

	Number of items (n=147)
<b>Year of publication</b>	
2020-2021	12
2015-2019	57
2010-2014	36
2005-2009	21
2000-2004	15
Pre-2000	6
<b>Type of literature</b>	
Journal article	135
Book chapter	4
Online document	3
Letter	2
PhD thesis	2
Journal article collection	1
<b>Type of work presented</b>	
Reflection on a process evaluation	56
Development of a process evaluation approach	38
Systematic review	16
Discussion and recommendations on broad topic of process evaluation	14
Editorial	7
Empirical research	6
Multiple strands of work	3
Literature synthesis	2
Systematic review protocol	2
Handbook	1
Process evaluation guidance	1
Review of reviews	1
<b>Field of practice</b>	
Health	143
Education	4
<b>Country of lead author</b>	
UK	62
USA	36
Australia	12
Netherlands	10
Denmark	4
South Africa	4
Canada	3
Brazil	1
Finland	1
France	1
Ireland	1
New Zealand	1
Norway	1
Singapore	1
Sweden	1
Zambia	1
Zimbabwe	1
<b>Focus of literature item</b>	
Process evaluation approach / framework / guidance	51
Methodological / operational / ethical issues	37
Use of a method / theory in process evaluation	20
Review of process evaluations	19
Value of process evaluation	15
Multiple foci	5

<b>Type of accompanying evaluation</b>	
Trial	83
Not specified	43
Standalone process evaluation	9
Pilot/feasibility study	5
Intervention development	2
Pragmatic formative process evaluation	2
Quasi-experimental	2
Health impact assessment	1

<b>Theme</b>	<b>Sub-themes</b>	<b>Examples</b> <i>*Denotes potential negative consequences</i>
<b>Relationships</b>	<b>Relationships between process evaluation participants</b>	<p>Data collection process building trust and identity within a group of process evaluation participants (25)</p> <p>Providing process evaluation participants from different research sites opportunities to network with each other (26)</p> <p>Promoting wider inter-organisational collaboration and learning (27)</p> <p><i>*Potential negative consequence of status issues and concerns about repercussions between process evaluation participants in group data collection (25)</i></p>
	<b>Relationships between researchers and process evaluation participants and other stakeholders</b>	<p>Activities such as qualitative interviews and stakeholder involvement in research enhancing trust, communication, and a sense of mutual understanding between researchers and process evaluation participants (25, 26, 28)</p> <p>Contribute to broader research/practice partnerships and collaborations (29)</p> <p><i>*Potential negative consequences of feeding back negative findings to intervention implementers and stakeholders straining relationships and reducing morale and engagement, particularly if not handled sensitively (26, 30)</i></p> <p><i>*Possible tension if stakeholders expect feedback during RCTs but this cannot be provided as it would harm the RCT's ability to establish causality (30, 31)</i></p> <p><i>*Potential misunderstandings about purpose of evaluation as grading performance rather than learning opportunities (30)</i></p>
<b>Giving people a voice</b>	<b>Empowerment or disempowerment of process evaluation participants</b>	<p>Asking process evaluation participants how to improve interventions signified they were listened to and empowered, however with the important caveat that their views were acted upon (32).</p> <p>Promoting the voices of everybody involved, reflecting dignity and validity of multiple viewpoints (25)</p> <p>Appreciation from process evaluation participants of being asked about their views, experiences, and feelings, about which they were seldom asked (33)</p> <p>Appreciation from process evaluation participants giving opinions in meetings that clinical leaders also present to hear their voice (34)</p> <p><i>*Potential negative consequence of process evaluation participant disempowerment if views not acted on (32), inadequate representation of different stakeholders (35), researcher perspectives privileged (35), researcher use of esoteric language (36), voices perceived as going into a research 'black hole' (34)</i></p>
<b>Education</b>	<b>Educating students</b>	<p>Providing students with opportunities to gain experience in research (37)</p> <p>Gaining PhDs through conducting process evaluations (38)</p>
<b>Ethical issues</b>	<b>Consent</b>	<p><i>*Conducting observations in settings where some people are not participants in the evaluation (39)</i></p> <p><i>*Ethical issues around consent for research use of routinely collected clinical data (40).</i></p>
	<b>Confidentiality</b>	<i>*Confidentiality of individual participant responses, and sensitive handling of information that could be detrimental to others (25, 26)</i>

