

### Additional File 1: Included literature items

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
Aarestrup et al. (1)	2014	Denmark	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	To present a systematic approach to plan process evaluation of the implementation of randomised multicomponent interventions.
Abildgaard et al. (2)	2016	Denmark	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	To shed light on what type of knowledge of the intervention is gained from qualitative and quantitative process evaluation data.
Abraham et al. (3)	2014	UK	journal article	discussion and recommendations on broad topic of process evaluation	health	trial	Process evaluation approach / framework / guidance	This article ... has developed brief guidance to journal editors to improve the reporting of evaluations of behaviour change interventions, thereby serving as an addition to reporting statements such as CONSORT.
Alia et al. (4)	2015	USA	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	To demonstrate how process evaluation is used to assess implementation of, and to provide formative feedback for, a culturally tailored, motivational plus family-based weight loss program.
Audrey et al. (5)	2006	UK	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	We describe the extensive process evaluation embedded within the trial and, rather than focusing on resultant

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								data, we consider the potential for such detailed examination of process to affect the intervention's delivery, receipt and outcome evaluation.
Bakker et al. (6)	2015	Netherlands	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	Describes the development of a method to concisely summarize the results of process evaluations of complex multi-component interventions.
Bakker et al. (7)	2013	Netherlands	Letter to journal	discussion and recommendations on broad topic of process evaluation	health	trial	Methodological / operational / ethical issues	n/a
Baranowski and Stables (8)	2000	USA	journal article	reflection on a PE	health	trial	Process evaluation approach / framework / guidance	The process evaluation results from the nine 5-a-Day projects were overviewed.
Biron and Karanika-Murray (9)	2014	Canada	journal article	discussion and recommendations on broad topic of process evaluation	health	not specified	Process evaluation approach / framework / guidance	We discuss how intervention process evaluation (IPE), an emerging field in intervention research, can enhance our understanding of why organizational interventions for stress succeed or fail.
Boeije et al. (10)	2015	Netherlands	journal article	discussion and recommendations on broad topic of process evaluation	health	trial	Methodological / operational / ethical issues	This paper addresses the methodological challenges that accompany the use of a combination of research methods to evaluate complex interventions.

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Brand et al. (11)	2019	UK	journal article	reflection on a PE	health	pilot/feasibility study	Methodological / operational / ethical issues	We describe and illustrate how a realist approach to formative process evaluation develops contextualised intervention theory that can underpin more adaptable and scalable interventions. We discuss challenges and benefits of this approach.
Branscum and Hayes (12)	2013	USA	journal article	review of reviews	health	not specified	Review	Reports the use of process evaluations in childhood obesity prevention interventions implemented over the past three decades.
Britton et al. (13)	1998	UK	Letter to journal	discussion and recommendations on broad topic of process evaluation	health	trial	Value of process evaluation	n/a
Buckley and Sheehan (14)	2009	Australia	journal article	reflection on a PE	health	not specified	Process evaluation approach / framework / guidance	Sought to provide examples of how to operationalize a process evaluation of an effective programme.
Bunce et al. (15)	2014	USA	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	The specific methods used in such ethnographic process evaluations are rarely presented in detail; our objective is to stimulate a conversation around the successes and challenges of specific data collection methods in health care settings.

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Butterfoss (16)	2006	USA	journal article	literature synthesis	health	not specified	Methodological / operational / ethical issues	This review provides a synthesis of published public health and social science literature to determine how process evaluation has been used to examine community participation and its intermediary role in health and social change outcomes.
Byng et al. (17)	2005	UK	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	This article explores how a relatively low-cost evaluation, using qualitative methods and Pawson and Tilley's realistic evaluation (RE) framework (1997) can both help explain the results of the trial and provide generalizable conclusions about service development of relevance to practitioners and policy makers.
Byng et al. (18)	2008	UK	journal article	reflection on a PE	health	trial	Value of process evaluation	This paper builds a picture of how the intervention, as a whole, had its effects and how the process evaluation adds meaning to the results of the trial.
Chandler et al. (19)	2015	UK	journal article	empirical research	health	trial	Use of a method / theory in process evaluation	To examine the application of core concepts from Complexity Theory to explain the findings from a process evaluation undertaken in a trial evaluating implementation strategies for

