Identifying critical intervention, contextual and implementation features in systematic reviews: Intervention component analysis ten years on

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ABSTRACT

Background: It is now widely recognised that in addition to providing robust evidence about intervention effectiveness, systematic reviews need to provide decision-makers with information about critical intervention, contextual and implementation features that support successful outcomes. Our 2015 paper introduced Intervention Component Analysis (ICA), a method comprised of three key approaches for examining trials within an effectiveness synthesis: a) an inductive approach to coding trial features; b) extraction of trialists perspectives about the strengths and limitations of features and experiences of implementation; and c) an assessment of identified features in relation to outcomes to assess which appear to be important. In this paper we reflect on how ICA has since been employed by ourselves and others to demonstrate the variety of ways it has been applied and to support further developments of the method.
Methods: In March 2025 we searched Google Scholar for papers citing the 2015 ICA paper. We extracted information on: the year of publication; whether ICA was employed as an analysis method or simply cited; which aspects of ICA were employed; whether ICA was employed in combination with other synthesis methods; and any innovations to or refinements of the method. We also conducted several in-depth case studies to explore variation in application and illustrate the benefits of ICA.
Findings: We identified 95 papers citing the 2015 paper of which 44 reported using or drawing on ICA in their analysis and a further 4 protocols reported a plan to use ICA; the remainder (n = 47) cited but did not use ICA. Of the 48 that used or planned to use ICA, most (n = 38) used or planned to use it in combination with another method such as a meta-analysis or qualitative comparative analysis whilst 10 used ICA as the sole method of analysis. We identified several innovative applications of ICA including the use of existing frameworks or logic models alongside the inductive coding method.
Discussion: Use of ICA allows systematic reviewers to better understand 'how' interventions work. ICA has been found by ourselves and others to be both useful and flexible – able to be tailored to both large and small reviews, suitable for use as a stand-alone tool or alongside existing theories or taxonomies, useful as a tool for understanding intervention variation only or as a tool for explaining variation in outcomes. Potential future avenues for development include the use of subgroup analysis and meta-regression to test the theories generated by ICA.

What is already known

- To enhance their utility in decision-making, systematic reviews need to provide detailed information about critical intervention, contextual and implementation features in addition to robust, but broad-brush, evidence on effectiveness.
- First introduced in 2015, Intervention Component Analysis (ICA) offers a formal and rigorous yet relatively streamlined approach to identify key intervention content and implementation processes.

What this paper adds

- An analysis of papers citing the ICA method demonstrates that it has been widely used.
- Reviewers employing the method have introduced a range of innovations to adapt, extend or enhance the approach.
- Examples of ICA use show it to be a flexible approach that can successfully identify and communicate critical information about the content and implementation processes of complex interventions.

1. Background

It is widely recognised that systematic reviews provide robust evidence about intervention effectiveness (Norman and Griffiths, 2014). However, it is increasingly recognised that to support real-world decisions, reviews also need to provide detailed information about the intervention, contextual and implementation features that support successful outcomes. Intervention Component Analysis (ICA), a formal and rigorous yet relatively streamlined approach to identify key intervention content and implementation processes, was developed in response to this need (Sutcliffe et al., 2015). In this paper we reflect and elaborate on the key steps of the method and describe the 'state of the art' - i.e. how the original method has been applied and extended since it was first published 10 years ago.

1.1. Intervention complexity and systematic reviews

Conventional systematic reviews which pool the results of randomised controlled trials (RCTs) to understand intervention effectiveness draw strength from being based on probabilistic causal logic, i.e. where similar intervention effects are observed multiple times, one can confidently predict that further interventions are also likely to achieve similar outcomes. Reviews of RCTs also draw on counterfactual causal logic, i.e. alternative explanations for intervention effects are ruled out by use of control groups and random allocation (Shpitser and Pearl, 2008). The causal logic underpinning systematic reviews of intervention effects means they can offer robust and reliable evidence about intervention effects. However, they can fail to offer deep understanding of how or why interventions achieve their observed effects. This lack of detailed information about important intervention features has been highlighted as a significant limitation to the utility of systematic reviews for informing policy and practice (Hoffmann et al., 2017).

Several factors are recognised as impeding reviewers' ability to address this limitation. First, there is the problem of substandard reporting in trials (Hoffmann et al., 2013), although tools such as the CONSORT statement and Tidier Checklist have been developed to mitigate this problem (Hoffmann et al., 2014). A related factor is the complexity of many non-pharmacological interventions. Since ICA was first published, systematic reviewers have increasingly recognised that many health and social interventions are characterised by complexity; i. e. they have multiple interacting components, and their effects are likely to be moderated by contextual factors and by implementation procedures (Lewin et al., 2017; Pfadenhauer et al., 2017; Petticrew et al., 2019; Pfadenhauer, 2021; Skivington et al., 2021). For example, exercise-based falls prevention interventions for people in aged care facilities may have multiple interacting components (e.g. a range of educational and/or physical exercise sessions), and their effects may be moderated by contextual factors (e.g. the size of the facility or the mobility levels of participants) and by implementation factors (e.g. the skills and manner of the people delivering the intervention). Not only does this complexity increase the challenge of adequate reporting, it undermines the ability of established statistical approaches to distinguish the impact of different intervention features on outcomes (Pfadenhauer et al., 2017; Petticrew et al., 2019; Skivington et al., 2021).

Whilst conventional systematic reviews can provide robust evidence of whether interventions characterised by complexity will *typically* result in beneficial outcomes, and the *typically* expected degree of benefit, the individual trials will likely vary in the degree of benefits they offer, with some potentially resulting in harmful outcomes. This leaves decision-makers seeking to use systematic reviews to inform practice uncertain about exactly what intervention features to implement, how best to implement them and whether they will work in their context and with their populations (Glasziou et al., 2014). ICA was developed to bridge this gap between broad-brush evidence of effectiveness and the fine-grained detail needed to support real-world implementation of complex interventions. ICA was also designed to overcome the challenge of poor intervention reporting (Sutcliffe et al., 2015).

