB), we hypothesised that changes in thiazide prescribing would be reflected in changes in intention, consistent with changes in attitude and subjective norm, with no change to their perceived behavioural control (PBC), and tested this alongside the RCT…*A *strength of this study is its use of a well-tested theory of behaviour operationalized according to best recommended practice to investigate the underlying mechanisms of an implementation intervention.*" (Presseau) This theory informed their process evaluation to explore if their intervention of printed educational materials increased practitioners' intention to prescribe according to recommendations in the guidelines.

Self Determination theory - "*self-determination theory which proposes that real shifts in behaviour arise through heightened autonomy or personal ownership of behavioural success*." (Chalder) This theory informed their theoretical model underpinning their intervention to improve physical activity for the management of depression.

Grounded theory- *" This qualitative study was conducted with the objective of better understanding the PP intervention in the BETTER Trial described above, including the development of the PP role, perceived barriers, facilitators, benefits and disadvantages, and of exploring the feasibility and sustainability of this approach for CDPS."* (Manca) This study used grounded theory to better understand their intervention as implemented and to retrospectively describe their intervention theory.

Diffusions of Innovation-"*Key principles, which derive from diffusion of innovations theory, include working initially with practices and clinicians that not only have an interest in the innovation and view it as compatible with their needs, values, and resources, but also have the ability to try it with minimal investment and observe its impact*." (Dietrich) The theory was used to inform their practice change strategy for the sustainability of a chronic care model for depression proven effective in an RCT.

Determinant Frameworks

PARIHS as an implementation model-"*We used the Promoting Action on Research in Health Services (PARIHS) framework as an 'Implementation model' to assist clinical partners in adopting the health-coaching intervention. The PARIHS framework posits three interrelated elements that influence successful implementation of evidence-based practices: the (I) perceived strength of the 'evidence', (ii) 'context' of the environment and (iii) 'facilitation' support created for implementation of the intervention….Using a codebook developed a priori from sub elements of the PARIHS framework "* (Naik) This study used PARIHS to inform their participatory approach between research team and primary health care teams, and also used it in evaluation of the qualitative data in assessing the building of the partnership to test and implement a health-coaching intervention.

Implementation theories

NPT- Normalisation Process Theory -"*as part of mixed-methods process evaluation, semi-structured interviews were conducted by phone with 27 providers participating in the study. Interviews were audio-taped and transcribed. Thematic content analysis was used to identify themes. Themes were categorized according to the four domains of Normalization Process Theory (NPT)".* (Vest) The authors discuss how the findings are informing their ongoing implementation strategies e.g. clinical mentors for the general practitioners who described a discomfort in their lack of expertise in screening and managing early chronic kidney disease. (other papers include: Burridge ,Coupe, Gask, Hanley, Vest)

Evaluation frameworks

MRC- Medical Research Council's framework for complex interventions,-"*The MRC framework provided a useful structure through which to examine our theoretical hypothesis and analyse the feasibility evidence*." (Sturt)
"*Guided self-help intervention was developed following a modelling phase which involved a systematic review, meta synthesis and a consensus process…"* (Lovell) The authors used the MRC framework for intervention development. Similarly Byrne et al also used the MRC framework for intervention development of literature review, focus group discussion and modelling and then interviews to refine the intervention.

REAIM- "*The process evaluation followed the RE-AIM (Reach, Efficacy/effectiveness, Adoption, Implementation and Maintenance) framework. Data were collected on attendance and attrition for classroom-based CBT and attention control PSHE by programme facilitators. An independent observer attended 5% of classroom based CBT sessions to assess treatment fidelity. Feedback was gathered from teachers, young people and facilitators using questionnaires and qualitative interviews*." (Stallard) (other papers include: Stallard, Wozniak, Lakeverld)

Realist Evaluation-
"*All data assigned to codes relating to the polypill strategy in CVD management were analysed …and the Realist framework of context–mechanism–outcomes utilized to develop the themes*" (Liu) The framework was used to guide the analysis of the qualitative data.

The use of theoretical frameworks seems to enable an in-depth investigation of stakeholders' perspectives of the perceived mechanisms of the intervention; by in a sense, providing a checklist of actions and behaviours to be examined.(19-29) An illustrative example is the PE of a trial in improving primary care referrals of patients with diabetic retinopathy to specialists through the use of educational printed materials. (29) A behavioural theory was used to inform the design and use of a questionnaire to explore the mechanism of the intervention. It was found that the primary care providers' intention to refer patients was the same before and after the trial, and this may have explained their negative trial results. The authors highlighted that the use of existing behavioural theory enhanced the '*generalisability and replicability*' of their methods.

Interaction with contextual factors: In fourteen papers the interaction of the intervention and contextual factors were explicitly explored. As mentioned above, theoretical frameworks often facilitated a closer and systematic way to consider context. For example, authors examined if there was 'contextual integration' i.e. organisational changes necessary to integrate a collaborative model of care for depression into routine practice. (30) Otherwise, contextual factors (e.g. impact of the introduction of a new policy (31)) were reported retrospectively in some papers in a more ad hoc manner- as reported implementation facilitators and barriers, or discussed as possible influences on the outcomes.

Methods used

Most authors clearly justified the choice of their methods and clearly stated the studies' purpose. The methods could be categorised as: qualitative studies (e.g. interviews, focus group discussions, documentary analysis), quantitative (e.g. processes of care, baseline demographics, secondary outcomes) and studies which presented the synthesis of qualitative and quantitative data sources to indicate implementation, acceptability, fidelity and reach. Most of the qualitative studies were of reasonable quality as assessed by the consolidated criteria of reporting of qualitative research (COREQ). (See Table 2 and Appendix 3 for more detail.)

Table 2: Summary of the methodology used and quality assessment of the studies

Stage of process evaluation	Methodology & Methods	Analysis	Quality criteria
Feasibility/ Piloting 20 Studies	9 studies used theories or frameworks. 18 used interviews. 3 used focus group discussions, 4 used questionnaires or surveys, 2 studies used routine monitoring data, field notes, minutes of meetings and observations.	Thematic analysis, constant comparative approach most commonly used, with some using framework analysis.	Planning: Team description: 11Y, 6N, 3 N/A Design and Conduct: Purpose: 20 Y Intervention description and causal assumptions clarified: 5 Y , 6 unclear, 9 N/A, 0 N Justify choice of timing and methods: 19Y, 1 N COREQ covered out of the 3 domains (17 applicable studies): 3 domains: 11 2 domains: 4 1 domain: 3 Reporting Clearly labelled as process evaluations: 5 Protocol/full report: 8
Evaluation of effectiveness 43 studies	12 studies used existing theories and frameworks. (6 Classic theories, 3 evaluation frameworks, 3 implementation theories) 2000-2004: 3 studies documented specific processes of care as part of the process evaluation, which were reported as part of the main trial. 4 studies investigated acceptability of an intervention using surveys/questionnaires. 2005 onwards- 12 studies used interviews alone to explore implementation and acceptability; 20 studies used interviews triangulated with other sources of data (e.g. chart audit). 2 studies used routine administrative data to indicate fidelity. 3 studies used questionnaires or surveys.	Descriptive statistics were used for the quantitative data. Thematic, constant comparison and framework analysis for the qualitative data. The studies that used mixed methods, used the quantitative data to indicate level of implementation, reach and the dose. This was used to triangulate the qualitative findings on implementation and intervention acceptability. The studies which used evaluation frameworks (e.g. REAIM) and implementation theories (e.g. NPT) used them for the analysis and presentation.	Planning: Team description: 21 Y, 21 N, 1 NA Design and Conduct: Purpose: 43 Intervention description and causal assumptions clarified: 25 Y, 8 Unclear, 5N/A, 5N Justify choice of timing and methods:40Y, 1 N, 2NA Report whether the process data are analysed blind to trial outcomes/ or post hoc: 29Y, 7N, 7N/A COREQ covered out of the 3 domains (30 applicable studies): 3 domains: 12 2 domains: 13 1 domain: 5 Reporting Clearly labelled as process evaluations: 17 (of note- 2 before 2008, 6 till 2015, and 9 after 2015) Protocol/full report: 21
Post evaluation 6 studies	1 study used existing theory. 2 studies used interviews, 2 used documentary analysis, and 1 used the administrative data and registry data	Descriptive statistics, subgroup analysis and thematic analysis.	Planning: Team description: 3 Y, 2 N, 1 NA Design and Conduct: Purpose: 6 Intervention description and causal assumptions clarified:0Y, 2 unclear, 2 N/A, 2 N Justify choice of timing and methods: 5Y, 1 N COREQ covered out of the 3 domains (3 applicable studies): 3 domains: 1 2 domains: 1 1 domain: 1 Reporting Clearly labelled: 0 Protocol/full report: 1

A strength of some studies was the triangulation of quantitative indicators with the qualitative findings of the acceptability and implementation of the intervention to determine intervention fidelity (i.e. whether the intervention was delivered per protocol). (See Appendix 2 for more detail.) (32, 33) The data sources indicating intervention fidelity included routine administrative data, trial/study management logs (22) and trial secondary outcomes. (34-36) Innovative indicators of e-health interventions included recording process measures such as time logged on by participants. (37) Other methods to determine intervention fidelity across multiple sites was having independent expert assessors reviewing intervention delivery using standardised forms. Three studies investigated 'for whom' an intervention had an impact on with the use of logistical regression of baseline demographics to identify relationships of the participants' characteristics with the primary or secondary outcomes. (38)

Sampling limitations in the qualitative studies were described as potentially introducing bias in the findings about intervention acceptability/mechanisms. (19, 20, 24-26, 29, 39-43) For example, authors highlighted that respondents who having agreed to be interviewed may have a more favourable opinion of the intervention. (19, 39, 44-46) Maximum variation sampling (types of participants, socio-demographics, by 'negative' baseline of outcome characteristics'), comparing the characteristics of participants who did not partake in the interviews/surveys with the participants who did and triangulation with other data sources may increase the robustness of such findings. (20, 21, 23, 29, 39, 40, 47)

(3) Process evaluation findings under mechanisms, implementation and context

Does the intervention fit local needs?

Stakeholders were generally motivated to adopt/implement the complex intervention if it addressed the contextual gap in care i.e. intervention fit. For example, a nurse-led secondary prevention clinic was implemented effectively when the health providers perceived it as improving team work, care continuity and providing a 'safety net' for the patients. In contrast, at other sites, this intervention was poorly implemented by the health care providers who viewed it as duplicating the existing model of care. (48) As another example, general practitioners reported that training them to manage acute and discrete episodes of depression, did not improve their management of depression. This was because

this training did not upskill them for the chronic and relapsing nature of depression associated with personality and social problems increasingly seen in primary care. (42, 49) Similarly, patients' health literacy about their chronic disease (e.g. effectiveness of lifestyle modification for diabetes) was crucial as it affected engagement with the primary health care services, and their uptake of the intervention. (23, 26, 50-52)

Do key actors believe in and adopt their 'assigned' roles and responsibilities?

The extent to which key actors believed in and adopted their 'assigned' roles and responsibilities as part of implementing the complex intervention was a key theme under the heading 'Implementation.' (22, 27, 28, 43, 44, 49, 53) For example, in a study which used tele-monitoring to improve management of COPD patients in the community- there were differing views of the role of the patient. Some health providers described concerns that tele-monitoring would reinforce the 'sick role' of the patient, and an over-reliance on technology and practitioner support; and as such were less willing to implement this model of care. On the other hand, some patients described that tele-monitoring was empowering as it provided knowledge and increased access to health practitioners who could provide reassurance in the management of the disease- and were keen to continue this model of care.(23)

Facilitators to improve key actors' uptake of the interventions included the provision of intense training over a transition period prior to the start of the trial, significant research support, and ongoing communication with the researchers to help identify key actor's concerns and tailor implementation strategies to address them. For example, implementation strategies to ensure adequate communication between nurse practitioners and general practitioners were essential in task-shifting models of care. This facilitated greater trust between nurse practitioners and doctors which was needed to effectively deliver collaborative services. (43, 53) Such strategies were especially relevant for collaborative care interventions where new tasks were introduced within established hierarchical systems and interaction between different stakeholders was necessary for effective implementation.

Is the context of the intervention conducive?

Health system structures such as governance, health financing structures and workforce, were often mentioned as impacting on intervention implementation. Governance structures was pivotal to the successful adoption of the intervention (24, 34). For example, an intervention to enhance referrals to mental health services was implemented well at a site when it was perceived as 'service delivery' and directly supported by the mental health trust. In comparison, uptake of the intervention was limited when the intervention was not viewed as 'service delivery' and was considered 'primary research'. (34) Similarly, cultivating a strong partnership between researchers and clinicians through the formation of clinical advisory teams facilitated the intervention implementation in bureaucratic and geographically complex environments. (24) A limited workforce and equipment shortages, and inadequate funding structures were reported by several authors as barriers to the adoption of the intervention. For example, health providers stated that the lack of government reimbursement for allied health services reduced the acceptability of the tele-health model of care for ongoing monitoring of diabetes at home. (40) General practitioners reported that time constraints in their busy practices prevented them from using the skills they learnt through an educational intervention to better manage depression. (42) Likewise, macro level context such as medication being out of stock in rural Zambia, was a barrier to the better outcomes, in spite of an evidence-based intervention to improve clinical assessment and management. (33)

Importantly, an iterative collaborative approach was described as a facilitator of intervention fit. (19, 37, 46, 51, 52, 54, 55). For example, study authors described how early stakeholder involvement identified the key characteristics of the lay worker needed (i.e. female, with visibility in the community) for their intervention to improve mental health care in India. This preparatory phase in the development of their model of care led to a definitive RCT with positive outcomes. In their process evaluation of the RCT- they found that the provision of a lay worker was not relevant for the private primary care practitioners with established therapeutic relationships with their patients, but more so for the public health providers who were time poor. These findings would then inform future scale up of the intervention within the right context (i.e. public health system) for the intervention. (54, 56)

Discussion

Statement of principal findings

To our knowledge this is the first systematic appraisal using MRC guidance on process evaluations of primary care interventions. 66 of 69 studies were conducted in high-income countries; whilst cardiovascular disease, diabetes and depression were the most frequently studied conditions. There was an overall lack of consistency in the way PEs were conducted and reported. Indeed there was a lack of consistency in nomenclature with only 47 of the 69 studies identifying as 'process evaluations' although their purpose were essentially as such. Few studies (n=30) were underpinned by an intervention theory- description of hypothesised intervention mechanisms of action within local contextual factors. Most studies used robust sampling strategies and frequently triangulated qualitative and quantitative data to better understand the mechanisms of implementation. The MRC PE guidance with its focus on the interaction/configuration between context, implementation and mechanisms of intervention, provided a useful framework for the synthesis of the findings. The findings of these studies can be synthesised into a number of key messages: 1) that often there was a fundamental mismatch between what the intervention was designed to achieve and local needs, 2) that the roles and responsibilities of key actors required to implement the intervention were often not clearly understood and; 3) that health system context – factors such as governance, financing structures and workforce – were often critical to implementation and as a consequence there were a number of studies where the unanticipated influence of these adversely impacted on implementation.

Comparison to other literature and implications

A key finding is identifying the breadth of literature which fits the MRC definition of process evaluation. This highlights the growing scope in this field to potentially address the evidence to practice gap through greater understanding of the interactions between intervention mechanisms, context and implementation. (13, 57, 58) However, greater consistency is needed in the reporting of PEs – as this would facilitate evidence synthesis, prevent research duplication and enhance transferability of interventions to other settings. (59) We note that the consistency in reporting seems to have increased since the publication of the MRC guidance.

An important finding is that theoretical frameworks helped guide a more in-depth development of intervention theory, design and implementation. (13, 60) The MRC PE guidance suggests that PE can help to explain the outcomes variations, and by doing so help refine the intervention theory. (18) We note that given the growing focus on self–management for chronic diseases, that the theories around behavioural change (e.g. empowerment) were most commonly used. Secondly, the focus on organisational change and the adoption of guidelines in NCDs, meant that implementation theories such as Normalisation Process Theory (NPT) were particularly relevant. Thus, there should be more consistent use of theoretical frameworks, recognising that different frameworks will be applicable to different settings. In addition, the use of checklists such as the Template for Intervention Description and Replication (TIDieR), or the Standardised for Reporting Implementation (StaRI) will ensure consistency in the reporting of intervention theory and implementation, thus reducing research waste. (57, 61, 62)

We found that the intervention interaction with dynamic contextual factors was often inconsistently reported or reported retrospectively in an ad hoc manner. This gap has been similarly reported in the literature. (63)These findings emphasis MRC PE guidance's value in explicitly appraising context through "*examining factors that shape theories, and affect implementation, and act to 'sustain the status quo, or potentiate effects*." (4) However, this guidance is relatively broad and non-specific, and the question remains as to what should be explored a priori, and how best to report such findings. For example, the Context and Implementation of Complex Interventions (CICI) framework highlights seven domains of context ("*geographical, epidemiological, socio-cultural, socio-economic, ethical, legal and political context"*) that could be examined.(57) Similarly, STaRI checklist has context as an item in the methods (*i.e. "consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere"*) and in the results ("*contextual changes (if any) which may have affected outcomes"*.)(61) These domains are comprehensive, and as a consequence if a study is to examine only a subset of these factors, it is better that it this is pre-specified in full acknowledgment of the evaluation as a whole. This should be consistently reported, and linked through a full report or reference to a protocol. (4) As a baseline, a standardised PHC template informed by the questions of "*Does the intervention fit local needs? Do the key actors believe in and adopt their 'assigned' roles*

and responsibilities? Is the health system context (looking specifically at health workforce, governance, health financing structures and availability of medications) conducive?" and relevant implementation theories (e.g. NPT) could be presented for testing in a systematic way. This could be done by primary health care researchers engaging with stakeholders at various time points, and iteratively added to. (64-66) Such an approach could potentially facilitate a greater shared understanding between stakeholders and greater consistently in the reporting of context. (63, 65, 67-69)

Most of these studies were conducted in high income countries with established PHC systems and universal health coverage (e.g. National Health Service in the UK). Therefore, some primary care interventions (e.g. improving referrals in collaborative care) may be of limited relevance to LMIC PHC systems given the different context especially with regards to health system structures. (70, 71) This reinforces the need for more formative research with local stakeholders when developing evidence-based interventions which addresses local needs, and minimises the unanticipated consequences of health system factors. (72, 73)

Strengths and limitations of this study

We were unable to conduct a subgroup analysis of implementation findings by country context (i.e. of high income countries as compared to lower middle income countries)as we identified studies conducted mainly in high income countries. Some studies conducted in LMIC initially identified in the search were excluded because they did not meet our criteria (not RCTs, not on NCDs) and as such, a review with different inclusion criteria may be better suited for this secondary objective. Another limitation, is that we appraised the studies using a tool which we developed based on the MRC guidance (4), which has not been tested elsewhere. This was challenging given the heterogeneous studies that were included. For example, we only assessed qualitative methods with COREQ, and did not appraise the quality of statistical methods such as modelling. A strength of this review is having a multidisciplinary team of authors with vast experience in clinical trials and process evaluations to enable a reflexive thematic synthesis and interpretation of the papers. (74)

Conclusion

Greater consistency is needed in the reporting of, and the methods used, in PEs. In particular there should be more consistent use of theoretical frameworks to inform intervention theory; and the triangulation of qualitative and quantitative data. Greater emphasis on formative research in designing primary care interventions is needed so that they are clearly aligned with the needs of local stakeholders, that the roles and responsibilities of key actors are better understood and that unanticipated consequences arising from context-specific barriers to implementation are minimised. We hope this review will inform future process evaluations and facilitate the sustainability of evidence-based interventions.

Declarations

Abbreviations:

MRC: Medical Research Council

PE: Process Evaluations

NPT: Normalisation Process Theory

NCD: Non-communicable diseases

LMIC: Low and middle income countries

PHC: Primary health care

RCT: Randomised Controlled Trials

TIDieR: Template for Intervention Description and Replication

COPD: Chronic Obstructive Pulmonary Disease

COREQ: consolidated criteria of reporting of qualitative research

STaRI: Standardised for Reporting Implementation

CICI: Context and Implementation of Complex Interventions

Original protocol: This has been published in an open access journal and is referenced in the manuscript.

Ethical Approval and Consent to participate : not applicable

Competing interests: The authors declare that they have no competing interests.

Authors' contributions: HL and SJ concieved the idea for a systematic review of process evaluations. DP, SJ and MH provided guidance to HL in the development of the protocol. AM, JM, and MN assisted with the selection of papers, data extraction and analysis. TL assisted with the adjudication of the papers. HL drafted the manuscript and all authors contributed to the revisions of the manuscript and approved the final manuscript.

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Figures and Tables

Figure 1: PRISMA figure

Figure 2: MRC PE framework with tallies of studies, methods and synthesised findings.

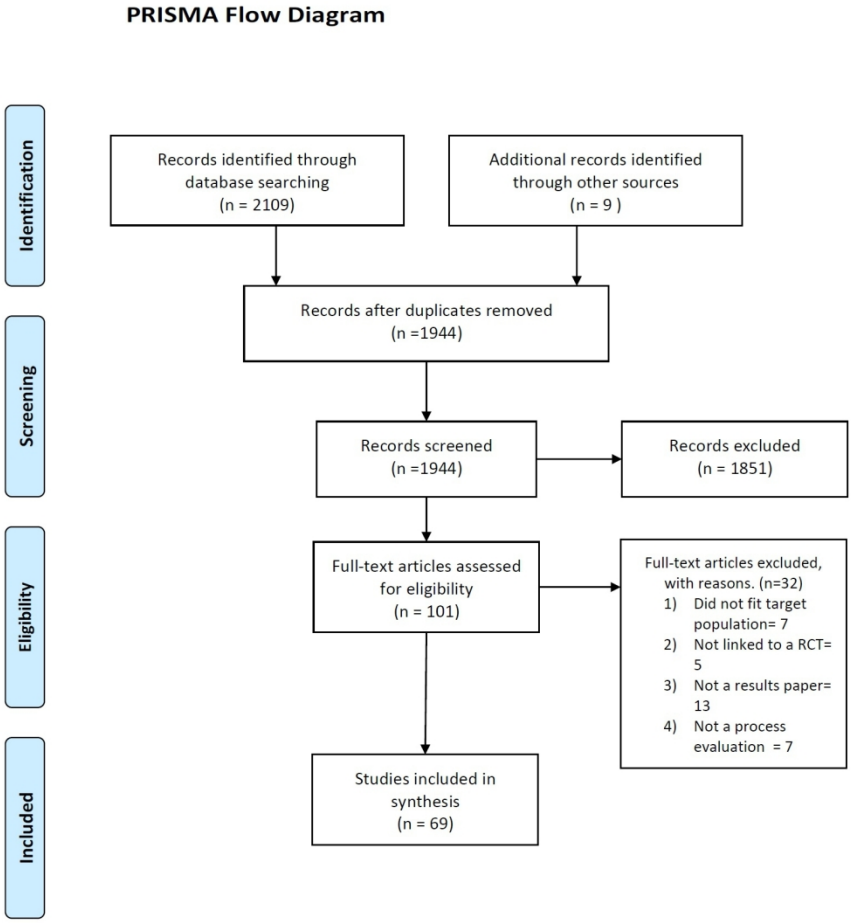
Box 1: Illustrative examples of the use of Theories and Frameworks (embedded in the main text)

Table 1: Summary of the characteristics of the included studies (embedded in the main text)

Table 2: Summary of the methodology used and quality assessment of the studies (embedded in the main text)

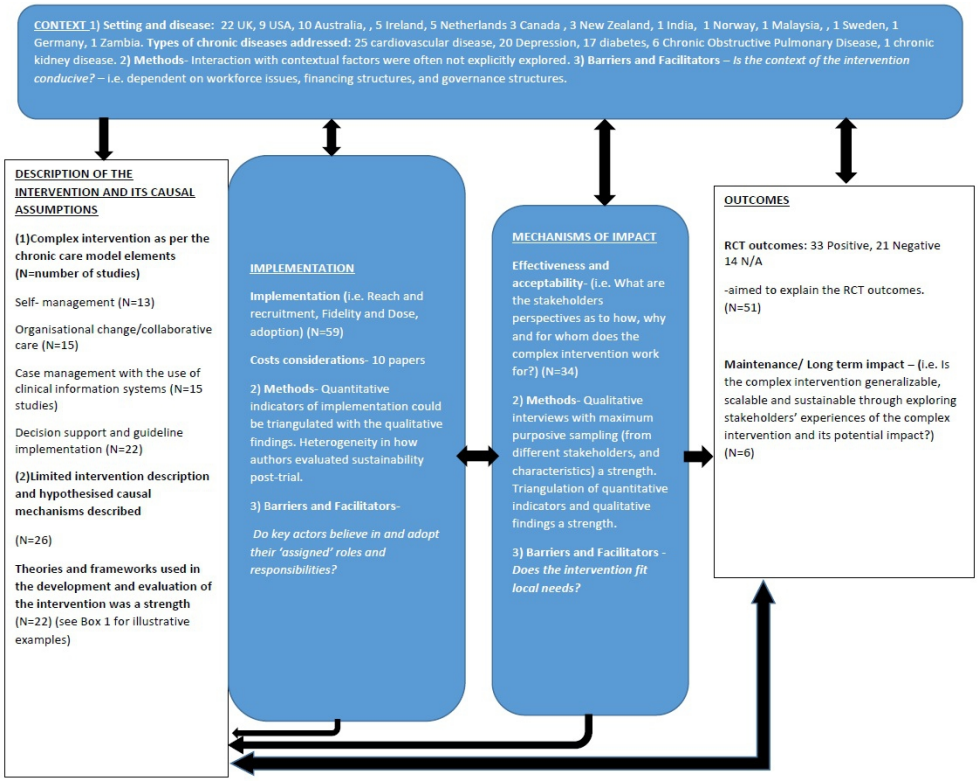
APPENDIXES

1) Table 1- PICO table (organised into sections based on the types of NCDs, and within each section, studies are ordered by years)
2) Table 2- Methods table, organised into sections based on stage of process evaluation, and within each section, ordered by years)
3) Table 3- Quality of studies table as informed by the MRC recommendations and the COREQ
4) Table 4- Illustrative examples for the synthesised findings
5) Research checklist: PRISMA Statement



PRISMA Flow Diagram showing the searching, screening and identification of papers

479x507mm (96 x 96 DPI)



An overview of our findings is depicted in this MRC process evaluation framework which the depicts the interactions between areas of the process evaluation in blue (i.e. the context, mechanisms, implementation) and how that interacts to produce outcomes (in white) which is used to inform and refine the hypothesised intervention theory. The intervention theory is described in the text box. Tallies of studies, methods and synthesised qualitative findings of strengths and limitations, implementation barriers and facilitators are summarised in this modified diagram.