Theme	Sub-themes	Examples <i>*Denotes potential negative consequences</i>
	<b>Participant harm</b>	<i>*Potential emotional ill-effects on process evaluation participants such as embarrassment (1), feeling nervous, threatened, uncomfortable being observed (41)</i> <i>*Disruption and burden to practice settings</i>
	<b>Acting on process data suggesting problems with the outcome evaluation</b>	<i>*Ethical dilemmas when process evaluations do not have a formative role but identify problems with an intervention/outcome evaluation (42, 43)</i> Potential role for process evaluations to monitor the ethical conduct of RCTs (42)
<b>Financial</b>	<b>Inefficiency and waste</b>	<i>*Potential for process evaluations to waste money through inefficiency and collecting too much data (1)</i>
<b>Impact on the outcome evaluation</b>	<b>Increasing likelihood of positive outcome results</b>	Correcting implementation formatively may increase the likelihood of positive outcome results (11, 39, 44, 45) Realist formative process evaluation in pilot trial resulted in intervention being more adaptable to individual and local contexts and therefore more likely to demonstrate effect in full trial (46) Realist formative process evaluation in pilot trial providing in-depth implementation and delivery knowledge for main trial (46) <i>*Potential for certain process evaluation data collection methods such as in-depth interviews to enhance intervention effects (47)</i> <i>*Potential Hawthorne effects (1)</i>
	<b>Increasing staff engagement with the evaluation</b>	Providing feedback to stakeholders through monitoring and quality control may generate enthusiasm, which may be beneficial to the success of the intervention and evaluation (24) Staff delivering interventions are likely to expect and wish to improve their practice (34, 48), and therefore collaboration to formatively improve interventions may have the value of engaging and motivating staff involvement (34) Formative process evaluation may help sustain staff interest and engagement in trials lasting several years (49) Formative improvement of trial processes likely to enhance cooperation of staff collecting process data and timely correction of problems which threaten the evaluation (50)
	<b>Adding burden to outcome evaluation staff and participants</b>	<i>*Potential burden of process evaluation data collection on intervention staff and participants (1, 7)</i>
	<b>Meeting a requirement</b>	Fulfilling a requirement to include a process evaluation from funding bodies and research commissioners (51, 52), guidance (2, 53), or calls within fields (54, 55)

Theme	Sub-themes	Examples <i>*Denotes potential negative consequences</i>
	<b>Adding bias to outcome evaluation</b>	<p><i>*Outcome evaluators gaining insight into how the intervention is functioning which may bias their interpretation of outcomes (1, 56)</i></p> <p><i>*Possibility of unblinded process evaluators accidentally revealing participant allocations to outcome evaluators (1)</i></p>