1.2. The context in which intervention component analysis (ICA) was developed

The review for which ICA was developed was on electronic prescribing interventions to reduce clinician errors when prescribing medications to children. Whilst many of the included studies found that electronic prescribing reduced errors compared to controls, a small number found that errors, and harms resulting from those errors increased (Sutcliffe et al., 2015) with one trial finding an increase in mortality (Han et al., 2005). It was vital to identify the factors that distinguished interventions with beneficial outcomes from those with tragically harmful ones. A significant challenge to this work was that the terminology used and the level of detail in descriptions of electronic prescribing intervention varied widely. ICA was developed as a pragmatic way to provide vital detailed information whilst also overcoming the problems with intervention reporting.

Our 2015 paper outlines the ICA method, as well as how and why we developed it (Sutcliffe et al., 2015). Since 2015, we have continued to employ ICA, refining and extending its application. We have also been interested to see how others have used the method. The aim of this paper is to reflect and elaborate on ICA and to illustrate variation in the ways it has been applied by ourselves and others over the past decade.

2. Steps in conducting ICA

The overarching aim of ICA is to develop theoretical insights about which intervention design, implementation and contextual features contribute to an intervention's effectiveness (or lack of). In the 2015 paper we described ICA as:

> "In essence, the ICA approach aims to identify what an effective intervention 'looks like'. It is suitable for situations where we have a group of similar interventions—aiming to impact on the same outcome—but which differ from one another in small ways, and we do not know which are important in terms of impacting on the outcome. However, it is particularly appropriate in situations where existing programme theory has been unable to explain variance in outcomes and where there is suboptimal information about the interventions under scrutiny (i.e. low-quality intervention descriptions and a lack of process evaluations)."

2.1. Overview

As illustrated in Fig. 1, ICA comprises two key stages. The first stage aims to understand how intervention features, as well as aspects of their implementation and context, vary across the trials included in the review.

This information is then used in the second stage, where reviewers examine whether differences between interventions appear to be associated with differences in outcomes across the set of interventions.

2.2. Stage 1: how do interventions differ from one another?

The original ICA paper described two key approaches for understanding intervention variation, both of which draw on inductive qualitative methods.

2.2.1. Stage 1a: inductive coding of intervention descriptions

Line-by-line inductive thematic coding of intervention descriptions is used to capture intervention features, how they are implemented and their context.

The reason for drawing on inductive qualitative methods is to address the problem of intervention reporting, i.e. inconsistencies across the trials in terms of the level of detail provided, the way interventions
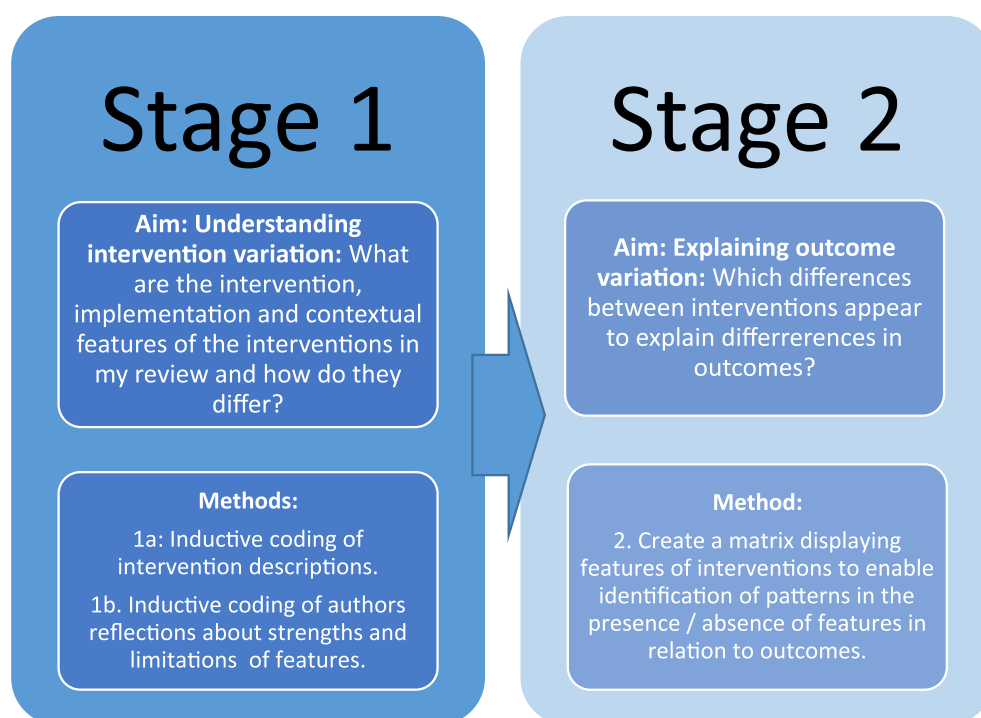
Fig. 1. Aims and methods of the key stages of ICA.

are described and the language used to describe different intervention features.

For example, in the original ICA on electronic prescribing we found that some trials provided scant information about the interventions and they emphasised or de-emphasised different elements. The use of line-by-line coding, a tool widely used in qualitative data analysis and synthesis (Thomas and Harden, 2008), supported meticulous capturing of all available information about interventions, rather than cherry-picking elements emphasised by authors or those that appeared pertinent.

We also found that intervention features were inconsistently described. For example, 'structured order sets' (which allow a prescriber to select with one click a complete order for commonly prescribed medicines) were variously described as 'order sets', 'pre-constructed orders' and 'default prescriptions'. The inductive approach enabled identification and categorisation of similar but inconsistently described concepts across the trials.

Inductive thematic coding also supported generation of higher-order descriptive themes to group features. For example, we were able to group electronic prescribing features as 'front-end decision tools' (those that are actively accessed and manipulated by the user to support decision-making, such as dose calculators and structured order sets) and 'back-end decision tools' (system features which were automatically triggered such as 'alerts'). This thematic grouping supported comparison across trials.

