

**Challenging Procedures Used in Systematic Reviews by Promoting a Case-Based
Approach to the Analysis of Qualitative Methods in Nursing Trials**

Author Manuscript

Dr. Elizabeth G. Creamer, Professor Emerita
School of Education
Virginia Polytechnic Institute and State University
1750 Kraft Drive, Blacksburg, VA 24060
540-449-9256
creamere@vt.edu

Dr. Timothy C. Guetterman, Assistant Professor
Department of Family Medicine
University of Michigan Medical School
1018 Fuller Street
Ann Arbor, MI 48104-1213
734-998-7120, Ext. 304
tguetter@med.umich.edu

Ishtar Govia, Ph.D.
Lecturer, Caribbean Institute for Health Research (CAIHR) – Epidemiology Research Unit
The University of the West Indies, Mona Campus
Kingston 7, Jamaica
(1-876) 977-6151-2 (ext. 274)
ishtargovia@gmail.com

Michael D. Fetters, MD, MPH, MA
Department of Family Medicine
1018 Fuller St, Ann Arbor, MI 48105

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/NIN.12393](https://doi.org/10.1111/NIN.12393)

This article is protected by copyright. All rights reserved

734-998-7120
mfetters@umich.edu

Author Manuscript

DR. ELIZABETH GREENE CREAMER (Orcid ID : 0000-0002-6897-0869)

Article type : Original Article

Challenging Procedures Used in Systematic Reviews by Promoting a Case-Based Approach to the Analysis of Qualitative Methods in Nursing Trials

ABSTRACT

This methodological discussion invites critical reflection about the procedures used to analyze the contribution of qualitative and mixed methods research to nursing trials by mounting an argument that these should rest on multiple publications produced about a project, rather than a single article. We illustrate the value added of this approach with findings from a qualitative, cross-case analysis of three critical case exemplars from nursing researchers that each used a qualitative approach with a mixed method phase. The holistic lens afforded by a case-based approach informs nursing inquiry by documenting that the critical case exemplars presented evidence of (a) a sustained commitment of resources and expertise for the qualitative methods that extended across more than one phase of the trial, (b) the impact of the qualitative methods on the trial or its aftermath, (c) deploying a theoretical or conceptual framework for a variety of purposes, and (d) integrating qualitative and quantitative data for purposes of extending explanatory power. Findings challenge the practice of linking purposes served by qualitative and mixed methods to a single trial phase.

Keywords: nursing research, systematic review, randomized controlled trials, qualitative methods, intervention, qualitative mixed method designs, mixed methods

There is evidence of the increasing presence of a qualitative component to randomized controlled trials (RCT) in health-related interventions. RCTs are a specialized type of intervention that utilize an experimental design and a control group (Boeje, Drabble, & O’Cathain, 2015). Results from a systematic mapping review of publications appearing in peer reviewed journals indicates that the number of references to RCTs with a qualitative component almost tripled between 2001 and 2009 (O’Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013). Authors of a cluster of systematic reviews have been critical about the adequacy of reporting that documents the integration and impact of qualitative methods in health interventions and trials. With limited information and an over-riding ambition to detect the impact of qualitative research on trials generally frustrated, these researcher have expressed reservations about the amount of resources and expertise committed over the life of the project (i.e., Drabble & O’Cathain, 2015; Lewin, Glenton, & Oxman, 2009; O’Cathain et al., 2014; O’Cathain et al., 2017; Song, Sandelowski, & Happ, 2010). Procedures used routinely in systematic reviews, however, may account for an under-estimation of both the ways qualitative methods have been used with RCTs and their impact.

The detailed documentation of purposes served by both qualitative and mixed methods in trials (e.g. Creswell, Fetters, Plano Clark & Morales, 2009; Creswell, Shope, Plano Clark, & Green, 2006; Johnson & Schoonenboom, 2016; Palinkas, 2014) seems to stand in sharp contrast with the conclusions drawn from systematic reviews. The contribution of a qualitative approach is almost always categorized relative to its role in one of three phases of the trial (pre, during, after). Benefits prior to executing the intervention include to help tailor an intervention to the context, to recruit participants, and to structure data collection instruments and protocols (Creswell et al., 2009; Creswell et al., 2006). Once an intervention is underway, qualitative data can contribute to mid-course adjustments, and to calibrate both anticipated and unanticipated outcomes (Levati et al., 2016; Sandelowski, 1996). An explanation for why the effectiveness of a trial might vary across sites or participant groups is one of the benefits of a qualitative component after an intervention is completed (Drabble & O’Cathain, 2015).

Reporting practices and publishing norms complicate attempts to identify ways that either a mixed methods or qualitative component were integrated in a trial (O’Cathain et al., 2013; Drabble, O’Cathain, Thomas, Rudolph, & Hewison, 2014). The ways that qualitative research impacted a trial is rarely articulated explicitly (Lewin et al., 2009; O’Cathain et al., 2013). Even

in a systematically collected and relatively large sample of articles, insufficient documentation made it difficult to assess the justification for the qualitative approach, to understand the sampling and analytical procedures, or its contribution to explaining its outcomes (Lewin et al., 2009). Limitations in the amount of space devoted to qualitative research methods in publications and grant proposals is a significant shortcoming in determining its role in an intervention (Drabble et al., 2014).

Drawing conclusions from a single article can be misleading when it is part of a larger body of work (Maxwell, Chmiel, & Rogers, 2015). The practice of publishing qualitative and quantitative findings in separate manuscripts makes it challenging to determine if integration occurred and, if so, for what purpose (Archibald, Radil, Zhang, & Hanson, 2015; Bryman, 2007). Maxwell et al. (2015) maintained that they benefited by turning to book-length examples to get sufficient details about mixed methods procedures and the way integration occurred. They argued that the assumption that integration of qualitative and quantitative data rarely occurs is often inaccurate because it is based only on the documentation afforded by a single article. It is likely that Maxwell et al.'s argument extends to evaluating the role of a theoretical component where more ample documentation is likely to reveal its role extends across phases and serves more purposes than simply to frame the study. Clinical trials typically span multiple years, involve a team of investigators, and produce a series of publications. A case-based approach that bases the analysis on multiple publications related to an intervention is likely to be a more accurate indicator of the ways that a qualitative approach impacted a trial than analysis that is restricted to extracting data from a single publication. Unlike systematic reviews where data are extracted but there is generally not close reading of the text (MacLure, 2005), a case-based method requires close reading of text (Schoonenboom, 2019).