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								recommendations about reducing surgical fasting times.
Cheng and Metcalfe (20)	2018	Singapore	journal article	editorial	health	trial	Methodological / operational / ethical issues	n/a
Chrisman et al. (21)	2002	USA	journal article	reflection on a PE	health	standalone PE	Process evaluation approach / framework / guidance	This article reports the design we constructed and how it has worked so far.
Cornwall and Aghajanian (22)	2017	UK	journal article	reflection on a PE	health	standalone PE	Use of a method / theory in process evaluation	This article considers the contribution participatory process evaluation can make to impact assessment, using a case study of a study carried out to evaluate.
Crutzen et al. (23)	2012	Netherlands	journal article	reflection on a PE	health	not specified	Use of a method / theory in process evaluation	This study aimed to demonstrate the potential of Google Analytics as a process evaluation method for Internet delivered interventions, using a website about sexual health as an example.
Cunningham et al. (24)	2000	USA	journal article	reflection on a PE	health	quasi-experimental	Methodological / operational / ethical issues	Included in the paper are the purposes of each process method, problems identified, and their resolution. Suggestions are made for use of process evaluation in community health education programs.
De Silva et al. (25)	2014	UK	journal article	development of a PE approach	health	not specified	Process evaluation	We propose a theory-driven approach to the design and

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							approach / framework / guidance	evaluation of complex interventions by adapting and integrating a programmatic design and evaluation tool, Theory of Change (ToC), into the MRC framework for complex interventions.
Diaz et al. (26)	2014	USA	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	To use a newly devised set of criteria to review the study design and scope of collection of process, outcomes and contextual data for evaluations and implementation research of integrated community case management (iCCM) in Sub-Saharan African.
Ekambareshwar et al. (27)	2021	Australia	journal article	systematic review	health	not specified	Review	We aimed to summarise the literature in early childhood obesity prevention interventions delivered via telephone or text messages for evidence of application of process evaluation primarily to evaluate stakeholders' acceptability of interventions.
Ellard and Parsons (28)	2010	UK	book chapter	discussion and recommendations on broad topic of process evaluation	health	not specified	Methodological / operational / ethical issues	This chapter discusses issues relating to formative process evaluation and process evaluation; explores the research methods used; and discusses the integration of process and outcome data.

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Ellard et al. (29)	2011	UK	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	A process evaluation was commissioned alongside the trial and we report the protocol for this process evaluation.
Evans et al. (30)	2015	UK	Journal article	editorial	health	pragmatic formative process evaluation	Process evaluation approach / framework / guidance	n/a
Ferm et al. (31)	2018	Denmark	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	The aims of this paper were, first, to develop a model for a comprehensive quantitative implementation evaluation and, second, to operationalize it in the process evaluation of the stepped-wedge cluster randomized controlled trial.
Francis et al. (32)	2008	UK	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	This study illustrates the use of theory-based process evaluation to uncover processes underlying change in implementation trials.
Franzen et al. (33)	2009	USA	journal article	reflection on a PE	health	standalone PE	Value of process evaluation	The present study illustrates how a systematic process evaluation study can improve program activities.
French et al. (34)	2020	UK	journal article	systematic review	health	trial	Review	We aimed to describe the frequency, characteristics, labelling, value, practical conduct issues, and accessibility of published process evaluations within

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								pragmatic RCTs in health services research.
Frost et al. (35)	2020	UK	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	We used Social Practice Theory to guide a Type 1 Hybrid Trial: a mixed methods process evaluation of a complex intervention for heart failure. The objective of this paper is to explore the value of Social Practice Theory for implementation science.
Gale et al. (36)	2019	USA	journal article	reflection on a PE	health	standalone PE	Use of a method / theory in process evaluation	We present our method for conducting a framework-guided rapid analysis (RA) and a comparison of these findings to an in-depth analysis of interview transcripts.
Gensby et al. (37)	2018	Norway	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	This study design article is a proposal on a theory-driven and interactive research methodology for a process evaluation of a pragmatic intervention trial, known as STAIR.
Gobat et al. (38)	2021	UK	journal article	reflection on a PE	health	pragmatic formative process evaluation	Process evaluation approach / framework / guidance	This study reports a novel approach to modelling and refining the programme theory of a whole-school restorative approach, alongside plans to scale up through a national educational infrastructure in order to support robust scientific evaluation.