2.2.2. Stage 1b: inductive coding of authors reflections

Inductive coding of authors reflections about the experience of developing and implementing the intervention is captured from the discussion sections of trial reports, using the same inductive thematic coding approach.

The purpose is to augment understanding of the intervention with what we described in the 2015 paper as 'informal data'. Capturing trialists' reflections allows reviewers to tap into a wealth of information that is typically underutilised in systematic reviews. It may include reflections on the strengths and limitations of intervention features, experiences of developing and/or implementing an intervention, as well as how context influenced outcomes. Trialists' reflections are based on

'real-world' experiences of delivering the intervention and therefore offer an 'on-the-ground' view of how an intervention worked (or not) in practice (Sutcliffe et al., 2015).

For example, in the original ICA on electronic prescribing, authors' reflections indicated that, customisation of the system for use with children and comprehensive 'front-end decision support' were key factors in error reduction. The analysis of author reflections also highlighted the importance of engaging with stakeholders during development, efforts to foster familiarity with the system prior to implementation, ensuring technical infrastructure is adequate and appropriate; and the value of planning and iteration (Sutcliffe et al., 2015).

2.3. Stage 2: which differences between interventions appear to explain differences in outcomes?

To provide an overview of the differences between interventions, a matrix can be produced to 'map' each intervention according to the presence or absence of different intervention (or contextual or implementation) features identified in stage 1. This allows reviewers to compare across interventions to see if those with successful outcomes are qualitatively different from those with negligible or harmful outcomes. For example, if there are intervention or implementation features that are consistently present among successful interventions, and these features are also consistently absent among unsuccessful ones, then the ICA generates insight into the features that may be critical to an intervention's success. As Fig. 2 below illustrates, the matrix from the original ICA highlighted how studies showing harmful effects of electronic prescribing (King et al., 2003; Han et al., 2005) were not aligned with the findings from Stage 1 as they were unmodified commercially available packages, not specifically designed for use with children, and had limited 'front-end' decision support.

The remainder of this article examines how we and others have applied the method and illustrates variation in the ways ICA has been applied and showcases innovations and advances in its application.

Study (studies with negative findings in italics)	Country	Paediatric specific	Front-end decision support			Back-end decision support		
			Dose calculation	Order sets	Info access	Alerts	Mandatory fields	Access security
Unmodified commercially available packages								
Han et al. (2005) [31]	USA					✓	✓	
Jani et al. (2010) [33]	UK				✓	✓	✓	
King (2003) [37]	Canada				✓			
Walsh (2008) [46]	USA	✓	✓		✓	✓		✓
Customised commercially available packages								
Cordero (2004) [28]	USA	✓	✓	✓	✓	✓	✓	
Del Beccaro (2006) [30]	USA	✓		✓	✓	✓		✓
Holdsworth (2007) [32]	USA	✓	✓	✓	✓	✓	✓	
Kadmon (2009) [34]	Israel	✓		✓	✓	✓		✓
Kazemi (2011) [35]	Iran	✓	✓	✓	✓	✓	✓	
Keene (2007) [36]	USA	✓		✓	✓			✓
Upperman (2005) [44]	USA	✓	✓	✓	✓	✓	✓	
Warrick (2011) [47]	UK	✓	✓	✓	✓			
Bespoke packages (developed by trialists/hospitals)								
Lehmann (2004) [38]	USA	✓	✓	✓	✓	✓	✓	✓
Lehmann (2006) [39]	USA	✓	✓	✓	✓	✓		
Maat (2013) [40]	Netherlands	✓	✓	✓	✓			
Potts (2004) [41]	USA			✓	✓	✓		
Sowan (2010) [42]	USA	✓		✓	✓			
Vardi (2007) [45]	Israel	✓	✓		✓	✓		✓
Unidentified package type								
Barnes (2009) [29]	USA				✓	✓		
Sullins (2012) [43]	USA							

Fig. 2. Features of electronic prescribing interventions.

3. Methods

To identify reviews, we searched Google Scholar in March 2025 for all articles citing the Sutcliffe et al. (2015) paper. We read each identified paper to verify that it cited the 2015 paper and removed any duplicates. We excluded protocols where the review had subsequently been published to avoid double counting. We coded each paper to capture the date of publication and to distinguish whether ICA was used in the analysis or whether it was only cited for information as a methodological resource/innovation. For reviews where ICA was used in the analysis we additionally captured: the topic of the review; the number of studies included in the ICA; whether the ICA was informed by theory; which aspects of ICA were employed; whether the ICA was focused on intervention, implementation or contextual features; whether the application involved an innovation or advance to the method; and whether the authors reflected on the strengths and limitations of the ICA method.

4. Findings

Our searches identified 95 papers that cite the Sutcliffe et al. (2015) ICA paper; most of which were published in the last three years (n = 53 published in or after 2022).

Approximately half of the papers (n = 47) cited the original ICA paper in the introduction or discussion but did not actually use the method. These included papers that cited the 2015 paper in the background, for example when justifying the use of 'informal data' from trials (Taylor et al., 2023) or when acknowledging the benefits of focusing on experiences of implementation (Allan et al., 2023). Some of these papers cited ICA in the discussion section of their review, for example when considering further research that might be useful (Boonpattharatthiti et al., 2024). Several papers were methodological papers that recommended the ICA approach as useful, for example when examining implementation issues (Cargo et al., 2018) or when assessing complex interventions in a systematic review (Lewin et al., 2017; Jimenez et al., 2018).