Purpose and Contribution

This methodological discussion invites critical reflection about the use of systematic reviews to assess the contribution of qualitative and mixed methods research to randomized control trials (RCTs) in nursing. These are often referred to in the text as a “trial”. It is our argument that drawing conclusions based on data extracted from a single article from a complex, multi-year project underestimates the impact of the mixed method and qualitative methods of a trial.

We mount an argument that this type of assessment is better achieved through a more holistic, case-based approach that rests on careful analysis of the text and a cluster of publications produced about a project, rather than a single article. The “art” of case-based research lies in its capacity to “disrupt assumptions derived from other forms of understanding” (Thorne, 2012, p. 282). We illustrate the value added of this type of case-based approach with findings from a qualitative, cross-case analysis of three critical case exemplars from nursing researchers that each used qualitative approaches with a mixed methods phase. The wider lens has the benefit of exploring ways that a conceptual framework and integrative procedures that combine qualitative and quantitative approaches can occur not only within a single phase of a trial but extend across phases. A case-based approach also makes it possible to dis-entangle the purposes played by qualitative methods and mixed methods. Implications of the analysis extend to policy makers and those who establish funding priorities by proposing that there is more fidelity to evaluating a complex, multi-strand intervention by analyzing a larger body of data.

Methodological Approaches to Weighing the Contribution of Qualitative and Mixed

Method Approaches in Trials

In this section we consider several topics related to findings from systematic reviews and other types of research that has investigated the contribution of qualitative methods to an intervention or trial. First, we summarize different methodological approaches that have been used to deconstruct the contribution of qualitative methods to trials. Second, we itemize the critique that has been put forward for the ways qualitative methods are often used in trials. Next, we turn to a brief re-analysis we conducted of raw data supplied in a table from the systematic review completed by Lewin et al. (2009). Our secondary analysis of the data supplied in a table by Lewin et al. (2009) contests common assumptions about how qualitative methods are used in trials, including that they are usually reported in a separate publication.

Methodological Approaches that Isolate Key Features of a Research Design

Reviews of the ways that qualitative research has been used with RCTs and other clinical interventions have largely used one of two methodological frameworks, both of which ground analysis in a single article. One is a quantitatively oriented systematic review and the second is a qualitative approach based on a case analysis of exemplars. The systematic literature review traces back to the evidence-based movement in medicine that was used initially almost exclusively to summarize evidence about the effectiveness of a particularly medical treatment

(Boell & Cecez-Kecmanovic, 2015). These base their claim of objectivity to the procedural validity associated with the systematic procedures used to sample and screen the body of literature in order to pool or aggregate results or generate themes (Sandelowski, 2007). The link to the evidence-based movement is also evident in their intent to identify “what works” and “what works best” (Hammersley, 2001). The use of systematic reviews is not restricted to RCTs or to health fields (Petticrew, 2001).

The second approach is principally a qualitative one that prioritizes developing a more comprehensive understanding, but generally with a smaller number of articles. It uses in-depth case studies and a cross-case comparison to extract themes, but still bases the analysis on a single usually methodologically oriented article. Hesse-Biber (2012), Creswell and colleagues (Creswell et al., 2006; Creswell et al., 2009), and Johnson and Schoonenboom (2016) are just a few examples of authors who have used articles as case studies to explore the ways that qualitative and quantitative data were collected, analyzed, and/or integrated in RCTs that used mixed methods. Drabble and O’Cathain (2015) combined the two methodological approaches by incorporating case examples with data from a scoping review.

The Critique Emerging from Reviews

Authors of the cluster of systematic reviews that assessed the role of a qualitative approach in trials seem to juggle a concern for methodological rigor with awareness of the mediating effect of publishing conventions and page restrictions enforced by journals (i.e., Drabble & O’Cathain, 2015; Levati et al., 2016; Lewin et al., 2009; O’Cathain et al., 2014; O’Cathain et al., 2017; Song et al., 2010). The purpose of this cluster of articles differ from other types of systematic reviews designed to measure the effect of a treatment. Each of this cluster of systematic reviews created a structured protocol to extract information from the included articles about the purposes served by qualitative methods, its impact on the trial data, and the timing of qualitative phase. An auditable protocol does not require the researcher actually read the articles (MacLure, 2005). It is one of the steps that makes a systematic review systematic (Sandelowski, 2007). The protocols in the six systematic reviews assumed a compartmentalized design where the qualitative, quantitative, and mixed methods were each a factor in only one phase of the trial.

Lewin et al. ‘s review (2009) is the oldest of the critiques. Writing when the idea of using qualitative methods in trials was a relatively new one, Lewin et al. (2009) summarized their critique of the methodological rigor of these publications when they concluded: “Most of the

qualitative studies were carried out before the trial, had important methodological shortcomings, and the findings were poorly integrated with those of the trial” (p. 6). Table 1 expands this critique by summarizing the limitations identified in systematic reviews and other literature about the conventional uses of qualitative methods with RCTs. Each of the criticisms about the role qualitative methods have played in trials is linked to a reference. In the table, the critiques are organized into one of four categories: (a) investment of resources and expertise, (b) integration of qualitative and quantitative data, (c) impact on the trial, and (d) theoretical framework.

 Insert Table 1 About Here

Each of the criticisms about the role qualitative methods have played in trials derives from the convention in systematic reviews of analyzing a single article and isolating the purposes served to a single phase (pre-, during, after) of the research process.

Results from a Systematic Review that Challenge the Critique of a Qualitative Component

Lewin et al. (2009) provided a detailed data table that made it possible for us to conduct additional calculations to test some of the assumptions that have been made about the use of qualitative methods with trials. The table provided by Lewin et al. (2009) lists the characteristics of 23 studies of trials with a qualitative component. The majority of these (14 of 23) reported on research conducted during pre-trial and, consequently, offered limited information about how qualitative methods contributed to the trial. The data table identifies the trial stage during which the qualitative research was undertaken, the qualitative methodological approach, reasons for including qualitative methods, and nature and degree qualitative and trial data were integrated in analysis and interpretation (see Table 1 in Lewin et al., 2009).