PROCESS EVALUATION VARIABLES	POTENTIAL IMPACTS ON THE VALUE OF PROCESS EVALUATION KNOWLEDGE		
	Credibility	Accuracy	Completeness
<b>What is evaluated?</b>	<p>Arguments that process evaluations should be standardised to include set components and enable easier cross-study comparison (1, 5, 24, 57, 58)</p>	<p>Potential for incorrect conclusions to be drawn when insufficient or incorrect processes/participants are included (1, 31)</p> <p>Not taking temporal dimensions into account risks inaccurate interpretation of findings (59)</p> <p>Arguments that process evaluations which conceptualise context, mechanisms of action, and implementation as uni-dimensional, static, and linear may lead to inaccurate conclusions (40, 46, 59-61)</p> <p>Potential for sampled participants/sites to all have had similar experiences so findings do not reflect experiences of whole sample (62)</p>	<p>Arguments for all process evaluations including certain 'essential' components (4, 24, 57)</p> <p>Arguments against 'tick-box' approach to deciding on components (63)</p> <p>Arguments for stakeholder involvement in selection of processes and participants (1, 44, 64); potential to miss information through solely basing choices on researcher views (64, 65)</p> <p>Importance of including outcome evaluation processes as well as intervention processes (12, 66-68)</p> <p>Arguments that meaningful interpretation of findings requires analysis of all processes (69, 70)</p> <p>Potential for researchers to only be directed to 'showcase' sites (33)</p> <p>Problems using qualitative findings from small numbers of sites to make universal changes to interventions (10)</p> <p>Arguments that process evaluation methods should take account of changes over time, including evolving context (63), intervention teething problems (38, 71), and learning curve effects (55), continuation of intervention beyond trial (4)</p> <p>Debate between using logic models (1) and more complex theoretical models (63, 72-74) to theorise interventions.</p> <p>Advocation of using a complex systems perspective to take into account broader systems in which interventions take place (75)</p> <p>Debates about how fidelity should be conceptualised (1, 76, 77)</p> <p>Potential to gain richer understanding through aspects often not investigated, including impact by interaction and emergence (33) and relational dynamics (61)</p>
<b>How are processes evaluated?</b>	<p>Doubt from triallists over the credibility of qualitative findings (43), qualitative findings not being</p>	<p>Some qualitative approaches felt to have stronger explanatory capability than others, such as ethnography (34), and the use of theoretical explanatory frameworks (55)</p>	<p>Ability of methods to uncover the unknown (11, 36, 46, 65, 67)</p> <p>Qualitative process evaluations being designed to be subservient to trials (71), avoiding looking for problems (43), framing questions around</p>

PROCESS EVALUATION VARIABLES	POTENTIAL IMPACTS ON THE VALUE OF PROCESS EVALUATION KNOWLEDGE		
	Credibility	Accuracy	Completeness
	<p>properly integrated (78), issues judging whether qualitative or quantitative data are more reliable (79). Difficulties applying nuanced and diverse qualitative findings to interventions developed as uniform in an RCT (10)</p> <p>Potential for rapid qualitative methods to preserve depth of analysis while also providing timely actionable findings (80)</p>	<p>Speculative links between factors identified qualitatively and outcomes may not be accurate (68)</p> <p>Potential misleading findings from post-hoc analyses (81, 82)</p> <p>Data collection tools being unable to capture different eventualities of what actually happened (41)</p>	<p>researchers' rather than participants' concerns (83), being undertaken as separate studies (71)</p> <p>Challenges of developing tools to capture all aspects of tailored flexible interventions (41)</p>
<b>Practical conduct</b>		<p>Bias introduced during participant recruitment - selective gatekeeping (26), overrepresentation of engaged participants (32, 71, 84)</p> <p>Intervention staff collecting data may introduce bias (1, 40, 48, 71, 82)</p> <p>Routine practice data incomplete or poor quality (12, 40)</p> <p>Low interrater reliability (85), inconsistency between researchers covering different sites (41)</p> <p>Participants may be more willing to honestly express concerns if researchers are separate from the trial (38, 43, 72)</p> <p>Potential for socially desirable narratives (67, 86), recall bias (48, 87), memory limitations (59),</p>	<p>Participants as co-evaluators can strengthen evaluation through gaining richer information (89)</p> <p>Qualitative data analysis without knowledge of outcomes may prevents useful exploration of unexpected outcomes (10, 13)</p> <p>Participants not returning accurate/timely data – in particular lack of motivation in control sites (41)</p>

PROCESS EVALUATION VARIABLES	POTENTIAL IMPACTS ON THE VALUE OF PROCESS EVALUATION KNOWLEDGE		
	Credibility	Accuracy	Completeness
		<p>inattentive responding (59), and intentional false reporting (59)</p> <p>Analysis of qualitative data with knowledge of outcomes may bias interpretation (13, 88) and result in data dredging (81).</p>	
<b>Dissemination</b>		Limited discussion of quality, validity, and credibility in publications (9, 40, 63, 90)	<p>Sometimes not published (1, 78, 91), with no justification of why elements were published over others (71)</p> <p>Process evaluation publications divorced from outcome publications (9, 12, 54, 63, 78, 92); lengthy time periods between publications (12)</p>

