Multiprofessional perceptions of clinical research delivery and Clinical Research Nursing: Exploring the interface between clinical service delivery and clinical research delivery in the NHS.

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Reflecting on this long, but exciting journey, a staggering number of people have influenced and supported me along the way. When asked to present my career to date for a number of aspiring researchers a few years ago, I depicted the experiences using the metaphor of a tree, with leaves that grew and fell, and the watering cans and sunshine that had enabled growth. Each of the leaves, watering cans and the sunshine had the face of key individuals who have supported me along the way. That metaphor stays with me today, and if every single person who had influenced or supported me in some way on this journey were part of that tree, it would likely be a Giant Redwood.

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GCM methodology may serve as an enabler to undertaking Critical Realist Research.

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DISSEMINATION

The early results of the Realist Synthesis detailed in chapter four of this thesis, were shared at the Royal College of Nursing, International Nursing Research Conference in 2019. The Visual Presentation with Expert Review (ViPER) session for which the work was accepted is discussed within the thesis. Reference is made to the utility of the ViPER as a stakeholder engagement session and informing the next steps in the empirical data collection.

The Realist Synthesis was published open access in 2022 as follows:

Tinkler, L., Robertson, S. and Tod, A. (2022) 'Multi-professional perceptions of clinical research delivery and the Clinical Research Nurse role: a realist review', Journal of Research in Nursing, 27(1-2), pp. 9-29.

The article is available at:
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The Empirical, GCM phase of this doctoral study was submitted and accepted as an oral abstract at the Royal College of Nursing International Nursing Conference which took place in September 2022. Unfortunately, due to unexpected illness, I was unable to deliver this presentation, however, the plan is to re-submit the abstract to the next conference for 2023.

Following an invitation, the early results of this work were tested and discussed with a range of Clinical Research Nurses and Clinical Nurses at a dedicated webinar hosted by the Oncology Nursing Society in partnership with Cancer Research UK in March 2022.

A methodological discussion paper is underway to propose a potential set of key principles to consider, when using GCM as an enabler in collecting data from a critical realist perspective. These potential principles result from the experience of combining both GCM and Critical Realism during this doctoral study. This paper is a collaboration with a methodological expert in GCM Dr Scott Rosas.

A further journal article will be prepared for submission during 2023, detailing the empirical data collection and results of this work.

LIST OF TABLES AND FIGURES

GLOSSARY/ABBREVIATIONS

NIHR	National Institute for Health and Care Research
NIHR-CRN	National Institute for Health and Care Research Clinical Research Network
GCM	Group Concept Mapping
CRNurse	Clinical Research Nurse
NHS	National Health Service
NMAHPs	Nurses, Midwives and Allied Health Professionals
IACRN	International Association of Clinical Research Nurses
UK	United Kingdom
CLRN	Comprehensive Local Research Network
HLOs	High Level Objectives (Targets set by the NIHR for Clinical Research Deliver in the NHS)
CTNQ	Clinical Trials Nursing Questionnaire
UKCRC	United Kingdom Clinical Research Collaboration
US	United States
AHP	Allied Health Professional
DHSC	Department of Health and Social Care
CMO	Context Mechanism Outcome
ViPER	Visual Presentation with Expert Review
RCN	Royal College of Nursing
EU	European Union
PIL	Participant Information Leaflet
CNO	Chief Nursing Officer (for NHS England)

DECLARATION

I, the author, confirm that the Thesis is my own work. I am aware of the University's Guidance on the Use of Unfair Means (www.sheffield.ac.uk/ssid/unfair-means). This work has not previously been presented for an award at this, or any other, university.

The Realist Synthesis outlined in chapter four of this thesis was published open access in March of 2022 as follows:

Tinkler, L., Robertson, S. and Tod, A. (2022) 'Multi-professional perceptions of clinical research delivery and the Clinical Research Nurse role: a realist review', Journal of Research in Nursing, 27(1-2), pp. 9-29.

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ABSTRACT

Introduction & Background

Clinical research activity generates multiple health benefits. Resistance/avoidance at the interface between research delivery and clinical service delivery may affect the success of research. Little is known about how those practicing alongside, yet outwith clinical research teams, view research delivery and the Clinical Research Nurse role.

Methods

A realist review was undertaken to first generate theories about the interface between research delivery and clinical service delivery. A group concept mapping (GCM) phase then tested one such theory by asking Nurses, Midwives and AHPs outwith research teams about their role in relation to the delivery of research. Participants sorted views thematically before considering their likelihood of generating resistance/avoidance behaviours and importance to address.

Results

The realist review generated 13 programme theories, one of which was tested in the GCM phase. Participants responded to an open-ended statement, then sorted and rated the dataset. Analysis produced a set of visual maps. The final concept map contained 99 unique statements sorted into 6 conceptual clusters 1. “*We value & understand the importance of research”, 2. “How it should be & how we could work together”, 3.* “Behaviours, beliefs & missed opportunities”, 4. “*Dissonance & disengagement”, 5. “Time & capacity affects our ability to engage” and 6. “I keep thinking of ways to facilitate research as everyone’s business but it is hard”.*

Rating revealed three clusters most likely to generate resistance/avoidance behaviours (three, four and five), and two as most important to address (two and five).