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Grant et al. (39)	2012	UK	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	This paper presents the mixed-method process evaluation protocol of a cluster randomized trial, drawing on a framework designed by the authors.
Grant et al. (40)	2013	UK	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	Develop our own framework for designing process evaluations of cluster-randomised controlled trials.
Grant et al. (41)	2016	UK	Journal article	editorial	health	trial	Use of a method / theory in process evaluation	n/a
Grant et al. (42)	2020	UK	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	We address this gap in the literature by presenting a number of important considerations for process evaluation using a case study design.
Gray and Shaw (43)	2019	Canada	journal article	reflection on a PE	health	not specified	Methodological / operational / ethical issues	The purpose of this paper is to explore summative, process and developmental approaches to evaluating complex interventions to determine how to best test this mess.
Griffin et al. (44)	2014	UK	journal article	development of a PE approach	health	trial	Process evaluation approach /	In this paper, we add to the current literature by describing a comprehensive approach to process evaluation undertaken

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							framework / guidance	in a trial of a complex, primary school-based obesity prevention intervention;
Griffin et al. (45)	2017	UK	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	The aim of this paper is twofold: 1) to demonstrate a replicable method of process evaluation data synthesis for use by other complex health intervention researchers, and 2) to present the results of the WAVES study process evaluation, demonstrating how the intervention was delivered and received.
Harachi and Fleming (46)	1999	USA	journal article	reflection on a PE	health	not specified	Use of a method / theory in process evaluation	This article illustrates the utilization of process measures from a multicomponent school-based prevention program to examine implementation of a teaching staff development intervention, and the program's underlying theoretical basis.
Harvey and Jan (47)	2017	Australia	journal article	editorial	health	trial	Multiple	n/a
Hatcher and Bonell (48)	2016	South Africa	journal article	editorial	health	trial	Value of process evaluation	n/a
Havermans et al. (49)	2016	Netherlands	journal article	systematic review	health	not specified	Review	This systematic review aimed to explore which process variables are used in stress

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								management intervention (SMI) evaluation research.
Hawe et al. (50)	2004	Canada	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	In this paper, we describe a combination of qualitative and quantitative methods in place to track the unfolding of a large scale primary care and community development intervention in maternal health in Australia.
Haynes et al. (51)	2014	Australia	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	This protocol provides a worked example of how to embed process evaluation in the design and evaluation of a complex intervention trial.
Haynes et al. (52)	2016	Australia	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	In this paper, we identify and respond to the fidelity assessment challenges posed by novel contextualised interventions (i.e. interventions that are informed by composite social and psychological theories and which incorporate standardised and flexible components in order to maximise effectiveness in complex settings).
Helitzer et al. (53)	2000	USA	journal article	reflection on a PE	health	not specified	Methodological / operational / ethical issues	In examining this component of the process evaluation, the paper presents the important benefits of monitoring implementation and providing

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								early feedback to the training process.
Hickey et al. (54)	2016	Ireland	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	In this paper, a process evaluation protocol for an early years parenting intervention, the Parent and Infant (PIN) program, is described.
Hulscher et al. (55)	2003	Netherlands	journal article	development of a PE approach	health	not specified	Multiple	This paper explores the purpose and value of process evaluation on QI interventions and addresses the issue of what data should be collected (“what to measure”) and data collection methods (“how to measure”).
Humphrey et al. (56)	2016	UK	online document	handbook	education	not specified	Process evaluation approach / framework / guidance	The purpose of this introductory handbook is to provide guidance to Endowment Foundation (EEF) evaluators (and, indeed, other researchers) on how to conduct high-quality implementation and process evaluations (IPE) at the various stages of intervention development and testing (e.g. pilot, efficacy, effectiveness).
Humphrey et al. (57)	2016	UK	online document	literature synthesis	education	not specified	Review	To draw together existing knowledge regarding the aims, functions and methods of implementation and process evaluation (IPE) in relation to

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								educational interventions, with a view to subsequently informing guidelines for researchers.
Irvine et al. (58)	2012	UK	journal article	reflection on a PE	health	pilot/feasibility study	Process evaluation approach / framework / guidance	This study assesses the utility of novel techniques for process evaluation involving no face to face contact.
Jansen et al. (59)	2009	Netherlands	journal article	systematic review	health	trial	Review	This article aims to review the contribution of qualitative research to developing community based interventions in primary care evaluated by means of the pragmatic trial methodology.
Kelley et al. (60)	2001	USA	journal article	reflection on a PE	health	standalone PE	Value of process evaluation	To use process evaluation methods to describe the development of a hospital-based mental health clinic for children facing medical stressors.
Kostamo et al. (61)	2019	Finland	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	To describe how to use the critical incident technique (CIT) to conduct in qualitative process evaluation to identify events, including intervention elements, which LMI trial participants perceived to enable or support behavior change.

