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**Hernon, O., Dalton, R. & Dowling M (2019) Clinical Research Nurses' Expectations and Realities of their role: A Qualitative Evidence Synthesis. Journal of Clinical Nursing (accepted in press)**

## **ABSTRACT**

**Aims:** To synthesise the available body of qualitative studies relating to clinical research nurses' experiences of their role.

**Methods:** A systematic search of the literature in five databases was undertaken: CINAHL, Medline, Embase, Pubmed, Proquest. Thomas and Harden's three-stage approach to thematic analysis was followed using the ENTREQ statement for reporting.

**Results:** Nineteen studies reported in 20 papers (with a total of 232 nurses) were included in the synthesis. Three analytical themes with six subthemes were identified: 'identity; 'meeting targets' and 'patient advocate'.

**Conclusions.** Clinical research nurses experience isolation and contributing to this is their perception of non-research nurses' lack of understanding for their role. This can result in difficulties when recruiting study participants. Clinical research nurses can experience internal conflict between being a patient advocate and adhering to a trial protocol

**Relevance to clinical practice.** Training is needed to help research nurses develop skills to face challenges in order to ensure safe and ethical care is provided to research participants whilst also ensuring high quality data collected for the study.

**Keywords.** Clinical Research Nurse, Clinical Trial Nurse, Clinical Trial Coordinator, Research Nurse, Role, Qualitative.

### **What does this article contribute to the wider global clinical community?**

- Clinical research nurses play a central role in the recruitment of study participants but often feel isolated in their role
- Clinical research nurses must develop good relationships with ward staff who are gatekeepers to patient recruitment.
- Clinical research nurses consider themselves patient advocates throughout a patient's time on a trial and even following the trial's completion.
- Clinical research nurses can experience internal conflict when the needs of patients do not fit with those of a trial.

## Introduction

Clinical research is a rapidly increasing field (Smith *et al.* 2018) and plays an important role in providing evidence to support improvements in patient care by investigating treatments and methods of care provided (Hyland and Clarke Moloney 2016). The amount and intricacy of clinical trials are increasing and many have positive impacts on patient care (Lawan 2017). Clinical trial participation requires additional follow up visits and monitoring which may augment the usual standard of care that patients receive (Lawan 2017). Clinical research professionals are from a variety of backgrounds such as science, pharmacy and nursing (Society of Clinical Research Associates, no date). Roles within clinical research include clinical research associates, research coordinators, research nurses and data managers (Connolly *et al.*, 2004). Globally, nurses working in clinical research roles practice under the title of 'Clinical Research Nurse' (International Association for Clinical Research Nursing [IACRN], 2016).

The title clinical research nurse (CRN) is also commonly referred to as 'Clinical Research Coordinator' or 'Clinical Trial Coordinator' (Rickard and Roberts, 2008). Internationally a range of different titles are used with the role and the process of transitioning to a clinical research nurse may be unplanned (Smith *et al.* 2018). Clinical research nurse is the preferred term and CRNs are often the first health care professional to work with research patients on a new intervention, drug or device (Hastings *et al.* 2012). Working as a clinical research nurse is considered an exciting role for nurses who have an interest in expanding their knowledge and skills and want to make a difference in patient care (Poston and Beuscher 2010). In addition, the clinical research nurse role has no standard definition (Hyland and Clarke Moloney 2016). Suggested roles of the clinical research nurse include managing patient safety,

and the informed consent process, recording accurate data and planning appropriate follow-up care (Hastings et al. 2012).

The role also involves care for study participants across different health conditions and ensuring that the research team adheres to the requirements of the study protocol (Smith et al. 2018). Furthermore, clinical research nurses provide participants with information about their health, the condition and its treatments (Lawan, 2017). By managing the research study, monitoring its participants for any events, supporting and educating study participants and their families, the CRN works to attain the study objectives whilst also ensuring participant rights and safety is maintained (Hastings et al. 2012). Moreover, although the principal investigator of the study maintains the overall responsibility of the study and its activities, the clinical research nurse aides this by coordinating the daily management of the research trial (Poston and Beuscher 2010). CRNs are therefore influential in the developing, implementing, maintaining and supporting clinical research studies (Smith *et al.* 2018). They also can promote patients to better care for their health (Lawan, 2017), and their knowledge of a specific area being researched helps in the safe and efficient daily management of study participants (Poston and Beuscher, 2010).

Initially, a scoping search was undertaken to help guide the focus of this synthesis (Flemming *et al.*, 2019). The scoping search revealed a number of qualitative studies reporting on the challenges of the role (Hill and MacArthur 2006; Höglund *et al.*, 2010; Kunhunny and Salmon 2017; Spilsbury *et al.*, 2008). This informed our decision to focus the review on qualitative studies which explored and described clinical research nurses' expectations and realities of their role. This type of review will contribute to the strategic goal of improving awareness and understanding of clinical research nursing (one of the four strategic goals of the clinical research nurse strategy (2017-2020)

outlined by the National Institute of Health Research [NIHR]) (Hamer, 2017) by exposing research nurses' own experiences of their role.

## **Aims and Methods**

The aim of this qualitative evidence synthesis (QES) was to synthesise all available qualitative studies describing clinical research nurses' expectations and realities of their role. A QES was therefore the most appropriate choice of review. Synthesis was guided by Thomas and Harden's approach (2008) using the ENTREQ statement (enhancing transparency in reporting the synthesis of qualitative research (Tong et al., 2012)).

The terms 'systematic review of qualitative research studies' and 'qualitative evidence synthesis' belong to the 'qualitative review family' (Sutton et al., 2019), however, qualitative evidence synthesis is the term promoted by the Cochrane Collaboration's Qualitative Research Methods Group (Grant and Booth, 2009).

A strength of qualitative evidence synthesis is its peeling back of a deeper meaning on issues across time and geographical distance (Booth, 2016). The individual qualitative studies in qualitative evidence synthesis expose richness of experience and a subsequent synthesis presents themes with international relevance, which serve to inform practice and education in clinical research nursing. Moreover, a comprehensive synthesis of qualitative research exploring the clinical research nurse's role can reveal gaps to inform future research (Sandalowski and Barroso, 2010).