303x235mm (96 x 96 DPI)

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Author	Title	Year	Setting	Disease Condition	RCT Outcomes	Cost Considerations (Y/N/NA)
1. Gask L, Ludman E, Scaefer J.	Qualitative study of an intervention for depression among patients with diabetes: how can we optimise patient-professional interaction	2006	Primary health care, Manchester UK	Depression and Diabetes	Positive	N
2. Chew-Graham CA, Lovell K, Roberts C, Baldwin R, Morley M, Burns A, et al	A randomised controlled trial test the feasibility of a collaborative care model for the management of depression in older people	2007	Primary Care trust, Manchester	Depression	Positive	N
3. Lovell K, Bower P, Richards D, Barkham M, Sibbald B, Roberts C, et al	Developing guided self-help for depression using the Medical Research Council complex interventions framework: A description of the modelling phase and results of an exploratory randomised controlled trial	2008	Primary care Units England. United Kingdom	Depression	Negative	N
4. Slade M, Gask L, Leese M, McCrone P, Montana C, Powell R, Stewart M, Graham-Chew C	Failure to improve appropriateness of referrals to adult community mental health services—lessons from a multi-site cluster randomized controlled trial	2008	General Practice, Community Services. London & Manchester, United Kingdom	Depression (Mental Health)	negative	Y
5. Gask L, Bower P, Lovell K, Escott D, Archer J, Gilbody S, Lankshear A, Simpson AE, Richards DA.	What work has to be done to implement collaborative care for depression? Process evaluation of a trial utilizing the Normalisational Process Model	2010	Primary health care, UK	Depression	NA	N
6. Chalder M, Wiles NJ, Campbell J, Hollinghurst SP, Searle A, Haase AM, et al	A pragmatic randomised controlled trial to evaluate the cost-effectiveness of a physical activity intervention as a treatment for depression: The treating depression with physical activity (TREAD) trial	2012	General practices in the Bristol and Exeter areas, United Kingdom	Depression	Negative	Y
7. Bennett M, Walters K, Drennan V, Buszewicz M	Structured Pro-Active Care for Chronic Depression by Practice Nurses in Primary Care: A Qualitative Evaluation	2013	General Practice. United Kingdom	Depression	Positive	N
8. Stallard P, Phillips R, Montgomery AA, Spears M, Anderson R, Taylor J, et al	A cluster randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents	2013	Schools. United Kingdom	Depression	Negative	Y
9. Coupe N, Anderson E, Gask L, Sykes P, Richards DA, Chew-Graham C	Facilitating professional liaison in collaborative care for depression in UK primary care; A qualitative study utilising normalisation process theory	2014	Primary care GP. Bristol, London, and greater Manchester. United Kingdom	Depression	Positive	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Synthesis (depression in UK)	Types of intervention: collaborative care models, introducing CBT in schools, introduction of physical activity,	9 studies in UK looking at depression between 2006-2014)			4 positive RCTs, 4 negative and 1 NA.	3/9 studies for costs analysis.
10. Oishi SM, Shoai R, Katon W, Callahan C, Unutzer J, Arean P, et al	Impacting late life depression: Integrating a depression intervention into primary care	2003	Primary care Practices. United States	Depression	NA (not complete)	N
11. Dietrich AJ, Oxman TE, Williams JW, Kroenke K, Schulberg HC, Bruce M, et al	Going to scale: Re-engineering systems for primary care treatment of depression	2004	5 Medical groups and health plans in the USA, with 60 practices participating	Depression	Positive	NA
12. Gask L, Dixon C, May C, Dowrick C	Qualitative study of an educational intervention for GPs in the assessment and management of depression	2005	Group Health Clinics. Western Washington. USA	Depression	Negative	N
13. Lee PW, Dietrich AJ, Oxman TE, Williams Jr JW, Barry SL	Sustainable impact of a primary care depression intervention	2007	Health care organisations. USA	Depression	Positive	N
14. Chung B, Jones L, Dixon EL, Miranda J, Wells K, Community Partners in Care Steering Council	Using a Community Partner Participatory Research Approach to Implement a Randomised Controlled Trial: Planning Community Partners in Care	2010	USA (community multi agencies for minority groups)	Depression	NA	N
15. Chaney EF, Rubenstein LV, Liu CF, Yano EM, Bolkan C, Lee M, et al	Implementing collaborative care for depression treatment in primary care: A cluster randomized evaluation of a quality improvement practice redesign	2011	Primary care settings, Veteran affairs in several states USA	Depression	Positive	Y
16. Rapp AM, Chavira DA, Sugar CA, Asarnow JR	Integrated Primary Medical-Behavioral Health Care for Adoolescent and Young Adult Depression: Predictors of Service Use in Youth Partners in Care Trial.	2017	Primary Health Care USA	Depression	Positive	N
Synthesis (depression in USA)	All 7 studies were a version of collaborative care models either between primary and tertiary care, or increasing the outreach through settings outside of health.	7 studies in USA looking at depression.			4 positive, 2 NA and 1 negative	1Y, 4 N, 1 NA
17. Thornett AM, Mynors-Wallis LM	Credibility of problem-solving therapy and medication for the treatment of depression among primary care patients	2002	Primary Care setting, South Australia	Depression	Positive	NA
18. Gensichen J, Guethlin C, Sarmand N, Sivakumaran D,	Patients' perspectives on depression case management in general practice - A qualitative study	2012	General Practices. Germany	Depression	Positive	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Jager C, Mergenthal K, et al						
19. Chatterjee S, Chowdhary N, Pednekar S, Cohen A, Andrew G, Araya R, et al	Integrating evidence-based treatments for common mental disorders in routine primary care: Feasibility and acceptability of the MANAS intervention in Goa, India	2008	Primary Health care, Goa, India	Depression	Positive	N
20. Richter-Sundberg L, Nystrom ME, Krakau I, Sandahl C	Improving treatment of depression in primary health care: A case study of obstacles to perform a clinical trial designed to implement practice guidelines	2015	Primary Health care Units. Sweden	Depression	NA	N
Synthesis (depression)	**Interventions mostly around collaborative care through increasing expertise of different roles (e.g. lay worker, nurse for pro-active care, GP for PHC) (15 studies), at times to implement practice guidelines (4 studies), and trialling specific interventions such as physical exercise and CBT (2 studies).**	**2003-2015**	**9 were in UK, 6 in USA, and 1 Sweden, 1 Germany, 1 Australia and 1 in India.**	**Overall 19 studies in depression**	**10 positive RCTs, 5 Negative, 4 NA**	**4/19 Y, 13 N, 2 NA**
1. Tai SS, Nazareth I, Donegan C, Haines A	Evaluation of general practice computer templates. Lessons from a pilot randomised controlled trial	1999	North London. United Kingdom	Diabetes and asthma)	Positive	N
2. Hetlevik I, Holmen J, Kruger O, Kristebsen P, Iversen H, Furuseth K	Implementing Clinical guidelines in the treatment of Diabetes Mellitus in General Practice	2000	Norway	Diabetes Mellitus	Negative	N
3. Ilag LL, Martin CL, Tabaei BP, Isaman DJ, Burke R, Greene DA, et al	Improving diabetes processes of care in managed care	2003	United States, nine university- affiliated primary care internal medicine practices affiliated with a managed care organisation.	Diabetes	Negative on main outcome measures but positive on process outcomes	N
4. Smith S, Bury G, O'Leary M, Shannon W, Tynan A, Staines A, Thompson C	The North Dublin randomized controlled trial of structured diabetes shared care	2004	Ireland	Diabetes	Neutral	N
5. Jackie Sturt, Hafrun Taylor, Andrea Docherty, Jeremy Dale, Taylor Louise	A psychological approach to providing self-management education for people with type 2 diabetes: the Diabetes Manual	2006	Primary health care UK	Diabetes	NA	NA
6. Pylypchuk G, Vincent L, Wentworth J, Kiss A, Perkins N, Hartman S, et al	Diabetes risk evaluation and microalbuminuria (DREAM) studies: Ten years of participatory research with a First Nation's home and community model for type 2 diabetes care in northern Saskatchewan	2008	First Nations, Northern Saskatchewan, Canada	Diabetes type 2	not significantly positive	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

7. Smith S, Paul G, Kelly A, Whitford D, O'Shea E, O'Dowd T	Peer support for patients with type 2 diabetes: Cluster randomised controlled trial	2011	General Practice. Ireland	Type 2 Diabetes mellitus	Equivalent	Y
8. Ratanawongsa N, Bhandari VK, Handley M, Rundall T, Hammer H, Schillinger D	Primary care provider perceptions of the effectiveness of two self-management support programs for vulnerable patients with diabetes	2012	Community health network. San Francisco	Type 2 Diabetes mellitus	Positive	N
9. Lakerveld J, Bot S, Chinapaw M, van Tulder M, Kingo L, Nijpels G	Process evaluation of a lifestyle intervention to prevent diabetes and cardiovascular diseases in primary care	2012	Semi-rural region of West Friesland	Type 2 diabetes mellitus	Negative	Y(economic evaluations done separately)
10. Paul G, Keogh K, D'Eath M, Smith SM	Implementing a peer-support intervention for people with type 2 diabetes: A qualitative study	2013	General Practices, Ireland	Type 2 Diabetes mellitus	positive	N
11. Carlisle K, Warren R	A qualitative case study of tele-health for in-home monitoring to support the management of type 2 diabetes	2013	Queensland. Australia	type 2 diabetes	Positive	N
12. Grimshaw JM, Presseau J, Tetreo Jm , Eccles MP, Francis JJ, Godin G, Graham ID, Hux, JE, Johnston M, Legare F, Lemyre L, Robinson N, Zwarenstein M.	Looking inside the black box: results of a theory-based process evaluation exploring the results of a randomized controlled trial of printed educational messages to increase primary care physicians' diabetic retinopathy referrals	2014	Primary care setting, Ontario, Canada	Diabetes leading to retinopathy)	Negative	N
13. Burridge LH, Foster MM, Donald M, Zhang J, Russell AW, Jackson CL	Making sense of change: patients' views of diabetes and GP-led integrated diabetes care	2014	Primary Care, Brisbane. Australia	Type 2 Diabetes	NA	N
14. Naik AD, Lawrence B, Kiefer L, Ramos K, Utech A, Masozera N, et al	Building a primary care/research partnership: lessons learned from a tele-health intervention for diabetes and depression	2015	Primary care teams Veterans affair Medical centre in Southern USA	Depression & uncontrolled diabetes	not stated in paper	N
15. Eborall HC, Dallosso HM, McNicol S, Speight J, Khunti K, Davies MJ, et al	Explaining engagement in self-monitoring among participants of the DESMOND self-monitoring trial: A qualitative interview study	2015	Primary care trust, United Kingdom	type 2 diabetes mellitus	Positive	N
16. Ramadas A, Chan C, Oldenburg B, Hussien Z, Quek K	A Web-Based Dietary Intervention for People with Type 2 Diabetes: Development, Implementation, and Evaluation	2015	In the community, recruited from outpatient medical clinics of public hospitals Kuala Lumpur. Malaysia	Type 2 Diabetes Mellitus	Positive	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

17. Kenealy TW, Parsons MJG, Rouse PB, Doughty RN, Sheridan NF, Hindmarsh JKH, Masson SC, Rea HH.	Tele-care for Diabetes, CHF or COPD; Effect on Quality of Life, Hospital Use and Costs. A Randomised Controlled Trial and Qualitative Evaluation	2015	New Zealand	Diabetes, Chronic Heart Failure, COPD	Neutral	Y
Synthesis (diabetes)	**The interventions included improving guidelines referral and treatment (7 studies), patient self-management and community support (7 studies) and tele-health (3 studies).**	**1999-2016**	**3 Ireland, 1 Norway, 2 USA, 2 Canada (1 of the First Nations), 3 UK, 2 Australia, 1 New Zealand, 1 Malaysia**	**17 studies on diabetes (2 included other chronic disease)**	**6 Positive, 10 Negative/Neutral, 1 N/A**	**3/16 Y, 13/16 N, 1/16 NA**
1. Pearl A, Wright S, Gamble G, Doughty R, Sharpe N	Randomised trials in general practice--a New Zealand experience in recruitment	2003	General Practices .New Zealand	Heart failure	Positive	NA
2. Lobo CM, Euser L, Kamp J, Frijling BD, Severens JL, Hulscher MEJL, et al	Process evaluation of a multifaceted intervention to improve cardiovascular disease prevention in general practice	2003	General Practices, Netherlands	Cardiovascular Disease	Positive	Y
3. Weiss MC, Montgomery AA, Fahey T, Peters TJ	Decision analysis for newly diagnosed hypertensive patients: a qualitative investigation	2004	General Practice. South West-England. United Kingdom	Hypertension	Positive	N
4. Murchie P, Campbell NC, Ritchie LD, Thain J	Running nurse-led secondary prevention clinics for coronary heart disease in primary care: Qualitative study of health professionals' perspectives	2005	North East Scotland, UK	Cardiovascular Disease (Coronary Heart Disease)	Positive	N
5. Byrne M, Cupples ME, Smith SM, Leathem C, Corrigan M, Byrne MC, et al	Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK Medical Research Council framework	2006	General Practices Urban & Rural Settings The island of Ireland, where 2 different healthcare systems exist. In the north, in line with Britain, the National Health Service allows everyone free access to general practice and hospital services. In the south, a mixed public and private healthcare system operates, with less than 30% of the population qualifying for free general practice and hospital services.	Cardiovascular disease	Positive	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

6.	Heaven, B, Murtagh, M. Rapley, T.May, C., raham, R. Kaner, E., Thomson, R.	Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention	2006	GP clinics in UK	CVD (AF patients at risk for a stroke)	NA	NA
7.	Clark RA, Yallop JJ, Piterman L, Croucher J, Tonkin A, Stewart S, et al	Adherence, adaptation and acceptance of elderly chronic heart failure patients to receiving healthcare via telephone-monitoring	2007	General Physicians, Rural Australia	Cardiovascular disease	Positive	N
8.	Fakiri FE, Hows MW, Uitewaal PJM, Frenken RA, Bruijnzeels MA.	Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in general practices in deprived neighbourhoods	2008	General practices in deprived neighbourhoods, United Kingdom	Cardiovascular disease	Negative	N
9.	Wentzlaff DM, Carter BL, Ardery G, Franciscus CL, Doucette WR, Chrischilles EA, et al	Sustained Blood Pressure Control Following Discontinuation of a Pharmacist Intervention	2011	Iowa. United States of America	Hypertension	positive	N
10.	Passey ME, Laws RA, Jayasinghe UW, Fanaian M, McKenzie S, Powell-Davies G, et al	Predictors of primary care referrals to a vascular disease prevention lifestyle program among participants in a cluster randomised trial	2012	2 Rural 3 urban Division of General practice in New South Wales. Australia	Cardiovascular disease	Positive	N
11.	Nelson P, Cox H, Furze G, Lewin RJP, Morton V, Norris H, et al	Participants' experiences of care during a randomized controlled trial comparing a lay-facilitated angina management programme with usual care: a qualitative study using focus groups	2013	District General Hospital, North England. United Kingdom	Cardiovascular disease (Angina)	Positive	NA
12.	Fairbrother, Peter McCloughan, Lucy Adam, Geraldine Brand, Richard Brown, Cecil Watson, Mary Cotter, Nicola Mackellaig, Juliet McKinstry, Brian	Involving patients in clinical research: The Telescot patient panel	2013	Primary health care Scotland, UK	CVD (Stroke)	NA	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

13. Hanley, J.Ure, J.Pagliari, C. Sheikh, A.McKinstry, B.	Experiences of patients and professionals participating in the HITS home blood pressure tele-monitoring trial: A qualitative study	2013	Primary health care in Edinburgh, UK	CVD with Hypertension as the major risk factor	Positive	N
14. Laws, R. A, Fanaian, M, Jayasinghe, U. W.McKenzie, S. Passey, M.Davies, G. P.Lyle, D. Harris, M. F	Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial	2013	Urban and rural PHC in Australia	CVD prevention	positive (changes in self- reported physical behaviours, but only those referred to life style modification program achieved improvement in diet or weight.	N
15. Manca DP, Greiver M, Carroll JC, Salvalaggio G, Cave A, Rogers J, et al	Finding a BETTER way: A qualitative study exploring the prevention practitioner intervention to improve chronic disease prevention and screening in family practice	2014	Primary care, Canada (urban setting)	Chronic disease- diabetes and heart disease (among others)	positive	N
16. Liu H, Massi L, Laba TL, Peiris D, Usherwood T, Patel A, Cass A, Eades AM, Redfern J, Hayman N, Howard K, Brien JA, Jan S.	Patients' and Providers' Perspectives of a Polypill Strategy to Improve Cardiovascular Prevention in Australian Primary Health Care: A Qualitative Study Set Within a Pragmatic Randomized, Controlled Trial.	2015	Australia PHC	CVD	Positive	Y
17. Liu H, Laba T, Massi L, Jan S, Usherwood T, Patel A, Hayman N, Cass A, Eades A, Peiris D.	Facilitators and barriers to implementation of a pragmatic clinical trial in Aboriginal health services.	2015	Australia PHC	CVD	NA	NA
18. Liu H, Massi L, Eades AM, Howard K, Peiris D, Redfern J, Usherwood T, Cass A, Patel A, Jan S, Laba T.	Implementing a pragmatic randomised controlled trial in Australia: lessons learnt from the Kanyini Guidelines Adherence with the Polypill study (Kanyini GAP)	2015	Australia PHC	CVD	NA	NA
19. Huntink E, Wensing M, Timmers IM, Lieshout JV	Process evaluation of a tailored intervention programme of cardiovascular risk management in general practices	2016	Netherlands	Cardiovascular risk management (high cardiovascular risk, and depressive symptoms)	Negative	N
20. Parsons, J. A. Yu, C. H. Y. Baker, N. A.	Practice doesn't always make perfect: A qualitative study explaining why a trial of an educational toolkit did not improve quality of care	2016	General Practices in Ontario, Canada	CVD prevention	Negative (possible harms)	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

	Mamdani, M. M. Bhattacharyya, O. Zwarenstein, M. Shah, B. R.						
21.	Presseau J, Grimshaw J, Tetroe JM, Eccles MP, Francis JJ, Godin G, Graham ID, Hux JE, Johnston M, Legare F, Lemyre L, Robinson N, Zwarenstein M.	A theory-based process evaluation alongside a randomised controlled trial of printed educational messages to increase primary care physician's prescription of thiazide diuretics for hypertension	2016	Ontario, Canada	Cardiovascular disease management (prescription of thiazide for hypertension)	Negative	N
22.	Yan LD, Chirwa C, Chi BH, Bosomprah S, Sindano N, Mwanza M, Musatwe D, Mulenga M, Chilengi R.	Hypertension management in rural primary care facilities in Zambia: a mixed methods study	2017	Rural Zambian clinics	Hypertension	NA (ongoing trial)	NA
23.	Wells S, Rafter N, Kenealy T, Herd, Geoff, Eggleton K, Lightfoot R, Arcus K, Wadham A, Jiang Y, Bullen C.	The impact of a point of care testing device on CVD risk assessment completion in New Zealand primary-care practice: A cluster randomised controlled trial and qualitative investigation	2017	General practices in Northland region, New Zealand.	CVD risk assessment	Negative	Y
24.	Grant A, Dreischulte T, Guthrie B	Process evaluation of the data-driven quality improvement in primary care (DQIP) trial: active and less active ingredients of a multi-component complex intervention to reduce high-risk primary care prescribing	2017	Primary Health care in UK. 33 practices from one Scottish health board	Cardiovascular and renal adverse events	Positive	N
25.	Grant A, Dreischulte T, Guthrie B	Process evaluation of the Data-driven Quality Improvement in Primary Care (DQIP) trial: case study evaluation of adoption and maintenance of a complex intervention to reduce high-risk primary care prescribing	2017	Primary Health care in UK. 33 practices from one Scottish health board	Cardiovascular and renal adverse events	Positive	N

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Synthesis (CVD)	**Ten of the studies were about improving the screening and management of CVD using best-practice guidelines. (e.g. educational materials to improve referral, or decision analysis). Ten of the studies were about organisational change with models of care that incorporated new roles such as a nurse-led clinic, or the use of a lay worker for angina management, and technology (e.g. tele-monitoring, point of care testing). 5 of the studies explored trial implementation such as recruitment of patients and providers, and were less about the intervention.**	**2013-2017**	**2 New Zealand, 2 Netherlands, 9 UK, 1 Ireland, 6 Australia, 1 USA, 3 Canada, 1 Zambia (interesting that is so international, which I assume has to do with the recognition of CVD)**	**25 studies in CVD. (1 for chronic diseases, in which CVD is mentioned)**	**15 Positive, 5 Negative, and 5 N/A**	**3 Y, 15 N, 6 NA**
1. Van Den Bemt L, Schermer TRJ, Smeele IJM, Boonman-de Winter LJM, Van Boxem T, Denis J, et al	An expert-supported monitoring system for patients with chronic obstructive pulmonary disease in general practice: Results of a cluster randomised controlled trial	2009	General Practice. Netherlands	COPD	Negative	N
2. Casey D, Murphy K, Cooney A, Mee L, Dowling M.	Developing a structured education programme for clients with COPD	2011	Primary care, Ireland	COPD	NA	N
3. Julia A. E. Walters,E, Helen Courtney-Pratt , Helen Cameron-Tucker, Mark Nelson, Andrew Robinson, Jenn Scott, Paul Turner, E. Haydn Walters and Richard Wood-Baker	Engaging general practice nurses in chronic disease self-management support in Australia: Insights from a controlled trial in chronic obstructive pulmonary disease	2012	Australia PHC	COPD	NA	N
4. Fairbrother P, Pinnock H, Hanley J, McCloughan L, Sheikh A, Pagliari C, et al	Exploring tele-monitoring and self-management by patients with chronic obstructive pulmonary disease: A qualitative study embedded in a randomized controlled trial	2013	Lothian. Scotland, UK	Chronic Obstructive Pulmonary Disease	NA	N
5. Van der Weegen S, Verwey R et al	The Development of a Mobile Monitoring and Feedback Tool to Stimulate Physical Activity of People with a Chronic Disease in Primary Care: A User-Centred Design	2013	Netherlands PHC	Chronic Obstructive Pulmonary Disease or Type 2 diabetes	NA	NA

Appendix 1: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

6. Vest BM, York TRM, Sand J, Fox CH, Kahn LS	Chronic kidney disease guideline implementation in primary care: A qualitative report from the TRANSLATE CKD study	2015	Primary Care Practices, New York. United States	Chronic Kidney Disease	Positive	N
7. Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L	Process evaluation of physical activity counselling with and without the use of mobile technology: A mixed methods study	2016	Netherlands	Chronic Obstructive Pulmonary Disease or Type 2 diabetes	Positive	NA
Synthesis (COPD, and CKD)	**4 of the studies were about improving self-management of patients through educational materials, or use of monitoring, with support from health providers. 2 of the studies were about stimulating physical activity through the use of technology. 1 study was about implementing management guidelines in CKD in PHC.**	**2009-2016**	**3 Netherlands, I Ireland, 1 UK (Scotland), 1 USA, 1 Australia**	**6 addressing COPD (2 including other chronic disease), 1 addressing CKD.**	**2 Positive, 1 Negative, 4 N/A**	**0 Y, 5 N, 2 N/A.**
Overall Synthesis of 69 studies in total	**Overall, the complex primary care interventions fit within the general categories of facilitating patient self-management (13 studies), organisational change to include collaborative care (16 studies), facilitating better case management using clinical information systems (e.g. tele-health) (15 studies), and the use of decision support and guideline implementation (e.g. referral systems) (22 studies). In addition, 5 studies were exploring the conduct of trials in primary health care e.g. the recruitment of patients.**	**1999-2017**	**22 UK, 9 USA, 1 Sweden, 1 Germany, 10 Australia, 1 India, 3 Canada, 5 Ireland, 1 Norway, 3 New Zealand, 1 Malaysia, 5 Netherlands, 1 Zambia In addition, 2 studies focused on First Nations peoples in Australia and in Canada. 3 studies (Chung, Fakiri, Ratangawonsa) were focused on the populations living in disadvantage.**	**20 Depression, 17 Diabetes, 25 CVD, 6 COPD and 1 CKD.**	**33 Positive, 21 Negative and 14 Not applicable.**	**10 Y, 47 N, 11 Not applicable.**