ICA was explicitly described as an analysis approach employed in the remaining 48 papers: n = 37 reviews explicitly employed ICA as an analysis method, n = 4 protocols described an explicit plan to use ICA as an analysis method, and a further n = 7 reviews applied a method that drew on ICA, for example used 'aspects' of the approach (Harris et al., 2019) or a variation of the approach (Burchett et al., 2017). Many of these reviews were focused on healthcare interventions (n = 37); a large proportion of these focused specifically on care for older people (n = 9). Other healthcare focused reviews were on maternity care (n = 2), mental healthcare (n = 2) and treatments for specific conditions (n = 6) such as cancer. Non-healthcare reviews (n = 11) focused on social issues such as prevention of violence and abuse (n = 8) or education (n = 3). Below we document how these reviews vary in their approach to using the ICA method.

4.1. Flexibility in employing the different stages of ICA

Of the 48 reviews that explicitly used, planned to use, or drew on ICA in their analysis, nine were unclear about which stages they used; examination of the remaining 38 illustrates the flexibility of the method.

Very few (n = 3) used or planned to use all stages (1a, 1b and 2) (Burchett 2022, Corbett 2018, Rotevatn, 2019). Most used either one (n = 20 reviews) or two stages (n = 16 reviews) only. For example, Dawson and colleagues describe using only the coding of trialist's reflections (stage 1b) and the comparison of features with outcomes (stage 2), because they were able to draw on existing taxonomies to extract

features of the falls prevention interventions in place of stage 1a. Similarly, Burchett et al. (2017) described using only stages 1a and 1b as they were not able to cross-tabulate the effectiveness findings with the information about intervention features for stage 2, due to wide variation in the extent and types of information available. As such, they employed a meaning-based approach, documenting each outcome of interest alongside explanatory factors relating to the intervention, context and study design (Burchett et al., 2017).

Of those employing a single stage, most employed stage 1a (inductive coding of intervention descriptions) (n = 13), a few employed stage 1b (capturing trialist's reflections) (n = 4) or stage 2 (using ICA to compare intervention features with outcomes) (n = 3). Of those using two aspects most used a combination of 1a and 1b (n = 8); others combined stages 1a and 2 (n = 5) and stages 1b and 2 (n = 3). This variation illustrates the utility of individual ICA stages, and the possibility to adapt the approach used to suit individual reviews.

4.2. Variation in focus on intervention, implementation or contextual features

Reviews also varied in the extent to which the ICA focused on intervention features or additionally (and in some cases exclusively) on either implementation or contextual features. Most reviews focused on a mix of intervention, implementation and/or contextual factors. For example, in their review of rapid diagnostic tests for Malaria (Burchett et al., 2017) explicitly describe 'going broader than the ICA approach by also capturing information about delivery and context' (p. 4). Several reviews focused exclusively on intervention components (Sands et al., 2020; Ahmed et al., 2024; Comer et al., 2024) whilst others focused exclusively on implementation. For example, Bosqui et al. cite ICA in support of their approach to conducting an '*implementation* component analysis' in their review of parenting and family interventions in lower and middle-income countries for child and adolescent mental health (Bosqui et al., 2024). This variation again illustrates how review authors can adapt the ICA approach to meet the needs of their specific review objectives.

4.3. Using ICA across large and small reviews

ICA is a synthesis method that facilitates close engagement with studies, although this hasn't stopped it being applied in very large reviews. One example is Spiga et al.'s (2024) review of differential effects of interventions to prevent obesity among children and young people, where ICA was used to inform the coding of 255 intervention arms across 210 trials (Spiga et al., 2024). In this case, the use of ICA was mainly confined to Stage 1a to understand intervention components (see stages above). By contrast, Broder-Fingert et al. (2020) applied ICA to identify the core components of family navigation for autism spectrum disorder, working with just four studies in their review and using ICA to understand intervention components and trialist's experiential evidence (Stages 1a and 1b) (Broder-Fingert et al., 2020).

Of the reviews using ICA or an approach informed by ICA, approximately half (n = 22) examined fewer than 20 papers and half analysed 20 papers or more (n = 18) (n.b. the number of papers analysed was unclear in 4 papers). Among the studies that used all three stages of ICA (Corbett et al., 2018; Rotevatn et al., 2020; Burchett et al., 2022), these included 9–17 trials, perhaps indicating that the fullest application of ICA remains confined to reviews that include small to moderate numbers of studies to allow reviewers to develop 'empirical intimacy' and to really get to know studies well.

4.4. The role of theory in ICA – using theories to support ICA and evaluating ICA derived theories using other synthesis methods

Theory is the product of a synthesis of different types of knowledge; theory describes a phenomenon, including its concepts and how they relate to each other, and is used to generalise from the specific to the broad (Thomas et al., 2024).

The initial application of ICA did not involve drawing explicitly on theory, instead we saw the approach as complementary to theory and considered that reliance on a-priori programme theory may constrain the development of a fuller understanding of how interventions 'work' in the real world (Sutcliffe et al., 2015). This was borne of a concern that an overly narrow focus on evidencing programme theories was not commensurate with seeking to understand 'what happened' during an intervention. Against a background where process evaluations remain rarely published (Cargo et al., 2018), ICA was viewed as an inductive remedy to unpick situations where there may be implementation failure (i.e. where the intervention was unsuccessful due to problems with its implementation) and/or where there was theory failure (i.e. where the outcomes diverged from the expectations described in the programme theory). It was neither necessary to adopt a theoretical framework to conduct an ICA; nor was it expected that ICA would (always) generate theory that could be tested. In the ten years since its original application, the role of theory within ICA has broadened. Across systematic reviews that utilise ICA, approximately one third draw explicitly on theory (n = 13/37). Three detailed case studies are provided below and depicted in Fig. 3, to illustrate the ways in which (i) ICA benefitted from drawing on established (middle range) sociological theory to guide the synthesis (case study 1); (ii) programme theory and interdisciplinary theoretical concepts were incorporated into the synthesis alongside ICA (case study 2); and (iii) ICA can generate a theory that can then be tested using other methods (case study 3).