The study question was: What are clinical research nurses' experiences of their role? Synthesising the available qualitative studies to answer the study question results in

a collection of findings, which can inform practice in a manner by which single studies cannot (Flemming 2007).

### *Search Strategy.*

The SPIDER framework (Sample, Phenomenon of Interest, Design, Evaluation, Research) (Cooke *et al.* 2012), was used to devise the research question, help identify keywords, develop the inclusion/exclusion criteria and guide the search strategy (Table 1). The scoping search revealed a limited number of qualitative studies. Therefore no date limit was applied in order to capture the complete body of qualitative literature. A systematic search in five databases was undertaken: CINAHL, Medline, Embase, Pubmed, Proquest. Grey literature (theses and conference proceedings) were also searched. The database searches was completed by 20-01-2019 and identified 3,675 sources. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (Moher *et al.*, 2009) was used, with a flow chart documenting the identification, screening, eligibility decisions taken and summary of records included (Figure 1).

### *Screening and study selection.*

Screening of title and abstract was undertaken by OH and RD in the online screening and data extraction platform Covidence© (Covidence.org, 2017), using pre-determined inclusion criteria, as follows:

1. Qualitative studies describing clinical research nurses, clinical trial nurses, clinical research nurse managers and clinical research nurse co-ordinators' experiences of their role;

2. Qualitative studies describing clinical research nurses, clinical trial nurses, clinical research nurse managers and clinical research nurse co-ordinators' experiences of recruitment to trials;
3. Qualitative studies describing clinical research nurses, clinical trial nurses, clinical research nurse managers and clinical research nurse co-ordinators' experiences of data collection/data entry;
4. Qualitative studies to include mixed methods (if the qualitative aspect of study utilises qualitative data collection and analysis), ethnography, phenomenology, grounded theory, lived experience, narrative analysis, generic qualitative;
5. Studies in the English language only.

Pre-determined exclusion criteria were as follows:

1. Studies specific only to clinical research associate/non-nurse experience;
2. Studies relating to other nurses who were not in clinical research roles,
3. Studies with a quantitative methodology
4. Non-English language studies.

MD resolved any conflicts. Full text screening was then undertaken on 50 studies by OH and MD (Figure 1), resulting in nineteen studies (one study reported in two papers) included in the synthesis (Table 2).

### *Quality assessment*

Quality appraisal of each study was undertaken by OH and MD and guided by the Critical Appraisal Skills Programme framework (CASP, 2017). No study was excluded based on their CASP score. The appraisal of each study's methodological limitations was not used to exclude studies. It is argued that even if a study is assessed to be of low quality it may still provide new insights (Noyes et al. 2008). Moreover, our appraisal of each study was included as one of four components in assessing our confidence in the findings from the review (Lewin et al. 2018 a,b) (Table 3).

### *Data extraction and thematic analysis.*

Thematic analysis was undertaken by OH and MD. Thomas and Harden's (2008) three-stage approach to thematic analysis was used to guide the synthesis of the included papers. All of the included studies were read in full and the data extracted from each study's findings. Line-by-line coding of each study findings (i.e. verbatim participants' accounts and researchers' interpretations) was undertaken by OH and compared against codes across all the included studies. Following this, OH and MD grouped related codes into logical descriptive themes. In the next stage, all of the generated descriptive themes were reviewed by OH and MD in light of the review question. Further grouping of concepts was undertaken resulting in final three higher order analytical themes, each with two sub-themes.

An assessment of confidence in the review findings was undertaken by OH and MD using GRADE-CERQual (Confidence in Evidence of Reviews of Qualitative Research) (Lewin *et al.*, 2018 a,b) (Table 3). A CERQual assessment allows the researcher to judge confidence in each of the review findings and also in the findings overall guided by four elements; methodological limitations, coherence, adequacy of data and relevance (Lewin *et al.* 2018a,b).

## **Results**

Nineteen studies were included in the synthesis. One study was reported in two papers (Lawton *et al.*, 2011; 2012). Sample sizes varied across the studies ranging from 3 to 20, with a total of 232 nurses interviewed from five countries. Most of the studies were undertaken in the UK (8), with the others undertaken in the US (5), Australia (3), New



Zealand (2) and Sweden (1) (Table 2). The most common methodology was qualitative descriptive using semi-structured interviews. Three higher order themes with two subthemes were identified across the studies: 1) Identity (subthemes: new identity, lone ranger); 2) Meeting targets (subthemes: gatekeeper, targets); 3) Patient advocate (subthemes: duty of care, role conflict).

Using CERQual, a verdict of 'high confidence' in all but one sub-theme was reached (we agreed on 'moderate confidence' for the subtheme of 'role conflict').

## **Identity**

In the early days of their new role, research nurses experienced a **new identity**, felt like "*a fish out of water*" (Tinkler *et al.*, 2018, p.322), and felt a need for additional training and support (Höglund *et al.* 2010; p.246; Kampelman, 2015; Kunhunny and Salmon 2017; Tinkler *et al.*, 2018). While initial training focused on study protocols, research nurses were expected to carry out study procedures without training (Kyte *et al.*, 2013; Kampelman, 2015). Even with experience in the role, research nurses wanted training (Kampelman, 2015; Tinkler *et al.*, 2018), because with each study there were different study specifics (Kunhunny and Salmon 2017). However, over time research nurses found an ease within their role as a "*small cog in a big machine*" (Tinkler *et al.*, 2018, p.324).

Being a **lone ranger** was part of the role and described as "*difficult*" (Hill, 2018, p.54).

In comparison to other health care professionals, research nurses often worked alone and did not feel as supported as their ward environment counterparts when in difficult circumstances (Hill and MacArthur 2006; Höglund *et al.*, 2010; Spilsbury *et al.*, 2008).