Conclusion

A range of contextual factors are likely to generate resistance/avoidance behaviours. Eliciting the views of participants practicing outwith research delivery structures provided an opportunity for new perspectives to be heard. Participants expressed a desire for time to engage with research and increased opportunities for those outside of clinical research delivery to be involved with supporting studies. Improved communication between clinical research delivery teams and clinical service delivery was considered pivotal to the success of research.

CHAPTER 1. INTRODUCTION

"As for the future, your task is not to foresee it, but to enable it."

Antoine de Saint Exupery

1.0 Introduction

This introductory chapter sets out a theoretical frame for the doctoral research presented within this thesis. The chapter commences by introducing the chosen focus of the research, which broadly relates to the delivery of clinical research in the NHS. The specific focus is on the Clinical Research Nurse (CRNurse) role, with an emphasis on relationships between the CRNurse and clinical colleagues who practice outwith research structures.

A brief background will situate the research delivery landscape within the current context of a global pandemic, whilst providing concise evidence of its fundamental position within the NHS. The challenges of delivering research in the current healthcare system will be briefly analysed. The CRNurse role as an intervention will be introduced and the benefits of implementing such roles to address challenges with recruitment to research will be analysed.

This initial chapter will go on to defend personal and professional motivations for undertaking the doctoral research, providing evidence of the need for the research. The intended aims and objectives of the doctoral research will be set out alongside an outline of the subsequent thesis chapters.

1.1 Background

The focus of this doctoral work was on uncovering the personal beliefs and perceptions of Nurses, Midwives and AHPs (NMAHPs) who are not involved in the delivery of clinical research, yet may work alongside teams who deliver clinical research in the NHS. The specific beliefs and perceptions explored related to the delivery of clinical research and the CRNurse role in the NHS. This research is an important next step for the evidence base, not previously evidenced within the published literature. By exploring such views, it was possible to then identify those with the potential to impact positively or negatively on professional relationships between CRNurses and colleagues outwith research structures.

Fundamental gaps are present within the existing evidence base, and contemporary literature provides data to build a case for exploring these views (Hill, 2018; Hernon *et al* 2020; McNiven *et al* 2021). The views of these individuals in relation to research delivery, have provided important insights into what generates avoidance and resistance behaviours reported to be present at the interface between research delivery and clinical service delivery. Such behaviours impact negatively on CRNurses morale, job satisfaction and ability to successfully deliver research (Tinkler, *et al* 2018; Tinkler and Robinson, 2020; Hernon, *et al* 2020).

The global response to the novel Coronavirus COVID-19 brought into sharp focus the unquestionable value of research activity in enabling early diagnosis, improving treatments and outcomes, hastening recovery, preventing ill-health and reducing mortality. Research has remained central to the international response to the COVID-19 pandemic, from the pursuit of viable treatment options, (RECOVERY Collaborative Group *et al* 2020), to the efforts in developing and rolling out vaccines in record-breaking timeframes (Lopez *et al* 2021), to generating data to support daily government decision making on lockdowns, facial-mask wearing, and social distancing (Scientific Advisory Group for Emergencies, 2020-2022).

Research activity has been constant in the United Kingdom (UK) National Health Service (NHS) since its inception in 1948. Research has led to the confirmation of links between smoking and cancer, surgical discoveries and advances in genetics that have improved the lives of millions of people, preventing ill-health, prolonging life, and eradicating diseases (NHS England, 2013; NHS England, 2017). Research is also fundamental to the UK economy, providing employment opportunities and contributing to a vibrant life sciences sector (Department of Health, 2017; NHS England, 2019).

The power and importance of research is further illustrated via increasing associations evidenced between individual and healthcare organisation engagement in research, and improved healthcare performance (Boaz *et al* 2015). There is also evidence to support the view that research active organisations have lower mortality rates and improved Care Quality Commission ratings (Ozdemir *et al* 2015; Jonker and Fisher, 2018). Encouraging messaging about the impact and importance of research is espoused, alongside the publication of numerous national strategies, statutory guidance, and a fundamental acknowledgement across clinical and medical professions that practice should be based on sound evidence (Health and Care Professions Council, 2016; Nursing and Midwifery Council, 2018; General Medical Council, 2020). Yet delivering research in the NHS is acknowledged as less than straightforward. Many challenges are evident in implementing complex clinical trials in an NHS at the height of a workforce crisis, with ever stretched funding demands. The challenges of delivering research in today's NHS will now be explored.

1.2 The challenges of delivering research in the NHS

Despite the collective strength of evidence, positive messaging and careful strategising, numerous complexities remain evident in the successful delivery of research in the NHS. Many research studies fail to recruit and retain the target number of participants required to enable the original research question to be answered in a timely fashion (Donovan *et al* 2014; Adams, Caffrey and McKevitt, 2015; Skea, Treweek and Gillies, 2017; Kearney *et al* 2018; Gardner, 2018; National Institute for Health Research, 2022).

As a result, research into clinical research recruitment and retention is now commonplace. Such activity has led to the development of a dedicated database of recruitment research to support the selection of recruitment strategies for clinical research (Kearney *et al* 2018). Additionally, the Trialforge initiative was developed to improve the efficiency of clinical research through increasing the evidence base for decision making in the design and delivery of studies (Treweek *et al* 2015).