Case study 1 draws on theory in its most 'classical' sense – in this case a sociological theory that attempts to make predictions about relationships. Other examples draw on different types of theory including 'theories' drawn from earlier Qualitative Evidence Synthesis (for example (Zahroh et al., 2022)), from the synthesis of theories occurring alongside the ICA (for example (Melendez-Torres et al., 2024)), as well as logic models (for example (Zahroh et al., 2022, 2023)). Some of the theories used focus on implementation and mechanisms around behaviour change (for example (Sands, 2020; Sands et al., 2020)), while others focus more on the substantive issue (for example the theory of human functioning and school organisation in (Ponsford et al., 2022)). Case study 2 provides an example where different theories were combined to complement the conduct of the ICA.

Even among systematic reviews not explicitly using theory, the approach used to conduct the ICA may be based on a 'theory' of what is important to know about an intervention. Several reviews (for example (Xiong, 2019; Caldwell et al., 2021; Lu et al., 2023)) use the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014) as a guide for what to extract and examine within the review. The TIDieR checklist, while not a theory per se, is informed by theory and supports the extraction of twelve items around an intervention's materials, procedure, tailoring, modifications, and the extent to which it was delivered as planned (Hoffmann et al., 2014). While our focus on theory here may appear to be somewhat esoteric, particularly given that ICA is very much an applied approach, the examples show that for many reviewers, using theory, or a theory-informed framework such as the TIDIER checklist, helped them to get started with conducting ICA.

The original paper highlighted the potential to use ICA in conjunction with other methods, particularly recommending its use with Qualitative Comparative Analysis (QCA). Approximately three-quarters of reviews that use ICA do so in combination with other methods (n = 27/37). Nine reviews used ICA to develop a theory of core intervention components, processes and contextual features that was subsequently tested using QCA (Boulton et al., 2021; Sutcliffe et al., 2022, 2025; Zahroh et al., 2022, 2023; Outhwaite et al., 2023; Suen et al., 2023, 2024). Case Study 3 elaborates on how ICA can provide a theoretical foundation for conducting a QCA. Other reviews describe using the results of ICA to inform the design of sub-group analyses within a meta-
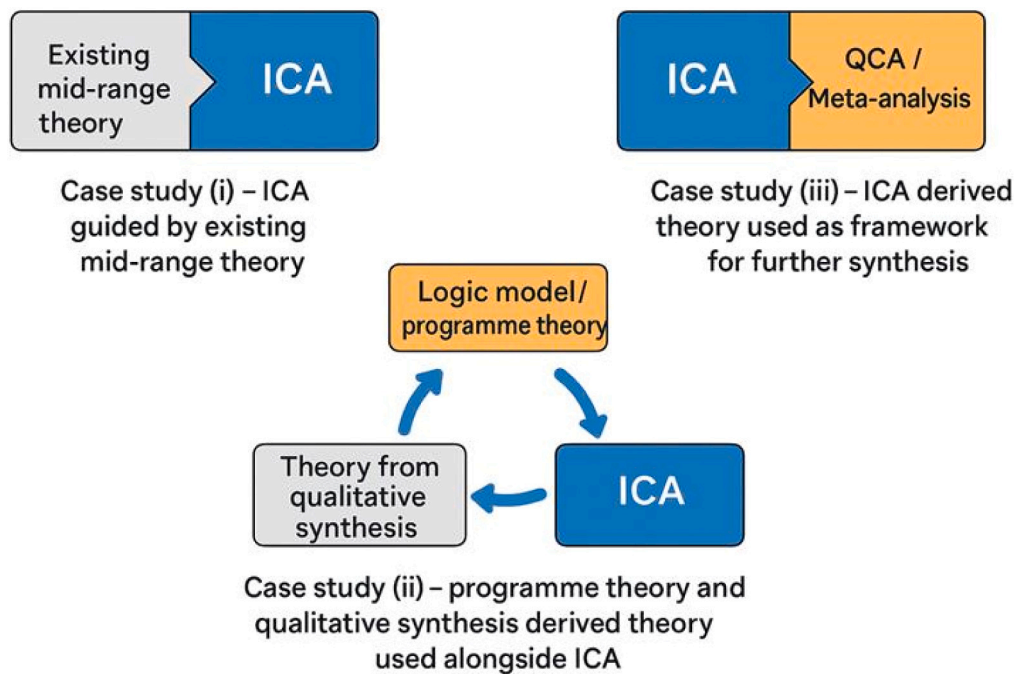
Fig. 3. Examples of ways in which ICA can be guided by, integrated with, or used to develop theory.

Case study 1: Using theory to guide an ICA within a rapid review

Background to the use of ICA: The inductive techniques employed in ICA require in-depth study-level knowledge developed through line-by-line coding. Thematic synthesis produces a narrative structure around the emergent themes. This process can be a lengthy one, where theme development potentially involves identifying mechanisms, implementation processes, population and contextual characteristics, and intervention components. In reviews examining a broad range of interventions, and where timescales are tight, this can be challenging. This set of circumstances faced the review team in this case study. Within a rapid review context, drawing on theory was invaluable for providing a framework to guide inductive line-by-line coding.

The context and focus of the review: The review focused on remotely delivered interventions to ameliorate social isolation and loneliness among older people (Boulton et al., 2021). It covered a broad range of interventions including telephone befriending, online calls with family and friends, web-based discussion groups that support asynchronous and synchronous interactions, and multi-tool interventions. The rapid review needed to be completed within six weeks to inform the UK government's urgent response to the COVID-19 pandemic (Boulton et al., 2021).

Stages of ICA implemented: 1a and 1b

How was theory used?: We drew on Robert Weiss's 'Fund of Sociability' (known as the Provisions of Relationships framework) (Weiss, 1969) to structure our synthesis of the data. This middle-range theory – i.e. a form of theory that offers explanations that can be tested and are closer to empirical observations – has its origins in social psychology (Thomas et al., 2024). The theory was developed to understand why people require relationships. We inferred that it could provide a suitable framework upon which to base (the interpretation of) interventions in our review, as if interventions could foster connections that address the different reasons for why people have relationships, then they would likely be effective for addressing loneliness.