The additional layer of analysis we applied to the data supplied by Lewin et al. (2009) disputes several common assumptions made about qualitative methods in trials. Table 2 lists five assumptions that are made about the use of qualitative methods in trials. It juxtaposes each with results from our additional analysis of the raw data supplied by Lewin et al. (2009).

 Insert Table 2 About Here

The results summarized in Table 2 raise questions about the assumption that qualitative findings are limited to a single article, that they are authored by someone different from who authored the principal article about the trial, and that a specific qualitative approach is rarely identified. Given that most of the articles reported on research methods used at the pre-trial phases, it is not surprising that the authors could find no evidence of how the findings were integrated with the trial.

We anticipated that shifting from an analytical strategy based on extracting data from a single article about a multi-year research project would generate different conclusions than one based on access to the more expansive documentation of research methods that is supplied by a series of inter-related articles, especially when one includes a methodologically oriented piece. The more expansive documentation made it possible to expand the query to examine the contribution of a theoretical perspective, the ways qualitative methods were integrated in the trial, and about how qualitative and quantitative methods were used interactively.

Methods and Procedures

Selection of Critical Cases

In qualitative research, the process of selecting critical cases involves using expert judgment to identify a small number of important cases that have the potential to exert the greatest impact on knowledge and practice (Patton, 2001). Our search to identify critical cases included reviewing each of the examples listed in the data tables in Lewin et al. (2009) and O’Cathain et al. (2013). While this strategy risked identifying examples that now seem dated, it fit our methodological aim to provide a comparison of conclusions drawn about quality when the unit of analysis was a single article and when it involved multiple articles. It had the benefit of helping us to identify a set of cases that were from a similar time frame to those analyzed by Lewin et al. (2009) and O’Cathain et al. (2013).

We established four selection criteria to screen the cases. The first selection criterion was wording in the purpose statement of the article that explicitly framed the study as a mixed methods approach that utilized one or more of the five qualitative methodological “traditions” identified by Creswell and Poth (narrative research, phenomenological research, grounded theory, ethnography, and case study) (2018). The second criterion ruled out many potential examples. That was that evidence was provided that the qualitative and quantitative data and/or

methods were integrated rather than simply combined. By that we mean, that the methods were interdependent and integrated in substantive and intentional ways. A third selection criterion was that we were satisfied that there was sufficient documentation of the methods to allow a cross-case comparison.

Through an iterative process, our team of researchers with expertise in mixed methods narrowed the pool to three critical case exemplars that the team members agreed utilized robust qualitative and mixed methods. We located examples of narrative research (i.e., Ritchie, Schulz, & Bryce, 2007) and phenomenology (i.e. Kwakye et al., 2016) that fit our selection criteria but were forced to drop them from our analysis because there was not sufficient documentation of the research procedures. The final selection of exemplars afforded an unusual level of transparency about the research methods but left us with two cases that failed to achieve intended outcomes.

Analytical Procedures

After locating a full complement of articles for each of the critical case exemplars, we conducted a qualitative cross-case analysis of between three to five articles by the same first author for each project which resulted in a total of 12 articles or about 60,000 words. Authorship practices differ by discipline, but in medical fields, early career researchers are generally listed first, while the principal investigator assumes the last authorship position. The rationale for restricting the articles to the same first author is because the project being reported was part of the research for a doctoral dissertation. The decision to limit the case selection to examples that had produced at least one article with “mixed methods” in the title makes the critical cases even more unusual. It meant that we had access to an unusual level of transparency about the ways that qualitative and quantitative sources of data were integrated. Reference to a wider body of documentation ameliorates the concern often repeated in systematic reviews that there is not enough information to feel confident about drawing conclusions of the rigor of the research methods.

We approached the analysis with an abductive mindset. Abduction is one of three approaches to reasoning that include induction (generalizing from the specific to the general) and deduction (generalizing from the general to the specific) (Locke, Golden-Biddle, & Feldman, 2008). We juggled back and forth between an exploratory and confirmatory stance with an awareness of the critiques emanating from the systematic reviews and a search for anything new

that might emerge. We probed each article in ways that sought to disentangle the purposes served by the qualitative and the mixed methods analytical procedures. Analyses relied heavily on explicit language in the articles. We were struck by how our perceptions about the research design shifted from the initial impression of the first article we located. We looked for similarities and differences between our critical case exemplars in the ways they used qualitative methods and mixed methods.

Findings

Table 3 provides a case-based matrix that summarizes key features of the qualitative element of the three critical cases and links the methodological approach with the phase of the RCT (pre-, during-, post-trial). The table is organized by lead-author and related publications, the principal qualitative methodological approach or approaches, and the phases in the trial where the qualitative methods were implemented. It also identifies the value-added of qualitative data, which we distinguish from the contribution of mixed methods.

Insert Table 3 About Here

Features that distinguish the critical cases are that they reflect a commitment that extended from six to more than ten years. The qualitative approach extended across more than one phase and served, not one, but multiple purposes that varied by project. These are not, as Sandelowski (2007) imagined, retrospective reconstructions completed only post-trial. Analytical procedures may have varied by qualitative method (case study, ethnography, grounded theory) but we could not detect any pattern that supports the assertion that different qualitative methods serve distinct purposes.

The critical cases share a number of characteristics that are not part of our initial selection criteria, but also differ in some important ways. Among the shared qualities is that each trial was led by a nursing researcher and reports on results from a project linked to a doctoral dissertation. None were drug trials. Each is centered on a topic related to the health of women. More than one qualitative approach is identified in two of the exemplars (Saint Arnault et al., 2002, 2009; Hoddinott et al., 2006a, 2006b, 2007). The identification of a specific qualitative method seemed to be a reflection that two of the critical cases have a pervasive qualitative priority built in from the pre-trial phase. Saint Arnault is the only author to describe the intervention as successful in

achieving its intended outcomes. This is not unusual given that most complex interventions fail to demonstrate the intended effects (Levati et al., 2016). Methodological insight is possible even when an intervention is unsuccessful.