The majority of research on research focuses on the practicalities of study delivery, adopting a positivist approach to measuring the impact of discrete interventions and their outcomes on improving study efficiency. Seeking to achieve marginal gains (Treweek *et al* 2018), optimising recruiter training in relation to equipoise, and introducing study participation during treatment discussions (Mills *et al* 2018; Donovan *et al.*, 2016), has led to a greater awareness of the complexities of study recruitment. Evidence suggests that such interventions have led to improvements (Rooshenas *et al* 2018; Mills *et al* 2018; Treweek *et al* 2018). However, national data indicate that research studies continue to fall short of achieving their recruitment targets (National Institute for Health Research, 2022). According to NIHR data presenting activity over the last six years, the highest percentage of studies successfully recruiting to time and target in any single quarter was 60.1% (Quarter 2 2019-20) and the lowest was 51.4% (Quarter 1 2021-22). This indicates that a significant gap remains in the efficacy of interventions to improve recruitment to research.

The success of research, from the generation of an initial idea, to dissemination and adoption, relies fundamentally upon shared purpose, strong collaboration and effective communication between all stakeholders at every stage (van der Graaf *et al* 2021). The central activity of delivering the research at a site, identified by Tramm *et al* (2013) as a complex intervention, requires a robust, multidisciplinary approach (McCabe and Ness, 2021). Effective communication between the wide range of departments and teams, essential in facilitating a study, is vital to ensuring patient safety and the rigour of the data collected to answer the research question (Zucchelli *et al* 2018; McCabe and Ness, 2021). All individuals involved should be appropriately trained and have a clear understanding of their role and responsibilities, including those of others in the research team. The Clinical Research Nurse (CRNurse) role is one such role widely accepted as pivotal to the facilitation of research at the delivery stage. The CRNurse role has been recognised as a successful intervention in improving the recruitment and retention of research participants; yet evidence also suggests it is poorly understood outside of clinical research team structures. The CRNurse role is subject to a range of challenges with the potential to affect those practicing within such roles, both personally and professionally. Specifically, challenges are apparent in relation to successfully delivering research and building effective relationships with key colleagues (Isaacman and Reynolds, 1996; Spilsbury, Petherick and Cullum, 2008; American Nurses Association, 2016; Brady, 2017).

The CRNurse role will be introduced and described in the following section of this chapter. Whilst chapter two will provide an in-depth exploration of role definitions and development both within England and beyond, the next section briefly introduces some of the complexities that may influence how the role is viewed by those outwith research structures.

1.3 The clinical research nurse role

The role of the CRNurse is specialised, complex and multifaceted, with a range of associated titles found in the international literature (Hernon *et al* 2020). The responsibilities of the CRNurse are broad and vary significantly between clinical and research team contexts. The CRNurse is often the first person a patient may encounter when being exposed to the possibilities of participating in clinical research. The CRNurse continues to provide care, interventions, follow up and support to patients along their clinical research journey (Hernon *et al* 2020).

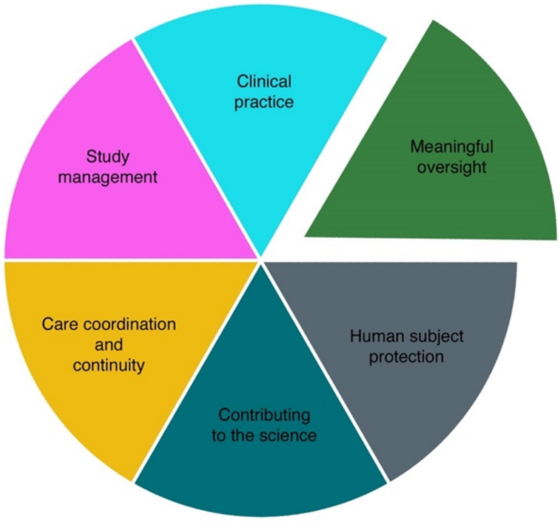
The lack of a unified and agreed definition of the role in the UK or internationally has added to historical difficulties in clearly defining the role. This has led to much debate for those within the area of practice and has added to the complexity of understanding the role for those outwith research structures.

Internationally, five domains of practice - originally developed and proposed by the National Institutes for Health (National Institutes of Health Clinical Center, 2010) and subsequently accepted by the International Association of Clinical Research Nurses (IACRN) (2012) and the American Nurses Association (2016) - provide a contemporary framework within which to define the CRNurse role. The five domains are as follows:

- Study management
- Clinical practice
- Human subject protection
- Contributing to the science
- Care coordination and continuity

Whitehouse and Smith (2018), further developed this framework in the UK and Ireland. Their work resulted in the addition of a sixth domain to include the meaningful oversight of the CRNurse. This sixth domain incorporated leadership, mentorship, and supervision by CRNurses with expertise in the specific domain of CRNursing (Figure 1.1).

Figure 1.1 Adapted domains of clinical research nursing practice (Whitehouse and Smith 2018)



Whilst there have been historical difficulties in mapping the size and composition of the CRNurse workforce, a unique national census, the first of its kind, undertaken during 2021 identified a minimum of 7469 CRNurses practicing across the UK and Ireland (Ford, 2022). These CRNurses self-identified as practicing in a range of contexts and settings, and a paper is underway to report the full findings. The CRNurse role and its implementation within the NHS, has evolved considerably over recent decades and now incorporates examples of advanced and consultant level practice (NHS England, 2021). This was reflected within the census as the NHS banding of CRNurse roles ranged from bands five to band nine.