Appendix 2: Table of methods and methodology of individual studies

Author	Title	Year	Labelled as Process Evaluation (Y/N)	Stated Purpose (Y/N)	Protocol (Y/N)	Processes examined at which stage	Use of Theory (Y/N)	Methods	Analysis
Tai SS, Nazareth I, Donegan C, Haines A	Evaluation of general practice computer templates. Lessons from a pilot randomised controlled trial	1999	N	Y	N	Feasibility and Piloting	N	qualitative (semi-structured interviews designed to assess the users' views) and quantitative (change in use of the template during the study period)	NA
Weiss MC, Montgomery AA, Fahey T, Peters TJ	Decision analysis for newly diagnosed hypertensive patients: a qualitative investigation	2004	Qualitative study	Y	N	Feasibility and Piloting	N	Semi-structured Interviews	Decision Analysis
Jackie Sturt, Hafrun Taylor, Andrea Docherty, Jeremy Dale, Taylor Louise	A psychological approach to providing self-management education for people with type 2 diabetes: the Diabetes Manual	2006	N	Y	N	Feasibility	Y	Using the MRC complex intervention framework the intervention was developed. Theory driven, needs assessment through focus group, and the use of a feasibility survey	Use of a survey to determine the feasibility of the developed intervention to be further tested in a definitive RCT
Byrne M, Cupples ME, Smith SM, Leathem C, Corrigan M, Byrne MC, et al	Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK Medical Research Council framework	2006	N	Y	N	Feasibility and Piloting	Y	Semi structured Interviews	NR
Chew-Graham CA, Lovell K, Roberts C, Baldwin R, Morley M, Burns A, et al	A randomised controlled trial test the feasibility of a collaborative care model for the management of depression in older people	2007	N	Y	N	Feasibility and Piloting	N	Semi-structured Interviews and questionnaires	Thematic analysis
Clark RA, Yallop JJ, Piterman L, Croucher J, Tonkin A, Stewart S, et al	Adherence, adaptation and acceptance of elderly chronic heart failure patients to receiving healthcare via telephone-monitoring	2007	N	Y	Y	Feasibility and piloting	N	Triangulation of descriptive statistics, feedback surveys and qualitative analysis of clinical notes.	Thematic analysis of the clinical notes and open ended comments from survey and triangulated with the satisfaction survey.
Lovell K, Bower P, Richards D, Barkham M, Sibbald B, Roberts C, et al	Developing guided self-help for depression using the Medical Research Council complex interventions framework: A description of the modelling phase and results of an exploratory randomised controlled trial	2008	N	Y	N	Feasibility and piloting	yes- use of MRC	Interviews, systematic review and modelling.	Framework analysis

Appendix 2: Table of methods and methodology of individual studies

Chatterjee S, Chowdhary N, Pednekar S, Cohen A, Andrew G, Araya R, et al	Integrating evidence-based treatments for common mental disorders in routine primary care: Feasibility and acceptability of the MANAS intervention in Goa, India	2008	N	Y	N	Feasibility and Piloting & post evaluation	N	Stakeholder semi structured interviews	Thematic analysis
van Steenkiste B, van der Weijden TM, Stoffers JH, Grol RP	Patients' responsiveness to a decision support tool for primary prevention of cardiovascular diseases in primary care	2008	Y	Y	N	Feasibility and Piloting	N	routine monitoring data, observations (e.g. Patients' actually having read the booklet and returning for the second consultation; comprehension and perceived relevance of the information; perceived reassurance.)	Descriptive statistics, and logistic regression to dependent variables and independent variables.
Chung B, Jones L, Dixon EL, Miranda J, Wells K, Community Partners in Care Steering Council	Using a Community Partner Participatory Research Approach to Implement a Randomised Controlled Trial: Planning Commnunity Partners in Care	2010	N	Y	N	Feasibility	Y	Baseline survey, community dialogue to obtain community feedback	NA
Gask L, Bower P, Lovell K, Escott D, Archer J, Gilbody S, Lankshear A, Simpson AE, Richards DA.	What work has to be done to implement collaborative care for depression? Process evaluation of a trial utilizing the Normalisational Process Model	2010	Y	Y	N	Feasibility and piloting (exploratory trial)	Normalisation Process Model	Pre study data collection of focus group and interviews, and post study data collection of interviews	Used a template or apriori coding manual from normalisation process model.
Casey D, Murphy K, Cooney A, Mee L, Dowling M.	Developing a structured education programme for clients with COPD	2011	N, Development of programme	Y	N	Feasibility and Piloting	N	Content analysis and concept analysis and 2 qualitative studies	Constant Comparative approach
Chalder M, Wiles NJ, Campbell J, Hollinghurst SP, Searle A, Haase AM, et al	A pragmatic randomised controlled trial to evaluate the cost-effectiveness of a physical activity intervention as a treatment for depression: The treating depression with physical activity (TREAD) trial	2012	N, Qualitative study	Y	Y	Feasibility and Piloting	Y (Self Determination Theory)	Interviews	NA
Bennett M, Walters K, Drennan V, Buszewicz M	Structured Pro-Active Care for Chronic Depression by Practice Nurses in Primary Care: A Qualitative Evaluation	2013	N	Y	Y	Feasibility and Piloting	N	In depth interviews	Thematic analysis

Appendix 2: Table of methods and methodology of individual studies

Carlisle K, Warren R	A qualitative case study of telehealth for in-home monitoring to support the management of type 2 diabetes	2013	N	Y	Y	Feasibility and Piloting	N	Semi structured Interviews	Not described.
Van der Weegen S, Verwey R et al	The Development of a Mobile Monitoring and Feedback Tool to Stimulate Physical Activity of People with a Chronic Disease in Primary Care: A User-Centered Design	2013	N	Y	N	Feasibility	Y	Qualitative individual interviews and focus group. Literature search re behaviour change and self-management	Three staged iterative process. Literature review to identify end users and context, stage 2, the literature, experts and patient representatives consulted to set up a use case. Stage 3 where individual interviews and focus groups based on the use case helped to identify end user requirements, and build a prototype.
Fairbrother, Peter McCloughan, Lucy Adam, Geraldine Brand, Richard Brown, Cecil Watson, Mary Cotter, Nicola Mackellaig, Juliet McKinstry, Brian	Involving patients in clinical research: The Telescot patient panel	2013	N	Y	Y	Feasibility	N	Patient' panel and Focus groups	Thematic
Ramadas A, Chan C, Oldenburg B, Hussien Z, Quek K	A Web-Based Dietary Intervention for People with Type 2 Diabetes: Development, Implementation, and Evaluation	2015	Y	Y	Y	Feasibility and Piloting	N	Self-administered questionnaire (to determine program reception)	Descriptive statistics of the process evaluation measures.

Appendix 2: Table of methods and methodology of individual studies

Naik AD, Lawrence B, Kiefer L, Ramos K, Utech A, Masozera N, et al	Building a primary care/research partnership: lessons learned from a telehealth intervention for diabetes and depression	2015	Formative evaluation	Y	N	Feasibility and Piloting, and Evaluation of effectiveness	Y	Qualitative data from the research/clinical partnership meetings that was recorded and coded. Triangulated with other information such as research staff personal communication, field notes and minutes of meetings.	Qualitative Framework analysis
Vest BM, York TRM, Sand J, Fox CH, Kahn LS	Chronic kidney disease guideline implementation in primary care: A qualitative report from the TRANSLATE CKD study	2015	Y	Y	Y	Feasibility and Piloting	Y	Semi-structured Interviews	Thematic Content Analysis
Synthesis	**The quality data items do not fit these studies as they seem to be more applicable to the effectiveness stage. Though the COREQ ones still matter for the qualitative study/methods. The methods (literature search, consensus process, focus group interviews) can inform the intervention development and subsequent evaluation (e.g. testing of change in determinants). Use of classic theory especially psychological/behavioural ones seem relevant for chronic diseases given the emphasis on self-management as reflected in Box 1.**	**1999 - 2016**	**5 labelled as process evaluations**	**20 to stated purpose.**	**8 Y**	**20 Studies**	**9**	**18 used interviews. 3 used focus group discussions, 4 used questionnaires or surveys, 2 studies used routine monitoring data, field notes, minutes of meetings and observations.**	**Thematic analysis, constant comparative approach most commonly used, with some using framework analysis.**
Hetlevik I, Holmen J, Kruger O, Kristensen P, Iversen H, Furuseth K	Implementing clinical guidelines in the treatment of diabetes mellitus in general practice: Evaluation of effort, process, and patient outcome related to implementation of a computer-based decision support system	2000	Y	Y	N	Effectiveness	N	Use of number of patient registrations (fraction as the process evaluation) and a questionnaire to determine user friendliness, perceived benefit and feedback about implementation strategies	Quantitative analysis according to variables and across two time points.
Thornett AM, Mynors-Wallis LM	Credibility of problem-solving therapy and medication for the treatment of depression among primary care patients	2002	N	Y	N	Evaluation of effectiveness	N	Credibility scale questionnaires, Kruskall-Wallis rank test of relationships.	Statistical analysis
Ilag LL, Martin CL, Tabaei BP, Isaman DJ, Burke R, Greene DA, et al	Improving diabetes processes of care in managed care	2003	N	Y	N	Evaluation of effectiveness	N	Quantitative measures of processes of care (e.g. measuring HbA1c), and a Likert scale acceptability survey given to the health providers	Quantitative analysis between groups, with hierarchical liner mixed models for continuous models for categorical variables to control for random subject effects and random practice-site effects.

Appendix 2: Table of methods and methodology of individual studies

Lobo CM, Euser L, Kamp J, Frijling BD, Severens JL, Hulscher MEJL, et al	Process evaluation of a multifaceted intervention to improve cardiovascular disease prevention in general practice	2003	Y	Y	N	Evaluation of effectiveness	N	Implementer reports and questionnaires to health providers	Descriptive statistical analysis.
Pearl A, Wright S, Gamble G, Doughty R, Sharpe N	Randomised trials in general practice--a New Zealand experience in recruitment	2003	N	Y	N	effectiveness	N	Evaluation questionnaire	Descriptive
Smith S, Bury G, O'Leary M, Shannon W, Tynan A, Staines A, Thompson C	The North Dublin randomized controlled trial of structured diabetes shared care	2004	N	Y	N	Evaluation of effectiveness	N	processes of care and qualitative study, (and outcome study reported together)	Triangulation of mixed methods
Gask L, Dixon C, May C, Dowrick C	Qualitative study of an educational intervention for GPs in the assessment and management of depression	2005	N	Y	Y	Evaluation of effectiveness (Y)	N	Interviews	Qualitative Content Analysis
Gask L, Ludman E, Scaheffer J.	Qualitative Study of an intervention for depression among patients with diabetes: how can we optimise patient-professional interaction?	2006	N	Y	N	Evaluation of effectiveness	N	Qualitative semi structured interviews and content analysis of recorded case management (i.e. the intervention itself)	Constant Comparative approach
Heaven, B. Murtagh, M. Rapley, T. May, C. Graham, R. Kaner, E. Thomson, R.	Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention	2006	N	Y	N	Post hoc effectiveness ?	Y (informed by ideas of symbolic interactionism, phenomenology and critical psychology.	Mixed Methods: Part of an observational study alongside a RCT (comprising of video of consultation) and participant interview post clinic and 3 months post clinic (* this study only reports on the 3-5 days post clinic interviews.	Constant Comparative approach to the qualitative data, and informed by ideas from symbolic interactionism, phenomenology and critical psychology.
Fakiri FE, Hows MW, Uitewaal PJM, Frenken RA, Bruijnzeels MA.	Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in general practices in deprived neighbourhoods	2008	Y	Y	N	Evaluation of effectiveness-fidelity and reach	N	Fidelity data e.g. ranking of the intervention as delivered by the protocol, and the Reach data through the number of consultations completed	Descriptive analysis

Appendix 2: Table of methods and methodology of individual studies

Slade M, Gask L, Leese M, McCrone P, Montana C, Powell R, Stewart M, Graham-Chew C	Failure to improve appropriateness of referrals to adult community mental health services—lessons from a multi-site cluster randomized controlled trial	2008	N	Y	Y	Evaluation of effectiveness	N	Outcomes, process data was presented and implementation was explored through the nested qualitative data.	Logistics analysis and thematic analysis of the qualitative data.
Van Den Bemt L, Schermer TRJ, Smeele IJM, Boonman-de Winter LJM, Van Boxem T, Denis J, et al	An expert-supported monitoring system for patients with chronic obstructive pulmonary disease in general practice: Results of a cluster randomised controlled trial	2009	Y	Y	N	Evaluation of effectiveness	N	For the process evaluation, the respiratory experts' database was examined to collect data on their recommendations. The nurse consultant collected data on GPs' implementation of recommendations. Patient questionnaires comprised questions about disease management. (i.e. documentary analysis and questionnaires)	Compared the implementation across control and intervention groups. Process evaluation and outcome evaluation was presented together.
Smith S, Paul G, Kelly A, Whitford D, O'Shea E, O'Dowd T	Peer support for patients with type 2 diabetes: Cluster randomised controlled trial	2011	Y	Y	Y	Evaluation of effectiveness	N	Interviews and FGD's. Routine monitoring data	Descriptive parallel qualitative analysis based on descriptive phenomenology
Passey ME, Laws RA, Jayasinghe UW, Fanaian M, McKenzie S, Powell-Davies G, et al	Predictors of primary care referrals to a vascular disease prevention lifestyle program among participants in a cluster randomised trial	2012	N	Y	Y	Evaluation of effectiveness	N	Routine monitoring data	Univariate analysis
Gensichen J, Guethlin C, Sarmand N, Sivakumaran D, Jager C, Mergenthal K, et al	Patients' perspectives on depression case management in general practice - A qualitative study	2012	N	Y	Y	Evaluation of effectiveness	N	Interviews	Content Analysis

Appendix 2: Table of methods and methodology of individual studies

Julia A. E. Walters,E, Helen Courtney-Pratt , Helen Cameron-Tucker, Mark Nelson, Andrew Robinson, Jenn Scott, Paul Turner, E. Haydn Walters and Richard Wood-Baker	Engaging general practice nurses in chronic disease self-management support in Australia: insights from a controlled trial in chronic obstructive pulmonary disease	2012	N	Y	N	Effectiveness	N	Mixed methods (quant survey and interviews)	Iterative thematic analysis with triangulation of quant data
Ratanawongsa N, Bhandari VK, Handley M, Rundall T, Hammer H, Schillinger D	Primary care provider perceptions of the effectiveness of two self-management support programs for vulnerable patients with diabetes	2012	N	Y	Y	Evaluation of effectiveness	N	self-administered questionnaire	Descriptive analysis
Lakerveld J, Bot S, Chinapaw M, van Tulder M, Kingo L, Nijpels G	Process evaluation of a lifestyle intervention to prevent diabetes and cardiovascular diseases in primary care	2012	Y	Y	Y	Evaluation of Effectiveness	Re-AIM	Questionnaires	Confirmatory factor analysis
Paul G, Keogh K, D'Eath M, Smith SM	Implementing a peer-support intervention for people with type 2 diabetes: A qualitative study	2013	N	Y	Y	Evaluation of effectiveness	N	Stakeholder interviews and FGD	Framework analysis and a matrix based method of analysing qualitative data.
Nelson P, Cox H, Furze G, Lewin RJP, Morton V, Norris H, et al	Participants' experiences of care during a randomized controlled trial comparing a lay-facilitated angina management programme with usual care: a qualitative study using focus groups	2013	N	Y	Y	Evaluation of Effectiveness	N	Focus group discussions	Thematic analysis
Fairbrother P, Pinnock H, Hanley J, McCloughan L, Sheikh A, Pagliari C, et al	Exploring tele monitoring and self-management by patients with chronic obstructive pulmonary disease: A qualitative study embedded in a randomized controlled trial	2013	N	Y	Y	Evaluation of effectiveness-views of the intervention	Schermer three degress of telemetric self management	Semi structured Interviews	Framework analysis

Appendix 2: Table of methods and methodology of individual studies

Stallard P, Phillips R, Montgomery AA, Spears M, Anderson R, Taylor J, et al	A cluster randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents	2013	Y	Y	Y	Evaluation of effectiveness	REAIM	Questionnaires and Qualitative Interviews	Thematic analysis
Hanley, J. Ure, J. Pagliari, C. Sheikh, A. McKinstry, B.	Experiences of patients and professionals participating in the HITS home blood pressure tele-monitoring trial: A qualitative study	2013	N	Y	Y	Effectiveness (though informed by interviews at the pilot and feasibility stage, and there was a protocol-evolution allowed)	Y (Normalisation process theory)	Semi-structured qualitative interviews and a focus group to validate the findings and discuss implementation	Ongoing iterative analysis "*The trial context permitted triangulation with quantitative data. Owing to the protocolpermitted evolution in practice, it gives an indication of some of the issues which would need to be addressed for BP telemonitoring to be used in routine practice*."
Laws, R. A. Fanaian, M. Jayasinghe, U. W. McKenzie, S. Passey, M. Davies, G. P. Lyle, D. Harris, M. F	Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial	2013	N	y	y	effectiveness	N	Mixed methods of quantitative analysis of survey, clinical audit data, practice questionnaire on capacity for preventive care, and referral and attendance records, interviews with implementers of the program	Quantitative data analysis (to find the characteristics and the factors influencing attendance) and qualitative thematic analysis.
Manca DP, Greiver M, Carroll JC, Salvalaggio G, Cave A, Rogers J, et al	Finding a BETTER way: A qualitative study exploring the prevention practitioner intervention to improve chronic disease prevention and screening in family practice	2014	N	Y	N	Evaluation of effectiveness	Y (Grounded theory)	semi-structured interviews and focus groups	Constant Comparative approach
Richter-Sundberg L, Nystrom ME, Krakau I, Sandahl C	Improving treatment of depression in primary health care: A case study of obstacles to perform a clinical trial designed to implement practice guidelines	2015	N	Y	N	Evaluation of effectiveness	N	Semi-structured Interviews	qualitative analysis

Appendix 2: Table of methods and methodology of individual studies

Eborall HC, Dallosso HM, McNicol S, Speight J, Khunti K, Davies MJ, et al	Explaining engagement in self-monitoring among participants of the DESMOND self-monitoring trial: A qualitative interview study	2015	N	Y	N	Evaluation of effectiveness	N	Qualitative semi structured interviews	Constant Comparative approach
Grimshaw JM, Presseau J, Tetreo Jm , Eccles MP, Francis JJ, Godin G, Graham ID, Hux, JE, Johnston M, Legare F, emyre L, et al..	Looking inside the black box: results of a theory-based process evaluation exploring the results of a randomized controlled trial of printed educational messages to increase primary care physicians' diabteic retinopathy referrals	2014	Y	Y	Y	Evaluation of effectiveness	Y (Theory of planned behavior)	Surveys at two time points	Compared groups factorially on changes at the two time points pre and post intervention. Thematic analysis of the open comment section
Burridge, L. H. Foster, M. M. Donald, M. Zhang, J. Russell, A. W. Jackson, C. L.	Making sense of change: patients' views of diabetes and GP-led integrated diabetes care	2014	N	Y	N	Evaluation of effectiveness	Y, Normalisation Process Theory	Qualitative study (as part of a mixed methods evaluation)	Thematic Analysis with a modified framework based on NPT.
Coupe N, Anderson E, Gask L, Sykes P, Richards DA, Chew-Graham C	Facilitating professional liaison in collaborative care for depression in UK primary care; A qualitative study utilising normalisation process theory	2014	N	Y	Y	Evaluation of effectiveness	Normalization process theory (NPT)	Interviews	Thematic analysis
Kenealy TW, Parsons MJG, Rouse PB, Doughty RN, Sheridan NF, Hindmarsh JKH, Masson SC, Rea HH.	Telecare for Diabetes, CHF or COPD; Effect on Quality of Life, Hospital Use and Costs. A Randomised ControlledTrial and Qualitative Evaluation	2015	N	Y	N	Evaluation of effectiveness	N	Individual and focus group interviews and questionnaire. (note that other process measures such as the nurse keeping a log of their activities for calculation of health care use was also collected)	Thematic analysis

Appendix 2: Table of methods and methodology of individual studies

Liu H, Massi L, Laba TL, Peiris D, Usherwood T, Patel A, Cass A, Eades AM, Redfern J, Hayman N, Howard K, Brien JA, Jan S.	Patients' and Providers' Perspectives of a Polypill Strategy to Improve Cardiovascular Prevention in Australian Primary Health Care: A Qualitative Study Set Within a Pragmatic Randomized, Controlled Trial.	2015	Y	Y	Y	Effectiveness	Y	Qualitative interviews and triangulation with outcomes, and knowledge of trial implementation	Iterative thematic analysis, with the use of the Realist framework to guide the development of the themes.
Liu H, Laba T, Massi L, Jan S, Usherwood T, Patel A, Hayman N, Cass A, Eades A, Peiris D.	Facilitators and barriers to implementation of a pragmatic clinical trial in Aboriginal health services.	2015	Y	Y	Y	Effectiveness	N	Qualitative interviews and triangulation with outcomes, and knowledge of trial implementation	Iterative thematic analysis
Liu H, Massi L, Eades AM, Howard K, Peiris D, Redfern J, Usherwood T, Cass A, Patel A, Jan S, Laba T.	Implementing a pragmatic randomised controlled trial in Australia: lessons learnt from the Kanyini Guidelines Adherence with the Polypill study (Kanyini GAP)	2015	Y	Y	Y	Effectiveness	N	Qualitative interviews and triangulation with outcomes, and knowledge of trial implementation	Iterative thematic analysis
Huntink E, Wensing M, Timmers IM, Lieshout JV	Process evaluation of a tailored intervention programme of cardiovascular risk management in general practices	2016	Y	Y	N	Evaluation of effectiveness	N	Mixed methods- quantitative measures (survey results and scoring of recorded motivational interviews) and qualitative data of interviews conducted.	Quantitative analysis of the scores, and qualitative analysis using the pre-specified tailored intervention for chronic diseases
Presseau J, Grimshaw J, Tetroe JM, Eccles MP, Francis JJ, Godin G, Graham ID, Hux JE, Johnston M, Legare F, Lemyre L, Robinson N, Zwarenstein M.	A theory-based process evaluation alongside a randomised controlled trial of printed educational messages to increase primary care physician's prescription of thiazide diuretics for hypertension	2016	Y	Y	Y	Evaluation of effectiveness	Y (Theory of planned behaviour)	Pre, post postal questionnaire to a random sub-sample of family physicians in each trial arm	Analysis of co-variance to test for group differences using a 2X3 factorial design and content analysis of the open ended question about perceived barriers to thiazide prescription. Tested whether baseline measures of TPB constructs predicted self-reported thiazide prescribing

Appendix 2: Table of methods and methodology of individual studies

Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L	Process evaluation of physical activity counselling with and without the use of mobile technology: A mixed methods study	2016	Y	Y	Y	Evaluation of effectiveness	N	Mixed methods (using semi-structured interviews, questionnaires to patients and use of IT tool through system logging)	Descriptive analysis and triangulation of findings.
Parsons, J. A. Yu, C. H. Y. Baker, N. A. Mamdani, M. M. Bhattacharyya, O. Zwarenstein, M. Shah, B. R.	Practice doesn't always make perfect: A qualitative study explaining why a trial of an educational toolkit did not improve quality of care	2016	Y	Y	N	Effectiveness	N	In-depth semi-structured telephone interviews with physicians who received the tool kit. And written commentary from reflective feedback forms collected from 10% of practices randomised and approached) who participated in chart audit as part of the clinical data study.	Qualitative description which entails an inductively- derived thematic analysis, and triangulated with the written comments from the questionnaires
Yan LD, Chirwa C, Chi BH, Bosomprah S, Sindano N, Mwanza M, Musatwe D, Mulenga M, Chilengi R.	Hypertension management in rural primary care facilities in Zambia: a mixed methods study	2017	N	Y	Y	Evaluation of effectiveness	N	Data on novel retrospectively generated process and outcome indicators for hypertension management, informed by those from Western countries, but adapted to the Zambian primary care clinics. Extracted using EMR. Semi-structured in-depth interviews with health care providers and a representative from the central medication distribution agency .	We used an explanatory sequential design by conducting a quantitative analysis of outcome measures , which was then explained through a qualitative follow up component.
Wells S, Rafter N, Kenealy T, Herd, Geoff, Eggleton K, Lightfoot R, Arcus K, Wadham A, Jiang Y, Bullen C.	The impact of a point of care testing device on CVD risk assessment completion in New Zealand primary-care practice: A cluster randomised controlled trial and qualitative investigation	2017	N	Y	N	Evaluation of effectiveness	N	Qualitative data on practice processes for CVD risk assessment and feasibility of POC testing were collected at the end of the study by interviews and questionnaire.	Braun and Clarke's approach to thematic analysis was used to generate initial codes, collate codes into potential themes and refine the identified themes and categories into a coherent pattern.