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Koutsouris et al. (62)	2019	UK	journal article	reflection on a PE	education	trial	Value of process evaluation	The significance of a process evaluation for understanding randomised controlled trials (RCTs) of complex teaching interventions in a classroom setting is discussed in relation to the evaluation of the Integrated Group Reading (IGR) programme trial
Lee et al. (63)	2011	Canada	journal article	reflection on a PE	health	pilot/feasibility study	Process evaluation approach / framework / guidance	This article describes a fresh, ethnographically informed approach focused on alignments of project components in a pilot multisite, multilevel community-based falls prevention study in Canada
Lee et al. (64)	2013	USA	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	To use and review a conceptual model of process evaluation and to examine the implementation of a nutrition education curriculum,
Leeming et al. (65)	2016	UK	journal article	discussion and recommendations on broad topic of process evaluation	health	trial	Process evaluation approach / framework / guidance	In this paper, we discuss the limitations of evidence gained from measuring large-scale outcomes in RCTs and argue that greater use of qualitative research can enhance understanding of key processes in supporting breastfeeding.

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Legrand et al. (66)	2018	France	journal article	empirical research	health	not specified	Methodological / operational / ethical issues	The aim of this study was to describe the practices of health promotion professionals when evaluating interventions and their transferability and to identify these professionals' needs in relation to a tool that will guide them during monitoring and evaluation.
Leontjevas et al. (67)	2012	Netherlands	journal article	development of a PE approach	health	trial	Methodological / operational / ethical issues	In this article, a model is presented that divides process evaluation data into first and second order process data.
Limbani et al. (68)	2019	South Africa	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	We report on challenges and lessons learned from undertaking process evaluation of seven hypertension intervention trials funded through the Global Alliance of Chronic Diseases (GACD).
Linnan and Steckler (69)	2002	USA	book chapter	development of a PE approach	health	not specified	Use of a method / theory in process evaluation	n/a
Liu et al. (70)	2016	Australia	journal article	systematic review protocol	health	trial	Review	We aim to consolidate the methodology and methods from process evaluations of complex interventions in PHC and their findings of facilitators and barriers to intervention implementation.

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Liu et al. (71)	2019	Australia	journal article	systematic review	health	trial	Review	We synthesised the methods used in PEs of primary care interventions, and their main findings on implementation barriers and facilitators.
Lorencatto et al. (72)	2016	UK	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	This protocol presents methods for assessing fidelity across five dimensions proposed by the Behaviour Change Consortium fidelity framework, including intervention designer-, provider- and recipient-levels.
Lytle et al. (73)	1994	USA	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	This paper discusses the challenges faced when collecting process evaluation information in a school-based, multicenter field trial.
Maar et al. (74)	2017	Canada	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	We present a framework for the process evaluations for mHealth interventions in multiple cultural settings.
Manchaiah et al. (75)	2014	UK	journal article	discussion and recommendations on broad topic of process evaluation	health	not specified	Methodological / operational / ethical issues	The main focus of this paper is to discuss the importance of “evaluating the process of change” (i.e., process evaluation) in people with disability by studying their lived experiences.
Masterson-Algar (76)	2016	UK	PhD thesis	multiple strands of work	health	trial	Multiple	The aim of this study is to advance thinking and practice in process evaluation and



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								clinical trial methodology within the field of neurological rehabilitation.
Masterson-Algar et al. (77)	2016	UK	journal article	systematic review	health	trial	Review	To systematically review how process evaluations are currently designed, what methodologies are used and how are they developed alongside or within neurological rehabilitation trials.
Masterson-Algar et al. (78)	2018	UK	journal article	empirical research	health	trial	Process evaluation approach / framework / guidance / guidance	This paper reports on the development of new consensus guidelines that address the specific challenges of conducting process evaluations alongside clinical trials of rehabilitation interventions.
May et al. (79)	2007	UK	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	The paper develops this by first discussing the development of the theoretical model, and then applies it to two case studies of complex trials that combine both treatment and organizational interventions in primary care. In the conclusion, the implications of such models for the development of process evaluations are discussed.
May et al. (80)	2018	UK	journal article	systematic review	health	not specified	Review	The aims of this review were to review this literature; to