The increasing number of blended research related roles exacerbates perceived complexity in relation to understanding the CRNurse role. The expansion of clinical academic roles, for example, has been a positive development in enabling CRNurses to lead their own research alongside delivering the research of others.

However, it is important in setting the scene for this work, that the activities of a CRNurse should not be confused with those of a nurse researcher. This confusion is common and has been debated in the literature over recent decades with CRNurses seeking to define their work and demonstrate how it differs to that of nurse researchers; yet confusion remains (Gordon, 2008; Johnson and Stevenson, 2010; Hardicre, 2013; Jones, 2015). A CRNurse's main focus is on balancing the delivery of a range of research study protocols (not led or developed by the CRNurse) with the care of patients participating in clinical research (American Nurses Association, 2016; Herena, Paguio and Pulone, 2018). The role of the nurse researcher in comparison, is based on the individual leading their own research, not that of others (thereby leading the development of study protocols), and the generation of new knowledge. This new knowledge is closely related to the progression of nursing theory, the nursing workforce, education or practice (Jones, 2015).

This brief introduction to the role has provided some early insight into complexities surrounding the role. Such complexity includes clearly defining the role and delineating it from other research activity present within nursing communities. These complexities are evident within CRNurse communities and remain the subject of much debate and exploration. It is therefore understandable that a perceived lack of understanding of the role exists in clinical teams who practice outside of, yet alongside, research delivery structures (Tinkler *et al* 2018; Tinkler and Robinson, 2020; Hernon *et al* 2020; McNiven *et al* 2021). The evidence briefly described thus far provides important motivators to explore potential factors that may lead to avoidance and resistance behaviours impacting on the CRNurse role. My personal and professional motivators for this study will be explored next.

1.4 Personal and professional motivations for the study

My personal and professional motivations towards undertaking this research originate from three sources. The first stems from my early experiences of delivering research as a CRNurse. I noted an increased level of emotional labour was required to navigate the complex and dynamic clinical contexts in which the role was required to operate. This brought about an awareness of the range of responses and behaviours displayed towards research activity in clinical settings. As I began to recognise a tacit sense of inconvenience of the CRNurse's presence in the clinical department, I began to question the extent to which the role is enabled to successfully deliver research, and the perceived effect on professional identity presented by the role (Tinkler *et al* 2018).

Secondly, there remains a lack of evidence in relation to what works well and what could work better (and in which contexts) in relation to the delivery of research by CRNurses. Little is known about how their interactions with colleagues outwith research delivery teams may affect the ultimate success of research in the NHS.

The evidence base related to the CRNurse role as an intervention to assist in the recruitment and retention of trial participants, indicates that a range of complexities impact the practice, perceptions, and experiences of CRNurses. These complexities appear to affect morale, job satisfaction, intention to remain in post and ultimately the ability of the CRNurse to successfully deliver research (Kunhunny and Salmon, 2017; Hill, 2018; Tinkler *et al* 2018; Tinkler and Robinson, 2020; Hernon, *et al* 2020).

Approaches to the implementation of the role appear to generate a range of behaviours at the interface between clinical research delivery and clinical service delivery. It is possible that this results from the role being situated liminally between clinical service delivery and pressures to facilitate research in order to meet constantly evolving healthcare needs (Stobbart, 2013).

Clinical research delivery is, in essence, a different facet of clinical service delivery. However, evidence suggests it is not always viewed in this way and a dichotomy between the two is apparent (van't Hoff and Selvaratam, 2018). Subsequently, behaviours displayed towards the CRNurse by colleagues outwith the research team are reported to vary broadly from acting in support of research delivery activities, to displaying gatekeeping behaviours and exhibiting resistance. Gatekeeping behaviours have the potential to jeopardise the success of research delivery (Hill, 2018; Tinkler *et al* 2018; Hernon, *et al* 2020; Tinkler and Robinson, 2020).

Increasing literature describes the work of CRNurses, the structure of research delivery in the NHS, and the experiences of CRNurses. A large proportion of this literature reports on how CRNurses think they are viewed by those outwith research teams. This literature describes the impact of a range of perceptions, experiences and behaviours on CRNurse practice. There is, however, minimal literature exploring how research delivery, and specifically the CRNurse role, is viewed by colleagues who are not involved in the delivery of research (Brown *et al* 2018; Alsleben, Alexander and Matthews, 2018; Aksoy *et al* 2018).

Thirdly, evidence generated from my own empirical research in the last decade, indicates that a range of intrinsic and extrinsic factors, could serve to mediate the success of research studies. Evidence ranges from individual beliefs and perceptions (micro level) to organisational and national leadership cultures (meso and macro level), with the CRNurse as a key conduit to this activity. Such evidence has been strengthened by informal dialogue with others in CRNurse roles, key stakeholders, funders and experts in the field (Tinkler *et al* 2018; Tinkler and Robinson, 2020; Hernon, *et al* 2020).

1.5 Aims and objectives

The overarching aim of this doctoral research study was to establish and analyse previously unexplored factors, perceived to generate behaviours by healthcare professionals in relation to the implementation of the CRNurse role in the NHS. The purpose was to identify what works, what could work better, and in which contexts, in relation to behaviours present at the interface between the CRNurse role (the delivery of clinical research) and clinical service delivery by healthcare professionals in the NHS. This work has specifically collected and explored the views of healthcare professionals practicing outside of, yet alongside, clinical research delivery structures in the NHS.