Four Aspects about the Value-Added of Qualitative and Mixed Methods Revealed by the Case-Based Analysis

Keeping in mind the critique that has been leveled about the ways qualitative methods have been incorporated in RCTs, we generated a list of four ways that the authors of the critical cases leveraged qualitative methods in a RCT. Regardless of the qualitative approach, the wider body of documentation about each of the three case exemplars provided documentation that qualitative methods (a) were introduced in more than one phase of the trial, (b) enhanced the impact of the trial or its implications, (c) utilized, developed, or refined a conceptual/theoretical framework, and (d) were integrated with quantitative data in ways that provided more robust conclusions. Embedding a qualitative and integrative element in more than one phase of a trial reflects a non-trivial investment of time, resources, and expertise.

The discussion that follows is organized by each of four areas that were identified in systematic reviews about the methodological rigor of the ways qualitative methods were used in trials. It incorporates data reported in Table 3.

Qualitative methods are evident in more than one phase of the trial. Contrary to a critique emerging from systematic reviews based on a single article, we found that when we framed our analysis at the project level, there was documentation of an investment of resources, time, and expertise that spanned more than one phase of the trial. For example, in the study about Japanese women experiencing depression (i.e., Saint Arnault et al., 2002, 2009) ethnography made an important contribution both pre- and post-trial. In the project about emergency room interactions (i.e., Catallo et al., 2012a, 2012b, 2013), grounded theory proved instrumental during and after the trial to find pivotal turning points in the process of disclosure. Qualitative approaches served a purpose in all phases of the trial targeted at improving breastfeeding rates among rural women (i.e., Hoddinott, 2006a, 2006b, 2007). Further evidence of the commitment of time and resources is that leaders of these projects continued to generate associated publications after the intervention concluded.

A qualitative approach served more than one purpose in each of the trials. Most of the purposes served have been singled out in the literature already. We are able to add to the

literature by pointing out that qualitative methods played a particularly strong role in the two cases where the interventions were not successful in achieving their intended impact. These two (i.e., Catallo et al., 2012a, 2012b, 2013; Hoddinott et al., 2006a, 2006b, 2007) used qualitative methods during or after the trial to identify variables that interfered with the expected impacts of the intervention. An explanation for why an intervention failed is useful because it contributes to the way others might design similar interventions.

Qualitative methods enhanced the impact of the trial or its implications to policy or practice. The methodological orientation adopted by the authors of the critical case exemplars and their unusual level of documentation afforded a more comprehensive view of ways that qualitative methodology impacted the implementation of the trial than is normally possible from the analysis of a single article. It also pointed to ways that even where it was not possible to demonstrate that the intervention succeeded in producing the intended outcomes, it was still possible for the trial to generate positive implications for policy and practice.

Authors of all three exemplars provided evidence that qualitative methods had an influence on the way that the intervention was implemented. Hoddinott (Hoddinott et al. 2006a, 2006b, 2007) is the only one of the case exemplars to provide explicit details about how qualitative research methods played a major role pre-trial to the implementation of the intervention. She used case study data amassed during the pre-trial phase to tailor the way the intervention was implemented at each site. Both Hoddinott and Catallo (Catallo et al., 2012a, 2012b, 2013) offered evidence of the impact of the qualitative data on the trial because they made mid-course adjustments to their intervention based on their qualitative data.

Two of the exemplars provided documentation of ways that the qualitative data had an impact that extended after the intervention was completed. For example, to meet the goal of increasing access to and use of health promotion strategies, after the intervention was completed successfully, Saint Arnault and Shimabukuro (2011) developed with them what they called a clinical ethnographic interview. It provided a way to explore mental and emotional distress and help-seeking behavior over the lifespan that could appropriately be used with other populations. Similarly, while the intervention initially was not successful in improving disclosure rates about domestic violence in emergency room settings, Catallo and her colleagues' use of grounded theory had a significant long-term implication because it ultimately resulted in revamping emergency room procedures.

Qualitative methods contributed to the development or refinement of a theoretical framework. A theoretical component is a third indicator that was revealed by the case-based analysis of the critical case exemplars. We define a theoretical framework as one that conceptualizes the interrelationships between concepts and provides an explanation for why and how these occur. Although the timing when the theoretical framework first came into play varied, in all cases it served multiple purposes and crossed phases of the trial. Two exemplars (Hoddinott et al., 2006a, 2006b, 2007; Saint Arnault et al., 2002, 2009) began their project by developing or adopting a theoretical model while the third added this after the trial was underway (Catallo et al., 2012a, 2012b, 2013). Qualitative data and procedures were central to the development of theory and its role in explaining results. None of authors reported on procedures to test or confirm their theoretical framework quantitatively.

The theoretical component was developed in different ways in each of the exemplars. After extensive engagement with the literature, Saint Arnault and her associates ultimately concluded that they needed to construct their own theory to understand culturally distinct patterns of help-seeking behavior among Japanese women living in the U.S (Saint Arnault et al., 2002, 2009). Finding that Western measures were ineffective, the authors used a variety of methods to construct a theoretical framework to guide implementation and ultimately refine the intervention. Hoddinott (Hoddinott et al., 2006a, 2006b, 2007) used grounded theory to develop a conceptual model prior to the implementation of the trial to help tailor the intervention to meet the needs of the different localities. Both she and Catallo used a conceptual model to explain the failure of the intervention to achieve its results. In both cases, these involved contextual and economic issues. Hoddinott returned to the model after the intervention concluded in order to develop an explanation for the disappointing result that breastfeeding rates actually declined in four of seven locales. Catallo (Catallo et al., 2012a, 2012b, 2013) turned to grounded theory to generate an explanation for the unexpected finding that patients scoring the highest on the screening device for partner violence were the least likely to disclose it during a visit to a hospital emergency room. She posited that privacy in the emergency room and trained personnel would increase patient disclosure but learned through interviews that what women were willing to disclose was driven by concern about police and losing custody of children.

Qualitative data were integrated with quantitative data in ways that contributed explanatory power to the conclusions. Language that indicated that qualitative and quantitative sources of data were integrated in ways that made a substantive contribution to the conclusions is the fourth way that the qualitative component was leveraged in these RCTs by being embedded across phases. By dedicating one article to mixed methods, two of the sets of authors provided an unusual level of transparency about this methodological dimension of their project (Saint Arnault & Fetters 2011; Catallo et al., 2013).