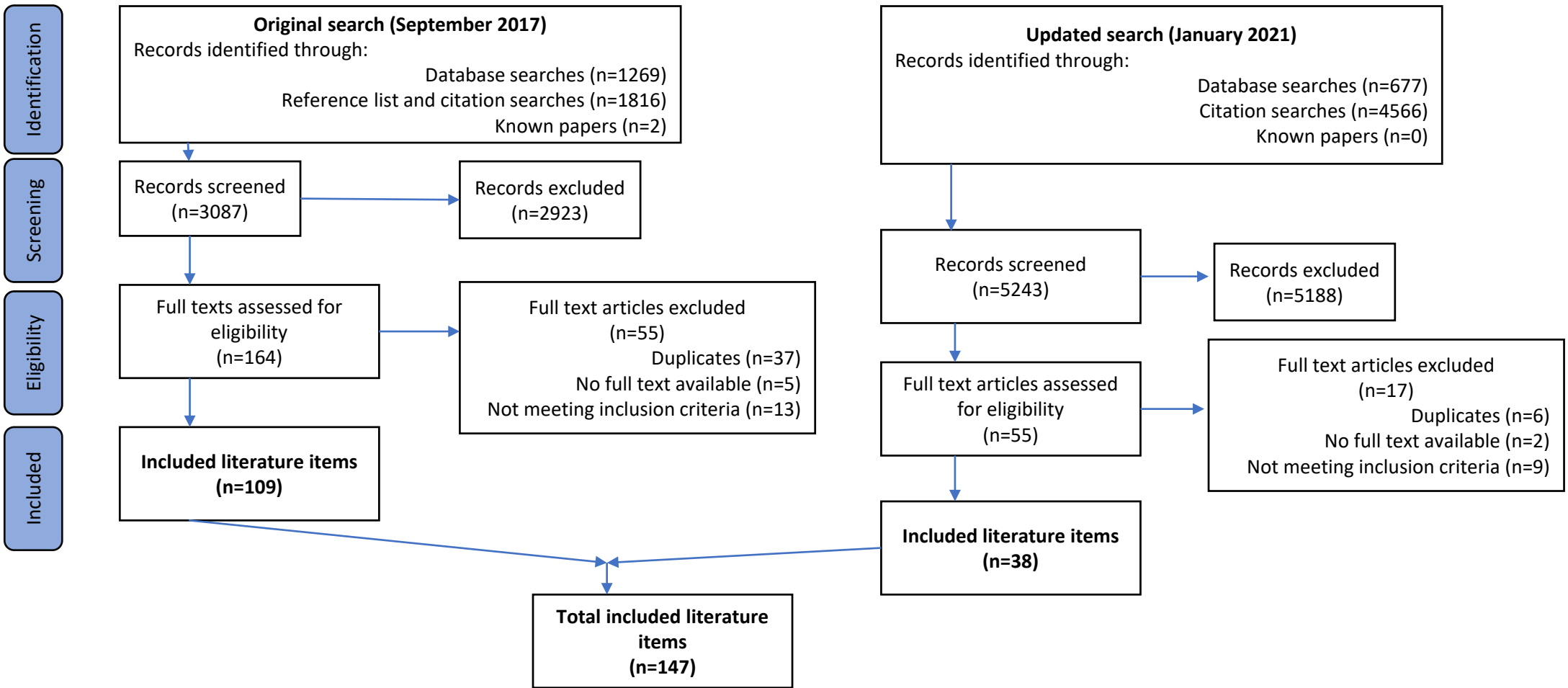


Theme	Sub-theme	Examples
<b>Process evaluation knowledge supporting implementation of interventions into practice</b>	<b>Improving implementation during the evaluation</b>	Continuously check and make adjustments to keep interventions ‘on track’ (98) by monitoring and correcting fidelity, adaptations, reach, and/or dose (24, 44, 48, 77, 97, 98)
	<b>Developing interventions more likely to be implemented successfully</b>	Formative process evaluation during piloting enhances development of sustainable and adaptable intervention, and develops robust implementation processes increasing likelihood of effectiveness in main trial (46) Formative process evaluation over entire evaluation allows implementation to be optimised and strengthened in real time (60, 89, 99)
	<b>Informing about transferability to other contexts post-evaluation</b>	Understanding of the required conditions for interventions to have desired effects, and assessment of intervention transferability to different settings (35, 40, 82, 100) Enable judgement about whether mechanisms would have the same effect in different settings (1, 94) Acceptability of interventions (101) Responses of different subgroups (27)
	<b>Informing how best to implement the intervention post-evaluation</b>	Necessary conditions for implementation to be effective in systems, such as new policies (99), allocation of sufficient resources (98) Necessary training and support for intervention deliverers (91, 102-104) How to tailor and adapt interventions in different contexts (40, 53, 62, 81, 83, 102) Strategies and monitoring systems to support implementation (46, 102, 105-107) Informing about relative importance and optimisation of different intervention components (6, 31, 40, 74, 107) Describing how flexible interventions were delivered in evaluation to aid replication (12) Assessment of extent to which intervention is deliverable in practice in the intended way (86)
	<b>Enhancing likelihood of intervention being implemented in practice post-evaluation</b>	Engaging stakeholders during process evaluation may contribute to successful implementation by those stakeholders after the evaluation (28, 108) Understanding processes of integrating interventions in dynamic complex settings (109) Providing evidence of feasibility and help convince clinicians and policymakers to adopt controversial but effective interventions (13) Highlighting potential implementation difficulties (13) Providing evidence of how intervention works in different contexts may mean more likely to be adopted in practice (100)