The views collected have enabled the exploration of unobservable structures - such as culture, perceptions of research delivery, attitudes towards research delivery, and the understanding/awareness of research delivery. These unobservable structures can be linked as causes of observable events, such as intentional or unintentional resistance or avoidance behaviours enacted at the interface between research delivery and clinical service delivery.

The chosen philosophical foundation on which this doctoral research methodology is based, critical realism, has been used to identify and explore:

a) a range of views from invited participants who practice outside of, yet alongside, clinical research delivery structures in the NHS

b) the perceived likelihood of these views in generating avoidance or resistance behaviours in relation to the delivery of clinical research by CRNurses

c) the perceived level of importance to address these views in practice

The intention of the study was to improve the job satisfaction and morale of CRNurses, benefit relationships at the interface between research delivery and clinical service delivery, and ultimately safeguard successful patient participation in research in the NHS.

The research was undertaken via two distinct, though linked phases: a realist review, and a group concept mapping study. The realist review was the first step in generating the theories to be tested in the empirical group concept mapping study phase. The views collected at both stages of the research enabled the exploration of unobservable structures, (culture; perceptions of research delivery; attitudes towards research delivery; understanding and awareness of research delivery) that cause observable events. Such events included intentional or unintentional resistance or avoidance behaviours, enacted at the interface between research delivery and clinical service delivery. Findings from the group concept mapping phase, informed by the realist review, were interpreted in partnership with participants to improve understanding of what works, what could work better and in which contexts in relation to behaviours present at the interface between the CRNurse role (the delivery of clinical research) and the delivery of clinical services by healthcare professionals in the NHS.

This doctoral study has enhanced the growing evidence base in relation to research delivery in the NHS, by assisting in identifying priorities and potential strategies that could improve the often-overlooked relationships that are integral to clinical research delivery.

This was achieved through the following overarching aims:

a) To understand how the Clinical Research Nurse role and research delivery is perceived by healthcare professionals operating outside of, yet alongside, clinical research teams within NHS organisations

b) To identify and characterise factors that may generate avoidance and resistance behaviours towards Clinical Research Nurses in healthcare professionals practicing at the interface between research delivery and clinical service delivery

c) To understand which factors are perceived as important to address by these healthcare professionals, in order to improve the relationships and interactions integral to successful clinical research delivery

d) To identify implications for future research to inform and improve practice

The specific objectives of this doctoral research were to:

a) Use an overarching theoretical proposition generated by the realist review, to form the basis of a focus prompt (open ended statement) which would enable the collection, sorting and rating of specific views from healthcare professionals operating outside of clinical research teams, on clinical research delivery within NHS organisations

b) Where possible, seek out rival theories through the group concept mapping work, by enabling participant interpretation of findings and exploration of participant views on how the findings correlate or contrast with the identified theories and their experiences in clinical service delivery

The intentions of this work were to further the discussion on how best to facilitate the delivery of research in the NHS; to contribute to balancing the evidence base and to promote effective integration of the CRNurse role within the broader activity of the NHS. This is important to maximise both benefits to patients and benefits to the research required to improve health and prevent ill-health. The benefit to patients would be increased opportunities to participate in research that is of relevance and value to their health (Department of Health, 2015). The benefit to the research landscape itself would be the increased timely and successful delivery of studies.

This introductory chapter has set out the broad theoretical frame for the doctoral research presented in this thesis, providing evidence of the need for this research.

A diagram illustrating the different stages of the research and setting out the flow of this thesis can be found in Appendix 1. The remaining chapters presented in this thesis will now be briefly introduced.

1.6 Thesis chapter summary

Chapter two builds on the introductions made in chapter one by providing an in-depth overview of what is known about the Clinical Research Nurse role. Building on this, an understanding of the barriers and facilitators that influence the potential integration of clinical research delivery will be discussed. Chapter two will draw on relevant international literature in addition to UK based research. The history of the National Institute for Health Research (NIHR) and England's NHS research delivery structures will be described. The chapter goes on to critique the broader and dynamic NHS context in which the clinical research nurse role operates, reflecting on the development of the role to set the scene for the doctoral research. This chapter then introduces key concepts related to the perceived barriers and facilitators to delivering research in the NHS and why these were important, to be further explored throughout the thesis.

Chapter three introduces the chosen philosophical foundations on which the doctoral research methodology was based. The chapter justifies this choice by exploring the history of critical realism followed by its relevance, suitability, and perceived value in exploring factors which may generate specific behaviours at the interface between research delivery (by clinical research nurses) and the provision of standard NHS services. The chapter then briefly introduces the two phases of the doctoral research which are a realist review and a group concept mapping study.

Chapter four presents the methodology and results of the realist review. It articulates the methodological approach which generated the theory subsequently selected for testing in the subsequent empirical study. This complex and iterative process is explained, drawing on relevant epistemological foundations and didactic training undertaken during the review. The chapter presents a critical analysis of the literature selected as part of the review and reports the thirteen theories generated. The chapter then explains the stakeholder engagement work undertaken during selection of the final theory and taken forward for testing in the resulting empirical study. The relevance and value of this methodological choice is debated and reflected upon in relation to its utility in providing the foundations of the empirical study.