Research nurses often felt "*invisible*" (Kunhunny and Salmon 2017, p.5129) and made

themselves appear “*invisible*” in an attempt to avoid being in the way of other health professionals (Cresswell and Gilmour 2014, p.22). They also felt “*isolated*” (Kunhunny and Salmon 2017, p.5129), “*pretty much self-contained*” (Schlichting 2016, p.55), and believed that their role was not understood (Höglund *et al.* 2010), describing others’ view of their role as ‘*cushy*’ (Hill and MacArthur 2006, p.44; Tinkler *et al.* 2018, p.324), and “*not a proper job*” (Tinkler *et al.* 2018, p.324).

### **Meeting targets**

In order to recruit study participants, CRNs had to work around staff **gatekeepers**. Healthcare professionals had some influence over patients and their decision to participate in study trials (Kunhunny and Salmon 2017; Mackle and Nelson 2018), and ward nurses could act as a barrier to recruitment (Mackle and Nelson 2018). Therefore, CRNs needed to develop relationships with ward staff in order to increase rates of recruitment (Zucchelli *et al.* 2018). However, developing these relationships was often a slow process (Cresswell and Gilmour 2014).

Recruitment also involved reaching “**targets**” (Kyte *et al.*, 2013, p.6), and CRNs felt pressure to “*recruit, recruit, and recruit*” (Kyte *et al.*, 2013, p.6). They often altered their work schedule and worked flexibly in order to be available for situations where they might recruit, such as clinic times (Zucchelli *et al.*, 2018), and strived to present themselves in a certain way to potential study participants to make a good “first impression” (Resnick *et al.* 2003). This heightened pressure to recruit could result in a deficient consenting process (Cresswell and Gilmour 2014; Höglund *et al.*, 2010; Tinkler *et al.*, 2018). Moreover, if CRNs did not recruit to targets, their work was

questioned and compared to other research nurses or research centres who were recruiting more participants (Spilsbury *et al.* 2008).

### **Patient advocate**

CRNs viewed themselves as patient advocates and referred to this role as their “**duty of care**” (Kyte *et al.* 2013, p.6), throughout the patient’s research journey and beyond (Kunhunny and Salmon 2017; Larkin *et al.* 2019; Lawton *et al.* 2012; Loh *et al.* 2002; Schlichting 2016; Tinkler *et al.* 2018). They considered patients first with the study taking second place (Höglund *et al.*, 2010; Kyte *et al.*, 2013; Larkin *et al.*, 2019), and some were motivated to make the transition to the CRN role in pursuit of helping make a patient’s life or health “*better*” (Rickard *et al.*, 2011, p.170). Even after the trial had finished, if contacted by patients, CRNs were happy to provide support (Schlichting 2016).

On first meeting potential participants, CRNs were “*welcoming but not persuasive*” (Cresswell and Gilmour 2014, p.22), because they believed that patients might agree to participate in trials feeling they had to or because of their trust of healthcare professionals (Davis *et al.*, 2002; Höglund *et al.*, 2010). Sometimes patients changed their minds about participating after meeting CRNs having been given more information (Kunhunny and Salmon 2017; Loh *et al.* 2002).

**Role conflict** is an aspect of the CRN role where there was tension between being a nurse and a research nurse, and essentially an advocate for “*two patients simultaneously*” (Larkin *et al.*, 2019, p.180). While some CRNs believed that the

patient always came first (Kyte *et al.*, 2013), others considered research data as a central duty of their role (Kyte *et al.*, 2013; Larkin *et al.*, 2019). CRNs often had to meet the needs of many (Larkin *et al.* 2019; Schlichting 2016) and in their attempts to keep patients on a trial strived to keep everyone happy by “*scratching backs*” and doing what they could to encourage participants remaining in the study (Kampelman 2016, p.71).

CRNs also believed that patients should be afforded extra attention because they were volunteering their time (Cresswell and Gilmour 2014; Kyte *et al.* 2013; Schlichting 2016). However, this extra attention could result in patients being “*ruined*” and contacting the research team for any issue not research related (Lawton *et al.*, 2012, p.578). In addition, giving this extra attention was considered unethical by some (Kampelman, 2015) and could result in role conflict when patients remained on a study despite it not being what the patient wanted (Höglund *et al.*, 2010). Additional patient attention was also considered unrealistic in the “*real world*” (Lawton *et al.*, 2012, p.579). In addition, CRNs nurses admitted that they sometimes decided whether or not to include patients into a trial based on their own judgement (Cresswell and Gilmour, 2014; Höglund *et al.*, 2010; Loh *et al.*, 2002), such as when they felt the patient was unable to provide informed consent (Loh *et al.* 2002). Finally, if a trial’s devised treatment plan was one that they would not typically recommend in current standards of practice, CRNs felt they were in conflict over their expertise and their role (Lawton *et al.*, 2011).

## Discussion

The findings of this evidence synthesis highlight the many challenges of the clinical research nurse role. The isolation and role conflict experienced by CRNs highlighted in this synthesis is reported elsewhere (Purdom et al., 2017; Rickard et al., 2011; Smith et al., 2018). In addition, it is argued that CRNs are inadequately prepared for their role (Wilkes et al., 2012) and need more training (Flocke et al., 2017). Protected learning time to allow for personal development has been suggested as one solution to this (Hamer, 2017), as well as a research nurse residency (RNR) programme (Showalter et al., 2017). Specific education programmes have been developed in response to staff shortage of clinical research nurses, such as the clinical research nurse programme at the City of Hope National Medical Center in California (Herena et al., 2018). Introducing the clinical research nursing role to nursing education at undergraduate level with the use of supplementary practice placements with CRNs could also help nurses' understanding of the role (Hill, 2018). The importance of introducing clinical research nursing to nursing education is also emphasised by McCabe et al., (2019) who highlight that although the CRN is relevant for nurses at all levels, it is not addressed in most curricula. The importance of education on how trials are managed to ensure protocol adherence and integrity of the research is also called for (McCabe et al., 2019).

The CRN's central role of recruitment and consenting is also highlighted elsewhere, along with the lack of appreciation of research nurses within the workforce (Wilkes *et al.* 2012). As noted in the findings CRN's are expected to recruit participants and reach their targets, however gatekeeping can act as a barrier in undertaking their role effectively. In situations where the work of CRNs is viewed negatively, clinical nurses may disengage and consider the nurse's role as "*not real*" (Whitehouse and Smith,

2018, p.28). While CRNs have developed their professional profile, Hamer (2017) warns that further attention is required in improving the awareness of research nursing, such as working with the whole clinical team (Hamer 2017).