Appendix 2: Table of methods and methodology of individual studies

Grant A, Dreischulte T, Guthrie B	Process evaluation of the data-driven quality improvement in primary care (DQIP) trial: active and less active ingredients of a multi-component complex intervention to reduce high-risk primary care prescribing	2017	Y	Y	Y	Evaluation of effectiveness	Y (NPT)	Data generation was by in-depth interview with key staff exploring participant's perceptions of the intervention components.	Analysis was iterative using the framework technique and drawing on normalisation process theory.
Grant A, Dreischulte T, Guthrie B	Process evaluation of the Data-driven Quality Improvement in Primary Care (DQIP) trial: case study evaluation of adoption and maintenance of a complex intervention to reduce high-risk primary care prescribing	2017	Y	Y	Y	Evaluation of effectiveness	Y (NPT)	Mixed-methods parallel process evaluation of a cluster trial, reporting the comparative case study of purposively selected practices.	Use of interviews at two time points and the use of quantitative data to explore whether the qualitative judgements made about implementation were consistent with observed data on reach, delivery, maintenance and effectiveness. Use of NPT alongside the cross and within-case comparisons.
Rapp AM, Chavira DA, Sugar CA, Asarnow JR	Integrated Primary Medical-Behavioral Health Care for Adolescent and Young Adult Depression: Predictors of Service Use in Youth Partners in Care Trial	2017	N	Y	Y	Evaluation of Effectiveness	Y (Behavioural Model of Health Service Use)	Secondary Analysis of data from the trial to investigator the predisposing factors (demographics), enabling factors (e.g. perceived stigma of depression) , need factors and outcomes (receipt of mental health services)	Statistical analyses, and plots of significant interactions. Investigating possible interactions between variables, and individual logistic regression for the possible independent variables, with mental health treatment as outcome. Algorithm to finally identify the subset of variables that best predicted mental health service use.

Appendix 2: Table of methods and methodology of individual studies

Synthesis		**2000 - 2017**	**16 labelled as process evaluations (13 after 2008, and 5 after 2015)**		**22 Y, and 16 N**	**44 studies**	**13 studies (7 Classic theories, 3 evaluation frameworks, 3 implementation theories)**	**2000-2004: 6 studies documented specific processes of care as part of the process evaluation, and were often reported as part of the main trial. The acceptability of an intervention was often investigated using surveys/questionnaires. 2005 onwards- 9 studies used only interviews to explore implementation and acceptability, 15 studies used interviews triangulated with other sources of data (e.g. chart audit). 5 studies used questionnaires or surveys. 1 study used secondary analysis of trial data.**	**Descriptive statistics were used for the quantitative data. Thematic, constant comparison and framework analysis for the qualitative data. The studies that used mixed methods, used the quantitative data to indicate level of implementation, reach and the dose. This was use to triangulate the qualitative findings on implementation and intervention acceptability.**
Oishi SM, Shoai R, Katon W, Callahan C, Unutzer J, Arean P, et al	Impacting late life depression: Integrating a depression intervention into primary care	2003	N	Y	Y	Post evaluation Implementation	N	Focus group discussions and semi structured interviews	Thematic analysis
Dietrich AJ, Oxman TE, Williams JW, Kroenke K, Schulberg HC, Bruce M, et al	Going to scale: Re-engineering systems for primary care treatment of depression	2004	N	Y	Y	Post-evaluation	Yes- Diffusion of Innovations theory	Documentary analysis of care manager logs, health care organisation's administrative data to access cooperation in implementation and changes in the processes of care in each practice. Clinical surveys	Descriptive
Lee PW, Dietrich AJ, Oxman TE, Williams Jr JW, Barry SL	Sustainable impact of a primary care depression intervention	2007	N	Y	Y	Post evaluation Implementation	N	Interviews	Descriptive evaluation
Pylypchuk G, Vincent L, Wentworth J, Kiss A, Perkins N, Hartman S, et al	Diabetes risk evaluation and microalbuminuria (DREAM) studies: Ten years of participatory research with a First Nation's home and community model for type 2 diabetes care in northern Saskatchewan	2008	N	N	N	Evaluation of effectiveness, and post intervention	N	documentary analysis, Population survey, pilot and randomised trial	documentary analysis

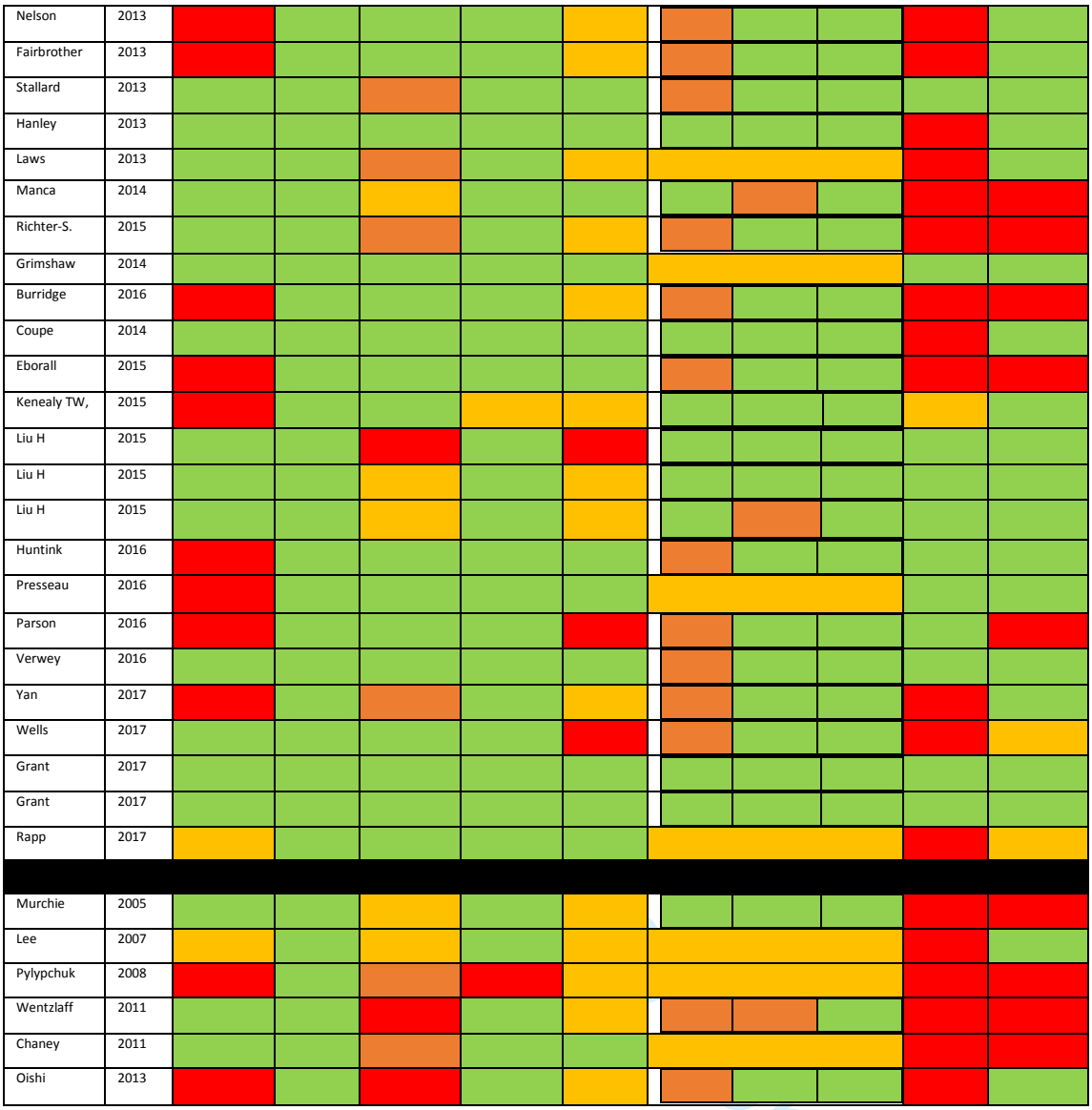
Appendix 2: Table of methods and methodology of individual studies

Wentzlaff DM, Carter BL, Ardery G, Franciscus CL, Doucette WR, Chrischilles EA, et al	Sustained Blood Pressure Control Following Discontinuation of a Pharmacist Intervention	2011	N	Y	Y	Post-evaluation implementation	N	routine monitoring data	Intention to treat analysis
Chaney EF, Rubenstein LV, Liu CF, Yano EM, Bolkan C, Lee M, et al	Implementing collaborative care for depression treatment in primary care: A cluster randomized evaluation of a quality improvement practice redesign	2011	N	Y	N	post evaluation Implementation	N	The study intervention is EBQI as applied to collaborative care implementation. The study uses a cluster randomized design as a formative evaluation tool to test and improve the effectiveness of the redesign process. Data sources include survey and administrative data sources, and the care manager registry-based measures (e.g. patients routinely referred outside of the trial).	The context evaluation is descriptive and uses subgroup analysis. (e.g. clinician adoption status)
Synthesis		**2003 - 2015**	**0 as process evaluations**	**5 Y, 1 N**	**4Y,**	**7 studies, (note the cross over with quality improvement studies)**	**NPT for 1**	**3 used interviews, 2 used documentary analysis, and 1 used the administrative data and registry data**	**Descriptive statistics, subgroup analysis and thematic analysis.**

Appendix 3: Quality Assessment

Author	Year	Planning (Y/N/ NA)	Design and Conduct (Y/N/NA)							Reporting (Y/N/NA)	
		Team description	Purpose clearly stated	Interven-tion and causal assumptions	Justify choice of timing and methods.	Report if analysis was done blind to trial outcomes / or post hoc	COREQ for qual studies. (31 items under Domain 1: research team and reflexivity, Domain 2: study design, Domain 3: analysis and reporting)			Clearly labelled	Linked to a full report of evaluation components / protocol paper.
Tai SS et al.	1999										
Weiss	2004										
Jackie Sturt,	2006										
Byrne	2006										
Chew-Graham	2007										
Clark	2007										
Lovell	2008										
Chatterjee	2008										
Van Steenkiste	2008										
Chung	2010										
Gask L,	2010										
Casey	2011										
Chalder	2012										
Bennett	2013										
Carlise	2013										
Van der Weegen	2013										
Fairbrother	2013										
Ramadas A,	2015										
Naik	2015										
Vest	2015										
Hetlevik	2000										
Thornett	2002										
Ilag	2003										
Lobo	2003										
Oishi	2003										
Pearl	2003										
Smith S	2004										
Gask L,	2005										
Gask L	2006										
Heaven, B.	2006										
Fakiri	2008										
Slade	2008										
Van Den Bemt	2009										
Smith	2011										
Passey	2012										
Genichen	2012										
Walters JAE	2012										
Ratanawongsa	2012										
Lakerveld J	2012										
Paul	2013										

Appendix 3: Quality Assessment



Notes on quality assessment: Quality was assessed using a pre-specified tool, based on the MRC PE guidance. 1) Planning: a) Degree of separation between outcome and process evaluation teams described. 2) Design and conduct: a) purpose clearly stated, b) Intervention clearly described, causal assumptions clarified. c) Justify choice of timing and methods. d) If applicable- Transparently whether the report of the process data are analysed blind to trial outcomes/ or post hoc. e) COREQ for qual studies. (31 items under Domain 1: research team and reflexivity, Domain 2: study design, Domain 3: analysis and reporting). 3) Reporting: a) Clearly labelled as PE. b) Published a full report of evaluation components or a protocol paper. These criteria were assessed by HL and MN and classified under yes (green), no (red), uncertain/unclear (orange), and not applicable (yellow). Additionally, studies with a qualitative study component was evaluated against the consolidated criteria for qualitative research checklist (COREQ) which has 31 individual items separated into 3 domains.(17) If more than one item was obviously or specifically mentioned for each of the three domains it was classified as yes (green), no (red) when it was obviously not present, and uncertain (orange).

Appendix 4- Illustrative examples for the synthesised findings

Implementation factors - illustrative examples
Mechanisms: Perceived Fit of the Intervention In a trial to increase the referral for diabetic retinopathy screening, physicians described that patient's lack of belief in screening, and access to specialists as key barriers to screening. Thus, the intervention of printed educational materials did not alter their referral behaviour. (Grimshaw)
Implementation: Roles and Responsibilities In study to integrate the role of a Depression Clinical Specialist with the primary care provider and the consulting psychiatrist- the process evaluation found "*DCSs spoke of the importance of a clear role within the health care team. The model envisions the DCS as a care manager who works in partnership with the patient and the PCP. DCSs pointed to the importance of not being perceived as taking over the patient's depression care. Instead, the DCS reports to the PCP whether a patient is experiencing side effects, for example, and discusses alternate treatment options, but it is the PCP who decides when to change dosage or medication type. DCSs noted the need to be flexible in working with different physician and system styles*." (Oishi)
Context: Health system structures From a process evaluation of the 'recruitment' of health care organisations in America to scale up an effective model of depression care- authors stated that: "*Additional momentum comes from the US Preventive Services Task Force (USPSTF) through its endorsement of depression screening in adults "in clinical practices that have systems in place to assure accurate diagnosis, effective treatment, and careful follow up." They state, "Benefits from screening are unlikely to be realized unless such systems are functioning well*." (Dietrich) The underlying capacity and knowledge of the implementers are described as conducive to their model of pro-active care for chronic depression using practice nurses: "*Practice nurses in the UK are employed by GPs to work in their practices as part of the primary healthcare team. They are at minimum Registered Nurses (RNs), usually with substantial nursing experience and some may have a specialist qualification in practice nursing, although it is not a formal requirement. A minority are also Registered Mental Health Nurses (RMHN), but most will have only received some theoretical background and short clinical placements in mental health settings during their RN course*." (Bennett)
Collaborative Approach "*The CBPR model guided development of a research/clinical partnership based on a facilitation team consisting of 'external facilitators' (research team), 'internal facilitators' (primary care leadership) and a 'clinical advisory committee' drawn from the primary care community. Qualitative themes focused on: how the intervention components ('evidence') aligned with local clinical cultures, barriers and facilitators to acceptance and adoption of the intervention processes within the context of clinical workflows and identified 'facilitators' of intervention uptake and sustainability*." (Naik) "*We found that using a Community-Partnered Participatory Research approach in the design phase (Vision) led to many changes in study design to improve the fit of the study with community priorities (e.g. Aligning community boundaries with existing county service planning areas), as well as enrich the study's potential scientific contributions (e.g., through expanded outcomes of community and policy relevance)*." (Chung)

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5,6 (published protocol
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6 (published protocol)
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5 (in protocol)
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6

PRISMA 2009 Checklist

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6,25
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6,23-25
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 1, and Appendix
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Table 2, and appendix
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Table 1, Appendix
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	7-11
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	6,7 Table, Appendix
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	6, and table 1
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	12-15

PRISMA 2009 Checklist

FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

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A systematic review of process evaluations of primary care interventions addressing chronic disease

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A systematic review of process evaluations of primary care interventions addressing chronic disease

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2 Figures, 2 Tables, 2 Boxes

6 Supplementary files : PRISMA checklist, 1 search strategy, 4 tables,

ABSTRACT

Objectives: Process evaluations (PE) alongside randomized controlled trials of complex interventions are valuable because they address questions of for whom, how and why interventions had an impact. We synthesised the methods used in PEs of primary care interventions, and their main findings on implementation barriers and facilitators.

Design: Systematic review using the UK Medical Research Council guidance for PE as a guide.

Data Sources: Academic databases (MEDLINE, SCOPUS, PsychInfo, CINAHL, EMBASE, Global Health) were searched from 1998 till June 2018.

Eligibility Criteria: We included PE alongside randomized controlled trials of primary care interventions which aimed to improve outcomes for patients with non-communicable diseases.

Data extraction and Synthesis: Two independent reviewers screened and conducted the data extraction and synthesis, with a third reviewer checking a sample for quality assurance.

Results: 69 studies were included. There was an overall lack of consistency in how PEs were conducted and reported. The main weakness is that only 30 studies were underpinned by a clear intervention theory often facilitated by the use of existing theoretical frameworks. The main strengths were robust sampling strategies, and the triangulation of qualitative and quantitative data to understand intervention's mechanisms. Findings were synthesized into 3 key themes: 1) a fundamental mismatch between what the intervention was designed to achieve and local needs, 2) the required roles and responsibilities of key actors were often not clearly understood and; 3) the health system context – factors such as governance, financing structures and workforce- if unanticipated could adversely impact implementation.

Conclusion: Greater consistency is needed in the reporting, and the methods of PEs. In particular, greater use of theoretical frameworks to inform intervention theory. More emphasis on formative research in designing interventions is needed to align the intervention with the needs of local stakeholders; and to minimise unanticipated consequences due to context-specific barriers.

Registration with PROSPERO Registry: registration number is CRD42016035572

Keywords: process evaluations, primary health care, complex interventions, systematic review, chronic disease, non-communicable disease, qualitative

Strengths and Limitations of the study

Strengths:

-Reflexive thematic synthesis and interpretation of the papers by a multidisciplinary team.

-Using a bespoke quality assessment tool based on the MRC guidance for process evaluations

Limitations:

- Given variations in lexicon, our search strategy may not have exhaustively captured all process evaluations of complex primary care interventions.

- Use of the framework and quality assessment tool to synthesise the findings have not been tested previously.

INTRODUCTION

An accessible, effective and affordable primary health care (PHC) system is needed to equitably reduce the rising non-communicable disease burden. (1-3) Complex interventions which comprise of "multiple interacting components (although additional dimensions of complexity include the difficulty in their implementation and the number of organisational levels they target)" are often used to reduce this burden. (4) These interventions often require individual and organisational behaviour change within dynamic health system contexts. (5) (6) Randomised controlled trials (RCTs) of complex primary care interventions have been conducted but there is often ambiguity as to what was implemented on the ground. (7-9) Process evaluations (PE) are conducted alongside trials to examine if a complex intervention was implemented as intended, and to explore if, for whom, how and why the intervention had an impact. (4)

A process evaluation is defined by the United Kingdom Medical Research Council (MRC) as a study to '*understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors'*. (4) The MRC process evaluation framework and guidance published in 2015 is based on the synthesis of influential frameworks and theories in public health research, and informed by the authors' process evaluations. (4) The key points are briefly summarised and elaborated upon in Box 1.

In the guidance, concepts of reach, fidelity, and adoption were highlighted as key to examining implementation quality. For example, assessing 'fidelity' would help determine whether the research was conducted as per protocol. The MRC guidance also highlighted the value of describing the intervention theory more explicity. i.e. providing the hypothesis relating to how the complex intervention could potentially interact with contextual factors

to produce variation in outcomes. (10, 11) Ideally, the intervention theory would determine the process (qualitative and quantitative) data to be collected and analysed before the RCT outcomes are known. The PE findings could potentially help explain variation in RCT outcome, refine the intervention theory and inform future research priorities. Recognising the need to facilitate implementation of evidence into practice and policy- the MRC guidance also expands on the importance for PEs to be conducted across all stages of research i.e. feasibility/piloting, evaluation of effectiveness, and post-evaluation stages. While the guidance was well-received, outstanding questions remain in this developing field. For example, what is the role of other theories and frameworks for process evaluations? What methods can be used and how? (12-14) Synthesising the collective 'experience' described in published process evaluations may answer some of these questions.

This review has two primary objectives. First, to review the methods used in published process evaluations and their alignment with the MRC guidance, and second to identify the key implementation barriers and facilitators reported in these process evaluations. We used the 3 key points (as summarised in Box 1) from the MRC guidance as a lens to evaluate the published literature, and employed it as a framework for synthesising our findings.

Box 1: Summary points of the MRC guidance for Process Evaluations:

1) Expanded on the **functions of the process evaluation**:
   Implementation: "What is implemented and how?"
   - Implementation process: What did the research team do?
   - Reach: Did you recruit participants that your intervention was intended to have an impact upon?
   - Fidelity: Did you do what you planned to do as per protocol?
   - Adaptation: What changes were made in the delivery of the intervention to the local context?
   - Dose: Is the frequency of the intervention delivered as planned?

   Mechanisms of impact: "How does the delivered intervention produce change?"
   - Participants' experiences of the intervention

- Mediators
- Unexpected consequences and pathways

Context: "How does the context affect implementation and outcomes?"

- Contextual factors which shape the theory of the intervention
- Contextual factors that could affect and be affected by implementation, mechanisms and outcomes.
- Causal mechanisms within the context that could potentiate the effects.

2) Provided a systematic approach to the **design and conduct** of process evaluations
   - Planning: relationships with stakeholders and degree of separation between evaluators and research team
   - Design and conduct: Describe intervention and causal assumptions, identify the key process questions and inform data collection.
   - Analysis: Use of reporting guidelines for methods. Transparently report whether process data is analysed and reported prior or after knowing outcomes.
   - Reporting: Intervention theory and how it informed data collection. Protocol to link multiple outputs.
3) Described and expanded on the **function of process evaluations across the different stages of development, evaluation and implementation**.
   - Development: feasibility and acceptability of implementation strategies and optimising design and evaluation of intervention
   - Effectiveness: fidelity of intervention, mechanisms of action and contextual factors
   - Post-evaluation implementation: implementation of intervention into usual practice, long term surveillance

METHODS

The systematic review protocol has been prespecified, and and published in detail as a separate protocol. (15) A summary of the methods is presented here according to the PRISMA guidelines. (See appendix 1 for the PRISMA checklist.) (16)

Eligibility Criteria for the randomised controlled trials with the included process evaluation

Population: patients with non-communicable diseases(Diabetes, Depression, Cardiovascular Disease, Chronic Obstructive Pulmonary Disease, Chronic Kidney Disease, Type 2 Diabetes Mellitus), and their primary care providers.(5)

Intervention: complex interventions which comprise "*multiple interacting components although additional dimensions of complexity include the difficulty of their implementation and the number of organisational levels they targe*t" within PHC.(4)

Comparator: the control condition may include treatment as usual, active control or placebo control.

Outcomes for this systematic review: (1) Strengths and limitations of each process evaluation using the MRC guidance as a reference point. (2) Identification of implementation barriers and facilitators for the complex interventions.

Timing: published data from 1998 till June 2018

Design: process evaluation of the included randomised controlled trials (RCTs) as defined by the MRC as '*a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors'*. (4) Given that process evaluations are often not explicitly labelled as such (11), we included studies with comparable aims.

Exclusion criteria: not a journal article, not a report based on empirical research, not reported in English, reviews and not human research.

Search strategy and data extraction: databases reporting academic publications (MEDLINE, SCOPUS, PsychInfo, CINAHL, EMBASE, Global Health) were searched. Standard systematic review methods were followed for searching screening and extracting data from eligible studies. (15) Our search strategy is included as appendix 2. Two reviewers (HL, AM) conducted most of the data extraction, with a third reviewer (MN) assisting in data extraction with some papers and as part of quality assurance, checked on the data

extraction for a 10% sample of the identified papers. Given that a key aim of this study was about process evaluation methodology- we deviated from the published systematic review protocol, by including our interpretation in addition to the study's strengths and limitations posited by the authors of those papers.

Data analysis and synthesis

Descriptive items (e.g. number of positive RCTs) were tallied and synthesised into 3 tables. (1) Overall characteristics: presenting the studies grouped into different diseases and ordered by year of publication. (Appendix 3); (2) Methods table: grouping studies by the stages of the process evaluation (i.e. feasibility/ piloting, effectiveness, post-evaluation) (Appendix 4); (3) Quality assessment: Findings based on a bespoke assessment tool which was designed based on some of the key recommendations from the MRC guidance and two other papers which had synthesised PE literature before (Appendix 5).

Extracted qualitative data were coded by HL, and grouped into categories of context, mechanisms and implementation. Inductive derivation of the key themes was done through constant comparison between the findings from the papers within each category and examining the relationships between them. Appendix 6 provides illustrative quotations. Using a modified MRC framework, we mapped our methodological and implementation findings to triangulate and synthesis our findings.

Patient and Public Involvement

While patient and public perspectives were synthesised from published papers, no public and patients were directly involved in this study.

FINDINGS

(1) Characteristics of included studies

We identified 69 studies. The PRISMA flowchart is presented in Figure 1. In summary, 66 studies were conducted in high income countries, 1 study in Zambia, 1 in Malaysia and 1 in India. Cardiovascular disease, diabetes mellitus, and depression were the conditions most often investigated, with only six studies on chronic obstructive pulmonary disease and one study on chronic kidney disease. Overall, the complex primary care interventions fit within the general categories of facilitating patient self-management (13 studies), organisational change to include collaborative care (15 studies), facilitating better case management using clinical information systems (e.g. tele-health) (15 studies), and the use of decision support and guideline implementation (e.g. referral systems) (22 studies). In addition, 5 studies explored the challenges when conducting trials in primary care e.g. the recruitment of patients.

Only 22 studies were labelled clearly as process evaluations, though this was more common in recent years. Twenty studies were conducted at the feasibility stage with five labelled as PEs, 43 studies at the effectiveness stage with 17 labelled as PEs, and six studies at the post-evaluation stage with none labelled as process evaluations.(The methods used at these different stages are described in greater detail in the next section.) In thirty-five studies the degree of separation between the process and outcome evaluation researchers was explicit. The cost considerations for the system and stakeholders was mentioned in 10 papers (see Table 1 for more detail). In Figure 2, the context of the studies and an overview of the main methodological and implementation findings are diagrammatically presented in an adapted PE framework.