Chapter five provides a detailed account of the work undertaken during the group concept mapping phase along with the results of each stage. This follows the sequential manner in which the data was collected, analysed and interpreted. The group concept mapping methodology is reported in detail, beginning with the planning work, and the process of developing and selecting the final focus prompt for use in early data collection. Next, sampling and recruitment activities are described, before explaining data collection activities undertaken at ideas generation. The chapter presents the raw data (statements) collected at ideas generation, then goes on to describe the subsequent steps of ideas synthesis, sorting, rating, analysis, and interpretation phases. This includes the eventual final, analysed dataset presented using a range of conceptual maps and matrices. The chapter then provides the subsequent interpretation of these results, forming a link to chapter six, where discussion takes place.

The utility of group concept mapping when implemented within a critical realist philosophy is discussed. The emergence of three potential guiding principles, identified during study conduct, are outlined, providing a unique methodological perspective and contribution to critical realist research and methods debate.

Chapter six presents what is now known as a result of the research undertaken, by comparing and contrasting this with what was previously known. The chapter provides a critical discussion of the findings shared in chapter five, making explicit links to relevant literature and to the realist review stage. The philosophical paradigm of critical realism continues to be applied as the backdrop to this discussion chapter. A range of recommendations are made, stating their relevance for practice. Critical reflections are offered, followed by a description of the perceived limitations noted across the doctoral work. This is achieved through a critique of the relevant study phases to elicit what went well, the potential limitations perceived, and what might have been done differently to optimise the results.

Chapter seven draws together the thesis, establishing clearly what has been revealed by the research in relation to the aims, objectives and theories set out in the early chapters. The chapter describes what has been achieved by undertaking this doctoral study, and how the research has progressed debate and discussion in this area. This chapter then offers further thoughts on what is the unique contribution to the philosophy in relation to the interface between the delivery of clinical research, specifically clinical research nursing in the NHS and standard of care clinical delivery.

1.7 Summary

In setting out the theoretical frame for the doctoral research presented in this thesis, I have introduced the focus of this research, which is behaviours present at the interface between clinical research delivery by CRNurses and clinical service delivery. This work specifically collects and explores the views of healthcare professionals practicing outside of, yet alongside, clinical research delivery structures in the NHS. I have explained my personal and professional motivations for undertaking the doctoral research, emphasised the need for the research, shared the intended aims and objectives and provided an outline of subsequent chapters.

The following chapter presents an in-depth overview of what is known about the Clinical Research Nurse role. Building on this further, a critique of the barriers and facilitators that influence the potential integration of clinical research delivery and the CRNurse role will be discussed.

CHAPTER 2. THE BACKGROUND AND CONTEXT OF CLINICAL RESEARCH NURSING

2.0 Introduction

In this chapter, the background, history, and evolution of clinical research delivery and the clinical research nurse (CRNurse) role in the NHS will be critically analysed. Historical evidence of the CRNurse role, the implementation of the National Institute for Health Research Clinical Research Network (NIHR-CRN) in 2006, and the resulting changes to England's NHS research delivery structures will be critiqued.

Clinical research delivery activity as we recognise it today was implemented in 2006 within existing NHS structures. This activity continues to be developed within those structures and is increasingly seen as core in health and care settings. Evidence will be presented of how broader NHS structures, strategies, and the historical development of the research landscape, have interacted over time to impact the implementation of the CRNurse role and the successful delivery of research. The evidence presented in this chapter, was in part located through a scoping review, which formed the first stage of the realist review detailed in chapter four. The remainder of the literature has been accumulated through pervious research, links with other individuals in the field and sharing of resources and evidence through networks and forums.

This doctoral work was undertaken and therefore framed within England's research delivery structures due to the uniqueness of the NIHR context. It follows therefore that the majority of the literature referenced is from a UK or English setting. Some relevant international literature is referenced in addition to UK based research however, providing points of comparison and contrast where appropriate.

This chapter continues to construct the case for research exploring the views of Nurses, Midwives and AHPs practicing outside of research structures. In pursuit of this, links will be drawn between the issues raised, the perceptions of CRNurses practicing within their roles, and their beliefs about how their work is viewed by colleagues outwith research structures. Personal reflection points, situated within separate text boxes, have been offered throughout the chapter, where felt to be relevant to the topic being discussed.

The chapter will begin by critiquing the evolution of clinical research and the CRNurse role.

2.1 The history of clinical research and evolving clinical research nurse roles

The evolution of clinical research can be traced as far back as studies of beans and pulses in biblical times (Bhatt, 2010). Perhaps the most widely recognised and earliest documented randomised controlled trial was conducted in 1747 by James Lind. Lind was a Scottish Doctor in the pursuit of an effective treatment for scurvy (Lind, 2004). Lind's name has since been adopted as the identity of a UK charitable foundation, whose activities are aimed at supporting the co-creation of research priorities through priority setting partnerships involving patients, the public, their carers, and the healthcare professionals involved in delivering related services.

Reflection point

The term 'delivery' itself was recently labelled as ambiguous during a peer review process of a paper I was lead author on (Tinkler and Robinson 2020), that addressed the CRNurse role. It led to a thought-provoking email debate with a journal editor about why I had selected and used the term in a paper submitted at the time. Whilst there was some acknowledgement that it had likely originated from National Institute for Health Research (NIHR) structures and appeared to be an accepted term within the research landscape, the journal editor was correct in their argument that it did not necessarily capture the essence of what the CRNurse did. We were unable to establish an alternative acceptable term, and the decision was therefore made to accept the term 'delivery', to ensure consistency in the paper.