The care provided to patients on trials is driven by both clinical indications and the study requirements (Hastings *et al.*, 2012). However, CRNs steeped in their clinical expertise can experience tension in a clinical environment where the focus is not concerned with patient care but with identifying new and improved practices or treatments to apply to a large population group (Hyland and Clarke Moloney, 2016). Their advocate role can be stressful as evidenced in a large survey reporting that stressors experienced by CRNs (n=589) included the struggle in caring for the research study participants (Matsumoto *et al.*, 2012). In response to this, it is argued that there is a need for promoting the connection between high quality care and high-quality research (Hamer 2017).

While role conflicts can occur at any time during a study, they appear strongly during the informed consent process (Cantini and Ells, 2007; Cresswell and Gilmour 2014; Godsken et al., 2018; Hill and MacArthur 2006; Höglund et al. 2010). Research nurses' role conflicts and ethical dilemmas within the informed consent process include being asked to approach patients about a study at an inappropriate time, patients not reading the consent form due to their trust of healthcare professionals and patients not being fully informed of what is required in the study (Cantini and Ells 2007).

This evidence synthesis adds to an increasing understanding of the CRN role which until more recently, had not been given sufficient attention (Rickard and Roberts, 2008). While the CRN role now has more clarity (Caselgrandi et al. 2016), differences in the role internationally are evident. For instance, in Australia and New Zealand the

role often includes the nurse undertaking their own research alongside coordinating other studies and in America, the role has specialist nurse recognition (Whitehouse and Smith, 2018). The speciality practice of clinical trial nurse has been recognised by the American Nurses Association and IACRN (IACRN, 2016), and moves to promote this are being pursued in the UK, Ireland and Taiwan (Hill, 2018). In tandem with this, it is argued that nurse education programmes should better prepare students on what the CRN role involves and the importance of clinical research knowledge to nursing practice (Alsleben et al. 2018).

Of the summary statements (Table 3), only one was deemed moderate confidence. The main reason for downgrading was on issues of relevance in a number of studies where the sample included research staff who were not nurses.

This study has a number of limitations. Only studies published in the English language were included. In three studies, it was not indicated which verbatim accounts were provided by clinical research nurses among participants which included research coordinators without a nursing background (Davis et al., 2002; Loh et al., 2002; Mercieca-Beber et al., 2018). Nevertheless, it was decided not to exclude these studies because most of the participants in all three studies had a nursing background.

## **Conclusion**

This review has highlighted the many challenges faced by clinical research nurses and their need for education, especially in the role transition phase, where education should focus on the clinical research nurse's responsibilities in terms of trial integrity. The subthemes of 'lone ranger' and 'targets' have highlighted the importance of developing collaborative relationships with ward-based staff who are important

gatekeepers to patient recruitment. In addition, clinical research nurses experience isolation due to their perception of non-research nurses' lack of understanding for their role. Relationships with non-research nurses could be enhanced by ensuring that undergraduate nurses are offered opportunities for placements with clinical research nurses. In addition, the internal conflict experienced by clinical research nurses when they feel that the trial requirement is at odds with the patient's best interest highlights the need for ongoing support. This could be achieved by adopting clinical supervision models of support for clinical research nurses.

Further research is needed on non-research nurses' understanding of trials, recruitment to trials and the clinical research nurse's role in recruitment. A deeper understanding of this would help identify any misconceptions of the clinical research nurse's role. Further research is also needed on education for novice clinical research nurses and how education affects the success of research studies, its recruitment and management.

### **Relevance to clinical practice**

This review suggests that clinical research nurses experience isolation from non-research nurse colleagues. Introducing the role of clinical research nursing at undergraduate level could help nurses' understanding of the role. Education could also be broadened to the wider multidisciplinary team to promote clinical research and demonstrate its benefits to both patients and healthcare and may promote a deeper interest among non-research staff.

This review also has relevance for nurse managers. Building relationships between clinical research nurses and clinical staff is essential for the success of clinical



research and nurse managers are ideally placed to take a leadership role in bridging any relationship gaps.

Finally, this review has highlighted the need for ongoing support for clinical research nurses when a trial requirement is at odds with the patient's best interests. This support could be achieved with the introduction of clinical supervision model. **References**