Table 1: Summary of the characteristics of the included studies

Disease Condition	interventions	Setting	RCT Outcomes	Cost Considerations (Y/N/NA)
20 studies on depression.	Interventions mostly around collaborative care through increasing expertise of different roles (e.g. lay worker, nurse for pro-active care, GP for PHC) (16 studies), times to implement practice guidelines (4 studies), and trialling specific interventions such as physical exercise and cognitive behaviour therapy. (2 studies).	9 UK, 7 USA, 1 Sweden, 1 Germany, 1 Australia 1 India.	11 positive RCTs, 5 Negative, 4 N/A	4/19 Y, 14 N, 2 N/A
17 studies on diabetes	The interventions included improving guideline-based referral and treatment (7 studies), patient self-management, community support (7 studies) and tele-health (3 studies).	3 Ireland, 3 UK, 1 Norway, 2 USA, 2 Canada (1 of the First Nations), 2 Australia, 1 New Zealand, 1 Malaysia	6 Positive, 10 Negative, 1 N/A	3/16 Y, 13/16 N, 1/16 N/A
25 studies on CVD.	10 studies were about improving the screening and management of CVD using best-practice guidelines. (e.g. educational materials to improve referral, or decision analysis). 10 studies were about organisational change with models of care that incorporated new roles such as a nurse-led clinic, or the use of a lay worker for angina management, and technology (e.g. tele-monitoring, point of care testing). 5 studies explored trial implementation such as recruitment of patients and providers, and were less about the intervention.	9 UK, 6 Australia, 3 Canada, 2 New Zealand, 2 Netherlands, 1 Ireland, 1 USA, 1 Zambia	15 Positive, 5 Negative, 5 N/A	3 Y, 15 N, 6 N/A
6 studies on COPD (2 including other chronic disease), and 1 addressing CKD.	4 studies were about improving self-management of patients through educational materials, or use of monitoring, with support from health providers. 2 studies were about stimulating physical activity through the use of technology. 1 study was about implementing management guidelines in CKD in primary health care.	3 Netherlands, 1 Ireland, 1 UK (Scotland), 1 USA, 1 Australia	2 Positive, 1 Negative, 4 N/A	0 Y, 5 N, 2 N/A.
Overall Synthesis of 69 studies in total. 20 Depression, 17 Diabetes, 25 CVD, 6 COPD and 1 CKD.	**Overall, the complex primary care interventions fit within the general categories of facilitating patient self-management (13 studies), organisational change to include collaborative care (16 studies), facilitating better case management using clinical information systems (e.g. tele-health) (15 studies), and the use of decision support and guideline implementation (e.g. referral systems) (22 studies). In addition, 5 studies were exploring the conduct of trials in primary health care e.g. the recruitment of patients.**	**22 UK, 10 Australia, 9 USA, 5 Ireland, 5 Netherlands, 3 Canada, 3 New Zealand, 1 Sweden, 1 Germany, 1 India, 1 Norway, 1 Malaysia, 1 Zambia In addition, 2 studies focused on First Nations peoples in Australia and in Canada. 3 studies were focused on the populations living in disadvantage.**	**33 Positive, 21 Negative 14 N/A**	**10 Y*, 47 N, 11 N/A**

Abbreviations: COPD: Chronic Obstructive Pulmonary Disease; CKD: Chronic Kidney Disease; CVD: Cardiovascular Disease; GP: General Practices; N: No; N/A: Not Applicable; RCT: Randomised Controlled Trial; UK: United Kingdom; USA: United States of America; Y: Yes.

* Of note two were full evaluation reports (outcome, process and economic evaluations) in the UK journal of Health Technological Assessments in addressing the question of whether an innovation with limited evidence base in a pragmatic setting (e.g. introducing cognitive behaviour therapy in schools) should be scaled up. Eight papers included descriptions of the how costs considerations such as financing incentives/ government subsidies impacted on intervention implementation.

(2) Process evaluations' strengths and limitations

Description of Intervention theory- clear intervention description and clarification of causal assumptions

Thirty papers were assessed as having clear intervention descriptions and clarification of causal assumptions, and in sixteen it was unclear because despite clear intervention descriptions, the causal assumptions were not described explicitly. An example of a paper that explicitly describes intervention theory is Grant et al who uses the Template for Intervention Description and Replication (TIDieR) checklist to clearly describe the researchers' assumptions of the intervention's mechanism as compared to the stakeholders' perspectives. (17)

Use of existing theories and frameworks: A strength of 22 studies was the use of existing theoretical frameworks to inform their intervention development and/or evaluation. (See Table 2) Theories and frameworks used are grouped according to Nilsen's proposed categories. (18) This is depicted in Box 2, with illustrative examples from the identified studies. In essence, eleven studies used classic theory to inform the development of the intervention theory. In eight studies determinant, implementation theories and evaluation frameworks were used to assist in the synthesis and analysis of qualitative data. The authors of two studies also used their findings and implementation theories to iteratively inform their implementation strategies. The evaluation frameworks were used by study

authors to comprehensively evaluate and synthesise their process evaluation data. The MRC framework for complex interventions was used to inform the approach to intervention development in three studies.

Box 2: Illustrative Examples of the use of Theories and Frameworks

Classic Theories

Theory of Planned behaviour-. "*Using the theory of planned behaviour (TPB), we hypothesised that changes in thiazide prescribing would be reflected in changes in intention, consistent with changes in attitude and subjective norm, with no change to their perceived behavioural control (PBC), and tested this alongside the RCT*…A *strength of this study is its use of a well-tested theory of behaviour operationalized according to best recommended practice to investigate the underlying mechanisms of an implementation intervention.*" (Presseau) This theory informed their process evaluation to explore if their intervention of printed educational materials increased practitioners' intention to prescribe according to recommendations in the guidelines.

Self Determination theory - "*self-determination theory which proposes that real shifts in behaviour arise through heightened autonomy or personal ownership of behavioural success*." (Chalder) This theory informed their theoretical model underpinning their intervention to improve physical activity for the management of depression.

Grounded theory- *" This qualitative study was conducted with the objective of better understanding the PP intervention in the BETTER Trial described above, including the development of the PP role, perceived barriers, facilitators, benefits and disadvantages, and of exploring the feasibility and sustainability of this approach for CDPS."* (Manca) This study used grounded theory to better understand their intervention as implemented and to retrospectively describe their intervention theory.

Diffusions of Innovation-"*Key principles, which derive from diffusion of innovations theory, include working initially with practices and clinicians that not only have an interest in the innovation and view it as compatible with their needs, values, and resources, but also have the ability to try it with minimal investment and observe its impact*." (Dietrich) The theory was used to inform their practice change strategy for the sustainability of a chronic care model for depression proven effective in an RCT.

Determinant Frameworks

PARIHS as an implementation model-"*We used the Promoting Action on Research in Health Services (PARIHS) framework as an 'Implementation model' to assist clinical partners in adopting the health-coaching intervention. The PARIHS framework posits three interrelated elements that influence successful implementation of evidence-based practices: the (I) perceived strength of the 'evidence', (ii) 'context' of the environment and (iii) 'facilitation' support created for implementation of the intervention….Using a codebook developed a priori from sub elements of the PARIHS framework "* (Naik) This study used PARIHS to inform their participatory approach between research team and primary health care teams, and also used it in evaluation of the qualitative data in assessing the building of the partnership to test and implement a health-coaching intervention.

Implementation theories

NPT- Normalisation Process Theory -"*as part of mixed-methods process evaluation, semi-structured interviews were conducted by phone with 27 providers participating in the study. Interviews were audio-taped and transcribed. Thematic content analysis was used to identify themes. Themes were categorized according to the four domains of Normalization Process Theory (NPT)".* (Vest) The authors discuss how the findings are informing their ongoing implementation strategies e.g. clinical mentors for the general practitioners who described a discomfort in their lack of expertise in screening and managing early chronic kidney disease. (other papers include: Burridge ,Coupe, Gask, Hanley, Vest)

Evaluation frameworks

MRC- Medical Research Council's framework for complex interventions,-"*The MRC framework provided a useful structure through which to examine our theoretical hypothesis and analyse the feasibility evidence*." (Sturt)
"*Guided self-help intervention was developed following a modelling phase which involved a systematic review, meta synthesis and a consensus process…"* (Lovell) The authors used the MRC framework for intervention development. Similarly Byrne et al also used the MRC framework for intervention development of literature review, focus group discussion and modelling and then interviews to refine the intervention.

REAIM- "*The process evaluation followed the RE-AIM (Reach, Efficacy/effectiveness, Adoption, Implementation and Maintenance) framework. Data were collected on attendance and attrition for classroom-based CBT and attention control PSHE by programme facilitators. An independent observer attended 5% of classroom based CBT sessions to assess treatment fidelity. Feedback was gathered from teachers, young people and facilitators using questionnaires and qualitative interviews*." (Stallard) (other papers include: Stallard, Wozniak, Lakeverld)

Realist Evaluation-
"*All data assigned to codes relating to the polypill strategy in CVD management were analysed …and the Realist framework of context–mechanism–outcomes utilized to develop the themes*" (Liu) The framework was used to guide the analysis of the qualitative data.

The use of theoretical frameworks seems to enable an in-depth investigation of stakeholders' perspectives of the perceived mechanisms of the intervention; by in a sense, providing a checklist of actions and behaviours to be examined. (19-29) An illustrative example is the PE of a trial in improving primary care referrals of patients with diabetic retinopathy to specialists through the use of educational printed materials. (29) A behavioural theory was used to inform the design and use of a questionnaire to explore the mechanism of the intervention. It was found that the primary care providers' intention to refer patients was the same before and after the trial, and this may have explained their negative trial results. The authors highlighted that the use of existing behavioural theory enhanced the '*generalisability and replicability*' of their methods.

Interaction with contextual factors: In fourteen papers the interaction of the intervention and contextual factors were explicitly explored. As mentioned above, theoretical frameworks often facilitated a closer and systematic way to consider context. For example, authors examined if there was 'contextual integration' i.e. organisational changes necessary to integrate a collaborative model of care for depression into routine practice. (30) Otherwise, contextual factors (e.g. impact of the introduction of a new policy (31)) were reported retrospectively in some papers in a more ad hoc manner. For instance, being reported as implementation facilitators and barriers, or discussed as possible influences on the outcomes.

Methods used

Assessing the studies based our bespoke assessment tool, we found that most authors (64/69) clearly justified their choice of methods and stated the studies' purpose; and most of the qualitative studies (42/50) were of a reasonable quality with 24/50 studies covering

all three domains of COREQ and 18/50 studies covering two domains. The methods could be categorised as: qualitative studies (e.g. interviews, focus group discussions, documentary analysis), quantitative (e.g. processes of care, baseline demographics, secondary outcomes) and studies which presented the synthesis of qualitative and quantitative data sources to indicate implementation, acceptability, fidelity and reach. (See Table 2 and Appendix 4 for more detail.)

Table 2: Summary of the methodology used and quality assessment of the studies

Stage of process evaluation	**Methodology & Methods**	**Analysis**	**Quality criteria**
Feasibility/ Piloting 20 Studies	9 studies used theories or frameworks. 18 used interviews. 3 used focus group discussions, 4 used questionnaires or surveys, 2 studies used routine monitoring data, field notes, minutes of meetings and observations.	Thematic analysis, constant comparative approach most commonly used, with some using framework analysis.	Planning: Team description: 11Y, 6N, 3 N/A Design and Conduct: Purpose: 20 Y Intervention description and causal assumptions clarified: 5 Y , 6 unclear, 9 N/A, 0 N Justify choice of timing and methods: 19Y, 1 N COREQ covered out of the 3 domains (17 applicable studies): 3 domains: 11 2 domains: 4 1 domain: 3 Reporting Clearly labelled as process evaluations: 5 Protocol/full report: 8
Evaluation of effectiveness 43 studies	12 studies used existing theories and frameworks. (6 Classic theories, 3 evaluation frameworks, 3 implementation theories) 2000-2004: 3 studies documented specific processes of care as part of the process evaluation, which were reported as part of the main trial. 4 studies investigated acceptability of an intervention using surveys/questionnaires. 2005 onwards- 12 studies used interviews alone to explore implementation and acceptability; 20 studies used interviews triangulated with other sources of data (e.g. chart audit). 2 studies used routine administrative data to indicate	Descriptive statistics were used for the quantitative data. Thematic, constant comparison and framework analysis for the qualitative data. The studies that used mixed methods, used the quantitative data to indicate level of implementation, reach and the dose. This was used to triangulate the qualitative findings on implementation and intervention acceptability. The studies which used evaluation frameworks (e.g. REAIM) and implementation theories (e.g. NPT) used	Planning: Team description: 21 Y, 21 N, 1 NA Design and Conduct: Purpose: 43 Intervention description and causal assumptions clarified: 25 Y, 8 Unclear, 5N/A, 5N Justify choice of timing and methods:40Y, 1 N, 2NA Report whether the process data are analysed blind to trial outcomes/ or post hoc: 29Y, 7N, 7N/A COREQ covered out of the 3 domains (30 applicable studies): 3 domains: 12 2 domains: 13 1 domain: 5 Reporting Clearly labelled as process evaluations: 17 (of note- 2 before 2008, 6 till 2015, and 9 after 2015) Protocol/full report: 21

	fidelity. 3 studies used questionnaires or surveys.	them for the analysis and presentation.	
Post evaluation 6 studies	1 study used existing theory. 2 studies used interviews, 2 used documentary analysis, and 1 used the administrative data and registry data	Descriptive statistics, subgroup analysis and thematic analysis.	Planning: Team description: 3 Y, 2 N, 1 NA Design and Conduct: Purpose: 6 Intervention description and causal assumptions clarified:0Y, 2 unclear, 2 N/A, 2 N Justify choice of timing and methods: 5Y, 1 N COREQ covered out of the 3 domains (3 applicable studies): 3 domains: 1 2 domains: 1 1 domain: 1 Reporting Clearly labelled: 0 Protocol/full report: 1

A strength of some studies was the triangulation of quantitative indicators with the qualitative findings of the acceptability and implementation of the intervention to determine intervention fidelity (i.e. whether the intervention was delivered per protocol). (See Appendix 3 for more detail.) (32, 33) The data sources indicating intervention fidelity included routine administrative data, trial/study management logs (22) and trial secondary outcomes. (34-36) Innovative indicators of e-health interventions included recording process measures such as time logged on by participants. (37) Other methods to determine intervention fidelity across multiple sites was having independent expert assessors reviewing intervention delivery using standardised forms. Three studies investigated 'for whom' an intervention had an impact on with the use of logistical regression of baseline demographics to identify relationships of the participants' characteristics with the primary or secondary outcomes. (38)

Sampling limitations in the qualitative studies were described as potentially introducing bias in the findings about intervention acceptability/mechanisms. (19, 20, 24-26, 29, 39-43) For example, authors highlighted that respondents who having agreed to be interviewed may

have a more favourable opinion of the intervention. (19, 39, 44-46) Maximum variation sampling (types of participants, socio-demographics, by 'negative' baseline of outcome characteristics'), comparing the characteristics of participants who did not partake in the interviews/surveys with the participants who did, and triangulation with other data sources may increase the robustness of such findings. (20, 21, 23, 29, 39, 40, 47)

(3) Process evaluation findings under mechanisms, implementation and context

Does the intervention fit local needs?

Stakeholders were generally motivated to adopt/implement the complex intervention if it addressed the contextual gap in care i.e. intervention fit. For example, a nurse-led secondary prevention clinic was implemented effectively when the health providers perceived it as improving team work, care continuity and providing a 'safety net' for the patients. In contrast, at other sites, this intervention was poorly implemented by the health care providers who viewed it as duplicating the existing model of care. (48) As another example, general practitioners reported that training them to manage acute and discrete episodes of depression, did not improve their management of depression. This was because this training did not upskill them for the chronic and relapsing nature of depression associated with personality and social problems increasingly seen in primary care. (42, 49) Similarly, patients' health literacy about their chronic disease (e.g. effectiveness of lifestyle modification for diabetes) was crucial as it affected engagement with the primary health care services, and their uptake of the intervention. (23, 26, 50-52)

Do key actors believe in and adopt their 'assigned' roles and responsibilities?

The extent to which key actors believed in and adopted their 'assigned' roles and responsibilities as part of implementing the complex intervention was a key theme under the heading 'Implementation.' (22, 27, 28, 43, 44, 49, 53) For example, in a study which used tele-monitoring to improve management of COPD patients in the community- there were differing views of the role of the patient. Some health providers described concerns that tele-monitoring would reinforce the 'sick role' of the patient, and an over-reliance on technology and practitioner support. Therefore, they were less willing to implement this model of care. On the other hand, some patients described that tele-monitoring was empowering as it provided knowledge and increased access to health practitioners who could provide reassurance in the management of the disease, and were thereby keen to continue this model of care. (23)

Facilitators to improve key actors' uptake of the interventions included the provision of intense training over a transition period prior to the start of the trial, significant research support, and ongoing communication with the researchers to help identify key actors' concerns and tailor implementation strategies to address them. For example, ensuring adequate communication between nurse practitioners and general practitioners was essential in task-shifting models of care. This facilitated greater trust between nurse practitioners and doctors which was needed to effectively deliver collaborative services. (43, 53) Such strategies were especially relevant for collaborative care interventions where new tasks were introduced within established hierarchical systems and interaction between different stakeholders was necessary for effective implementation.

Is the context of the intervention conducive?

Health system structures such as governance, health financing structures and workforce, were often mentioned as impacting on intervention implementation. Governance structures was pivotal to the successful adoption of the intervention. (24, 34) For example, an intervention to enhance referrals to mental health services was implemented well at a site when the intervention was perceived as 'service delivery' and directly supported by the mental health trust. In comparison, uptake of the intervention was limited when the intervention was not viewed as 'service delivery' and was considered 'primary research'. (34) Similarly, cultivating a strong partnership between researchers and clinicians through the formation of clinical advisory teams facilitated intervention implementation in bureaucratic and geographically complex environments. (24) Limited workforce and equipment shortages, and inadequate funding structures were reported by several authors as barriers to the intervention adoption. For example, health providers stated that the lack of government reimbursement for allied health services reduced the acceptability of the tele-health model of care for ongoing monitoring of diabetes at home. (40) General practitioners reported that time constraints in their busy practices prevented them from using the skills they learnt through an educational intervention to better manage depression. (42) Likewise, macro level context such as medication being out of stock in rural Zambia, was a barrier to the better outcomes, in spite of an evidence-based intervention to improve clinical assessment and management. (33)

Importantly, an iterative collaborative approach was described as a facilitator of intervention fit. (19, 37, 46, 51, 52, 54, 55) For example, study authors described how early stakeholder involvement identified the key characteristics of the lay worker needed (i.e. female, with visibility in the community) for their intervention to improve mental health care in India. This preparatory phase in the development of their model of care led to a

definitive RCT with positive outcomes. In their process evaluation of the RCT- they found that the provision of a lay worker was not relevant for the primary care practitioners in private practice who had established therapeutic relationships with their patients, but more so for the health providers in the public system who were time poor. These findings would then inform future scale up of the intervention within the right context (i.e. public health system) for the intervention. (54, 56)

DISCUSSION

Statement of principal findings

To our knowledge this is the first systematic appraisal using MRC guidance on process evaluations of primary care interventions. 66 of 69 studies were conducted in high-income countries; whilst cardiovascular disease, diabetes and depression were the most frequently studied conditions. There was an overall lack of consistency in the way PEs were conducted and reported. Indeed there was a lack of consistency in nomenclature with only 47 of the 69 studies identifying as 'process evaluations' although their purpose were essentially as such. Few studies (n=30) were underpinned by an intervention theory- description of hypothesised intervention mechanisms of action within local contextual factors. Most studies used robust sampling strategies and frequently triangulated qualitative and quantitative data to better understand the mechanisms of implementation. The MRC PE guidance with its focus on the interaction/configuration between context, implementation and mechanisms of intervention, provided a useful framework for the synthesis of the findings Mapping our findings upon the framework also gives our findings and assessment tools greater validity. The findings of these studies can be synthesised into a number of key messages: 1) that often there was a fundamental mismatch between what the intervention

was designed to achieve and local needs, 2) that the roles and responsibilities of key actors required to implement the intervention were often not clearly understood and; 3) that health system context – factors such as governance, financing structures and workforce – were often critical to implementation and as a consequence there were a number of studies where the unanticipated influence of these adversely impacted on implementation.

Comparison to other literature and implications

A key finding is identifying the breadth of literature which fits the MRC definition of process evaluation. This highlights the growing scope in this field to potentially address the evidence to practice gap through greater understanding of the interactions between intervention mechanisms, context and implementation. (13, 57, 58) However, greater consistency is needed in the reporting of PEs – as this would facilitate evidence synthesis, prevent research duplication and enhance transferability of interventions to other settings. (59) We note that the consistency in reporting seems to have increased since the publication of the MRC guidance.

An important finding is that theoretical frameworks helped guide a more in-depth development of intervention theory, design and implementation. (13, 60) The MRC PE guidance suggests that PE can help to explain the outcomes variations, and by doing so help refine the intervention theory. (18) We note that given the growing focus on self–management for chronic diseases, that the theories around behavioural change (e.g. empowerment) were most commonly used. Secondly, the focus on organisational change and the adoption of guidelines in NCDs, meant that implementation theories such as Normalisation Process Theory (NPT) were particularly relevant. Therefore, there should be more consistent use of theoretical frameworks, recognising that different frameworks will

be applicable to different settings. In addition, the use of checklists such as the Template for Intervention Description and Replication (TIDieR), or the Standardised for Reporting Implementation (StaRI) will ensure consistency in the reporting of intervention theory and implementation, thus reducing research waste. (57, 61, 62) We also note that there were only 6 'post–evaluation' studies identified. This is not surprising as implementation and translational research is a more recent phenomena and there may have been less funding for such work and greater difficulties in publishing such findings, a point likewise raised in the MRC guidance report in 2015. We anticipate, however, that more implementation research will be published as this emerging field matures.

We found that the intervention interaction with dynamic contextual factors was often inconsistently reported or reported retrospectively in an ad hoc manner. This gap has been similarly reported in the literature. (63)These findings emphasis MRC PE guidance's value in explicitly appraising context through "examining factors that shape theories, and affect implementation, and act to 'sustain the status quo, or potentiate effects." (4) However, this guidance is relatively broad and non-specific, and the question remains as to what should be explored a priori, and how best to report such findings. For example, the Context and Implementation of Complex Interventions (CICI) framework highlights seven domains of context ("*geographical, epidemiological, socio-cultural, socio-economic, ethical, legal and political context"*) that could be examined.(57) Similarly, STaRI checklist has context as an item in the methods (*i.e. "consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere"*) and in the results ("*contextual changes (if any) which may have affected outcomes"*). (61) These domains are comprehensive, and as a consequence if a study is to examine only a subset of these factors, it is better that it this is pre-specified in full acknowledgment of the evaluation as a whole.

This should be consistently reported, and linked through a full report or reference to a protocol. (4) As a baseline, a standardised PHC template informed by the questions of "*Does the intervention fit local needs? Do the key actors believe in and adopt their 'assigned' roles and responsibilities? Is the health system context (looking specifically at health workforce, governance, health financing structures and availability of medications) conducive*?" and relevant implementation theories (e.g. NPT) could be presented for testing in a systematic way. This could be done by primary health care researchers engaging with stakeholders at various time points, and iteratively added to. (64-66) Such an approach could potentially facilitate a greater shared understanding between stakeholders and greater consistently in the reporting of context. (63, 65, 67-69)

Most of these studies were conducted in high income countries with established PHC systems and universal health coverage (e.g. National Health Service in the UK). Therefore, some primary care interventions (e.g. improving referrals in collaborative care) may be of limited relevance to LMIC PHC systems given the different context especially with regards to health system structures. (70, 71) This reinforces the need for more formative research with local stakeholders when developing evidence-based interventions which addresses local needs, and minimises the unanticipated consequences of health system factors. (72, 73)

Strengths and limitations of this study

We were unable to conduct a subgroup analysis of implementation findings by country context (i.e. of high income countries as compared to LMIC) as we identified studies conducted mainly in high income countries. Some studies conducted in LMIC initially identified in the search were excluded because they did not meet our criteria (e.g. not RCTs,

not on NCDs) and as such, a review with different inclusion criteria may be better suited for this secondary objective. A second limitation is that despite our extended search terms to include components of chronic care model, and similar terms as process evaluations, we may not have exhaustively captured all process evaluations of complex primary care interventions. We note, however, that we reached thematic saturation in our analysis across the spectrum of studies which provides greater validity of our findings. Another limitation, is that we appraised the studies using a tool which we developed based on the MRC guidance (4), which has not been tested elsewhere. This was challenging given the heterogeneous studies that were included. For example, we only assessed qualitative methods with COREQ, and did not appraise the quality of statistical methods such as modelling. A strength of this review is having a multidisciplinary team of authors with vast experience in clinical trials and process evaluations to enable a reflexive thematic synthesis and interpretation of the papers. (74)

Conclusion

Greater consistency is needed in the reporting of, and the methods used, in PEs. In particular there should be more consistent use of theoretical frameworks to inform intervention theory; and the triangulation of qualitative and quantitative data. Greater emphasis on formative research in designing primary care interventions is needed so that they are clearly aligned with the needs of local stakeholders, that the roles and responsibilities of key actors are better understood and that unanticipated consequences arising from context-specific barriers to implementation are minimised. We hope this review will inform future process evaluations and facilitate the sustainability of evidence-based interventions.