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								identify and characterise the uses and limits of NPT in research on the implementation and integration of healthcare interventions; and to explore NPT's contribution to understanding the dynamics of these processes
Mbuya et al. (81)	2015	Zimbabwe	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	In this article, we present the SHINE PIP including definitions and measurements of key mediating domains, and discuss the implications of this approach for randomized trials.
McGill et al. (82)	2020	UK	journal article	systematic review	health	not specified	Process evaluation approach / framework / guidance	This systematic review aims to analyze published examples of process evaluations that utilize qualitative methods that involve a complex systems perspective and proposes a framework for qualitative complex system process evaluations.
McGraw et al. (83)	1994	USA	journal article	development of a PE approach	health	trial	Use of a method / theory in process evaluation	The process evaluation system used in the Child and Adolescent Trial for Cardiovascular Health (CATCH) is presented in this paper.
McIntyre et al. (84)	2020	UK	journal article	systematic review	health	trial	Review	In this study context, we reviewed (a) the proportion of process evaluations citing

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								theoretical approaches, (b) which theoretical approaches were cited, and (c) whether and how theories were used.
Moore (85)	2010	UK	PhD thesis	multiple strands of work	health	trial	Process evaluation approach / framework / guidance	This thesis develops a mixed-method framework exploring programme theory, diffusion, implementation, participant experiences and reach, which is applied to the evaluation of the Welsh National Exercise Referral Scheme (NERS).
Moore et al. (86)	2014	UK	online document	process evaluation guidance	health	not specified	Process evaluation approach / framework / guidance	This document provides researchers, practitioners, funders, journal editors and policy-makers with guidance in planning, designing, conducting and appraising process evaluations of complex interventions.
Moore et al. (87)	2014	UK	Journal article	editorial	health	not specified	Multiple	n/a
Moore et al. (88)	2015	UK	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	In this article, we provide an overview of the new framework and summarise our practical recommendations using one of the case studies as an example.
Morgan-Trimmer (89)	2015	UK	journal article	discussion and recommendations on broad topic of process evaluation	health	not specified	Methodological / operational / ethical issues	This article reflects on the current state of process evaluations of health behavior interventions and argues that evaluation practice in this area

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								could be improved by drawing on the social science literature to a greater degree.
Morgan-Trimmer and Wood (90)	2016	UK	journal article	discussion and recommendations on broad topic of process evaluation	health	not specified	Use of a method / theory in process evaluation	This article outlines the contribution that ethnography could make to process evaluations for trials of complex health behaviour interventions.
Morrels-Samuels et al. (91)	2018	USA	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	The purpose of this article is to present methods used to document and assess the implementation of the Youth Empowerment Solutions (YES) program.
Munodawafa et al. (92)	2018	South Africa	journal article	systematic review	health	not specified	Review	This review seeks to answer two main questions: (i) to what extent are qualitative process evaluations conducted on task shared interventions for perinatal depression in LAMICs; and (ii) what is the best way to synthesize emergent themes from the process evaluations with the MRC framework for conducting process evaluations [20]?
Munro and Bloor (93)	2010	UK	journal article	discussion and recommendations on broad topic of process evaluation	health	trial	Value of process evaluation	not stated
Murdoch (94)	2016	UK	journal article	development of a PE approach	health	trial	Process evaluation	In this paper I propose an alternative approach to the

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							approach / framework / guidance	design, implementation and analysis of process evaluations for complex health interventions through a consideration of trial protocols as textual documents, distributed and enacted at multiple contextual levels.
Murta et al. (95)	2007	Brazil	journal article	systematic review	health	not specified	Review	To conduct a systematic review of workplace stress management intervention studies that have incorporated process evaluation.
Murtagh et al. (96)	2007	UK	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	To understand participants' experiences and understandings of the interventions in the trial of a computerised decision support tool in patients with atrial fibrillation being considered for anti-coagulation treatment.
Nagy et al. (97)	2007	USA	journal article	reflection on a PE	health	standalone PE	Value of process evaluation	In this manuscript we report on the development, implementation, results, and lessons learned from a process evaluation plan initiated during the planning period for the Alabama Racial and Ethnic Approaches to Community Health (REACH 2010) program.
Nielsen and Abildgaard (98)	2013	UK	journal article	development of a PE approach	health	not specified	Process evaluation approach /	In this paper, we present an evaluation framework based on recent intervention