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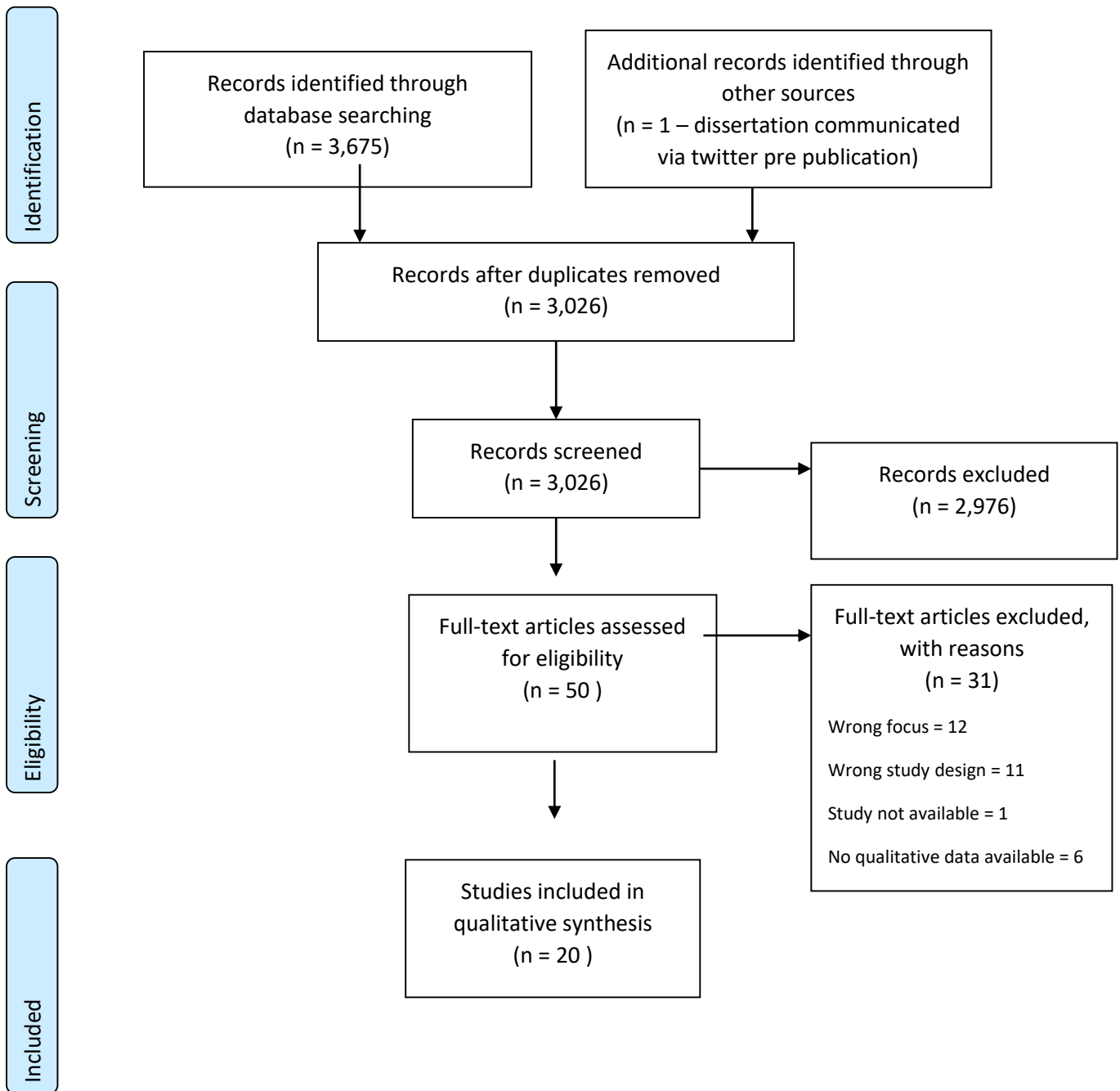
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**Table 1 Search Terms**

Search terms & Boolean operators (AND,OR).

<p>Clinical research nurs*  Clinical trial nurs*  Research nurs*</p>	<p>Experience  Role</p>	<p>Qualitative  Mixed methods  Focus groups*  Interview*  Observation*  Phenomen*  Grounded theor*  Ethnograph*  Lifeworld  Conversation analysis  Action research  Hermeneutic  Narrative  Content analysis  Colaizzi*  Heidegger  Van Manen  Merleu Ponty  Husserl  Questionnaire  Thematic  Descriptive  methodology  nominal group process</p>
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Figure 1 Prisma Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e100097. doi:10.1371/journal.pmed100097





**Table 2 Included studies**

Study No	Author(s) Country	Year	Design/ Method	Sample	Analysis	Study Focus	Methodological Quality CASP (10)
1	Cresswell and Gilmour New Zealand	2014	Qualitative descriptive. Semi-structured interviewing	N = 3 Clinical Research Nurses.	Thematic Analysis Approach	To explore the role of the clinical research nurse in the process of informed consent	9
2	Davis <i>et al.</i> US	2002	Qualitative descriptive. Focus groups using vignettes	N = 45 participants (of which 68% had nursing backgrounds) (n=30)	Transcript coding	To determine the extent to which study coordinators in clinical research shape the ethical conduct of clinical research and how their multiple roles protect study participants.	9
3	Hill UK	2018	Interpretative phenomenological analysis Semi-structured interviewing	N=10 clinical research nurses.	Interpretative phenomenological analysis	To explore how clinical research nurses make sense of their relationships with clinical nurses	10
4	Hill and MacArthur UK	2006	Mixed methods Questionnaire and focus group interviews	N=16 research nurses	Not described	To explore a range of professional issues facing research nurses	5
5	Höglund <i>et al.</i> Sweden	2010	Qualitative descriptive. In-depth interviewing	N=6 clinical research nurses	Inductive analysis	To describe and explore ethical dilemmas experienced by clinical research nurses	9
6	Kampelman US	2015	Qualitative descriptive. Interviewing using open questions guided by seven competency areas on nurse competency scale	N=11 clinical research nurses	Contextual analysis	To obtain an understanding of how clinical research nurses perceive their competence.	10
7	Kunhunny and Salmon UK	2017	Qualitative descriptive. Semi-structured interviewing	N=11 clinical research nurses	Thematic analysis	To explore the perspectives of clinical research nurses on their professional role identity	10

8	Kyte et al. (2013) UK	2013	Qualitative descriptive. Semi-structured interviewing	N = 16 clinical research nurses (study also included 10 trialists)	Iterative content analysis drawing on principles of grounded theory	To explore the experiences and views of clinical research nurses and clinical trialists of collecting and entering Health-related quality of life data.	9
9	Larkin et al., US	2019	Qualitative descriptive. Semi-structured interviewing	N=12 clinical research nurses	Content analysis	To describe the ethical challenges experiences by clinical research nurses	10
10	Lawton et al 2011 UK	2011	Qualitative descriptive. Interviewing informed by topic guides	N=12 research nurses (study also included 9 physicians & 45 patients)	Informed by principles of grounded theory	To understand why there was limited achievement of a trial target for glycaemic control.	9
11	Lawton et al 2012 UK	2012	As above	As above but only the research nurses and physician findings reported	As above	To explore research nurses' experiences of trial participation and trial delivery from inception to closeout.	9
12	Loh et al. Australia	2002	Qualitative descriptive Focus group interviewing (x3)	N=21 Data managers (14 had previously trained as nurses; 7 held social science qualifications)	Constant comparison method	To explore the views of data managers concerning the challenges, and rewards of the role. Also the similarities and differences between their role and the role of physicians in obtaining informed consent was explored.	8
13	Mackle & Nelson NZ	2018	Qualitative descriptive. Semi-structured interviewing	N=11 research nurses (Sample also included N=6 principle investigators; N=6 nurse managers)	Content and thematic analysis	To describe the role and responsibilities of ICU research nurses	10
14	Mercieca-Bebber et al.	2018	Qualitative descriptive. Semi-structured interviewing	N=20 trial coordinators	Content analysis	To explore cancer trial coordinators' roles and challenges in administering	9