The Fund of Sociability theory specified five characteristics of social interactions and relationships necessary for well-being and the avoidance of loneliness, plus an additional sixth that some people find important in supporting the development of relationships. These included intimacy (described as close relationships in the narrative), interaction, nurturance, self-worth, support, and availability. These characteristics were translated into expected intervention 'processes', and formed the basis for theorising how the interventions could support the development, or maintenance, of social relationships. For example, intimacy was 'translated' as the extent to which the intervention offered opportunities for participants to express feelings freely and without self-consciousness (e.g. opportunities for unstructured discussions with peers). Evidence was coded on the presence/absence of relationship characteristics supported by the intervention, and initial explanations for why some trials were more effective than others were formed. For example, one study failed to support intimacy, as trialists described participants 'feeling shy and having no idea what to talk [about] while using the videoconference equipment.' (Tsai and Tsai, 2011) (p. 1541). In contrast, intimacy was supported in another study through a 'Sharing Circle, in which the women exchanged feelings and life experiences, gave and received support, discussed issues' (Weinert et al., 2008).

What were the advantages of using theory in this ICA?: The use of a theory had two main benefits. First, it helped us to handle the breadth of intervention types in the review by providing a common rubric with which to interpret the results of a wide range of trials aiming to enact change in a common outcome, through focussing less on intervention 'components' (i.e. design features) and more on intervention 'processes' (i.e. mechanisms enacted). Secondly, it helped us to handle the compressed timeline; drawing on middle-range theory helped us gain purchase on how to interpret the results within a rapid timeframe.

Case study 2: Using theory alongside ICA to identify real world experiences from interventions

Background to the use of ICA: Theories of different forms can be used to inform an ICA. Some of the most valuable insights from ICA come from moving beyond existing theory and identifying the real-world experiences of participants and trialists within the studies.

The context and focus of the review: Caesarean section birth can be a lifesaving procedure when vaginal birth is not possible, but there are risks for women and babies. On a population level, where the rate of caesarean birth exceeds 15 %, this is unlikely to reduce mortality rates. Global caesarean section birth averages now exceed this, prompting concern and interest in how to reduce levels (Zahroh et al., 2023). This was the context facing Zahroh and colleagues who aimed to explore how interventions aimed at reducing caesarean birth should be designed, drawing on ICA as a core synthesis method. The team carried out two linked evidence syntheses – one exploring interventions aimed at pregnant women (Zahroh et al., 2023) and one aimed at healthcare providers (Zahroh et al., 2022).

Stages of ICA implemented: 1b

How was theory used?: To support the synthesis, the team developed a logic model, a graphical model that helps researchers to theorise how activities are sequenced into chains of outputs and outcomes and that depicts a theory of how an intervention is intended to 'work' (Kneale et al., 2024). A different theory was developed for each review (i.e. the way in which interventions for pregnant women were implemented and their resulting outcomes was expected to differ from interventions targeted at healthcare providers). There are different methods of creating logic models – from co-producing a theory with stakeholders (Kneale et al., 2025) through to drawing on existing templates (Rehfuess et al., 2018). In these reviews, the logic models were developed from the findings of several existing systematic reviews and a qualitative evidence synthesis. The logic model provided a basis for extracting data on trialists perceptions of intervention components for the ICA (Zahroh et al., 2023).

What were the advantages of using theory in this ICA?: The logic-models helped to structure and focus the data extraction of trialists views. The ICA helped to broaden the factors under consideration to include contextual conditions such as healthcare providers' beliefs on caesarean section, providers' willingness to change, and policies relating to caesarean section (p. 5) (Zahroh et al., 2022) as well as intervention-level factors such as the depth of the individualised approach and the nature of interactions between pregnant women and healthcare providers (p4) (Zahroh et al., 2023). These factors were not directly represented within the logic model. This example shows that a pre-existing theory, such as a logic model, can help to provide a (deductive) framework to support undertaking ICA. However, the inductive results of the ICA, based on informal observations around implementation, context, and relational factors, can provide a basis for adapting, expanding and even challenging theory. In both reviews, the team then progressed to test their expanded theory using other methods (Zahroh et al., 2022, 2023). The possibility of using ICA findings to support further synthesis is discussed in case study 3.

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analysis or to inform the choice of covariates in a meta-regression (Caldwell et al., 2021; Lu et al., 2023; Suen et al., 2023; Dawson, 2024; Melendez-Torres et al., 2024; Mino, 2024). This may be one reason why so few reviews use all ICA stages, i.e. because other analysis methods such as QCA and meta-analysis are used in place of stage 2 to test theories generated by stages 1a and 1b. Another systematic review offers a different perspective, where it was the limitations of QCA and the potential confounding effects of study quality that prompted the researchers to use ICA as an alternative method to QCA (Burchett et al., 2022) – in this case the synthesis was motivated by a need to develop and expand on theory rather than test it.

Suen et al.'s (2023) review provides an exemplar of how ICA can sit within a sequence of synthesis methods to generate evidence on how interventions should be designed effectively. A meta-analysis of trials that aimed to reduce the number of falls within aged care facilities (n = 11), was inconclusive, albeit with high levels of heterogeneity suggesting that some interventions may be effective. ICA was employed to develop a theory about the drivers of heterogeneity; it identified that both intervention co-design and tailoring the intervention to residents' intrinsic capabilities were factors that trialists viewed as particularly important. These factors were tested using QCA; the results provided further support for the theory. Further quantitative testing through sub-group analysis showed that a subgroup of studies that included both factors were effective in reducing the number of falls (Suen et al., 2023). In this example, the ICA was pivotal in generating a theory that was subsequently tested through multiple synthesis methods.