That unexpected editorial debate generated reflection on how individuals may accept titles and descriptors handed down, and then unconsciously contribute to misperceptions both within and outwith research communities by adopting the use of such terms rather than challenging their relevance as time passes.

The use and relevance of terminology forms part of the inherent complexity in defining and discussing CRN roles. It is also a contributory factor to the difficulties in tracing how early accounts of CRNurse work evolved into the dedicated, expert roles we see today.

Whilst it is more straightforward to trace the origins of medical involvement in research, it is impossible to determine a definitive point in history when nursing as a profession became involved in supporting what is now described as the delivery of clinical research. The vague and somewhat debated history may provide further insight into the continued complexity and ambiguity related to the role of the CRNurse and the delivery of clinical research in the NHS.

According to the National Council for the professional development of Nurses and Midwives (2008), very minimal published literature dating back to the 1970s was found during numerous published searches of several well-known medical and nursing databases referred to in their report. For example, Rickard *et al* (2006) located around ten papers dating back to the early 1980s, increasing slowly to a little more than fifty during the 1990s. The nature of accessible early literature predominantly comprises personal opinion pieces and descriptive accounts. For example, Hunt (1983) described what may be one of the earliest documented accounts of the CRNurse role as that of "*Medical Research Assistants*", who were predominantly employed directly by Doctors using their own personal research funds to employ the Nurse.

Jordan (1990) demonstrated that little had progressed by the early 1990s. She identified CRNurse posts at that time as "*created in the hospital consultant's own image*", as individuals continued to be predominantly positioned in isolated academic units and employed directly by doctors who controlled their work. Both Hunt and Jordan's opinion pieces feel particularly negative in tone, with titles and sub-headings that suggested one should avoid such research delivery roles.

"Overworked, Underemployed."

> *"Maura Hunt discusses the plight of nurses who are medical research assistants. They are often employed by doctors who treat them as research "handmaidens" and are only given routine tasks to do, such as taking samples. They are refused admission to the established nursing research societies because they are not researching nursing, therefore they have no guidelines for employment conditions."*

(Hunt, 1983) pg. 37

"Look before you Leap"

> *"Sally Jordan explains why becoming a research nurse may not be the most advantageous career move – and warns that it is no route to glamour."*
>
> (Jordan, 1990) pg. 42

Hunt and Jordan may have intended to raise awareness of this important work and generate debate about how to better support and organise such roles. Indeed, Hunt suggested that these nurses were seen as experts by some. However, it seems fair to suggest that these pieces may have been more damaging than supportive to both clinical research nursing and wider clinical communities and would not have served to encourage nurses to consider a role in research delivery at the time.

These early insights into the CRNurse role did, however, provide a voice for airing dissatisfaction and seeking out change. Hunt and Jordan's papers described how CRNurses were perceived as exploited "handmaidens", afforded little autonomy, provided with limited training and had poor career development or progression opportunities.

These early versions of the CRNurse role were also described primarily as that of a heavily administrative data collector and processor, tasked with mastering various unfamiliar IT skills, whilst the clinical elements of the role remained limited to routine delegated duties such as taking blood pressures and collecting urine samples.

Willems and Gumbrell (1990), described the CRNurse role as one which was responsible for ensuring that the trial runs smoothly, with practical and administrative components, including regular patient contact throughout the trial. Willems and Gumbrell (1990) went on to identify additional perceived benefits of the CRNurse role as a point of contact and a resource for managing queries, from the 'drugs company' to patients and other nursing staff, including teaching nursing staff about study drugs.

Both Hunt and Jordan made the earliest recognisable references to an emerging complexity in relation to the professional identity of the CRNurse, who appeared to belong neither to nursing research communities nor clinical nursing communities. Hunt (1983) noted the refusal of the nursing research community to accept the CRNurse as one of their own because the role was not one devoted to researching nursing practice itself.

Both Hunt and Jordan also referred to the negative perceptions of nursing colleagues outside of research structures, mainly in the ward environments where the CRNurses were required to operate. These accounts made the earliest suggestions that the work of CRNurses was not perceived to be valued by those outside of clinical research structures. This may provide the initial evidence of avoidance and resistance behaviours, as clinical colleagues and senior nurses were described as setting the CRNurse apart from the clinical ward nurse, placing no value in the role and showing little or no interest in their work.

Hunt also referred to an ambiguity in relation to defining the role, which is still recognised today. She suggested difficulties in differentiating between clinical practice and research practice, the role of the nurse researcher and the role of the research nurse.

Published literature began to emerge, originating predominantly from outside of the UK. This continued to indicate that CRNurse roles were more likely to be positioned within academic units, working mainly in isolation with medical colleagues (Willems and Gumbrell, 1990; Isaacman and Reynolds, 1996; Sadler *et al*, 1999). Continued confusion was also articulated in relation to role and title disparities. CRNurses noticed a lack of acknowledgement by nursing colleagues outside of research concerning the contribution of the Research Nurse role in their field of practice (Raja-Jones, 2002).