Declarations

Abbreviations:

MRC: Medical Research Council

PE: Process Evaluations

NPT: Normalisation Process Theory

NCD: Non-communicable diseases

LMIC: Low and middle income countries

PHC: Primary health care

RCT: Randomised Controlled Trials

TIDieR: Template for Intervention Description and Replication

COPD: Chronic Obstructive Pulmonary Disease

COREQ: consolidated criteria of reporting of qualitative research

STaRI: Standardised for Reporting Implementation

CICI: Context and Implementation of Complex Interventions

Original protocol: This has been published in an open access journal and is referenced in the manuscript.

Ethical Approval and Consent to participate : not applicable

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73. Luoto J, Shekelle PG, Maglione MA, Johnsen B, Perry T. Reporting of context and implementation in studies of global health interventions: a pilot study. Implement Sci. 2014 May 12;9:57. PubMed PMID: 24886201. Pubmed Central PMCID: 4043974.
74. Lewin S, Bohren M, Rashidian A, Munthe-Kaas H, Glenton C, Colvin CJ, et al. Applying GRADE-CERQual to qualitative evidence synthesis findings-paper 2: how to make an overall CERQual assessment of confidence and create a Summary of Qualitative Findings table. Implement Sci. 2018 Jan 25;13(Suppl 1):10. PubMed PMID: 29384082. Pubmed Central PMCID: 5791047.

Figures and Tables

Figure 1: PRISMA figure

Figure 2: MRC PE framework with tallies of studies, methods and synthesised findings.

Box 1: Summary points of the UK MRC guidance for process evaluations

Box 2: Illustrative examples of the use of Theories and Frameworks (embedded in the main text)

Table 1: Summary of the characteristics of the included studies (embedded in the main text)

Table 2: Summary of the methodology used and quality assessment of the studies (embedded in the main text)

APPENDIXES

1) Appendix 1: PRISMA Checklist
2) Appendix 2: Search Strategy
3) Appendix 3: PICO table (organised into sections based on the types of NCDs, and within each section, studies are ordered by years)
4) Appendix 4: Methods table, organised into sections based on stage of process evaluation, and within each section, ordered by years)
5) Appendix 5: Quality of studies table as informed by the MRC recommendations and the COREQ
6) Appendix 6: Illustrative examples for the synthesised findings

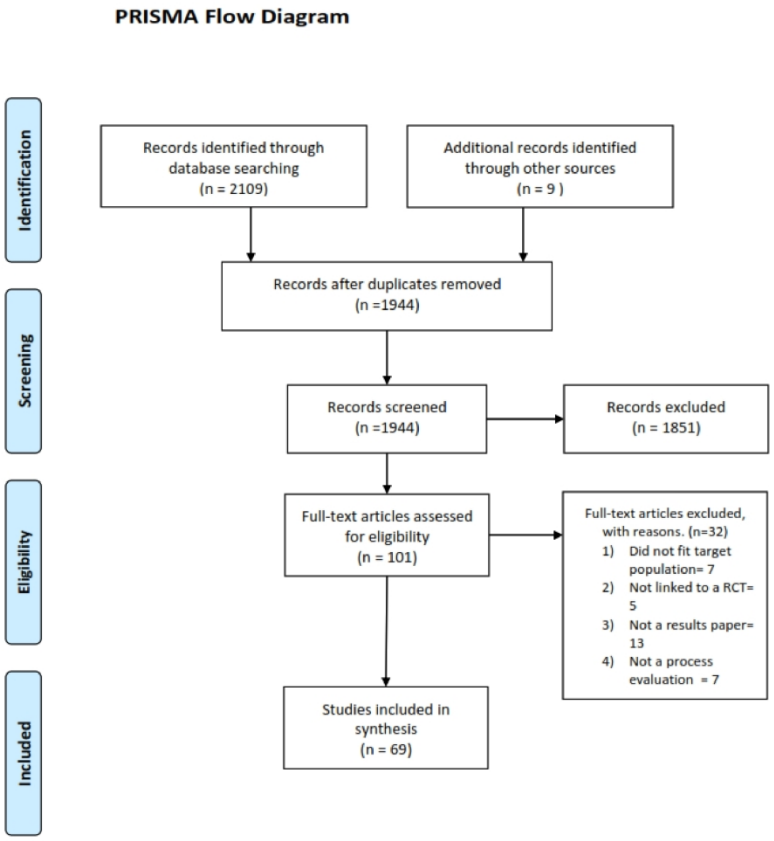

Figure 1: PRISMA Flow Diagram

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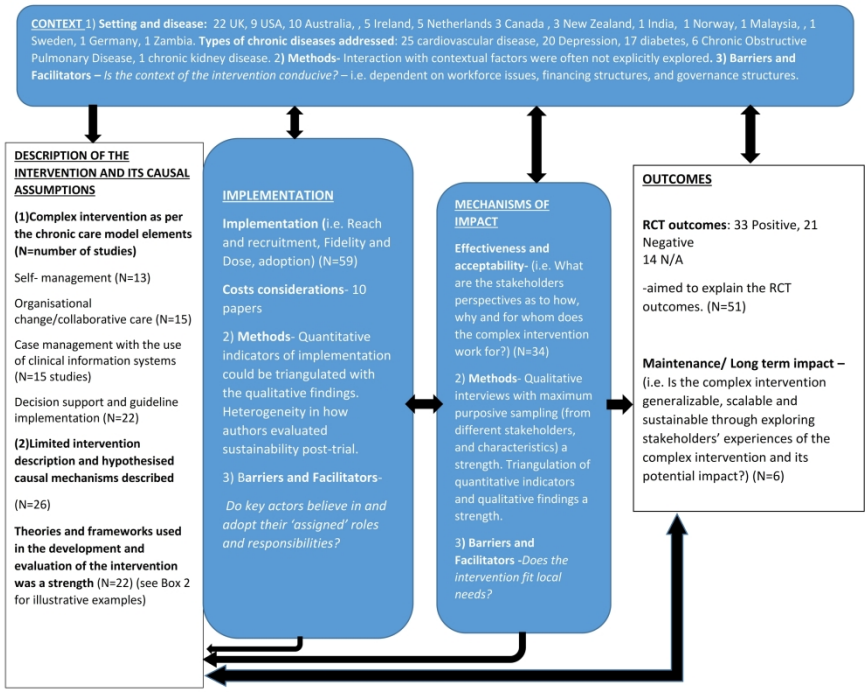

Figure 2. An overview of our findings is depicted in this modified MRC process evaluation framework which depicts the interactions between areas of the process evaluation in blue (i.e. the context, mechanisms, implementation) and how that interacts to produce outcomes (in white and right of the figure) which is used to inform and refine the hypothesised intervention theory (in white and left of the figure). Tallies of studies, methods and synthesised qualitative findings of strengths and limitations, implementation barriers and facilitators are summarised in this modified diagram.

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APPENDIX 1: PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5,6 (published protocol
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6 (published protocol)
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5 (in protocol)
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6-8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7, 8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8

APPENDIX 1: PRISMA 2009 Checklist

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8,14,15
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 1, and Appendix 3, 4
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Table 2, and appendix 5
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Table 1, Appendix 3
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	9-20
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	8,Table 2, Appendix 5
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20, fig 2

APPENDIX 1: PRISMA 2009 Checklist

Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	23-24
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	26

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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1	Program Evaluation.mp. or Program Evaluation/ ►	87714	Advanced	Display More ≫
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3	Qualitative research.mp. or Qualitative Research/ ►	90806	Advanced	Display More ≫
4	qualitative.mp. ►	477736	Advanced	Display More ≫
5	Clinical trials.mp. or Clinical Trial/ ►	1848296	Advanced	Display More ≫
6	Randomized Controlled Trials as Topic/ or Clinical Trials as Topic/ or randomised controlled trials.mp. ►	401314	Advanced	Display More ≫
7	complex interventions.mp. ►	2533	Advanced	Display More ≫
8	Mental Disorders/ or Primary Health Care/ or Chronic Disease/ or Diabetes Mellitus/ or chronic care model.mp. or Pulmonary Disease, Chronic Obstructive/ or Disease Management/ ►	1449344	Advanced	Display More ≫
9	Primary health care.mp. or Primary Health Care/ ►	158339	Advanced	Display More ≫
10	cardiovascular diseases.mp. or exp Cardiovascular Diseases/ ►	5530823	Advanced	Display More ≫
11	chronic kidney disease.mp. or exp Renal Insufficiency, Chronic/ ►	215546	Advanced	Display More ≫
12	exp Pulmonary Disease, Chronic Obstructive/ or Lung Diseases, Obstructive/ or Respiratory Tract Diseases/ or Chronic respiratory disease.mp. or Chronic Disease/ ►	594762	Advanced	Display More ≫
13	Obesity/ or Blood Glucose/ or Diabetes Mellitus, Type 2/ or Diabetes Mellitus/ or type 2 diabetes.mp. or Insulin/ or Hypoglycemic Agents/ ►	1698732	Advanced	Display More ≫
14	exp Depression/ or depression.mp. ►	1119824	Advanced	Display More ≫
15	general practice.mp. or Family Practice/ or General Practice/ ►	183431	Advanced	Display More ≫
16	family physician.mp. or Physicians, Family/ ►	89336	Advanced	Display More ≫
17	Social Support/ or Community Health Services/ or Community Mental Health Services/ or community support.mp. ►	294906	Advanced	Display More ≫
18	Social Environment/ or Adolescent/ or Social Support/ or Mental Disorders/ or Family Relations/ or family support.mp. or Family/ ►	3761942	Advanced	Display More ≫
19	case management.mp. or Community Mental Health Services/ or "Quality of Health Care"/ or "Delivery of Health Care"/ or Mental Disorders/ or Case Management/ or Chronic Disease/ or Patient Care Team/ ►	1303857	Advanced	Display Delete More ≫
20	self management.mp. or Self Care/ ►	89895	Advanced	Display More ≫
21	Primary Health Care/ or "Delivery of Health Care"/ or Organizational Innovation/ or organisational change.mp. ►	426297	Advanced	Display More ≫
22	Primary Health Care/ or Quality Assurance, Health Care/ or Chronic Disease/ or delivery system design.mp. or Diabetes Mellitus/ or "Delivery of Health Care"/ ►	1432354	Advanced	Display More ≫
23	Decision Making/ or Decision Support Techniques/ or Decision Making, Computer-Assisted/ or Decision Support Systems, Clinical/ or decision support.mp. ►	347732	Advanced	Display More ≫
24	Information Systems/ or Medical Records Systems, Computerized/ or clinical information systems.mp. or Electronic Health Records/ ►	120031	Advanced	Display More ≫
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Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Author	Title	Year	Setting	Disease Condition	RCT Outcomes	Cost Considerations (Y/N/NA)
1. Gask L, Ludman E, Scaefer J.	Qualitative study of an intervention for depression among patients with diabetes: how can we optimise patient-professional interaction	2006	Primary health care, Manchester UK	Depression and Diabetes	Positive	N
2. Chew-Graham CA, Lovell K, Roberts C, Baldwin R, Morley M, Burns A, et al	A randomised controlled trial test the feasibility of a collaborative care model for the management of depression in older people	2007	Primary Care trust, Manchester	Depression	Positive	N
3. Lovell K, Bower P, Richards D, Barkham M, Sibbald B, Roberts C, et al	Developing guided self-help for depression using the Medical Research Council complex interventions framework: A description of the modelling phase and results of an exploratory randomised controlled trial	2008	Primary care Units England. United Kingdom	Depression	Negative	N
4. Slade M, Gask L, Leese M, McCrone P, Montana C, Powell R, Stewart M, Graham-Chew C	Failure to improve appropriateness of referrals to adult community mental health services—lessons from a multi-site cluster randomized controlled trial	2008	General Practice, Community Services. London & Manchester, United Kingdom	Depression (Mental Health)	negative	Y
5. Gask L, Bower P, Lovell K, Escott D, Archer J, Gilbody S, Lankshear A, Simpson AE, Richards DA.	What work has to be done to implement collaborative care for depression? Process evaluation of a trial utilizing the Normalisational Process Model	2010	Primary health care, UK	Depression	NA	N
6. Chalder M, Wiles NJ, Campbell J, Hollinghurst SP, Searle A, Haase AM, et al	A pragmatic randomised controlled trial to evaluate the cost-effectiveness of a physical activity intervention as a treatment for depression: The treating depression with physical activity (TREAD) trial	2012	General practices in the Bristol and Exeter areas, United Kingdom	Depression	Negative	Y
7. Bennett M, Walters K, Drennan V, Buszewicz M	Structured Pro-Active Care for Chronic Depression by Practice Nurses in Primary Care: A Qualitative Evaluation	2013	General Practice. United Kingdom	Depression	Positive	N
8. Stallard P, Phillips R, Montgomery AA, Spears M, Anderson R, Taylor J, et al	A cluster randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents	2013	Schools. United Kingdom	Depression	Negative	Y
9. Coupe N, Anderson E, Gask L, Sykes P, Richards DA, Chew-Graham C	Facilitating professional liaison in collaborative care for depression in UK primary care; A qualitative study utilising normalisation process theory	2014	Primary care GP. Bristol, London, and greater Manchester. United Kingdom	Depression	Positive	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Synthesis (depression in UK)	Types of intervention: collaborative care models, introducing CBT in schools, introduction of physical activity,	9 studies in UK looking at depression between 2006-2014)			4 positive RCTs, 4 negative and 1 NA.	3/9 studies for costs analysis.
10. Oishi SM, Shoai R, Katon W, Callahan C, Unutzer J, Arean P, et al	Impacting late life depression: Integrating a depression intervention into primary care	2003	Primary care Practices. United States	Depression	NA (not complete)	N
11. Dietrich AJ, Oxman TE, Williams JW, Kroenke K, Schulberg HC, Bruce M, et al	Going to scale: Re-engineering systems for primary care treatment of depression	2004	5 Medical groups and health plans in the USA, with 60 practices participating	Depression	Positive	NA
12. Gask L, Dixon C, May C, Dowrick C	Qualitative study of an educational intervention for GPs in the assessment and management of depression	2005	Group Health Clinics. Western Washington. USA	Depression	Negative	N
13. Lee PW, Dietrich AJ, Oxman TE, Williams Jr JW, Barry SL	Sustainable impact of a primary care depression intervention	2007	Health care organisations. USA	Depression	Positive	N
14. Chung B, Jones L, Dixon EL, Miranda J, Wells K, Community Partners in Care Steering Council	Using a Community Partner Participatory Research Approach to Implement a Randomised Controlled Trial: Planning Community Partners in Care	2010	USA (community multi agencies for minority groups)	Depression	NA	N
15. Chaney EF, Rubenstein LV, Liu CF, Yano EM, Bolkan C, Lee M, et al	Implementing collaborative care for depression treatment in primary care: A cluster randomized evaluation of a quality improvement practice redesign	2011	Primary care settings, Veteran affairs in several states USA	Depression	Positive	Y
16. Rapp AM, Chavira DA, Sugar CA, Asarnow JR	Integrated Primary Medical-Behavioral Health Care for Adoolescent and Young Adult Depression: Predictors of Service Use in Youth Partners in Care Trial.	2017	Primary Health Care USA	Depression	Positive	N
Synthesis (depression in USA)	All 7 studies were a version of collaborative care models either between primary and tertiary care, or increasing the outreach through settings outside of health.	7 studies in USA looking at depression.			4 positive, 2 NA and 1 negative	1Y, 4 N, 1 NA
17. Thornett AM, Mynors-Wallis LM	Credibility of problem-solving therapy and medication for the treatment of depression among primary care patients	2002	Primary Care setting, South Australia	Depression	Positive	NA
18. Gensichen J, Guethlin C, Sarmand N, Sivakumaran D,	Patients' perspectives on depression case management in general practice - A qualitative study	2012	General Practices. Germany	Depression	Positive	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Jager C, Mergenthal K, et al						
19. Chatterjee S, Chowdhary N, Pednekar S, Cohen A, Andrew G, Araya R, et al	Integrating evidence-based treatments for common mental disorders in routine primary care: Feasibility and acceptability of the MANAS intervention in Goa, India	2008	Primary Health care, Goa, India	Depression	Positive	N
20. Richter-Sundberg L, Nystrom ME, Krakau I, Sandahl C	Improving treatment of depression in primary health care: A case study of obstacles to perform a clinical trial designed to implement practice guidelines	2015	Primary Health care Units. Sweden	Depression	NA	N
Synthesis (depression)	**Interventions mostly around collaborative care through increasing expertise of different roles (e.g. lay worker, nurse for pro-active care, GP for PHC) (15 studies), at times to implement practice guidelines (4 studies), and trialling specific interventions such as physical exercise and CBT (2 studies).**	**2003-2015**	**9 were in UK, 6 in USA, and 1 Sweden, 1 Germany, 1 Australia and 1 in India.**	**Overall 19 studies in depression**	**10 positive RCTs, 5 Negative, 4 NA**	**4/19 Y, 13 N, 2 NA**
1. Tai SS, Nazareth I, Donegan C, Haines A	Evaluation of general practice computer templates. Lessons from a pilot randomised controlled trial	1999	North London. United Kingdom	Diabetes and asthma)	Positive	N
2. Hetlevik I, Holmen J, Kruger O, Kristebsen P, Iversen H, Furuseth K	Implementing Clinical guidelines in the treatment of Diabetes Mellitus in General Practice	2000	Norway	Diabetes Mellitus	Negative	N
3. Ilag LL, Martin CL, Tabaei BP, Isaman DJ, Burke R, Greene DA, et al	Improving diabetes processes of care in managed care	2003	United States, nine university- affiliated primary care internal medicine practices affiliated with a managed care organisation.	Diabetes	Negative on main outcome measures but positive on process outcomes	N
4. Smith S, Bury G, O'Leary M, Shannon W, Tynan A, Staines A, Thompson C	The North Dublin randomized controlled trial of structured diabetes shared care	2004	Ireland	Diabetes	Neutral	N
5. Jackie Sturt, Hafrun Taylor, Andrea Docherty, Jeremy Dale, Taylor Louise	A psychological approach to providing self-management education for people with type 2 diabetes: the Diabetes Manual	2006	Primary health care UK	Diabetes	NA	NA
6. Pylypchuk G, Vincent L, Wentworth J, Kiss A, Perkins N, Hartman S, et al	Diabetes risk evaluation and microalbuminuria (DREAM) studies: Ten years of participatory research with a First Nation's home and community model for type 2 diabetes care in northern Saskatchewan	2008	First Nations, Northern Saskatchewan, Canada	Diabetes type 2	not significantly positive	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

7. Smith S, Paul G, Kelly A, Whitford D, O'Shea E, O'Dowd T	Peer support for patients with type 2 diabetes: Cluster randomised controlled trial	2011	General Practice. Ireland	Type 2 Diabetes mellitus	Equivalent	Y
8. Ratanawongsa N, Bhandari VK, Handley M, Rundall T, Hammer H, Schillinger D	Primary care provider perceptions of the effectiveness of two self-management support programs for vulnerable patients with diabetes	2012	Community health network. San Francisco	Type 2 Diabetes mellitus	Positive	N
9. Lakerveld J, Bot S, Chinapaw M, van Tulder M, Kingo L, Nijpels G	Process evaluation of a lifestyle intervention to prevent diabetes and cardiovascular diseases in primary care	2012	Semi-rural region of West Friesland	Type 2 diabetes mellitus	Negative	Y(economic evaluations done separately)
10. Paul G, Keogh K, D'Eath M, Smith SM	Implementing a peer-support intervention for people with type 2 diabetes: A qualitative study	2013	General Practices, Ireland	Type 2 Diabetes mellitus	positive	N
11. Carlisle K, Warren R	A qualitative case study of tele-health for in-home monitoring to support the management of type 2 diabetes	2013	Queensland. Australia	type 2 diabetes	Positive	N
12. Grimshaw JM, Presseau J, Tetreo Jm , Eccles MP, Francis JJ, Godin G, Graham ID, Hux, JE, Johnston M, Legare F, Lemyre L, Robinson N, Zwarenstein M.	Looking inside the black box: results of a theory-based process evaluation exploring the results of a randomized controlled trial of printed educational messages to increase primary care physicians' diabetic retinopathy referrals	2014	Primary care setting, Ontario, Canada	Diabetes(leading to retinopathy)	Negative	N
13. Burridge LH, Foster MM, Donald M, Zhang J, Russell AW, Jackson CL	Making sense of change: patients' views of diabetes and GP-led integrated diabetes care	2014	Primary Care, Brisbane. Australia	Type 2 Diabetes	NA	N
14. Naik AD, Lawrence B, Kiefer L, Ramos K, Utech A, Masozera N, et al	Building a primary care/research partnership: lessons learned from a tele-health intervention for diabetes and depression	2015	Primary care teams Veterans affair Medical centre in Southern USA	Depression & uncontrolled diabetes	not stated in paper	N
15. Eborall HC, Dallosso HM, McNicol S, Speight J, Khunti K, Davies MJ, et al	Explaining engagement in self-monitoring among participants of the DESMOND self-monitoring trial: A qualitative interview study	2015	Primary care trust, United Kingdom	type 2 diabetes mellitus	Positive	N
16. Ramadas A, Chan C, Oldenburg B, Hussien Z, Quek K	A Web-Based Dietary Intervention for People with Type 2 Diabetes: Development, Implementation, and Evaluation	2015	In the community, recruited from outpatient medical clinics of public hospitals Kuala Lumpur. Malaysia	Type 2 Diabetes Mellitus	Positive	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

17. Kenealy TW, Parsons MJG, Rouse PB, Doughty RN, Sheridan NF, Hindmarsh JKH, Masson SC, Rea HH.	Tele-care for Diabetes, CHF or COPD; Effect on Quality of Life, Hospital Use and Costs. A Randomised Controlled Trial and Qualitative Evaluation	2015	New Zealand	Diabetes, Chronic Heart Failure, COPD	Neutral	Y
Synthesis (diabetes)	**The interventions included improving guidelines referral and treatment (7 studies), patient self-management and community support (7 studies) and tele-health (3 studies).**	**1999-2016**	**3 Ireland, 1 Norway, 2 USA, 2 Canada (1 of the First Nations), 3 UK, 2 Australia, 1 New Zealand, 1 Malaysia**	**17 studies on diabetes (2 included other chronic disease)**	**6 Positive, 10 Negative/Neutral, 1 N/A**	**3/16 Y, 13/16 N, 1/16 NA**
1. Pearl A, Wright S, Gamble G, Doughty R, Sharpe N	Randomised trials in general practice--a New Zealand experience in recruitment	2003	General Practices .New Zealand	Heart failure	Positive	NA
2. Lobo CM, Euser L, Kamp J, Frijling BD, Severens JL, Hulscher MEJL, et al	Process evaluation of a multifaceted intervention to improve cardiovascular disease prevention in general practice	2003	General Practices, Netherlands	Cardiovascular Disease	Positive	Y
3. Weiss MC, Montgomery AA, Fahey T, Peters TJ	Decision analysis for newly diagnosed hypertensive patients: a qualitative investigation	2004	General Practice. South West-England. United Kingdom	Hypertension	Positive	N
4. Murchie P, Campbell NC, Ritchie LD, Thain J	Running nurse-led secondary prevention clinics for coronary heart disease in primary care: Qualitative study of health professionals' perspectives	2005	North East Scotland, UK	Cardiovascular Disease (Coronary Heart Disease)	Positive	N
5. Byrne M, Cupples ME, Smith SM, Leathem C, Corrigan M, Byrne MC, et al	Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK Medical Research Council framework	2006	General Practices Urban & Rural Settings The island of Ireland, where 2 different healthcare systems exist. In the north, in line with Britain, the National Health Service allows everyone free access to general practice and hospital services. In the south, a mixed public and private healthcare system operates, with less than 30% of the population qualifying for free general practice and hospital services.	Cardiovascular disease	Positive	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

6.	Heaven, B, Murtagh, M. Rapley, T.May, C., raham, R. Kaner, E., Thomson, R.	Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention	2006	GP clinics in UK	CVD (AF patients at risk for a stroke)	NA	NA
7.	Clark RA, Yallop JJ, Piterman L, Croucher J, Tonkin A, Stewart S, et al	Adherence, adaptation and acceptance of elderly chronic heart failure patients to receiving healthcare via telephone-monitoring	2007	General Physicians, Rural Australia	Cardiovascular disease	Positive	N
8.	Fakiri FE, Hows MW, Uitewaal PJM, Frenken RA, Bruijnzeels MA.	Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in general practices in deprived neighbourhoods	2008	General practices in deprived neighbourhoods, United Kingdom	Cardiovascular disease	Negative	N
9.	Wentzlaff DM, Carter BL, Ardery G, Franciscus CL, Doucette WR, Chrischilles EA, et al	Sustained Blood Pressure Control Following Discontinuation of a Pharmacist Intervention	2011	Iowa. United States of America	Hypertension	positive	N
10.	Passey ME, Laws RA, Jayasinghe UW, Fanaian M, McKenzie S, Powell-Davies G, et al	Predictors of primary care referrals to a vascular disease prevention lifestyle program among participants in a cluster randomised trial	2012	2 Rural 3 urban Division of General practice in New South Wales. Australia	Cardiovascular disease	Positive	N
11.	Nelson P, Cox H, Furze G, Lewin RJP, Morton V, Norris H, et al	Participants' experiences of care during a randomized controlled trial comparing a lay-facilitated angina management programme with usual care: a qualitative study using focus groups	2013	District General Hospital, North England. United Kingdom	Cardiovascular disease (Angina)	Positive	NA
12.	Fairbrother, Peter McCloughan, Lucy Adam, Geraldine Brand, Richard Brown, Cecil Watson, Mary Cotter, Nicola Mackellaig, Juliet McKinstry, Brian	Involving patients in clinical research: The Telescot patient panel	2013	Primary health care Scotland, UK	CVD (Stroke)	NA	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