For some reviews, ICA alone provided a sufficient synthesis method for unpacking and understanding how interventions work (n = 10/37). Those new to the method should not be deterred from using ICA alone, and there are good reasons why ICA alone can suffice in addressing research questions around how complex interventions work (or why they do not). Review authors using ICA as a standalone method emphasise the important theory-building contribution of ICA (for

example (Dawson et al., 2024; McLennan et al., 2024)). For example, ICA can generate theoretical insights about complex components and processes. One example is how much is the right type and level of exercise needed to reduce falls in residential aged care facilities, which was explored in Dawson (2024) where the results underscored that "the right exercise is a combination of exercise that targets balance and strength, tailored to the individual's physical and cognitive comorbidities and delivers moderate-intensity exercise" (p. 643) (Dawson et al., 2024). Others have used ICA in reviews exploring heterogeneous models of interventions, where the evidence is more disparate, to develop a theory about broad implementation factors that may be necessary to incorporate in effective interventions (McLennan et al., 2024; Sutcliffe et al., 2025).

4.5. An ICA of ICA: reviewers reflections on using ICA

One of the most common reflections on the utility of ICA provided by review authors was that it enables them to develop and explore theories of how interventions work and to identify critical features of complex or multicomponent interventions (Sutcliffe et al., 2022; Grech et al., 2023; Lu et al., 2023; Dawson et al., 2024). This theorising is viewed as particularly useful where there is a need to unpack and explore sources of heterogeneity in study effectiveness (Comer et al., 2024) and to consider "*whether the studies with negative outcomes are qualitatively different from those with positive outcomes, and if so, how*" (p. 575) (Ahmed et al., 2024). Other reviewers valued integrating evidence not usually considered in traditional reviews of intervention efficacy (McInnerney et al., 2021). ICA was viewed by some reviewers as a useful approach to integrate as part of a diversity of review methods and approaches (Sands et al., 2020; Boulton et al., 2021; Burchett et al., 2022).

Review authors also shared some of the challenges in its use. A recurring concern was about the treatment of studies of variable quality and the possibility that studies of lower methodological quality may

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Case study 3: Using theory generated through ICA as the basis for further synthesis

Background to the use of ICA: Several reviews employ ICA as a springboard for further analysis. In particular, there are several examples where ICA has been used to steer QCA. QCA is a case-based approach that shares some parallels with ICA. However, unlike ICA, theory is considered an absolute necessity when conducting QCA, due to the causal accounts that are generated through and underpin the interpretation of a QCA (Sutcliffe et al., 2024). In the absence of clear or pre-established programme theory of how interventions 'work', and in the absence of suitable middle-range or grand theory, the results of ICA have formed the theoretical framework for undertaking QCA.

The context and focus of the review: One of the first examples where ICA was used to support a QCA was in our analysis of flu vaccination drives among healthcare workers (Sutcliffe et al., 2022). While the review was published towards the tail end of the COVID-19 pandemic, the analysis took place during a time where there was heightened concern around ensuring that healthcare workers were vaccinated against COVID-19 to protect themselves and their patients. COVID-19 vaccination schemes were being considered or implemented across several healthcare settings. These included 'hard' mandates, where failure to comply with a vaccine mandate could result in dismissal, as well as soft mandates, where 'soft' pressure was put on staff to comply (e.g. through signing a declination form or wearing a public marker of vaccination status). Evidence from flu vaccination drives among healthcare workers showed large variation in the success of mandatory campaigns, even when stratified by hard or soft mandates. Our study involved a re-analysis of two existing reviews that provided evidence on the effectiveness and experience of flu vaccination drives among healthcare workers, which could in turn provide important evidence on how to implement similar initiatives during the COVID-19 pandemic.

Stages of ICA implemented: 1a and 1b

How was theory used?: We used ICA to generate a theory, i.e. an '"experience-based understanding of intervention mechanisms by tapping into trialists' informal reflections about how the interventions they evaluated worked 'on the ground'"' (p3) (Sutcliffe et al., 2022). We inductively coded authors' reflections on the barriers and facilitators of intervention success, identifying four factors. One example was 'don't go in cold', a factor that underscored trialists' observations that a successful intervention tended to be based on previous effort to improve vaccination rates, even if these previous efforts had been unsuccessful in and of themselves. For example, in one study included in the review, a trialist observed that "sequential expansion of the program over several years was a key element to the success" (Frenzel et al., 2016).

The ICA developed theory that trialists should avoid 'going in cold' but should expect to undertake preparatory work before the intervention; this was found in the subsequent QCA analysis to be sufficient for triggering a successful intervention. The QCA helped to develop further evidence around how different combinations of factors identified in the ICA triggered a successful intervention.

What were the advantages of using ICA in this way: The QCA helped to refine the theory of how to design a vaccination drive among healthcare workers, but it was the results of the ICA that provided the pre-requisite theoretical basis for QCA synthesis.

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disproportionately contribute to the findings (Sands et al., 2020; Burchett et al., 2022; Grech et al., 2023; Dawson et al., 2024). In Sands (2020) this was addressed through focussing on studies deemed to be of higher methodological quality, although in other reviews the possibility that lower quality studies were driving the interpretation was viewed as a caveat. This is not a limitation that is unique to ICA, although one that is worth further consideration. It is also notable that none of the reviews included here employed an assessment of the confidence in the ICA findings using approaches such as CERQUAL (Lewin et al., 2017). This perhaps speaks to a need for new approaches to assessing the quality of case-based synthesis approaches (see CARU-QCA as an example for QCA - (Kneale et al., 2020)). Other review authors reported more practical obstacles, including the absence of, or underreporting of, data to support conducting ICA (Lu et al., 2023; Dawson et al., 2024; McLennan et al., 2024), including an absence of sufficient evidence of effectiveness to progress to Stage 2 of ICA (Corbett et al., 2018). Review authors also described concerns that the inductive nature of ICA meant that there was a possibility that other review teams could reach different conclusions when synthesising the same data (Ahmed et al., 2024; Melendez-Torres et al., 2024), although also described that "*extensive auditing, second coding and reflection amongst the investigators*" could help to mitigate against this possibility (p. 142) (Melendez-Torres et al., 2024). These concerns are not necessarily insurmountable or unique to ICA, although do help to identify future priorities for the method.