<b>Theme</b>	<b>Sub-theme</b>	<b>Examples</b>
<b>Process evaluation knowledge informing development of interventions</b>	<b>Intervention modification</b>	<p>Optimisation through revealing reasons for positive outcomes (53, 84)</p> <p>Modification to avoid potentially harmful unintended effects (42, 110)</p> <p>Improvements to acceptability and usability (111, 112)</p> <p>Remove or modify intervention components (70, 91, 102, 113)</p> <p>Inform effective tailoring of interventions to different populations and contexts (62, 84, 102, 114)</p> <p>Improvements to intervention design (86)</p>
	<b>Developing intervention theory</b>	Develop, test, and refine intervention theory and causal mechanisms (33, 53, 83, 100, 115)
	<b>Future intervention design</b>	Process evaluations providing insights into reasons for ineffective interventions can provide knowledge to inform development of future interventions (90)
<b>Process evaluation knowledge improving practice and outcomes</b>	<b>Improvements during the evaluation</b>	<p>Formative process evaluations facilitated intervention development and therefore improved practice and outcomes (29, 30, 37, 97, 116)</p> <p>Improving standard care at trial sites by exposing gaps in current provision (12)</p> <p>Designing quality process evaluation from evaluation outset can help examine programme logic and potential for additional positive outcomes (117)</p> <p>Participation in process evaluation may have helped intervention reach goal of empowering youth (32)</p>
	<b>Improvements after the evaluation</b>	<p>Process evaluation knowledge ultimately can improve practice and outcomes in groups targeted by interventions through:</p> <ul style="list-style-type: none"> <li>• Facilitating timely implementation of effective interventions into practice (100, 106, 117)</li> <li>• Providing understanding of how interventions work (118)</li> <li>• Enhancing understanding of complexity (2)</li> </ul> <p>Knowledge about patient experience may help clinicians and patients decide which intervention to choose in practice if both are found to have similar effects in an RCT (13)</p> <p>Improving patient centred-care by considering patient views (119)</p> <p>Revealing and addressing inequalities in participant responses which may be masked by aggregate positive trial results (1)</p>
<b>Process evaluation knowledge</b>	<b>Wider knowledge about interventions</b>	<p>Inform wider theories about similar interventions (57, 96, 120-122)</p> <p>Generate questions and hypotheses for future research (9)</p> <p>Highlight need for other interventions to target different subgroups (123)</p>