Table 4 highlights the mixed methods element of the critical case exemplars and distinguishes its contribution from those of the qualitative methods. By “mixed methods”, we refer exclusively to how and when qualitative and quantitative data were integrated and for what purposes. The table identifies the procedures used to integrate qualitative and quantitative data, the phase when integration occurred, and its value-added. The phase of its use is identified because it reveals ways that the application of qualitative and mixed methods differed.

 Insert Table 4 About Here

Mixed methods played a more limited role than did qualitative methods in these trials. Unlike the findings from the use of qualitative methods, integration of data sources only occurred during one phase in each of the three critical cases. Integration occurred during pre-trial in one case, during the trial in another, and post-trial in the third.

Each of the case exemplars offered different reasons for why mixed methods were helpful in their project. In two case, the principal purpose is singular and aligns with the five rationales for integrating methods identified by Greene, Caracelli, and Graham (1989). In the breast-feeding study, during the pre-trial phase, Hoddinott (Hoddinott et al., 2006a, 2006b, 2007) used mixed methods in the early stages of the project to build case profiles for each research site to customize the intervention to local conditions. This fits what is referred to as a development purpose. A mixed method study powered by a development purpose, “seeks to use results from one method to help develop or inform the other method” (Greene et al., 1989, p. 259). Prior to the end of the trial, Catallo et al. (2013) explained their reason for using mixed methods this way: “to get greater context and explanation for preliminary quantitative findings arising from the RCT” (p. 2). This fits what Greene et al. (1989) referred to as an expansion

purpose. This is when mixed methods are used to extend the “breadth and range” of an inquiry (Greene et al., 1989, p. 259).

Saint Arnault and Fetters (2018) are the only critical case authors to list multiple reasons for integration. They identified these as “corroboration (triangulation), elaboration, and development” (p. 311). The elaboration purpose is most evident in the documentation they provided of the procedures that were used following the completion of the intervention. Also referred to as the complementarity purpose, this is when mixed methods are used to create a more holistic understanding of a phenomenon. Saint Arnault and Fetters (2018) integrated different sources of data for theoretical purposes. These included to confirm key constructs, to demonstrate relationships by linking symptom patterns with help-seeking behavior, and to add theoretical constructs to the theoretical framework that strengthened the applicability of the intervention to other settings.

Discussion

This commentary draws critical attention to procedures used in systematic reviews to weigh the contribution of qualitative and mixed methods to nursing related RCTs. We used a qualitative, case-based approach to compare how findings from three critical case exemplars stacked up against the limitations identified in the literature from six systematic review published between 2007 and 2017 (Drabble & O’Cathain, 2015; Levati et al., 2016; Lewin et al., 2009; O’Cathain et al., 2014; O’Cathain et al., 2017; Song et al., 2010).

Conclusions drawn from a systematic review by Lewin et al. (2009) are not entirely in accord with the descriptive data they supplied. Access to a wider body of documentation yielded a less critical view about the rigor and impact of the qualitative and mixed methods on the trials. Results dispute a number of methodological assumptions, including that the impact of qualitative methods is generally restricted to a single phase of the trial. The three critical cases dispute the broader trends revealed by the systematic reviews in that they (a) presented evidence of a more sustained commitment of resources and expertise for the qualitative methods that extended across more than one phase of the trial, (b) offered evidence of the impact of the qualitative methods on the trial or its aftermath, (c) deployed a theoretical or conceptual framework for a variety of purposes, and (d) integrated qualitative and quantitative data in a phase for purposes of extending explanatory power. In two of three cases either the qualitative or mixed methods procedures produced findings that had implications for policy and/or practice. The value-added

of the methods probably derives from the synergies of these strategies, rather than from any single dimension.

Despite the additional documentation we accessed, our findings confirm the assertion that qualitative methods are “essentialized” in trials. What is meant by that is that there is “no demonstrable recognition that qualitative research itself encompasses a diverse range of methodological approaches” (Song et al., 2010). While each of our case exemplars identified one or more specific qualitative methodology, the purposes served only varied slightly by methodology (case study, ethnography, grounded theory). None of our case exemplars prioritized quantitative methods and results in their reporting. These projects reflect our sampling selection of qualitatively dominant RCTs with a mixed method phase. Qualitative methods wove in and out several phases of the trials in all of our exemplars, but not in ways that is uniquely linked to a single qualitative tradition. It is possible that the tendency to essentialize qualitative approaches is more pronounced in mixed methods articles (Archibald et al., 2015).

There are other ways that findings were not entirely as expected. The cautionary note voiced by both Maxwell et al. (2015) and Archibald et al. (2015) that it is a challenge to identify the benefits of integration from a single article from a large project by in large held true but not in the way Maxwell et al. (2015) proposed. Maxwell et al. argued that a fuller body of work is necessary to identify how integration of qualitative and quantitative data occurs because it is very likely to cross phases. Our data do not support this claim. Unlike what we found about how qualitative methods were used, discussion about mixed methods was concentrated in a single methodological article and was associated with one phase of the research. That phase varied from prior, to during, to after the trial. We were surprised to find that mixed methods served more narrowly targeted purposes than the qualitative methods. This implies that the understanding communicated in a single article may be a more valid indicator of design features for mixed methods as it is used in practice, than it is for qualitative methods.

There are several limitations to this research, including that while the critical cases were screened carefully, they were not selected from a systematically collected sample and therefore are not representative of the wider body of literature produced about RCTs that report on using qualitative methods. Particularly given rapid evolutions on the field of mixed methods, the timing of the project and the small number of cases limited the ability to fully explore the ways mixed methods were used and the purposes it served. It happened with the exemplars we selected

that the first author produced publications about more than one phase of the trial. This might not be the case in other projects. It is possible that only analyzing exemplars with a cluster of multiple empirical publications by the same first author exaggerates the amount of time, expertise, and resources committed to qualitative methods in a typical trial.