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							framework / guidance	research and process-oriented organization theory.
Nielsen and Randall (99)	2013	Denmark	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	By drawing on existing intervention literature we present an evidence-based model containing three levels of elements that appear to be crucial in process evaluation.
Nielsen et al. (100)	2018	USA	journal article	reflection on a PE	health	trial	Value of process evaluation	Here, we report on some of the key findings from the PE conducted 1 year after programme implementation began (Olney, Behrman, Iruhiriye, van den Bold, & Pedehombga, 2013), how the findings were used to refine programme implementation and rectify weaknesses in real time through a series of consultations
Oakley et al. (101)	2004	UK	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	The article describes the methods used to collect process data, and some of the challenges involved.
Oakley et al. (102)	2006	UK	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	This paper outlines a framework for using process evaluation as an integral element of RCTs.
O'Cathain et al. (103)	2014	UK	journal article	multiple strands of work	health	trial	Value of process evaluation	To systematically explore how qualitative research is being used with trials and identify ways of maximising its value to

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								the trial aim of providing evidence of effectiveness of health interventions.
Odendaal et al. (104)	2008	South Africa	journal article	reflection on a PE	health	trial	Value of process evaluation	This article reviews the methods in a process evaluation of a home visitation programme.
Ottoson et al. (105)	2000	USA	journal article	reflection on a PE	health	not specified	Value of process evaluation	The purpose of this study was to explore process or contextual aspects of the work setting and their relationship to learning outcomes following CPE.
Palmer et al. (106)	2016	Australia	journal article	development of a PE approach	health	trial	Methodological / operational / ethical issues	This paper provides a description of a nested process evaluation design using mixed-methods to inform a cluster randomized controlled trial. It builds on current debates about the need to better systematize process evaluation data collection, analysis and reporting.
Parker et al. (107)	2019	USA	Journal article	editorial	health	pilot/feasibility study	Value of process evaluation	n/a
Parrott and Carman (108)	2019	USA	journal article	reflection on a PE	health	not specified	Methodological / operational / ethical issues	In this research and practice note, we reflect on our evaluation experiences with a public - private partnership designed to scale up a health and wellness program within a

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								large, urban school district at ten elementary schools.
Platt et al. (109)	2004	UK	book chapter	discussion and recommendations on broad topic of process evaluation	health	not specified	Methodological / operational / ethical issues	This chapter introduces the purposes, focus, and methods of process evaluation and explores some issues in the application of process evaluation using examples from two research projects.
Raine et al. (110)	2016	UK	journal article collection	discussion and recommendations on broad topic of process evaluation	health	not specified	Multiple	This collection of essays is intended to address at least the first part of the paradox, the relative lack of consensus about how to evaluate changes in services.
Ramsay et al. (111)	2010	UK	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	To illustrate the applicability of causal methods within randomised trials, we undertook a theory-based process evaluation study within an implementation trial to explore whether the cognitions of primary care doctors' predicted their test requesting behaviours and, secondly, whether the trial results were mediated by the theoretical constructs.
Redmond et al. (112)	2017	USA	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	The aim of this study was to describe a refined process evaluation model adapted for Web-based settings and used to assess the implementation



Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								of a Web-based intervention aimed to increase organ donation among African Americans.
Renger and Foltysova (113)	2013	USA	journal article	reflection on a PE	health	standalone PE	Process evaluation approach / framework / guidance	The purpose of this study is to report on our efforts at assessing the feasibility of capturing program planning phase deliberations and using them to design a process evaluation capable of providing information for making decisions about both quality control and quality improvement.
Reynolds et al. (114)	2014	UK	journal article	empirical research	health	trial	Process evaluation approach / framework / guidance	In this paper, we will draw on our experiences of 'doing' evaluation in a research context to present lessons learned for negotiating the reality of evaluation and reflecting on the subsequent implications for interpreting trial outcomes.
Ribeiro et al. (115)	2019	New Zealand	journal article	systematic review	health	trial	Review	This systematic review is designed to answer the following research question: How are process evaluation of complex interventions tested in RCTs in musculoskeletal disorders being conducted?