	Australia			(12 of these had nursing background; 4 had science/research background; 4 had both)		patient reported outcome questionnaires & establish any specific training needed	
15	Resnick et al. US	2003	Descriptive qualitative Diary/journal	N=8 research nurses	Content analysis	To explore research nurses' experiences of recruiting older women after hip fracture into exercise intervention studies	8
16	Rickard et al. Australia	2011	Mixed methods. Online survey and semi-structured interviewing	N=10 nurses working in research positions (1 physiotherapist also in the sample)	Modified Colaizzi's phenomenological method	To explore experiences of nurses employed in research positions regarding organisational structures and support for research career pathways.	10
17	Schlichting US	2916	Qualitative descriptive. Semi-structured interviewing	N=11 Research nurse coordinators	Lincoln and Guba analysis process	To obtain understanding of how research nurse coordinators perceive their role and if they experience any ethical dilemmas in their role.	10
18	Spilsbury et al. 2008 UK	2008	Qualitative descriptive Focus group interview (x1)	N=9 Clinical research nurses	Thematic content analysis	To explore the experience of being a clinical research nurse and experiences reacted to nursing-specific topics in clinical trials	9
19	Tinkler et al. UK	2018	Qualitative descriptive Focus group interviews (x4)	N=19 Clinical research nurses	Thematic analysis	To explore the experiences of clinical research nurses and highlight factors that may have an effect on a successful study delivery.	10
20	Zucchelli et al. UK	2018	Qualitative descriptive Semi-structured interviewing	N=12 Clinical research nurses	Thematic analysis	To examine clinical research nurses' experiences in recruitment in a large specialist care-based cohort study	9

**Table 4: CERQual**

Review Finding	Supporting Quotes	Studies contributing to the review findings	Confidence in evidence
<b>IDENTITY</b>	<p><i>“There was a lecture here at the hospital that covered questions on informed consent and some ethics... and we, the nurses, wanted to attend. But the PI said that ‘that’s not necessary’... ‘you don’t have to think about that.’” (Höglund et al. 2010; p.246)</i></p>	5-7, 8, 19	<b>High confidence</b>
<p><b><i>New Identity</i></b> On commencement of their new role, research nurses experience role transition and a need for training in this transition to their ‘new identity’.</p>	<p><i>“I think there could have been so much more teaching. I think you need some type of educational classroom where you can sit down and talk about what this research is, what are you doing, and what is important, how do you go about this, why and how. None of that is explained, and I am still learning...I still have so many questions.” (Kampelman 2015; p.65)</i></p> <p><i>“Unless you get good support and training, role transition is a big challenge. You don’t know anything when you start” (Kunhunny and Salmon 2017; p.5128)</i></p> <p><i>“All that the nurses have got really is the protocol, which is... it’s more for the PI [Principle Investigator], basically, because it’s so in-depth... and there’s the patient information sheet which is a whittled down version of the protocol. And there’s nothing really in between... for the nurses. There’s no [specific] guidance for us... So I think something in the middle would be nice.” (Kyte et al. 2013; p. e76625)</i></p> <p><i>“I didn’t think it would be so hard to adapt, because normally... I’m very used to changing jobs, there’s always the basics that you take with you and I’ve found the first couple of weeks were fine because you expect to be a fish out of water don’t you, but like week 3 woo hoo, still a fish out of water, week 6..... I think, when you go into another nursing role and you change specialties, I think 60% of the job is still the same and then you’ve got a learning curve, whereas with this, no it isn’t, it isn’t” (Tinkler et al. 2018; p.322)</i></p>		<p>Five studies with no concerns about coherence, adequacy or methodological limitations. One study with minor concerns about relevance (8)</p>

### **Lone Ranger**

Research nurses believe that many nursing colleagues do not understand their role. Their new role requires them to work independently which is a significant change from their previous role as part of the ward team.

*"The research nurses used Medtech, the practice management system, but they had to find times to go in and not be in anyone's way and all that and try and be invisible and not trip over anyone."* (Cresswell and Gilmour 2014; p.22)

*"I kind of arrived and no-body knew...Who is this person? And 'What is her role?', 'What are her responsibilities?'. 'She just seems to be swanning about not doing very much'. Emm...and that has been difficult"* (Hill, 2018, p.54)

*"I think they think [nurses] that we are not really busy and we don't do much, or we don't have the stress they have. We don't have the stress they have, but we do have a different stress or workload to manage"* (Hill, 2018, p.100)

*'Ward nurses think we have cushy, Monday to Friday, nine to five jobs and they don't realise that you are in at one in the morning doing blood samples or something and you know. I don't think that you get an awful lot of sympathy'* (Hill and MacArthur 2006; p.44)

*"There is too little information about our work and we have asked for more. They have to understand what we do and we have to show our work."* (Höglund et al. 2010; p. 246)

*"They (non-research staff) haven't got any idea what our responsibilities are or even what our job description is* (Kunhunny and Salmon 2017; p.5128)

*"We are really built to work independently, we are pretty much self-contained... I probably have been in situations where there is more help there than I realize, (but) we just have learned to do A to Z all by our self. "* (Schlichting 2016; p.55)

*Being on my own, and as [names CRN7] said, being autonomous. I've got to make these decisions myself, I've got nobody else to – I mean yeah you have other people around you, but the fear of failure too. The fear that you're not going to match up to the job, you know, that you've been put in post to do. (Spilsbury et al. 2008; p. 552)*

*"I do remember one nurse at x and, erm, someone off another ward, said I don't know what you doing here, you know cos I'd just changed jobs and I said oh I'm the research nurse, they said oh right, right and that nurse said "that's not a proper job"* (Tinkler et al. 2018; p. 324)

1, 3-5, 7, 17-19

### **High Confidence**

Eight studies with no concerns about relevance, coherence or adequacy. Seven studies with no methodologic limitations. One study with moderate concerns about methodologic limitations (4)

**MEETING TARGETS.**

**Gatekeepers**

Research nurses need to recruit patients to trials and acknowledge the role of gatekeepers in that process. Recruiting patients into research studies can be met with obstacles when liaising with clinical, non-research personnel. However, their assistance can also be very positive to the recruitment process if effective relationships exist.