Implications for Researchers in Nursing

The analysis provided here joins others by research methodologists who delve into the literature to locate exemplars that illustrate innovative practices and/or robust design features with the practical intent of providing examples that can be useful to others as they design research projects and write research proposals. Although we have seen that these same features do not inevitably translate to an intervention that achieves the outcomes prioritized at the design stage, they model elements of transparency about research methods that can be useful to others as they attempt to succinctly communicate their research methods to a diverse audience.

Transparency about research design and procedures has been the defining feature of most of the standards of reporting in mixed methods (e.g., Wisdom, Cavaleri, Onwuegbuzie, & Green, 2012; O'Cathain, Murphy, & Nichol, J., 2008).). Researchers can build transparency into their reporting by using the following strategies during reporting:

- Explicitly identify the learning for future trials that is expected from the qualitative and mixed method research undertaken.
- Document the ways that findings from quantitative and qualitative methods were integrated.
- Identify a specific qualitative methodology and provide a rationale for its use.
- Provide an explicit rationale for the selection of a conceptual or theoretical framework and describe how it contributed to the intervention.

Conclusions

Findings from this analysis have implications for nursing inquiry and the conduct of systematic reviews with research involving interventions with qualitative and mixed methods, including their reporting. It contributes to a wider body of methodological commentary that raise questions about the analytical procedures used in systemic reviews (e.g. Sandelowski, 2007; Boell & Cecez-Kecmanovic, 2015; MacLure, 2005; Hammersley, 2001). It disputes the assumption that the impact of qualitative methods is only at the pre-trial stage. A single article as

a unit of analysis may work for other purposes, but it's approach to extracting data rather than actually reading an article is less appropriate for drawing conclusions about methodological quality, particularly in complex, multi-phase projects.

In the future, systematic reviews about the methodological and theoretical properties of a trial can be strengthened by using the project, rather than the study, as the unit of analysis and by confirming design features by data supplied in multiple, inter-related publications. A single article as the unit of analysis is more appropriate in contexts other than RCTs which are necessarily multi-phase. A mixed methods approach could be used with this methodology to create the context for a more holistic appraisal by adding a phase with a case-based analysis and the selection of a cluster of articles from projects that reflect each phase of a trial. This could be used to compare trials utilizing different qualitative methodologies. The wider lens afforded by a holistic analysis of a body of articles produced over the life of a project will make it possible in the future to more fully explore the role of a theoretical framework in trials and if their presence is a significant predictor of outcomes.

The practice of categorizing purposes served by qualitative methods and then narrowly associating them with a single phase of a trial can be counterproductive to grasping the ways it influenced a trial. The temporal framework is “not a helpful way of categorizing these articles in practice” (Drabble & O’Cathain, 2015, p.414). The restrictions of this mindset may explain how re-analyses of some of the raw data supplied by Lewin et al. (2009) contradicted some of the conclusion drawn in their systematic review. Somewhat ironically, they criticized researchers for not providing documentation about how qualitative methods explained trial findings, even as the majority of articles were reporting on the use of qualitative methods pre-trial or at a point when data about the outcomes of the trial were not yet available.

In her critique of the methodological assumptions of systematic reviews and its claim to objectivity, Sandelowski (2007) imagines the reports analyzed as “after-the-fact reconstructions of studies” (p. 108) that report on the impact of the intervention. A limitation of systematic reviews that draw conclusions from reports produced pre- or during a trial is that these naturally will present a much narrower view of the impact of qualitative and mixed methods than one produced following the completion of trial. This is especially problematic when the goal is to evaluate the impact of the methods on the trial. For future research using systematic reviews, conclusions about impact and integration will have a more robust grounding if they are made

when sampling procedures ensure that the analysis is not biased by the inclusion of articles reporting only on its uses pre-trial.

References

- Archibald, M. M., Radil, A. I., Zhang, X., and Hanson, W. E. (2015). Current mixed methods practices in qualitative research: A content analysis of leading journals. *International Journal of Qualitative Methods*, 14 (2), 1-33.
- Boeije, H. R., Drabble, S. J., & O’Cathain, A. (2015). Methodological challenges of mixed methods in intervention evaluations. *Methodology*, 11 (4), 119-125.
- Boell, S. K., & Cecez-Kecmanovic, D. (2015). On being ‘systematic’ in literature reviews. *Journal of Information Technology*, 30, 161-173.
- Bryman, A. (2007). Barriers to integrating quantitative and qualitative research. *Journal of Mixed Methods Research*, 1 (1), 8-22.
- Catallo, C., Jack, S. M., Ciliska, D., & MacMillan, H. L. (2012a). Mixing a grounded theory approach with a randomized controlled trial related to intimate partner violence : What challenges arise for mixed methods research ? *Nursing Research and Practice* (article ID 798213; DOI:dx.doi.org/10.1155/2013/798213).
- Catallo, C., J., S. M., Ciliska, D., & MacMillan, H. L. (2012b). Identifying the turning point: Using the transtheoretical model of change to map intimate partner violence disclosure in emergency department settings. *International Scholarly Research Network* (article ID 239468; DOI:10.5402/2012/239468).
- Catallo, C., J., S. M., Ciliska, D., & MacMillan, H. L. (2013). Minimizing the risk of intrusion: A grounded theory of intimate partner violence disclosure in emergency departments. *Journal of Advanced Nursing*, 69 (6), 1366-1376. DOI:10.1111/j.1365-2648.2012.06128.
- Creamer, E. G., & Schoonenboom, J. L. (2018a). Introduction: Inter-method mixing as a gateway to methodological mixing. In E. G. Creamer & J. L. Schoonenboom (Eds.), *Methodological innovation in mixed method research*. *American Behavioral Scientist*, 62 (7), 879-886.