<b>Theme</b>	<b>Sub-theme</b>	<b>Examples</b>
<b>contributing to wider knowledge</b>	<b>Wider knowledge about implementation science</b>	<p>Knowledge about successful implementation strategies and behaviour change techniques (33, 71, 112, 124, 125)</p> <p>Understanding variation in outcome results according to factors associated with staff delivering interventions may be useful to inform wider research, policy, and practice (55, 81)</p> <p>Contribute insights into what facilitates implementation in public health programs (117)</p>
	<b>Wider knowledge about contexts</b>	Contribute to the evidence base about which types of interventions are fruitful to pursue, modify, or should be avoided within certain fields of practice (26, 47)
	<b>Wider knowledge about research methods</b>	<p>Methodological and theoretical contributions to process evaluation literature (1, 27, 29, 35, 84, 100, 102, 126, 127)</p> <p>Knowledge about optimal trial designs (90)</p>
<b>Financial value of process evaluation knowledge</b>	<b>Reducing costs of interventions</b>	<p>Identifying the active ingredients of interventions to inform removing minimally effective components (6, 40, 57)</p> <p>Demonstrating feasibility of implementing intervention in practice without a research grant (98)</p>
	<b>Justifying cost of evaluations</b>	<p>By explaining outcome results process evaluations may help justify money spent on trials with outcomes that are not positive (28, 128)</p> <p>Justifying costs of the intervention to funders (129)</p>
	<b>Informing financial management in wider contexts</b>	<p>Explaining outcome results may help avoid future expensive mistakes in interventions, theory, and research (67, 92)</p> <p>Understanding the mechanisms of interventions, and how they may affect other areas of health systems, may inform wider health investment (130)</p>
	<b>Avoiding research waste</b>	<p>Better provision of information on the influence of context on trial outcomes may help stop trial findings being ignored by policymakers and practitioners (131)</p> <p>The role of process evaluation knowledge in increasing the likelihood of interventions being successfully transferred to practice may be used to justify the expense of process evaluations (67)</p>
	<b>Ensuring interventions implemented correctly during evaluations</b>	Formative monitoring and correction of implementation may avoid financial waste through researching interventions which are not implemented correctly (64, 120)
<b>Value of process evaluation knowledge to</b>	<b>Adding knowledge not provided by the outcome evaluation</b>	<p>Unpacking an aggregate positive or negative outcome result which may mask considerable differences in individual benefit of interventions (1, 31, 82)</p> <p>Reasons for variability in outcomes and implementation (99)</p> <p>Qualitative process evaluations may discover unexpected outcomes that are difficult to predict or access using experimental methods (33, 63)</p>

Theme	Sub-theme	Examples
<b>the outcome evaluation</b>		<p>Investigating contextual factors not taken into account by outcome evaluation (33, 82)</p> <p>Explaining why interventions do or do not show effect in an outcome evaluation (58, 96)</p> <p>Providing knowledge about how interventions work in practice, including aspects of intervention of which investigators unaware (132), which aspects of intervention most important (112)</p> <p>Providing richer knowledge of how change occurred in ways that mattered to participants (33)</p> <p>Factors contributing to intervention implementation, including negotiations and compromises necessary for successful implementation (34)</p> <p>Unanticipated benefits of interventions (99)</p> <p><i>*Negative qualitative findings potentially demoralising trial team (92)</i></p>
	<b>Increasing the credibility of outcome evaluation methods</b>	<p>By adding knowledge to address criticisms of limitations of RCTs (81), process evaluations improve the science of RCTs, and help prevent abandonment of RCTs in favour of less rigorous non-experimental or non-randomised research methods (88)</p> <p>Perceptions that process evaluations address tendencies of experimental evaluators to not take into account vital information (1, 38, 54, 55)</p>
	<b>Improving or interpreting the quality of outcome evaluation results</b>	<p>Providing summative information about external validity (93, 128) and internal validity (114)</p> <p>Avoiding ‘type III errors’, or ‘false-negative’ trial results, where lack of effect is caused by poor implementation (87, 93)</p> <p>Formative process evaluations may help avoid erroneous trial results through maximising fidelity and therefore internal validity (48, 101, 121)</p> <p>Providing information to enable selection of most appropriate statistical methods for outcome evaluation (5)</p> <p>Providing knowledge about changes in implementation over time (59) and learning curve effects (55) to help interpret outcome results.</p> <p>Investigating potentially problematic areas of pragmatic trial design and conduct to support validity of outcome results (12)</p> <p>Through qualitative participatory process evaluation achieving ‘a more robust, rigorous and reliable source of evidence than the single stories that conventional quantitative impact evaluations generate’ (33)</p>
	<b>Improving outcome evaluation methods</b>	<p>Formative process evaluation enabling change to outcome study design prior to commencement (99)</p>