*“So instead of accessing the list of clients the case manager had that day, which would have been easy ... we had to go with this process which was a bit slower, and develop rapport with these people (the case workers).” (Cresswell and Gilmour 2014; p.21)*

*“There are still some people that you DREAD having to go and speak to. So, we had a patient a couple of days ago...it was this one particular person [a nurse], who I knew is going to be not very happy about it...you still dread it, you have to psych yourself up for going into the office to tell them. Even though her manager, everybody under the sun is completely happy with it, it doesn't matter you know you are going to get the “Scough [derisory noise]” (Hill, 2018, 56).*

*“Sometimes the nurses are a bit gate-keepery. When you say that you are going to see that patient, they are like ‘Oh, I know, but they are really sick’ it's like ‘yeah, I know. Is there a reason why I cannot approach them or their relatives about it?’ ‘Yeah, they are really sick” (Hill 2018, p.59)*

*“I always talk to them, [nurses] because they are just as important to our success of being able to conduct research as the doctors” (Hill, 2018, p. 64)*

*“if you are working against each other then it becomes a problem ....because they would actually sometimes give an impression to the patient that studies are not a good thing, it's as if they own the patients and they would try and prevent the research nurse from talking to this patient about this new study (Kunhunny and Salmon 2017; p.5129)*

*“one or two (senior doctors) here who are quite obstructive and always don't want the patients in the trials) (Mackle and Nelson 2018; p.5)*

*There was times when we felt that we had to support each other by going together [on to the wards]. We didn't really need each other for any other reason than to hold each other up! It's your turn to stand in front this time! [Laughter in the group]. (Spilsbury et al. 2008; p. 553)*

*“I do find it very helpful to have a handover from the nurse specialists so that I have a heads-up about who can or can't be recruited...” “If I want to know anything about a patient, [the clinical team] are very good at letting me know” (Zucchelli et al. 2018; p. e793)*

1, 3, 7, 13, 18, 20

**High Confidence –**

Six studies with no concerns about methodological limitations, relevance, coherence and adequacy.

## Targets

The target of recruited patients is of high priority of principal investigators. Research nurses can feel pressure to reach set targets and may find themselves going against their principles to achieve targets.

*"I know people who've said they've felt under pressure to consent people. I personally haven't found that but I can imagine that you might if you were part of a study where recruiting was really difficult. There would be a temptation to consent people not as rigorously as you might because you might feel you know desperate to have this person as part of your study."* (Cresswell and Gilmour 2014; p.23)

*"[...] we know that with one study we need to recruit 15 subjects to generate 1 years' salary surplus, but you are always on tenterhooks"* (Hill, 2018, p.65)

*"We might say: 'This doesn't feel right.' And then the doctor says that 'we take them, because they fit [the requirements for inclusion].' And we should just go and be some sort of help!"* (Höglund et al. 2010; p.245)

*We're told constantly... recruit, recruit, recruit... and for commercial trials you have to hit your targets... [but] you build up that very close relationship with people and yeah, it's... they are patients first."* (Kyte et al. 2013; p. e76625)

*"The first impression you make on the prospective participant is vital to the success of recruitment. Factors include: your appearance, your preparedness, and your personality and methods. Have all the necessary papers, pencils, cue cards, brochure, and forms readily at hand. Be ready to "sell" the study. Identify yourself and the project.* (Resnick et al. 2003; p. 272)

*I just felt sometimes I couldn't account for my day's work. And I knew that I was, sort of, wasn't skiving. I was doing my best. If I wasn't recruiting patients it was for a good reason. But sometimes to know that X centre had recruited however many patients was a little bit unhelpful to me.* (Spilsbury et al. 2008; p. 553)

*"See you have people telling you and you know yourself that it should be informed consent, the patient should go into it willingly and then you have other people saying but then on the other hand you've gotta get x amount of patients in"* (Tinkler et al. 2018; p. 323)

*"I have to juggle my hours around, my days around really, to fit in with clinics and op days...[clinics] do get changed... so I try to be flexible... you kind of fit in with everyone else"* (Zucchelli et al. 2018; p. e791)

1, 3, 5, 8, 15,  
18, 19, 20

## High Confidence

Eight studies with no concern on adequacy and coherence. Seven studies with no concerns about methodologic limitations and relevance. One study with moderate concerns about methodological limitations (15). One study with minor concern about relevance (8)



**PATIENT  
ADVOCATE**

**Duty of Care**

Research nurses believe they are a patient advocate even after the trial ends.

*“Commitment... to provide them with adequate support and assessment throughout the research so even though you might think, “Oh this patient is ringing me about their cold or something”. You still have to be their advocate or support them through whatever that [phone] call is because that is part of the research ” (Cresswell and Gilmour 2014; p.23)*

*“...because the patients “look to you as an advocate for them .... They [easily conclude that] you're recommending [what they should do].” (Davis, et al. 2002; pp.415-416)*

*“Your patient is key. Clinical needs always come first” (Hill, 2018, p.50).*

*OK, the research is very important. It is urgent to find new medicines and methods, but... not at the expense of the patients... The patient must always come first. Then, of course, you can feel that it is an important project you're working in, but I think we have an important role there... being on the patient's side.” (Höglund et al. 2010; p. 245)*

*“...because you (consultant PI) had not given all the information, I have actually given them (patient) what you might have left out”; I found that the consultant was not happy but obviously I had to be the advocate for this patient”. (Kunhunny and Salmon 2017; 5129)*

*“You have duty of care to that patient... Let other people worry about the massive numbers and the quality of the data... Your duty of care is there and then to that patient.” (Kyte et al. 2013; p. e76625)*

*Patient advocacy and protection in the study. That's my role, making sure things are done right for the patients. You know, the study's important,...but the patients are primary.” (Larkin et al. 2019; p.179)*

*...The information sheet...it's not in a format that's really patient friendly. Our role tends to be taking the information from the information sheet and putting it in friendly language. We tend to see the trial processes and inconveniences from the patients' point of view. Once they're confronted with the practical aspects, they may not choose the trial, although they may have said yes after seeing the doctor. (Loh et al. 2002; p.2417)*

1-3, 5, 7, 8,  
9, 12, 16,  
17,19,

**High Confidence –**

Eleven studies with no concerns on coherence and adequacy.  
Nine studies with no concerns about methodologic limitations.  
Eight studies with no concerns about relevance.  
One study with minor concerns about methodological limitations (12).  
One study with minor concerns about relevance (8).  
One study with moderate concerns about relevance (12).