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
Riley et al. (116)	2005	Australia	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	This paper presents issues which arose in the conduct of qualitative evaluation research within a cluster randomized, community-level, preventive intervention trial.
Roberts-Gray et al. (117)	2017	USA	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	To examine the utility of structuring the trial's process evaluation to forecast use, sustainability, and readiness of the intervention for wider dissemination and implementation.
Roe and Roe (118)	2004	USA	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	This article describes dialogue boxes, a process evaluation tool that has proven extremely useful in diverse health promotion program and planning efforts.
Rycroft-Malone et al. (119)	2018	UK	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	This paper presents an exemplar of a multi-country realist process evaluation that was embedded in the first international randomised controlled trial evaluating two types of facilitation for implementing urinary continence care recommendations.
Saarijärvi et al. (120)	2020	Sweden	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	In this article, process evaluation is described according to the Medical Research Council guidance and

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								its use exemplified through a randomized controlled trial evaluating the effectiveness of a transition program for adolescents with chronic conditions.
Saunders et al. (121)	2005	USA	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	The purpose of this article is to describe and illustrate the steps involved in developing a process evaluation plan for any health promotion program.
Scantlebury et al. (122)	2020	UK	journal article	reflection on a PE	health	trial	Process evaluation approach / framework / guidance	The paper aims, through a qualitative process evaluation, to explore some of the factors that may have affected the delivery of the REFORM intervention and highlight how project-specific fidelity can be assessed using a truly mixed-methods approach when informed by qualitative insights.
Scott et al. (123)	2014	Canada	journal article	systematic review protocol	health	not specified	Review	This study focuses on improving process evaluations by synthesizing current evidence on process evaluations conducted alongside experimental designs for evaluating KT interventions.
Scott et al. (124)	2019	Canada	journal article	systematic review	health	not specified	Review	This study synthesizes current evidence of KT process evaluations to provide future

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								methodological recommendations.
Segrott et al. (125)	2017	UK	journal article	reflection on a PE	health	trial	Use of a method / theory in process evaluation	In doing so, this paper aids interpretation of outcome effects within the trial, develops our understanding of how SFP 10–14 could be implemented in a UK setting, and assesses the potential for ENPT to contribute to understanding of implementing social interventions within complex systems.
Sharma et al. (126)	2017	Canada	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	Building from previous frameworks, we illustrate a methodology to evaluate implementation processes of the complex CLIP intervention, assess mechanisms of impact and identify emerging unintended causal pathways.
Shepherd et al. (127)	2019	Australia	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	This paper describes methods of defining and measuring outcomes of implementation success.
Siddiqui et al. (128)	2018	UK	journal article	reflection on a PE	education	trial	Use of a method / theory in process evaluation	In this paper, we explain the concept of aggregated trials in schools, and the protocols we followed for the process evaluation in order to gain more information than usual

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								on the feasibility of conducting aggregated trials.
Simuyemba et al. (129)	2020	Zambia	journal article	reflection on a PE	health	standalone PE	Methodological / operational / ethical issues	This article highlights complexities of this type of real-time evaluation and shares lessons learnt on conducting such evaluation from the Zambian experience.
Stappers et al. (130)	2020	Netherlands	journal article	reflection on a PE	health	health impact assessment	Methodological / operational / ethical issues	The aim of this paper is to explore and describe the role of context in explaining the developments within the integrated urban reconstruction project and its presumed health effects over time, and to draw implications for evaluation theory and methodology such as spatial or urban health impact assessment.
Strange et al. (131)	2006	UK	journal article	reflection on a PE	health	trial	Methodological / operational / ethical issues	This article has three aims: to outline the methods developed to link process and outcome data in the RIPPLE trial; to present the findings of this analysis; and to explore some of the methodological issues that arose, especially in using the process data to explain the impact on trial outcomes.