- Creswell, J. W., Fetters, M. D., Plano Clark, V. L., & Morales, A. (2009). Mixed method intervention trials. S. Andrew & E. J. Halcomb (Eds.) *Mixed methods research for nursing and health sciences* (pp. 161-180). Oxford, U.K. Blackwell Publishing.
- Creswell, J. W., & Poth, C. (2018). *Qualitative inquiry and research design: Choosing among five approaches* (4 edition). Thousand Oaks, CA. SAGE Publications.
- Creswell, J. W., Shope, R., Plano Clark, V. L., & Green, D. O. (2006). How interpretive qualitative research extends mixed methods research. *Research in the Schools*, 13, 1-11.
- Drabble, S. J., & O’Cathain, A. (2015). Moving from randomized controlled trials to mixed methods intervention evaluations. In S. Hesse-Biber & R. B. Johnson (Eds.). *The Oxford Handbook of Mixed and Multi Method Research* (pp. 406-425). Oxford, U.K. Sage.
- Gough, D., Oliver, S., & Thomas, J. (2017). *An introduction to systematic reviews* (2nd ed.). Thousand Oaks, CA: Sage.
- Greene, J. C., Caracelli, V. J., & Graham, W. F. (1989). Toward a conceptual framework for mixed-method evaluation designs. *Educational Evaluation and Policy Analysis*, 11 (3), 255-274.
- Hammersley, M. (2001). On ‘systematic reviews’ of research literatures: A ‘narrative’ response to Evans & Benefield. *British Educational Research Journal*, 27 (5), 543-554.
- Hesse-Biber, S. (2012). Weaving a multimethodology and mixed methods praxis into randomized control trials to enhance credibility. *Qualitative Inquiry*, 18(10).DOI:10.1177.1077800412456964.
- Hoddinott, P., Britten, J., & Pill, R. (2010). Why do interventions work in some places and not others: A breastfeeding support group trial. *Social Science and Medicine*, 70, 769-778.
- Hoddinott, P., Britten, J., Prescott, G., Tappin, D., Ludbrook, A., & Golden, D. J. (2009). Effectiveness of policy to provide breastfeeding groups (BIG) for pregnant and breastfeeding mothers in primary care: A cluster randomized controlled trial. *BMJ* 2009: 338a3026 doi: 10.1136/bmj.a3026.
- Hoddinott, P., Chalmers, M. M., & Pill, R. (2006a). One-to-one or group-based peer support for breastfeeding? Women’s perceptions of a breastfeeding peer coaching intervention. *Birth*, 33 (2), 139-146.

- Hoddinott, P., Lee, A. J., & Pill, R. (2006b). Effectiveness of a breastfeeding peer coaching intervention in rural Scotland. *Birth*, 33 (1), 27-36.
- Hoddinott, P., Pill, R., & Chalmers, M. (2007). Health professionals, implementation, and outcomes: Reflections on a complex intervention to improve breastfeeding rates in primary care. *Family Practice*, 24 (1), 84-91.
- Johnson, B., & Schoonenboom, J. (2015). Adding qualitative and mixed methods research to health intervention studies: Interacting with differences. *Qualitative Health Research*, 26 (5), 587-602.
- Palinkas, L. A. (2014). Qualitative and mixed methods in mental health services and implementation research. *Journal of Clinical and Child Adolescent Psychology*, 43(6), 851-861.
- Kwakyie, I., Garner, M., Baldwin, D. S., Bamford, S., Pinkney, V., Bishop, F. L. (2016). Altruism, personal benefit, anxieties: A phenomenological study of healthy volunteers' experiences in a placebo-controlled trial of duloxetine. *Human Psychopharmacology: Clinical and Experimental*, 31, 332-340.
- Levati, S., Campbell, P., Frost, R., Dougall, N., Wells, M., Donaldson, C., & Hagen, S. (2016). Optimisation of complex health interventions prior to a randomized controlled trial: A scoping review of strategies used. *Pilot and Feasibility Studies*, 2 (17). DOI 10.1186/s40814-016-0058-y.
- Lewin, S., Glenton, C., & Oxman, A. (2009). Use of qualitative methods alongside randomized controlled trials of complex healthcare interventions: Methodological study. *British Medical Journal*, 339. DOI: 10/1136/bmj.b3496.
- Levati, S., Campbell, P., Frost, R., Dougali, N., Wells, M., Donaldson, C., & Hagen, S. (2016). Optimization of complex interventions prior to randomized controlled trials: A scoping review of strategies used. *Pilot and Feasibility Studies*, 2 (17). DOI:10.1186/s40814-016-0058-y
- Locke, K., Golden-Biddle, K., & Feldman, M. S. (2008). Making doubt generative: Rethinking the role of doubt in the research process. *Organization Science*, 19(6), 907-918.
- Maxwell, J., Chmiel, M., & Rogers, S. E. (2015). Designing integration in multimethod and mixed methods research. In S. Hesse-Biber and R. B. Johnson (Eds), *The Oxford*

- Handbook of Multimethod and Mixed Methods Research Inquiry (pp. 223-239). Oxford, UK. Sage.
- MacLure, M. (2005). 'Clarity bordering on stupidity': where's the quality in systematic review. *Journal of Education Policy*, 20 (4), 393-416.
- O'Cathain, A., Goode, J., Drabble, S. J., Thomas, K. J., Rudolph, A., & Hewison, J. (2014). Getting added value from using qualitative research with randomized controlled trials: A qualitative interview study. *Trials*, 15: 215-227.
- O'Cathain, A., Thomas, K. J., Drabble, S. J., Rudolph, A., & Hewison, J. (2013). What can qualitative research do for randomized controlled trials? A systematic mapping review. *BMJ Open* 2013;3. DOI:10.1136/bmjopen-2013-002889.
- O'Cathain, A., Murphy, E., & Nichol, J. (2008). The quality of mixed methods studies in health services research. *Journal of Health Services Research and Policy*, 13(2), 92-98.
- Patton, M. (2001). *Qualitative research and evaluation methods*. Thousand Oaks: CA. SAGE.
- Petticrew, M. (2001). Systematic reviews from astronomy to zoology: Myths and misconceptions. *British Medical Journal*, 322, 98-101.
- Ritchie, D., Schulz, S., & Bryce, A. (2007). One size fits all? A process evaluation – the turn of the 'story' in smoking cessation. *Journal of the Royal Institute of Public Health*, 121, 341-348.
- Schoonenboom, J. (2019). Develop your case! How controversial cases, subcases, and moderated cases can guide you through mixed methods data analysis. *Frontiers in Psychology*, 10. Doi:10.3389/fpsyg.2019.01369.
- Sandelowski, M. (1996). Using qualitative methods in intervention studies. *Research in Nursing and Health*, 19, 359-364.
- Sandelowski, M. (2007). Reading, writing and systematic review. *JAN Research Methodology*, 64 (1), 104-110.
- Schoonenboom, J. (2019). Develop your case! How controversial cases, subcases, and moderated cases can guide you through mixed methods data analysis. *Frontiers in Psychology*. DOI:10.3389/fpsyg.2019.01369.
- Song, M. K., Sandelowski, M., & Happ, M. B. (2010). Current practices and emerging trends in conducting mixed methods intervention studies in health sciences. In A. Tashakkori & C.