*"[as a nurse] you are always on the lookout for something better, a better process of doing something or better at making your clients ride through life better and making their health better or whatever it is .... Research is the big step further"* (Rickard et al. 2011; p.170)

*"I take my role as an advocate very strongly and I think that my role as an advocate for the patient actually trumps everything. Um, and yes they [are] on a protocol and that is very important, but their safety trumps everything and so if there was something that was happening and they were on a protocol and I felt like they were being compromised or they were unsafe, that is something I would bring to the attention of the PI or the attending physician. I wouldn't let the protocol dictate necessarily what was happening to the patient if I didn't feel it was in the best interest of the patient."* (Schlichting 2016; p.68)

*"I've actually come away from being with a coinvestigator or PI or whatever and said to the person you do realise that it's your choice, that it's your choice to go into this study and you don't have to because of exactly what you've just said there, because I think they do sometimes feel a little bit under pressure, the doctor knows best type of thing"* (Tinkler et al. 2018; p. 323)

**Role Conflict**

Research nurses sometimes experience an internal conflict between what is right for the patient and what is required in the trial.

*"It's more of a holistic judgment really based on the patient's condition, and the family and what's gone on already ... so even if there's a [low risk] study you could consent for, maybe you wouldn't."* (Cresswell and Gilmour 2014; p.22)

*"I have great nurses working for me and [sometimes] I could pull my hair out because I can't get them in the research mode"* (Davis et al. 2002; p.414) – [referring to nurse study coordinators who had issues with protocols that deviated from the standard of care].

*"It's not just going to be what would get past an ethics committee, or not, it's what you consider would be unreasonable to ask a real person rather than a scientific subject to be put through"* (Hill and MacArthur 2006; p. 45)

*"It can sometimes be difficult when you see that people don't feel alright; to keep on convincing them to stay in [the study] when it means a lot of extra work for them".* (Höglund et al. 2010; p.244)

1, 2, 4-6, 8-11, 12 14, 17, 19,

**Moderate Confidence**

Thirteen studies with no concern on adequacy and coherence. Eleven studies with no concerns on methodologic limitations. Nine studies with no concerns about relevance. One study with moderate concerns

*“So I think we try to make everyone happy, so they keep coming back to sign the consent to be in the study. We do a lot of scratching backs just to keep people happy because they are here because they are voluntary so you should do everything in their power to never want to make them leave. You make all the accommodations to persuade them to stay even when they want to go sometimes. It is not really ethical, but we do it.”* (Kampelman 2015; p.71)

*“You have got this ethical dilemma between the research and the, and the patient, but your patient always comes first, so there shouldn’t really be an ethical dilemma.”* (Kyte et al. 2013; p. e76625)

*I mean you’re moving the state of the science forward and I think that’s just really important and I think it’s different than when you work on a floor and you’re taking care of patients and you’re getting them to a point of wellness...I mean the needs of the many outweigh the needs of the few and I think in research you’re definitely dealing with the needs of the many.* (Larkin et al. 2019; p.180)

*“I think it’s difficult really because I’ve been doing it for x number of years and obviously was very comfortable with those particular insulins. And whether it be a fault of the protocol or the system or just my thinking, I don’t know, but it did make you stop and think, ‘well that just seems too much.’”* (Lawton et al. 2011; p.6)

*“I sometimes found myself in a bit of a dilemma where I think off trial, I wouldn’t be doing this [adhering to trial protocol]”* (Lawton et al. 2011, p.6)

*“They did get a lot of attention and they did get ruined (laughter). If they had anything, they got an ingrown toenail, I just put them straight on to the podiatrist. You know, they got very good attention and they liked that, and it kept them motivated”* (Lawton et al. 2012; p.578)

*The doctor can make the decision from the medical point of view whether he feels that the patient is eligible for that study, according to the study criteria. But I had a case...I straight away said: I don’t think this person’s appropriate. I didn’t believe that the patient could give informed consent...he’s not capable of signing a document and understanding what he is doing. To me, that showed how little she (the physician) really thought about the patient.* (Loh et al. 2002; p. 2417)

about  
methodological  
limitations (4).  
One study with  
minor concerns  
about  
methodological  
limitations (12).  
Two studies with  
moderate concerns  
about relevance (2,  
12). Two studies  
with minor  
concerns about  
relevance (8, 14)

*“Occasionally I've had such a patient, “Look, we're not going to do the questions today”, and a patient has surprised me and said, “No, that's ok, I'll do them” (Mercieca-Bebber et al. 2018)*

*“Because I won't, I will not coordinate a study that I do not believe in. If I feel it will harm a patient, and I have never worked for a PI who has taken (that kind of ) a study. I did more drug studies, and I had a really good PI, and he would not take a study that he thought was harmful to the patient in the long run.” (Schlichting 2016; p.61)*

*“And it was such a strain because I'm not a seller by nature and I was just pulling on jeans that I haven't got, so you know I'd be alright for the first half hour then you know I'd gradually start to weigh down. I think it was something about the quality of the interaction was not the nurse patient relationship that I was used to and I couldn't relate to it and, erm, you got turned down a lot, cos you're not used to being turned down as a nurse because you're used to being in a supportive role” (Tinkler et al. 2018; p. 323)*