13. Hanley, J.Ure, J.Pagliari, C. Sheikh, A.McKinstry, B.	Experiences of patients and professionals participating in the HITS home blood pressure tele-monitoring trial: A qualitative study	2013	Primary health care in Edinburgh, UK	CVD with Hypertension as the major risk factor	Positive	N
14. Laws, R. A, Fanaian, M, Jayasinghe, U. W.McKenzie, S. Passey, M.Davies, G. P.Lyle, D. Harris, M. F	Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial	2013	Urban and rural PHC in Australia	CVD prevention	positive (changes in self- reported physical behaviours, but only those referred to life style modification program achieved improvement in diet or weight.	N
15. Manca DP, Greiver M, Carroll JC, Salvalaggio G, Cave A, Rogers J, et al	Finding a BETTER way: A qualitative study exploring the prevention practitioner intervention to improve chronic disease prevention and screening in family practice	2014	Primary care, Canada (urban setting)	Chronic disease- diabetes and heart disease (among others)	positive	N
16. Liu H, Massi L, Laba TL, Peiris D, Usherwood T, Patel A, Cass A, Eades AM, Redfern J, Hayman N, Howard K, Brien JA, Jan S.	Patients' and Providers' Perspectives of a Polypill Strategy to Improve Cardiovascular Prevention in Australian Primary Health Care: A Qualitative Study Set Within a Pragmatic Randomized, Controlled Trial.	2015	Australia PHC	CVD	Positive	Y
17. Liu H, Laba T, Massi L, Jan S, Usherwood T, Patel A, Hayman N, Cass A, Eades A, Peiris D.	Facilitators and barriers to implementation of a pragmatic clinical trial in Aboriginal health services.	2015	Australia PHC	CVD	NA	NA
18. Liu H, Massi L, Eades AM, Howard K, Peiris D, Redfern J, Usherwood T, Cass A, Patel A, Jan S, Laba T.	Implementing a pragmatic randomised controlled trial in Australia: lessons learnt from the Kanyini Guidelines Adherence with the Polypill study (Kanyini GAP)	2015	Australia PHC	CVD	NA	NA
19. Huntink E, Wensing M, Timmers IM, Lieshout JV	Process evaluation of a tailored intervention programme of cardiovascular risk management in general practices	2016	Netherlands	Cardiovascular risk management (high cardiovascular risk, and depressive symptoms)	Negative	N
20. Parsons, J. A. Yu, C. H. Y. Baker, N. A.	Practice doesn't always make perfect: A qualitative study explaining why a trial of an educational toolkit did not improve quality of care	2016	General Practices in Ontario, Canada	CVD prevention	Negative (possible harms)	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Mamdani, M. M. Bhattacharyya, O. Zwarenstein, M. Shah, B. R.						
21. Presseau J, Grimshaw J, Tetroe JM, Eccles MP, Francis JJ, Godin G, Graham ID, Hux JE, Johnston M, Legare F, Lemyre L, Robinson N, Zwarenstein M.	A theory-based process evaluation alongside a randomised controlled trial of printed educational messages to increase primary care physician's prescription of thiazide diuretics for hypertension	2016	Ontario, Canada	Cardiovascular disease management (prescription of thiazide for hypertension)	Negative	N
22. Yan LD, Chirwa C, Chi BH, Bosomprah S, Sindano N, Mwanza M, Musatwe D, Mulenga M, Chilengi R.	Hypertension management in rural primary care facilities in Zambia: a mixed methods study	2017	Rural Zambian clinics	Hypertension	NA (ongoing trial)	NA
23. Wells S, Rafter N, Kenealy T, Herd, Geoff, Eggleton K, Lightfoot R, Arcus K, Wadham A, Jiang Y, Bullen C.	The impact of a point of care testing device on CVD risk assessment completion in New Zealand primary-care practice: A cluster randomised controlled trial and qualitative investigation	2017	General practices in Northland region, New Zealand,	CVD risk assessment	Negative	Y
24. Grant A, Dreischulte T, Guthrie B	Process evaluation of the data-driven quality improvement in primary care (DQIP) trial: active and less active ingredients of a multi-component complex intervention to reduce high-risk primary care prescribing	2017	Primary Health care in UK. 33 practices from one Scottish health board	Cardiovascular and renal adverse events	Positive	N
25. Grant A, Dreischulte T, Guthrie B	Process evaluation of the Data-driven Quality Improvement in Primary Care (DQIP) trial: case study evaluation of adoption and maintenance of a complex intervention to reduce high-risk primary care prescribing	2017	Primary Health care in UK. 33 practices from one Scottish health board	Cardiovascular and renal adverse events	Positive	N

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

Synthesis (CVD)	**Ten of the studies were about improving the screening and management of CVD using best-practice guidelines. (e.g. educational materials to improve referral, or decision analysis). Ten of the studies were about organisational change with models of care that incorporated new roles such as a nurse-led clinic, or the use of a lay worker for angina management, and technology (e.g. tele-monitoring, point of care testing). 5 of the studies explored trial implementation such as recruitment of patients and providers, and were less about the intervention.**	**2013-2017**	**2 New Zealand, 2 Netherlands, 9 UK, 1 Ireland, 6 Australia, 1 USA, 3 Canada, 1 Zambia (interesting that is so international, which I assume has to do with the recognition of CVD)**	**25 studies in CVD. (1 for chronic diseases, in which CVD is mentioned)**	**15 Positive, 5 Negative, and 5 N/A**	**3 Y, 15 N, 6 NA**
1. Van Den Bemt L, Schermer TRJ, Smeele IJM, Boonman-de Winter LJM, Van Boxem T, Denis J, et al	An expert-supported monitoring system for patients with chronic obstructive pulmonary disease in general practice: Results of a cluster randomised controlled trial	2009	General Practice. Netherlands	COPD	Negative	N
2. Casey D, Murphy K, Cooney A, Mee L, Dowling M.	Developing a structured education programme for clients with COPD	2011	Primary care, Ireland	COPD	NA	N
3. Julia A. E. Walters,E, Helen Courtney-Pratt , Helen Cameron-Tucker, Mark Nelson, Andrew Robinson, Jenn Scott, Paul Turner, E. Haydn Walters and Richard Wood-Baker	Engaging general practice nurses in chronic disease self-management support in Australia: Insights from a controlled trial in chronic obstructive pulmonary disease	2012	Australia PHC	COPD	NA	N
4. Fairbrother P, Pinnock H, Hanley J, McCloughan L, Sheikh A, Pagliari C, et al	Exploring tele-monitoring and self-management by patients with chronic obstructive pulmonary disease: A qualitative study embedded in a randomized controlled trial	2013	Lothian. Scotland, UK	Chronic Obstructive Pulmonary Disease	NA	N
5. Van der Weegen S, Verwey R et al	The Development of a Mobile Monitoring and Feedback Tool to Stimulate Physical Activity of People with a Chronic Disease in Primary Care: A User-Centred Design	2013	Netherlands PHC	Chronic Obstructive Pulmonary Disease or Type 2 diabetes	NA	NA

Appendix 3: Characteristics of individual studies (Population, Setting, Disease Condition, Outcomes)

6. Vest BM, York TRM, Sand J, Fox CH, Kahn LS	Chronic kidney disease guideline implementation in primary care: A qualitative report from the TRANSLATE CKD study	2015	Primary Care Practices, New York. United States	Chronic Kidney Disease	Positive	N
7. Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L	Process evaluation of physical activity counselling with and without the use of mobile technology: A mixed methods study	2016	Netherlands	Chronic Obstructive Pulmonary Disease or Type 2 diabetes	Positive	NA
Synthesis (COPD, and CKD)	**4 of the studies were about improving self-management of patients through educational materials, or use of monitoring, with support from health providers. 2 of the studies were about stimulating physical activity through the use of technology. 1 study was about implementing management guidelines in CKD in PHC.**	**2009-2016**	**3 Netherlands, I Ireland, 1 UK (Scotland), 1 USA, 1 Australia**	**6 addressing COPD (2 including other chronic disease), and 1 addressing CKD.**	**2 Positive, 1 Negative, 4 N/A**	**0 Y, 5 N, 2 N/A.**
Overall Synthesis of 69 studies in total	**Overall, the complex primary care interventions fit within the general categories of facilitating patient self-management (13 studies), organisational change to include collaborative care (16 studies), facilitating better case management using clinical information systems (e.g. tele-health) (15 studies), and the use of decision support and guideline implementation (e.g. referral systems) (22 studies). In addition, 5 studies were exploring the conduct of trials in primary health care e.g. the recruitment of patients.**	**1999-2017**	**22 UK, 9 USA, 1 Sweden, 1 Germany, 10 Australia, 1 India, 3 Canada, 5 Ireland, 1 Norway, 3 New Zealand, 1 Malaysia, 5 Netherlands, 1 Zambia In addition, 2 studies focused on First Nations peoples in Australia and in Canada. 3 studies (Chung, Fakiri, Ratangawonsa) were focused on the populations living in disadvantage.**	**20 Depression, 17 Diabetes, 25 CVD, 6 COPD and 1 CKD.**	**33 Positive, 21 Negative and 14 Not applicable.**	**10 Y, 47 N, 11 Not applicable.**

Appendix 4: Methods and methodology of individual studies

Author	Title	Year	Labelled as Process Evaluation (Y/N)	Stated Purpose (Y/N)	Protocol (Y/N)	Processes examined at which stage	Use of Theory (Y/N)	Methods	Analysis
Tai SS, Nazareth I, Donegan C, Haines A	Evaluation of general practice computer templates. Lessons from a pilot randomised controlled trial	1999	N	Y	N	Feasibility and Piloting	N	qualitative (semi-structured interviews designed to assess the users' views) and quantitative (change in use of the template during the study period)	NA
Weiss MC, Montgomery AA, Fahey T, Peters TJ	Decision analysis for newly diagnosed hypertensive patients: a qualitative investigation	2004	Qualitative study	Y	N	Feasibility and Piloting	N	Semi-structured Interviews	Decision Analysis
Jackie Sturt, Hafrun Taylor, Andrea Docherty, Jeremy Dale, Taylor Louise	A psychological approach to providing self-management education for people with type 2 diabetes: the Diabetes Manual	2006	N	Y	N	Feasibility	Y	Using the MRC complex intervention framework the intervention was developed. Theory driven, needs assessment through focus group, and the use of a feasibility survey	Use of a survey to determine the feasibility of the developed intervention to be further tested in a definitive RCT
Byrne M, Cupples ME, Smith SM, Leathem C, Corrigan M, Byrne MC, et al	Development of a complex intervention for secondary prevention of coronary heart disease in primary care using the UK Medical Research Council framework	2006	N	Y	N	Feasibility and Piloting	Y	Semi structured Interviews	NR
Chew-Graham CA, Lovell K, Roberts C, Baldwin R, Morley M, Burns A, et al	A randomised controlled trial test the feasibility of a collaborative care model for the management of depression in older people	2007	N	Y	N	Feasibility and Piloting	N	Semi-structured Interviews and questionnaires	Thematic analysis
Clark RA, Yallop JJ, Piterman L, Croucher J, Tonkin A, Stewart S, et al	Adherence, adaptation and acceptance of elderly chronic heart failure patients to receiving healthcare via telephone-monitoring	2007	N	Y	Y	Feasibility and piloting	N	Triangulation of descriptive statistics, feedback surveys and qualitative analysis of clinical notes.	Thematic analysis of the clinical notes and open ended comments from survey and triangulated with the satisfaction survey.
Lovell K, Bower P, Richards D, Barkham M, Sibbald B,	Developing guided self-help for depression using the Medical Research Council complex interventions framework: A description of the modelling phase and results of an exploratory	2008	N	Y	N	Feasibility and piloting	yes- use of MRC	Interviews, systematic review and modelling.	Framework analysis

Roberts C, et al	randomised controlled trial								

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Chatterjee S, Chowdhary N, Pednekar S, Cohen A, Andrew G, Araya R, et al	Integrating evidence-based treatments for common mental disorders in routine primary care: Feasibility and acceptability of the MANAS intervention in Goa, India	2008	N	Y	N	Feasibility and Piloting & post evaluation	N	Stakeholder semi structured interviews	Thematic analysis
van Steenkiste B, van der Weijden TM, Stoffers JH, Grol RP	Patients' responsiveness to a decision support tool for primary prevention of cardiovascular diseases in primary care	2008	Y	Y	N	Feasibility and Piloting	N	routine monitoring data, observations (e.g. Patients' actually having read the booklet and returning for the second consultation; comprehension and perceived relevance of the information; perceived reassurance.)	Descriptive statistics, and logistic regression to dependent variables and independent variables.
Chung B, Jones L, Dixon EL, Miranda J, Wells K, Community Partners in Care Steering Council	Using a Community Partner Participatory Research Approach to Implement a Randomised Controlled Trial: Planning Commnunity Partners in Care	2010	N	Y	N	Feasibility	Y	Baseline survey, community dialogue to obtain community feedback	NA
Gask L, Bower P, Lovell K, Escott D, Archer J, Gilbody S, Lankshear A, Simpson AE, Richards DA.	What work has to be done to implement collaborative care for depression? Process evaluation of a trial utilizing the Normalisational Process Model	2010	Y	Y	N	Feasibility and piloting (exploratory trial)	Normalisation Process Model	Pre study data collection of focus group and interviews, and post study data collection of interviews	Used a template or apriori coding manual from normalisation process model.
Casey D, Murphy K, Cooney A, Mee L, Dowling M.	Developing a structured education programme for clients with COPD	2011	N, Development of programme	Y	N	Feasibility and Piloting	N	Content analysis and concept analysis and 2 qualitative studies	Constant Comparative approach
Chalder M, Wiles NJ, Campbell J, Hollinghurst SP, Searle A, Haase AM, et al	A pragmatic randomised controlled trial to evaluate the cost-effectiveness of a physical activity intervention as a treatment for depression: The treating depression with physical activity (TREAD) trial	2012	N, Qualitative study	Y	Y	Feasibility and Piloting	Y (Self Determination Theory)	Interviews	NA
Bennett M, Walters K, Drennan V,	Structured Pro-Active Care for Chronic Depression by Practice Nurses in Primary Care: A Qualitative Evaluation	2013	N	Y	Y	Feasibility and Piloting	N	In depth interviews	Thematic analysis

Appendix 4: Methods and methodology of individual studies

Carlisle K, Warren R	A qualitative case study of telehealth for in-home monitoring to support the management of type 2 diabetes	2013	N	Y	Y	Feasibility and Piloting	N	Semi structured Interviews	Not described.
Van der Weegen S, Verwey R et al	The Development of a Mobile Monitoring and Feedback Tool to Stimulate Physical Activity of People with a Chronic Disease in Primary Care: A User-Centered Design	2013	N	Y	N	Feasibility	Y	Qualitative individual interviews and focus group. Literature search re behaviour change and self-management	Three staged iterative process. Literature review to identify end users and context, stage 2, the literature, experts and patient representatives consulted to set up a use case. Stage 3 where individual interviews and focus groups based on the use case helped to identify end user requirements, and build a prototype.
Fairbrother, Peter McCloughan, Lucy Adam, Geraldine Brand, Richard Brown, Cecil Watson, Mary Cotter, Nicola Mackellaig, Juliet McKinstry, Brian	Involving patients in clinical research: The Telescot patient panel	2013	N	Y	Y	Feasibility	N	Patient' panel and Focus groups	Thematic
Ramadas A, Chan C, Oldenburg B, Hussien Z, Quek K	A Web-Based Dietary Intervention for People with Type 2 Diabetes: Development, Implementation, and Evaluation	2015	Y	Y	Y	Feasibility and Piloting	N	Self-administered questionnaire (to determine program reception)	Descriptive statistics of the process evaluation measures.

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Naik AD, Lawrence B, Kiefer L, Ramos K, Utech A, Masozera N, et al	Building a primary care/research partnership: lessons learned from a telehealth intervention for diabetes and depression	2015	Formative evaluation	Y	N	Feasibility and Piloting, and Evaluation of effectiveness	Y	Qualitative data from the research/clinical partnership meetings that was recorded and coded. Triangulated with other information such as research staff personal communication, field notes and minutes of meetings.	Qualitative Framework analysis
Vest BM, York TRM, Sand J, Fox CH, Kahn LS	Chronic kidney disease guideline implementation in primary care: A qualitative report from the TRANSLATE CKD study	2015	Y	Y	Y	Feasibility and Piloting	Y	Semi-structured Interviews	Thematic Content Analysis
Synthesis	**The quality data items do not fit these studies as they seem to be more applicable to the effectiveness stage. Though the COREQ ones still matter for the qualitative study/methods. The methods (literature search, consensus process, focus group interviews) can inform the intervention development and subsequent evaluation (e.g. testing of change in determinants). Use of classic theory especially psychological/behavioural ones seem relevant for chronic diseases given the emphasis on self-management as reflected in Box 1.**	**1999 - 2016**	**5 labelled as process evaluations**	**20 to stated purpose.**	**8 Y**	**20 Studies**	**9**	**18 used interviews. 3 used focus group discussions, 4 used questionnaires or surveys, 2 studies used routine monitoring data, field notes, minutes of meetings and observations.**	**Thematic analysis, constant comparative approach most commonly used, with some using framework analysis.**
Hetlevik I, Holmen J, Kruger O, Kristensen P, Iversen H, Furuseth K	Implementing clinical guidelines in the treatment of diabetes mellitus in general practice: Evaluation of effort, process, and patient outcome related to implementation of a computer-based decision support system	2000	Y	Y	N	Effectiveness	N	Use of number of patient registrations (fraction as the process evaluation) and a questionnaire to determine user friendliness, perceived benefit and feedback about implementation strategies	Quantitative analysis according to variables and across two time points.
Thornett AM, Mynors-Wallis LM	Credibility of problem-solving therapy and medication for the treatment of depression among primary care patients	2002	N	Y	N	Evaluation of effectiveness	N	Credibility scale questionnaires, Kruskall-Wallis rank test of relationships.	Statistical analysis
Ilag LL, Martin CL, Tabaei BP, Isaman DJ, Burke R, Greene DA, et al	Improving diabetes processes of care in managed care	2003	N	Y	N	Evaluation of effectiveness	N	Quantitative measures of processes of care (e.g. measuring HbA1c), and a Likert scale acceptability survey given to the health providers	Quantitative analysis between groups, with hierarchical liner mixed models for continuous models for categorical variables to control for random subject effects and random practice-site effects.

Appendix 4: Methods and methodology of individual studies

Lobo CM, Euser L, Kamp J, Frijling BD, Severens JL, Hulscher MEJL, et al	Process evaluation of a multifaceted intervention to improve cardiovascular disease prevention in general practice	2003	Y	Y	N	Evaluation of effectiveness	N	Implementer reports and questionnaires to health providers	Descriptive statistical analysis.
Pearl A, Wright S, Gamble G, Doughty R, Sharpe N	Randomised trials in general practice--a New Zealand experience in recruitment	2003	N	Y	N	effectiveness	N	Evaluation questionnaire	Descriptive
Smith S, Bury G, O'Leary M, Shannon W, Tynan A, Staines A, Thompson C	The North Dublin randomized controlled trial of structured diabetes shared care	2004	N	Y	N	Evaluation of effectiveness	N	processes of care and qualitative study, (and outcome study reported together)	Triangulation of mixed methods
Gask L, Dixon C, May C, Dowrick C	Qualitative study of an educational intervention for GPs in the assessment and management of depression	2005	N	Y	Y	Evaluation of effectiveness (Y)	N	Interviews	Qualitative Content Analysis
Gask L, Ludman E, Scaheffer J.	Qualitative Study of an intervention for depression among patients with diabetes: how can we optimise patient-professional interaction?	2006	N	Y	N	Evaluation of effectiveness	N	Qualitative semi structured interviews and content analysis of recorded case management (i.e. the intervention itself)	Constant Comparative approach
Heaven, B. Murtagh, M. Rapley, T. May, C. Graham, R. Kaner, E. Thomson, R.	Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention	2006	N	Y	N	Post hoc effectiveness ?	Y (informed by ideas of symbolic interactionism, phenomenology and critical psychology.	Mixed Methods: Part of an observational study alongside a RCT (comprising of video of consultation) and participant interview post clinic and 3 months post clinic (* this study only reports on the 3-5 days post clinic interviews.	Constant Comparative approach to the qualitative data, and informed by ideas from symbolic interactionism, phenomenology and critical psychology.
Fakiri FE, Hows MW, Uitewaal PJM, Frenken RA, Bruijnzeels MA.	Process evaluation of an intensified preventive intervention to reduce cardiovascular risk in general practices in deprived neighbourhoods	2008	Y	Y	N	Evaluation of effectiveness-fidelity and reach	N	Fidelity data e.g. ranking of the intervention as delivered by the protocol, and the Reach data through the number of consultations completed	Descriptive analysis

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Slade M, Gask L, Leese M, McCrone P, Montana C, Powell R, Stewart M, Graham-Chew C	Failure to improve appropriateness of referrals to adult community mental health services—lessons from a multi-site cluster randomized controlled trial	2008	N	Y	Y	Evaluation of effectiveness	N	Outcomes, process data was presented and implementation was explored through the nested qualitative data.	Logistics analysis and thematic analysis of the qualitative data.
Van Den Bemt L, Schermer TRJ, Smeele IJM, Boonman-de Winter LJM, Van Boxem T, Denis J, et al	An expert-supported monitoring system for patients with chronic obstructive pulmonary disease in general practice: Results of a cluster randomised controlled trial	2009	Y	Y	N	Evaluation of effectiveness	N	For the process evaluation, the respiratory experts' database was examined to collect data on their recommendations. The nurse consultant collected data on GPs' implementation of recommendations. Patient questionnaires comprised questions about disease management. (i.e. documentary analysis and questionnaires)	Compared the implementation across control and intervention groups. Process evaluation and outcome evaluation was presented together.
Smith S, Paul G, Kelly A, Whitford D, O'Shea E, O'Dowd T	Peer support for patients with type 2 diabetes: Cluster randomised controlled trial	2011	Y	Y	Y	Evaluation of effectiveness	N	Interviews and FGD's. Routine monitoring data	Descriptive parallel qualitative analysis based on descriptive phenomenology
Passey ME, Laws RA, Jayasinghe UW, Fanaian M, McKenzie S, Powell-Davies G, et al	Predictors of primary care referrals to a vascular disease prevention lifestyle program among participants in a cluster randomised trial	2012	N	Y	Y	Evaluation of effectiveness	N	Routine monitoring data	Univariate analysis
Gensichen J, Guethlin C, Sarmand N, Sivakumaran D, Jager C, Mergenthal K, et al	Patients' perspectives on depression case management in general practice - A qualitative study	2012	N	Y	Y	Evaluation of effectiveness	N	Interviews	Content Analysis

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Julia A. E. Walters,E, Helen Courtney-Pratt , Helen Cameron-Tucker, Mark Nelson, Andrew Robinson, Jenn Scott, Paul Turner, E. Haydn Walters and Richard Wood-Baker	Engaging general practice nurses in chronic disease self-management support in Australia: insights from a controlled trial in chronic obstructive pulmonary disease	2012	N	Y	N	Effectiveness	N	Mixed methods (quant survey and interviews)	Iterative thematic analysis with triangulation of quant data
Ratanawongsa N, Bhandari VK, Handley M, Rundall T, Hammer H, Schillinger D	Primary care provider perceptions of the effectiveness of two self-management support programs for vulnerable patients with diabetes	2012	N	Y	Y	Evaluation of effectiveness	N	self-administered questionnaire	Descriptive analysis
Lakerveld J, Bot S, Chinapaw M, van Tulder M, Kingo L, Nijpels G	Process evaluation of a lifestyle intervention to prevent diabetes and cardiovascular diseases in primary care	2012	Y	Y	Y	Evaluation of Effectiveness	Re-AIM	Questionnaires	Confirmatory factor analysis
Paul G, Keogh K, D'Eath M, Smith SM	Implementing a peer-support intervention for people with type 2 diabetes: A qualitative study	2013	N	Y	Y	Evaluation of effectiveness	N	Stakeholder interviews and FGD	Framework analysis and a matrix based method of analysing qualitative data.
Nelson P, Cox H, Furze G, Lewin RJP, Morton V, Norris H, et al	Participants' experiences of care during a randomized controlled trial comparing a lay-facilitated angina management programme with usual care: a qualitative study using focus groups	2013	N	Y	Y	Evaluation of Effectiveness	N	Focus group discussions	Thematic analysis
Fairbrother P, Pinnock H, Hanley J, McCloughan L, Sheikh A,	Exploring tele monitoring and self-management by patients with chronic obstructive pulmonary disease: A qualitative study embedded in a randomized controlled trial	2013	N	Y	Y	Evaluation of effectiveness-views of the intervention	Schermer three degress of telemetric self management	Semi structured Interviews	Framework analysis