- Teddlie (Eds.), *SAGE handbook of mixed methods in social and behavioral research* (pp. 725-747). Thousand Oaks, CA. SAGE.
- Saint Arnault, D. (2002). Help-seeking and social support in Japanese sojourners. *Western Journal of Nursing Research*, 24(3), 295-306.
- Saint Arnault, D. (2009). Cultural determinants of help seeking: A model for research and practice. *Research and Theory for Nursing Practice: An International Journal*, 23 (4), 259-278.
- Saint Arnault, D., & Fetters, M. D. (2011). ROI funding for mixed methods research: Lessons learned from the “mixed method analysis of Japanese depression” project. *Journal of Mixed Methods Research*, 5(4), 309-329.
- Saint Arnault, D., & Shimabukuro, S. (2011). The clinical ethnographic interview: A user-friendly guide to the cultural formulation of distress and help seeking. *Transcultural Psychiatry*, 49(2). DOI: 10.1177/1363461511425877.
- Tashakkori, A., & Creswell, J. W. (2007). Exploring the nature of research questions in mixed methods research (Editorial). *Journal of Mixed Methods Research*, 1(3), 207-211.
- Thorne, S. Editorial: What’s in a case? *Nursing Inquiry*, 19 (4), 281-282.
- Wisdom, J.P, Cavaleri, M.A., Onwuegbuzie, A.J., & Green, C. A. (2012). Methodological reporting in qualitative, quantitative, and mixed methods health services research articles. *Health Research and Educational Trust: Health Services Research*, 47 (2), 721-745.

Table 1

Summary of the Limitations Identified in the Literature about the Use of Qualitative and Mixed Methods Approaches with Trials

| Dimension | Critique/Source for Study Level Analysis |
|-------------------------------|--|
| Expertise/Resources | <p>Lack of adequate investment of resources and expertise (Lewin et al., 2009; O’Cathain et al., 2013; Song et al., 2010)</p> <p>No recognition that QUAL encompasses a diverse range of methodological approaches (Song et al., 2010)</p> |
| Integration of QUAL and QUANT | <p>No indication of QUAL and QUANT integration (Lewin et al., 2009)</p> |
| Impact on Trial | <p>Little evidence that the QUAL component impacted the trial or explained trial findings (Lewin et al., 2009)</p> |
| Theoretical Framework | <p>Little rationale provided for choice of theory or its role in study design (Davies, Walker, & Grimshaw, 2010)</p> |

Table 2

Additional Analysis from Data Reported by Lewin et al. (2007) that Counters Common Assumptions about the Use of Qualitative Methods in Trials

| Misperception | Data from 23 Cases |
|---|--|
| The findings from a qualitative phase are generally reported in a separate publication. | The qualitative element was reported in a separate article in only 9 of 23 cases. |
| The qualitative component is usually pre-trial. | The qualitative component was equally as likely to be during and after the trial, as pre-trial. |
| One member of a research team contributes the qualitative expertise. | The first author of the main article reporting on results and the one about reporting on the qualitative dimension were equally as likely to be the same as different. |
| Qualitative methods are essentialized and treated as if they are all the same. | Twelve of the 23 studies identified a specific qualitative approach (i.e., ethnography, case study, grounded theory). |
| Qualitative methods are limited to a single phase of the trial. | Of 23 studies, Lewin et al. only categorized two as using qualitative research in more than one phase. |

Table 3

Overview of the Topic, Methodological Approach, Phases Where Applied, and Value-Added of the QUAL Component of the Critical Case Exemplars

| Authors/ Timespan | No of Articles | Topic | Principal Qualitative Approach | QUAL Phase (s) in RCT | Value-Added of QUAL |
|---|---------------------------|---|---|--------------------------------------|--|
| Saint Arnault, 2002; Saint Arnault, 2009; Saint Arnault & Fetters, 2011; Saint Arnault & Shimabukuro, 2011 (1998-2011) | 4 | Depression among Japanese women in the U.S. | Ethnography | Pre, post | Explain how cultural factors influence help- seeking behavior; expand knowledge of unknown variables. |
| Catallo et al., 2012a, 2012b, 2013 (2005-2013) | 3 | Disclosure of intimate partner violence to healthcare professionals. | Grounded theory | During, post | Explain contradictory qualitative and quantitative findings from trial; identify conditions that mediate disclosure. |
| Hoddinott et al., 2006a, 2006b, 2007, 2009, 2010 (2004-2010) | 5 | Increase breast feeding rates | Grounded theory, case study | Pre, during, post | Input to modifying the intervention to adopt to local conditions; structuring |

Author Manuscript

| | | | | | |
|--|--|--|--|--|--|
| | | | | | instruments; explain contradictory data across sites. |
|--|--|--|--|--|--|

Table 4

Phase and Purposes Served by Mixed Methods in Three Critical Case Exemplars

| Topic | Phase | Procedure | Purpose Served by the Integration of Qualitative and Quantitative Data |
|---|--------------|---|--|
| Depression among Japanese women in the U.S. (Arnault et al.) | Post | Quantified QUAL codes for use in analysis | Confirm constructs in the preliminary theoretical model; demonstrate relationships by linking symptom patterns with help-seeking behavior; add theoretical constructs that strengthen applicability to other settings. |
| Disclosure of intimate partner violence to healthcare professionals (Catallo et al.). | During | Select participants for qualitative phase | Expand on findings from the trial; overcome limitations in the quantitative measure; input on procedures to encourage disclosure. |
| Increasing breastfeeding rates (Hoddinott et al.) | Pre | Cross-case comparison of site case matrices | Generate initial hypotheses, structure data collection; and construct a preliminary conceptual model. |