Finally, the evidence produced through conducting ICA was viewed by reviewers as holding resonance for decision-makers and researchers; for example "*novel evidence-based recommendations for future research aiming to develop and evaluate emotional disclosure-based interventions in palliative populations*" (p. 1340) (McInnerney et al., 2021). Others also reflected on the utility of the method to develop recommendations around which intervention components are important or essential to include in the design of future interventions (Walker, 2020; Grech et al.,

2023). These reflections help to locate ICA as an applied synthesis method that aims to aid reviewers in generating evidence on how interventions and policies should be designed. This evidence holds resonance in the development of recommendations as it is based on the real-world experiences of trialists who have been in the field implementing interventions.

5. Discussion

Since publishing ICA in 2015 we have found it a valuable tool that we have continued to use and develop. Our analysis demonstrates that other researchers have found ICA a useful addition to the plurality of methods within evidence synthesis. The many adaptations, refinements and advances to ICA that colleagues have achieved suggest that ICA is also flexible – able to be tailored to both large and small reviews; for use as a stand-alone tool or alongside existing theories or taxonomies; for exploring intervention, contextual and/ or implementation factors; and for understanding variation in these factors or as a tool for explaining variation in outcomes.

In reviewing others' experiences of using ICA, we recognise some of the concerns they raise, for example around handling studies of variable quality, poor intervention reporting and the use of inductive approaches. These concerns are not unique to ICA, and as illustrated above, researchers have continued to adapt and innovate ICA to meet their needs such that solutions to these issues may be at hand. Despite these potential limitations, review authors have clearly expressed the ability of ICA to provide vital information for decision-makers seeking to use systematic reviews. Since ICA was first published, reviewers and review users have increasingly recognised the need to provide evidence about the critical features and procedural details of complex interventions (Skivington et al., 2021). Similarly, in this period researchers have urged harnessing the power of mid-range theories to conduct theoretically

informative research to support intervention implementation (Kislov et al., 2019).

5.1. Future directions for ICA

In the original ICA paper, a complementarity between ICA and another case-based synthesis approach (QCA) was noted. We have observed a growing number of reviewers bringing both synthesis methods together to develop theory (ICA) and explore, test and refine this further (QCA) which is a welcome development. Several reviews provide further innovative examples where ICA has been used to inform subgroup analyses, either directly (for example (Caldwell et al., 2021)) or indirectly (for example (Suen et al., 2023)). There may be further scope for ICA derived theories to support subgroup analysis and meta-regression to address concerns about subgroups being developed without theoretical justification (Petticrew et al., 2019). Reviewers may also consider integrating ICA approaches alongside other qualitative evidence synthesis approaches. Some of the reviews included here have made inroads in this respect, with reviewers utilising ICA alongside thematic synthesis (for example (Rotevatn, 2019; Rotevatn et al., 2020)) and narrative synthesis (for example (Walker, 2020; Ahmed et al., 2024)). Some have even speculated that ICA may be usefully combined with further primary research (Grech et al., 2023) and one literature review appears to have integrated ICA alongside primary research (Walker and Hall, 2022). Further opportunities include using ICA in realist reviews, where the development of context-mechanism-outcome configurations are dependent on good quality reporting within studies, and where trialists experiences may be a useful preliminary step in developing a realist framework. As the original paper highlighted, ICA is particularly useful in systematic reviews where some interventions were found to be effective whilst others were found to cause serious harms; ICA could be used more extensively to consider the 'dark logic' of interventions to examine how intended intervention mechanisms are derailed resulting in adverse outcomes (Bonell et al., 2015).

Further opportunities include progressing how ICA derived theories are communicated and visualised. Few reviews used ICA findings to develop or adapt a logic model articulating how effective interventions are thought to 'work'. Sands (2020) used ICA to create a logic model for each individual study in their review, but there appears further potential to create a logic model to summarise evidence from across the studies (Sands, 2020; Sands et al., 2020). Since many of the ICA applications we reviewed aimed to identify critical intervention components, effective communication of these theories and what factors are needed to support them could better support the design of future interventions.

Other systematic review methods are supported by standards to improve both conduct and reporting. However, as this analysis of its use has shown, a key strength of ICA is its flexible nature, meaning that a predefined set of standards for reporting and conduct may stifle further innovation. However, to continue to progress the field it is vitally important for reviewers using ICA to provide clear information about which ICA stages they used, how they used them, and how they refined and / or adapted the approach.

5.2. Strengths and limitations

This paper sought to (i) describe the stages of ICA, (ii) explore how ICA has been used; (iii) and identify innovative practice and consider areas for future development.

Our analysis did not constitute a systematic review of the use of ICA, and therefore we risk having either missed some reviews or miscoded some. Despite this limitation, given that some of the included reviews are PhD theses, we believe that our process for identifying studies has enabled us to develop a comprehensive understanding of the range of ICA use in the literature.

A further limitation is that we have co-authored several of the reviews included in this exploration, so the results may be viewed as not impartial. We acknowledge this as a potential limitation, although it does not detract from the aim of this paper to showcase innovative practice and identify areas for future development.

The strength of this work is that we have laid out the ICA method, clarified the stages of ICA and how they can be flexibly incorporated within a review, and surfaced innovations in its use. We encourage future reviewers to adopt ICA and hope that by illuminating variation in the use of ICA this paper supports future reviewers to adopt it in a way that best meets the needs of their review.

6. Conclusions

Our analysis of the use and application of ICA over the last decade has demonstrated a rich seam of creativity and innovation. Variation in its application is consistent with the pragmatism with which ICA was conceived, and reflective of the need to continue to develop effective ways to identify and communicate critical information about the content and implementation processes of complex interventions.

CRediT authorship contribution statement

Katy Sutcliffe: Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization, Writing – review & editing, Writing – original draft. **Dylan Kneale:** Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization, Writing – review & editing, Writing – original draft.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

All data used in this study are available in the article. Further inquiries could be directed to the first author.

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