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Stallard P, Phillips R, Montgomery AA, Spears M, Anderson R, Taylor J, et al	A cluster randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents	2013	Y	Y	Y	Evaluation of effectiveness	REAIM	Questionnaires and Qualitative Interviews	Thematic analysis
Hanley, J. Ure, J. Pagliari, C. Sheikh, A. McKinstry, B.	Experiences of patients and professionals participating in the HITS home blood pressure tele-monitoring trial: A qualitative study	2013	N	Y	Y	Effectiveness (though informed by interviews at the pilot and feasibility stage, and there was a protocol-evolution allowed)	Y (Normalisation process theory)	Semi-structured qualitative interviews and a focus group to validate the findings and discuss implementation	Ongoing iterative analysis "*The trial context permitted triangulation with quantitative data. Owing to the protocolpermitted evolution in practice, it gives an indication of some of the issues which would need to be addressed for BP telemonitoring to be used in routine practice.*"
Laws, R. A. Fanaian, M. Jayasinghe, U. W. McKenzie, S. Passey, M. Davies, G. P. Lyle, D. Harris, M. F	Factors influencing participation in a vascular disease prevention lifestyle program among participants in a cluster randomized trial	2013	N	y	y	effectiveness	N	Mixed methods of quantitative analysis of survey, clinical audit data, practice questionnaire on capacity for preventive care, and referral and attendance records, interviews with implementers of the program	Quantitative data analysis (to find the characteristics and the factors influencing attendance) and qualitative thematic analysis.
Manca DP, Greiver M, Carroll JC, Salvalaggio G, Cave A, Rogers J, et al	Finding a BETTER way: A qualitative study exploring the prevention practitioner intervention to improve chronic disease prevention and screening in family practice	2014	N	Y	N	Evaluation of effectiveness	Y (Grounded theory)	semi-structured interviews and focus groups	Constant Comparative approach
Richter-Sundberg L, Nystrom ME, Krakau I, Sandahl C	Improving treatment of depression in primary health care: A case study of obstacles to perform a clinical trial designed to implement practice guidelines	2015	N	Y	N	Evaluation of effectiveness	N	Semi-structured Interviews	qualitative analysis

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Eborall HC, Dallosso HM, McNicol S, Speight J, Khunti K, Davies MJ, et al	Explaining engagement in self-monitoring among participants of the DESMOND self-monitoring trial: A qualitative interview study	2015	N	Y	N	Evaluation of effectiveness	N	Qualitative semi structured interviews	Constant Comparative approach
Grimshaw JM, Presseau J, Tetreo Jm , Eccles MP, Francis JJ, Godin G, Graham ID, Hux, JE, Johnston M, Legare F, emyre L, et al..	Looking inside the black box: results of a theory-based process evaluation exploring the results of a randomized controlled trial of printed educational messages to increase primary care physicians' diabteic retinopathy referrals	2014	Y	Y	Y	Evaluation of effectiveness	Y (Theory of planned behavior)	Surveys at two time points	Compared groups factorially on changes at the two time points pre and post intervention. Thematic analysis of the open comment section
Burridge, L. H. Foster, M. M. Donald, M. Zhang, J. Russell, A. W. Jackson, C. L.	Making sense of change: patients' views of diabetes and GP-led integrated diabetes care	2014	N	Y	N	Evaluation of effectiveness	Y, Normalisation Process Theory	Qualitative study (as part of a mixed methods evaluation)	Thematic Analysis with a modified framework based on NPT.
Coupe N, Anderson E, Gask L, Sykes P, Richards DA, Chew-Graham C	Facilitating professional liaison in collaborative care for depression in UK primary care; A qualitative study utilising normalisation process theory	2014	N	Y	Y	Evaluation of effectiveness	Normalization process theory (NPT)	Interviews	Thematic analysis
Kenealy TW, Parsons MJG, Rouse PB, Doughty RN, Sheridan NF, Hindmarsh JKH, Masson SC, Rea HH.	Telecare for Diabetes, CHF or COPD; Effect on Quality of Life, Hospital Use and Costs. A Randomised ControlledTrial and Qualitative Evaluation	2015	N	Y	N	Evaluation of effectiveness	N	Individual and focus group interviews and questionnaire. (note that other process measures such as the nurse keeping a log of their activities for calculation of health care use was also collected)	Thematic analysis

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Liu H, Massi L, Laba TL, Peiris D, Usherwood T, Patel A, Cass A, Eades AM, Redfern J, Hayman N, Howard K, Brien JA, Jan S.	Patients' and Providers' Perspectives of a Polypill Strategy to Improve Cardiovascular Prevention in Australian Primary Health Care: A Qualitative Study Set Within a Pragmatic Randomized, Controlled Trial.	2015	Y	Y	Y	Effectiveness	Y	Qualitative interviews and triangulation with outcomes, and knowledge of trial implementation	Iterative thematic analysis, with the use of the Realist framework to guide the development of the themes.
Liu H, Laba T, Massi L, Jan S, Usherwood T, Patel A, Hayman N, Cass A, Eades A, Peiris D.	Facilitators and barriers to implementation of a pragmatic clinical trial in Aboriginal health services.	2015	Y	Y	Y	Effectiveness	N	Qualitative interviews and triangulation with outcomes, and knowledge of trial implementation	Iterative thematic analysis
Liu H, Massi L, Eades AM, Howard K, Peiris D, Redfern J, Usherwood T, Cass A, Patel A, Jan S, Laba T.	Implementing a pragmatic randomised controlled trial in Australia: lessons learnt from the Kanyini Guidelines Adherence with the Polypill study (Kanyini GAP)	2015	Y	Y	Y	Effectiveness	N	Qualitative interviews and triangulation with outcomes, and knowledge of trial implementation	Iterative thematic analysis
Huntink E, Wensing M, Timmers IM, Lieshout JV	Process evaluation of a tailored intervention programme of cardiovascular risk management in general practices	2016	Y	Y	N	Evaluation of effectiveness	N	Mixed methods- quantitative measures (survey results and scoring of recorded motivational interviews) and qualitative data of interviews conducted.	Quantitative analysis of the scores, and qualitative analysis using the pre-specified tailored intervention for chronic diseases
Presseau J, Grimshaw J, Tetroe JM, Eccles MP, Francis JJ, Godin G, Graham ID, Hux JE, Johnston M, Legare F, Lemyre L, Robinson N, Zwarenstein M.	A theory-based process evaluation alongside a randomised controlled trial of printed educational messages to increase primary care physician's prescription of thiazide diuretics for hypertension	2016	Y	Y	Y	Evaluation of effectiveness	Y (Theory of planned behaviour)	Pre, post postal questionnaire to a random sub-sample of family physicians in each trial arm	Analysis of co-variance to test for group differences using a 2X3 factorial design and content analysis of the open ended question about perceived barriers to thiazide prescription. Tested whether baseline measures of TPB constructs predicted self-reported thiazide prescribing

Appendix 4: Methods and methodology of individual studies

Verwey R, van der Weegen S, Spreeuwenberg M, Tange H, van der Weijden T, de Witte L	Process evaluation of physical activity counselling with and without the use of mobile technology: A mixed methods study	2016	Y	Y	Y	Evaluation of effectiveness	N	Mixed methods (using semi-structured interviews, questionnaires to patients and use of IT tool through system logging)	Descriptive analysis and triangulation of findings.
Parsons, J. A. Yu, C. H. Y. Baker, N. A. Mamdani, M. M. Bhattacharyya, O. Zwarenstein, M. Shah, B. R.	Practice doesn't always make perfect: A qualitative study explaining why a trial of an educational toolkit did not improve quality of care	2016	Y	Y	N	Effectiveness	N	In-depth semi-structured telephone interviews with physicians who received the tool kit. And written commentary from reflective feedback forms collected from 10% of practices randomised and approached) who participated in chart audit as part of the clinical data study.	Qualitative description which entails an inductively- derived thematic analysis, and triangulated with the written comments from the questionnaires
Yan LD, Chirwa C, Chi BH, Bosomprah S, Sindano N, Mwanza M, Musatwe D, Mulenga M, Chilengi R.	Hypertension management in rural primary care facilities in Zambia: a mixed methods study	2017	N	Y	Y	Evaluation of effectiveness	N	Data on novel retrospectively generated process and outcome indicators for hypertension management, informed by those from Western countries, but adapted to the Zambian primary care clinics. Extracted using EMR. Semi-structured in-depth interviews with health care providers and a representative from the central medication distribution agency .	We used an explanatory sequential design by conducting a quantitative analysis of outcome measures , which was then explained through a qualitative follow up component.
Wells S, Rafter N, Kenealy T, Herd, Geoff, Eggleton K, Lightfoot R, Arcus K, Wadham A, Jiang Y, Bullen C.	The impact of a point of care testing device on CVD risk assessment completion in New Zealand primary-care practice: A cluster randomised controlled trial and qualitative investigation	2017	N	Y	N	Evaluation of effectiveness	N	Qualitative data on practice processes for CVD risk assessment and feasibility of POC testing were collected at the end of the study by interviews and questionnaire.	Braun and Clarke's approach to thematic analysis was used to generate initial codes, collate codes into potential themes and refine the identified themes and categories into a coherent pattern.

Appendix 4: Methods and methodology of individual studies

Grant A, Dreischulte T, Guthrie B	Process evaluation of the data-driven quality improvement in primary care (DQIP) trial: active and less active ingredients of a multi-component complex intervention to reduce high-risk primary care prescribing	2017	Y	Y	Y	Evaluation of effectiveness	Y (NPT)	Data generation was by in-depth interview with key staff exploring participant's perceptions of the intervention components.	Analysis was iterative using the framework technique and drawing on normalisation process theory.
Grant A, Dreischulte T, Guthrie B	Process evaluation of the Data-driven Quality Improvement in Primary Care (DQIP) trial: case study evaluation of adoption and maintenance of a complex intervention to reduce high-risk primary care prescribing	2017	Y	Y	Y	Evaluation of effectiveness	Y (NPT)	Mixed-methods parallel process evaluation of a cluster trial, reporting the comparative case study of purposively selected practices.	Use of interviews at two time points and the use of quantitative data to explore whether the qualitative judgements made about implementation were consistent with observed data on reach, delivery, maintenance and effectiveness. Use of NPT alongside the cross and within-case comparisons.
Rapp AM, Chavira DA, Sugar CA, Asarnow JR	Integrated Primary Medical-Behavioral Health Care for Adolescent and Young Adult Depression: Predictors of Service Use in Youth Partners in Care Trial	2017	N	Y	Y	Evaluation of Effectiveness	Y (Behavioural Model of Health Service Use)	Secondary Analysis of data from the trial to investigator the predisposing factors (demographics), enabling factors (e.g. perceived stigma of depression) , need factors and outcomes (receipt of mental health services)	Statistical analyses, and plots of significant interactions. Investigating possible interactions between variables, and individual logistic regression for the possible independent variables, with mental health treatment as outcome. Algorithm to finally identify the subset of variables that best predicted mental health service use.

Appendix 4: Methods and methodology of individual studies

Synthesis		**2000 - 2017**	**16 labelled as process evaluations (13 after 2008, and 5 after 2015)**		**22 Y, and 16 N**	**44 studies**	**13 studies (7 Classic theories, 3 evaluation frameworks, 3 implementation theories)**	**2000-2004: 6 studies documented specific processes of care as part of the process evaluation, and were often reported as part of the main trial. The acceptability of an intervention was often investigated using surveys/questionnaires. 2005 onwards- 9 studies used only interviews to explore implementation and acceptability, 15 studies used interviews triangulated with other sources of data (e.g. chart audit). 5 studies used questionnaires or surveys. 1 study used secondary analysis of trial data.**	**Descriptive statistics were used for the quantitative data. Thematic, constant comparison and framework analysis for the qualitative data. The studies that used mixed methods, used the quantitative data to indicate level of implementation, reach and the dose. This was use to triangulate the qualitative findings on implementation and intervention acceptability.**
Oishi SM, Shoai R, Katon W, Callahan C, Unutzer J, Arean P, et al	Impacting late life depression: Integrating a depression intervention into primary care	2003	N	Y	Y	Post evaluation Implementation	N	Focus group discussions and semi structured interviews	Thematic analysis
Dietrich AJ, Oxman TE, Williams JW, Kroenke K, Schulberg HC, Bruce M, et al	Going to scale: Re-engineering systems for primary care treatment of depression	2004	N	Y	Y	Post-evaluation	Yes- Diffusion of Innovations theory	Documentary analysis of care manager logs, health care organisation's administrative data to access cooperation in implementation and changes in the processes of care in each practice. Clinical surveys	Descriptive
Lee PW, Dietrich AJ, Oxman TE, Williams Jr JW, Barry SL	Sustainable impact of a primary care depression intervention	2007	N	Y	Y	Post evaluation Implementation	N	Interviews	Descriptive evaluation
Pylypchuk G, Vincent L, Wentworth J, Kiss A, Perkins N, Hartman S, et al	Diabetes risk evaluation and microalbuminuria (DREAM) studies: Ten years of participatory research with a First Nation's home and community model for type 2 diabetes care in northern Saskatchewan	2008	N	N	N	Evaluation of effectiveness, and post intervention	N	documentary analysis, Population survey, pilot and randomised trial	documentary analysis

Appendix 4: Methods and methodology of individual studies

Wentzlaff DM, Carter BL, Ardery G, Franciscus CL, Doucette WR, Chrischilles EA, et al	Sustained Blood Pressure Control Following Discontinuation of a Pharmacist Intervention	2011	N	Y	Y	Post-evaluation implementation	N	routine monitoring data	Intention to treat analysis
Chaney EF, Rubenstein LV, Liu CF, Yano EM, Bolkan C, Lee M, et al	Implementing collaborative care for depression treatment in primary care: A cluster randomized evaluation of a quality improvement practice redesign	2011	N	Y	N	post evaluation Implementation	N	The study intervention is EBQI as applied to collaborative care implementation. The study uses a cluster randomized design as a formative evaluation tool to test and improve the effectiveness of the redesign process. Data sources include survey and administrative data sources, and the care manager registry-based measures (e.g. patients routinely referred outside of the trial).	The context evaluation is descriptive and uses subgroup analysis. (e.g. clinician adoption status)
Synthesis		**2003 - 2015**	**0 as process evaluations**	**5 Y, 1 N**	**4Y,**	**7 studies, (note the cross over with quality improvement studies)**	**NPT for 1**	**3 used interviews, 2 used documentary analysis, and 1 used the administrative data and registry data**	**Descriptive statistics, subgroup analysis and thematic analysis.**

Appendix 5: Quality of studies table as informed by the MRC recommendations and the COREQ

Author	Year	Planning (Y/N/NA)	Design and Conduct (Y/N/NA)					Reporting (Y/N/NA)	
		Degree of separation between outcome and process evaluation teams described.	Clearly state their purpose.	The intervention should be clearly described and causal assumptions clarified * (I wonder if you should have uncertain)	Justify choice of timing and methods.	If applicable- Transparently whether the report of the process data are analysed blind to trial outcomes/ or post hoc	COREQ for qual studies. (31 items under Domain 1: research team and reflexivity, Domain 2: study design, Domain 3: analysis and reporting)	Clearly labelled	Published a full report of evaluation components or a protocol paper.
Tai SS et al.	1999	N	Y	NA	Y	NA		N	N
Weiss	2004	NA	Y	NA	Y	NA		N	N
Jackie Sturt,	2006	NA	Y	Y	Y	NA		N	N
Byrne	2006	NA	Y	NA	Y	NA		N	N
Chew-Graham	2007	Y	Y	NA	Y	NA		N	N
Clark	2007	Y	Y	NA	Y	NA		N	Y
Lovell	2008	Y	Y	Y	Y	NA		N	N
Chatterjee	2008	Y	Y	Y	Y	NA		N	N
Van Steenkiste	2008	N	Y	NA	Y	NA	NA	Y	N
Chung	2010	N	Y	NA	N	NA	NA	N	N
Gask L,	2010	N	Y	N/y*?	Y	NA		Y	Y
Casey	2011	Y	Y	Y	Y	NA		N	N
Chalder	2012	Y	Y	Y	Y	NA		N	Y
Bennett M,	2013	Y	Y	Y	Y	NA		N	Y
Carlise	2013	N	Y	Y*	Y	NA		N	Y
Van der Weegen	2013	N	Y	NA	Y	NA		N	N
Fairbrother	2013	Y	Y	Y	Y	NA		N	Y
Ramadas A,	2015	Y	Y	Y	Y	NA	NA	Y	Y
Naik	2015	Y	Y	Y*	Y	NA		N	Y
Vest	2015	Y	Y	Y	Y	NA		Y	Y
Hetlevik I, at al.	2000	N	NA	Y	NA	NA	NA	NA	NA
Thornett	2002	Y	Y	Y	Y	N	NA	N,	Y
Ilag	2003	Y	Y	N	Y	N	NA	N	N
Lobo CM,	2003	N	Y	Y	Y	Y	NA	Y	N
Oishi SM, et al	2003	N	N	N	Y			N	Y
Pearl	2003	N	Y	NA	Y	NA		N	N
Smith S,	2004	N	Y	Y*	Y	N		N	N
Gask L,	2005	N	Y	N	Y	Y		N	Y
Gask L	2006	Y	Y	Y	Y	Y		N	N
Heaven, B.	2006	N	Y	NA	Y	NA		NA	NA
Fakiri	2008	N	Y	Y	Y	Y	NA	Y	N
Slade	2008	Y	Y	Y*	Y	Y		N	Y
Van Den Bemt	2009	Y	Y	Y	Y	Y	NA	Y	N
Smith S,	2011	N	Y	Y	Y	N		Y	Y
Passey	2012	Y	Y	Y*	Y	Y	NA	N	Y
Genichen	2012	Y	Y	Y *	Y	Y		N	Y
Walters JAE,	2012	y	Y	Y	Y	NA		N	N
Ratanawongsa	2012	N	Y	Y	N	Y	NA	N	Y
Lakerveld J,	2012	N	Y	N	Y	Y	NA	Y	Y

Appendix 5: Quality of studies table as informed by the MRC recommendations and the COREQ

Paul G, Keogh	2013	N	Y	Y	Y	Y					N	Y
Nelson	2013	N	Y	Y	Y	NA					N	Y
Fairbrother	2013	N	Y	Y	Y	NA					N	Y
Stallard	2013	Y	Y	Y	Y	Y					Y	Y
Hanley	2013	Y	Y	Y*	Y	Y					N	Y
Laws, R. A.	2013	Y	Y	Y	y	NA	NA				NA	Y
Manca	2014	Y	Y	NA	Y	Y					N	N
Richter-S.	2015	Y	Y	Y	Y	NA					N	N
Grimshaw	2014	Y	Y	Y	Y	Y	NA				Y	Y
Burridge	2016	N	Y	N/Y*	Y	NA					N	N
Coupe	2014	Y	Y	Y	Y	Y					N	Y
Eborall	2015	N	Y	Y	Y	Y					N	N
Kenealy TW,	2015	N	Y	Y	NA	NA					NA	Y
Liu H,	2015	Y	Y	N	Y	N					Y	Y
Liu H,	2015	Y	Y	NA	Y	NA					Y	Y
Liu H	2015	Y	Y	NA	Y	NA					Y	Y
Huntink E,	2016	N	Y	Y * (logic model)	Y	Y					Y	Y
Presseau J,	2016	N	Y	Y	Y	Y	NA				Y	Y
Parsons,	2016	N	Y	Y	Y	N					Y	N
Verwey	2016	Y	Y	Y	Y	Y					Y	Y
Yan	2017	N	Y	N/Y*	Y	NA					N	Y
Wells S	2017	Y	Y	N/Y*	Y	N					N	NA
Grant	2017	Y	Y	Y * (Tidier)	Y	Y					Y	Y
Grant	2017	Y	Y	Y (researcher expected…)	Y	Y					Y	Y
Rapp	2017	NA	Y	Y	Y	Y	NA				N	NA
Murchie P,	2005	Y	Y	NA	Y	NA					N	N
Lee	2007	NA	Y	NA	Y	NA	NA				N	Y
Pylypchuk G,	2008	N	Y	Y	N	NA	NA				N	N
Wentzlaff	2011	Y	Y	N	Y	NA					N	N
Chaney	2011	Y	Y	Y	Y	Y	NA				N	N
Oishi	2013	N	Y	N	Y	NA					N	Y

(A) **Notes on using this to assess quality for the PE of feasibility studies**

1) Not many are labelled as process evaluations. This is in line with the evolution of the term process evaluations which now includes the different stages of research as per the MRC guidance for complex interventions.

2) The assessment of whether the intervention is clearly defined, and the causal mechanisms made explicit was also very difficult because at times I found that the intervention was really well described in the introduction or in the methods, with the authors describing possible factors that would influence the outcomes. (i.e. like causal mechanisms), or for the studies that are asking a specific causal mechanisms e.g. credibility of an intervention. Thus, for this stage, if the intervention is well described, and context is considered or being explored, I have stated yes. It is N/A, if the intervention is still being developed or the study is asking a different question, and no if the intervention is poorly described.

3) The qualitative components/ studies seem to be conducted well.

4) Degree of separation of teams- if stated is Y, if not stated is N, what is NA- if it seems irrelevant? Perhaps they should all be NA then. NA implies that stating this separation doesn't matter and so looking at this is not relevant. But as you have stated it is. I think perhaps if the COREQ reflexivity is Y, then it should be Y.

5) The protocol- should it be NA? I think it is either yes or n. But you can state that it is NA if it is the first study and there is nothing to link it to.

B) **Notes on using this to assess quality for the PE of effectiveness studies**

1) Intervention description and clarifying the causal mechanisms. Like before this was difficult to determine but it was clearer in terms of how the intervention should have a hypothesised mechanisms. At times, the qualitative study was trying to understand what the mechanisms are in the context of … As such, it was adding to the intervention theory. For example of case management and what the active ingredients are… E.g. Genischen. Re contextualising the intervention in the patient's experience. "explore the patients' perceptions of practice-based depression case management, their satisfaction with it and how living with depression contextualizes case management." So, if that was what they were trying to do, I have put it as Y, similar to KGAP for CMO. Reflecting the difference between how I analysed KGAP and ATTEND was making the hypothesised mechanisms clear. What about those that state clearly like in ATTEND what the intervention is about. I think the trouble with this is that it is not clear… unless you explicitly state that you are looking for a logic model, intervention theory or causal mechanisms. Then it would be N. Unless you split it to intervention described as per TiDIER and looks at contextual factors interaction with intervention as David suggested. Grants' papers provide a clear way of how this can be articulated that is less ad hoc. Either through Tider, a logic model or through specifying what the researcher's expected within context. So that the reader doesn't have to make a judgement call and it is clearer for the reader what is relevant what is context etc. and what are the characteristics that need to be in play for implementation. Using NPT seemed to be a good way to make explicit what the implementation strategies are too. If so, then those using NPT is a Y, and Uncertain for those who seem to be looking for the factors?

Appendix 6- Illustrative examples for the synthesised findings

Implementation factors - illustrative examples
Mechanisms: Perceived Fit of the Intervention In a trial to increase the referral for diabetic retinopathy screening, physicians described that patient's lack of belief in screening, and access to specialists as key barriers to screening. Thus, the intervention of printed educational materials did not alter their referral behaviour. (Grimshaw)
Implementation: Roles and Responsibilities In study to integrate the role of a Depression Clinical Specialist with the primary care provider and the consulting psychiatrist- the process evaluation found "*DCSs spoke of the importance of a clear role within the health care team. The model envisions the DCS as a care manager who works in partnership with the patient and the PCP. DCSs pointed to the importance of not being perceived as taking over the patient's depression care. Instead, the DCS reports to the PCP whether a patient is experiencing side effects, for example, and discusses alternate treatment options, but it is the PCP who decides when to change dosage or medication type. DCSs noted the need to be flexible in working with different physician and system styles*." (Oishi)
Context: Health system structures From a process evaluation of the 'recruitment' of health care organisations in America to scale up an effective model of depression care- authors stated that: "*Additional momentum comes from the US Preventive Services Task Force (USPSTF) through its endorsement of depression screening in adults "in clinical practices that have systems in place to assure accurate diagnosis, effective treatment, and careful follow up." They state, "Benefits from screening are unlikely to be realized unless such systems are functioning well*." (Dietrich) The underlying capacity and knowledge of the implementers are described as conducive to their model of pro-active care for chronic depression using practice nurses: "*Practice nurses in the UK are employed by GPs to work in their practices as part of the primary healthcare team. They are at minimum Registered Nurses (RNs), usually with substantial nursing experience and some may have a specialist qualification in practice nursing, although it is not a formal requirement. A minority are also Registered Mental Health Nurses (RMHN), but most will have only received some theoretical background and short clinical placements in mental health settings during their RN course*." (Bennett)
Collaborative Approach "*The CBPR model guided development of a research/clinical partnership based on a facilitation team consisting of 'external facilitators' (research team), 'internal facilitators' (primary care leadership) and a 'clinical advisory committee' drawn from the primary care community. Qualitative themes focused on: how the intervention components ('evidence') aligned with local clinical cultures, barriers and facilitators to acceptance and adoption of the intervention processes within the context of clinical workflows and identified 'facilitators' of intervention uptake and sustainability*." (Naik) "*We found that using a Community-Partnered Participatory Research approach in the design phase (Vision) led to many changes in study design to improve the fit of the study with community priorities (e.g. Aligning community boundaries with existing county service planning areas), as well as enrich the study's potential scientific contributions (e.g., through expanded outcomes of community and policy relevance)*." (Chung)