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
Tolma et al. (132)	2009	USA	journal article	reflection on a PE	health	intervention development	Methodological / operational / ethical issues	In this article, we describe the process evaluation planning that took place during the development of an action plan by a newly developed Turning Point community partnership.
Tolma et al. (133)	2011	USA	journal article	reflection on a PE	health	intervention development	Process evaluation approach / framework / guidance	To describe the systematic approach to process evaluation of a Turning Point initiative in central Oklahoma during the formation stage.
Tonkin-Crine et al. (134)	2016	UK	journal article	development of a PE approach	health	trial	Use of a method / theory in process evaluation	The current study aimed to follow a triangulation protocol to integrate mixed methods data previously collected in order to see whether such an approach could further inform the findings of the original process evaluation of the trial.
Toroyan et al. (135)	2004	UK	journal article	reflection on a PE	health	trial	Value of process evaluation	This paper outlines the process evaluation that was conducted alongside the first RCT of day care in the United Kingdom.
Tuchman (136)	2008	USA	journal article	development of a PE approach	health	pilot/feasibility study	Use of a method / theory in process evaluation	This article presents an exemplar of a model-guided process evaluation.
Turner et al. (137)	2006	Australia	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	This paper describes the development and implementation of an electronic, web-based application to simplify data

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								collection for this research process.
Viadro et al. (138)	1997	USA	journal article	reflection on a PE	health	quasi-experimental	Methodological / operational / ethical issues	In this paper, we discuss the steps taken to develop a process evaluation plan for an ongoing eight-year, community-based breast cancer screening program (NC-BCSP) for African American women in five rural North Carolina counties.
Wells et al. (139)	2012	UK	journal article	empirical research	health	trial	Methodological / operational / ethical issues	However, the diverse ways in which context may challenge the central tenets of the RCT, and the degree to which this information is known to researchers or subsequently reported, has received much less attention. In this paper, we explore these issues by focusing on seven RCTs of interventions varying in type and degree of complexity, and across diverse contexts.
Wickizer et al. (140)	1993	USA	journal article	development of a PE approach	health	standalone PE	Process evaluation approach / framework / guidance	This paper describes an approach developed to analyze community activation for health promotion and presents data on selected measures of activation collected in 28 communities in the western United States as part of the

Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								Community Health Promotion Grant Program evaluation.1
Wierenga et al. (141)	2013	Netherlands	journal article	systematic review	health	trial	Review	The aim of this review was therefore to: (1) further our understanding of the quality of process evaluations alongside effect evaluations for worksite health promotion programs (WHPPs), (2) identify barriers/facilitators affecting implementation, and (3) explore the relationship between effectiveness and the implementation process.
Wight and Obasi (142)	2003	UK	book chapter	discussion and recommendations on broad topic of process evaluation	health	trial	Methodological / operational / ethical issues	This chapter discusses four key intervention factors that can be of critical importance in interpreting outcome evaluations. These factors are: (1) the extent and quality of intervention delivery; (2) the mechanism; (3) the context; and, (4) the response of the target group. Finally, the chapter considers some key problems with process evaluations and how process and outcome data can be integrated.
Wilson et al. (143)	2009	USA	journal article	reflection on a PE	health	trial	Value of process evaluation	The purpose of this study was to demonstrate how formative program process evaluation was used to improve dose and



Reference	Year of publication	Country of lead author	Type of literature	Type of work presented	Field of practice	Type of accompanying outcome evaluation	Focus of literature item	Aim (where possible copied and pasted from original article text)
								fidelity of implementation, as well as reach of the intervention into the target population, in the "Active by Choice Today" (ACT) randomized school-based trial from years 1 to 3 of implementation.
Windsor et al. (144)	2000	USA	journal article	development of a PE approach	health	trial	Process evaluation approach / framework / guidance	To describe and apply a process evaluation model (PEM) for patient education programs for pregnant smokers.
Yamada et al. (145)	2010	Canada	journal article	development of a PE approach	health	not specified	Process evaluation approach / framework / guidance	To examine the content validity of the Process Evaluation Checklist (PEC), a newly developed measure to assess the fidelity of the EPIC intervention
Yeary et al. (146)	2012	USA	journal article	systematic review	health	not specified	Review	Thus, a systematic review of the utilization of process evaluation in church-based health programs was conducted.
Zbukvic et al. (147)	2020	Australia	journal article	systematic review	health	trial	Review	This paper reviews process evaluations associated with multilevel suicide prevention research trials.

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