Identification

Screening

Eligibility

Included

**Original search (September 2017)**  
Records identified through:  
Database searches (n=1269)  
Reference list and citation searches (n=1816)  
Known papers (n=2)

**Updated search (January 2021)**  
Records identified through:  
Database searches (n=677)  
Citation searches (n=4566)  
Known papers (n=0)

Records screened  
(n=3087)

Records excluded  
(n=2923)

Records screened  
(n=5243)

Records excluded  
(n=5188)

Full texts assessed for  
eligibility  
(n=164)

Full text articles excluded  
(n=55)  
Duplicates (n=37)  
No full text available (n=5)  
Not meeting inclusion criteria (n=13)

Full text articles assessed  
for eligibility  
(n=55)

Full text articles excluded  
(n=17)  
Duplicates (n=6)  
No full text available (n=2)  
Not meeting inclusion criteria (n=9)

**Included literature items  
(n=109)**

**Included literature items  
(n=38)**

**Total included literature  
items  
(n=147)**

## Process evaluation characteristics

### What/who is evaluated

- Choice of process evaluation framework and components
- How processes are conceptualised
- Who participates

### How processes are evaluated

- Ontological and epistemological standpoints
- Choice of methodology and methods

### Research conduct

- Participant recruitment
- Data collection
- Research team structure

### Dissemination

- Publication status
- Quality of reporting
- Links between publications
- Time to publication

Value is subjective and context-dependent.  
Potential tensions between values.

## How process evaluations may create value

Socio-technical processes of 'doing' the process evaluation

Features/qualities of process evaluation knowledge

Using process evaluation knowledge

15 Value themes

## How process evaluations may create value

Value created through the socio-technical processes of 'doing' the process evaluation



- ### Themes of value
- Relationships
  - Giving people a voice
  - Education
  - Ethical issues
  - Financial
  - Impact on the outcome evaluation

Value created through features/qualities of process evaluation knowledge



- Knowledge credibility
- Knowledge accuracy
- Knowledge completeness

Value created through using process evaluation knowledge



- Supporting implementation of interventions into practice
- Intervention development
- Improving practice and outcomes
- Contributions to wider knowledge
- Financial value of knowledge
- Impact on the outcome evaluation

## 1 What value do we want to create?

- Consider– what do we ultimately want to get out of this process evaluation? Who do we want to create value for and why? (including patients, professionals, staff, research participants, researchers, funders, healthcare / other organisations, students, public)
- Review the themes and subthemes of value included in the article text and reflect on whether these are values we could aim to achieve

## 2 What kind of knowledge will create this value?

- What does it need to tell us? Consider what would be useful to know if the intervention does or does not show outcome effectiveness.
- Consider the ontological and epistemological standpoints of the process evaluation and how these will be reconciled with outcome findings.
- How can we ensure the knowledge is as accurate and complete as possible and perceived as fit for purpose? How can we ensure limitations are acknowledged?
- What kind of knowledge is it possible to create in the contexts we are working in?
- How can we make best use of available resources to best create the knowledge that is likely to achieve the value we're aiming for?

## 3 How could the 'doing' of the process evaluation create or threaten value?

- Consider impacts of research and operational processes on intervention, outcome evaluation, research settings, participants, researchers, stakeholders.
- Consider ways of proactively addressing possible tensions, e.g. process data monitoring, clarifying expectations

## 4 Design the process evaluation to aim to create the desired value

- Decide which processes to evaluate and how to evaluate them, based on above reflections and decisions
- Plan dissemination and how knowledge will be used to create the value
- Document and report rationales for design decisions
- Review design with stakeholders to ensure there is best chance of achieving desired value. Consider further potential negative consequences and opportunities to create more value.