A gradual increase in CRNurse related literature is evident from the early 2000s. Again, the majority of this literature was generated from outside of the UK. Kenkre and Foxcroft's (2001) article on career pathways in clinical research, positioned the role of the CRNurse as one which was exciting and full of promise. Their paper described a range of excellent and unique career development opportunities and advocated for pay commensurate with the specialist knowledge and skills required by the role. Around this time the first five Wellcome Trust Clinical Research Facilities were established. This provided a focus for CRNurse roles not seen previously. The inception of the National Institute for Health Research (NIHR) in 2006, however, led to a major a step change in how research was organised, planned, and delivered across the NHS in England. The direct impact of the NIHR on the evolution of CRNurse roles specifically has not been empirically explored. A range of narrative literature has emerged since 2006, however, providing personal accounts of contemporary CRNurse roles and their experiences. As the NIHR is now the major funder and influencer of many CRNurse roles in England, and this research is situated within a context influenced heavily by the NIHR, its development and function will be briefly explored next.

2.2 The National Institute for Health Research

The Government strategy Best Research for Best Health (Department of Health, 2006) represented an ambitious plan from the UK government to position the UK as the best in the world for health research, development, and innovation. The strategy was established in response to noted changes in society and the environment, whilst also responding to challenges noted in the system which were known to impede the set-up and conduct of research in the NHS (Department of Health, 2006). Around the same time, the government had commissioned a review of publicly funded Healthcare Research. The review reported that the UK health research and development landscape was seen as a significant strength. Combining this strength with a national health service provided a unique selling point, attracting investment from large pharmaceutical and biotech companies. However, the Cooksey report also advocated that much work was still required to ensure that publicly funded health research was carried out more efficiently and effectively, in addition to facilitating the rapid translation of research findings into improvements in public health (Cooksey, 2006).

Best Research for Best Health (Department of Health, 2006) ultimately led to the inception of the NIHR. The NIHR spends around £1 billion Department of Health funding per year and was set up to be the research arm of the NHS. The NIHR’s mission was, and is today, to improve the health and wealth of the nation through funding, supporting, and facilitating high quality research that is relevant to the health of the nation.

At its outset, two separate arms were established. First, the NIHR Academy, responsible for funding and supporting the attraction, training and development of the best clinical research leaders in their fields. Second the Clinical Research

Network (NIHR-CRN), whose role is to enable high-quality health and care research in England by meeting the costs of additional resources and support services. The NIHR-CRN's activities are designed to support health and care organisations, staff, patients and service users, to be research active (NIHR 2022 b). The NIHR Academy, will not be explored further here, as their work was not associated with the practical elements of set-up, support and delivery of clinical research. In recent years, however, they have begun to acknowledge the existence and needs of the thousands of staff involved in the delivery of clinical research, often generated and funded by the Academy, and are now exploring how they might act in support such roles; however, this is very much in its infancy with little evidence of progress available to date.

The NIHR-CRN established a portfolio of research at its inception; an approach to enable the transparent and equitable organisation and prioritisation of studies, to effectively allocate support and infrastructure. Studies would be eligible to be included in the portfolio if they met specific criteria. The first criterion was to be defined as research, the second was to have appropriate ethical approval and finally was to be fully funded according to certain criteria. Specifically, how the research was funded would also influence eligibility, for example via nationally competitive charitable funding, or through industry funded commercial trials.

To achieve their aims, the NIHR-CRN introduced and administered twenty-six Comprehensive Local Research Networks (CLRNs) mapped to regional geography across England. These regional networks provided dedicated and targeted funding for a range of research roles which were hosted within NHS trusts. They also provided infrastructure to enable the rapid set up and delivery of the portfolio of research across the NHS landscape.

Alongside funding and infrastructure, came a set of ambitious targets in the form of seven high level objectives (HLOs), which remain largely unchanged and form the foundation of the NIHR-CRN's strategy and direction today. The intention of these seven HLOs were to increase the number of people participating in clinical research studies and to improve the speed at which this was achieved.

The NIHR-CRN has continuously evaluated its performance and evolved in response. For example, in 2009 the School for Social Care Research was set up to recognise and fund research in social care settings, and in April 2014 a significant change to the NIHR-CRN's structure and approach was implemented (Williams, Layfield and Layton 2013). At this time, the NIHR-CRN was significantly refined to phase out the topic specific networks and instead transform them into six divisions focusing on 30 specialty themes to incorporate all health-related areas. These themes would be supported by fifteen Local Clinical Research Networks (LCRNs) with whom we work today. In April 2022 the NIHR changed its name to the National Institute for Health and Care Research, to acknowledge its commitment to social care research, though the Acronym itself was not changed (National Institute for Health Research, 2022c).

The initial formation of the NIHR in England ultimately led to an increase in the number of NHS organisations contributing to the delivery of research. Engagement in research was required and later monitored via a statutory duty placed upon NHS organisations to support the delivery of the Department of Health's research aspirations through the HLOs (Department of Health, 2012).

The rise in engagement led to an increase in the need for CRNurse roles as a key intervention in supporting and facilitating the safe delivery of research protocols and the care of patients participating in research studies. The structure of the NIHR funded workforce also meant that CRNurses themselves were better able to collectively acknowledge themselves as part of a wider CRNurse community, and as a potentially unique function in the nursing workforce. They were enabled to link across geography and landscape and began to contribute to the literature related to CRNurse roles. This created debate and discussion regarding the future of such roles and enabled CRNurses to advocate for training, development and acknowledgement outside of their unique structures as an integral element of the NHS pathway.

The next section explores the literature reporting on the CRNurse role since the implementation of the NIHR. However, the bulk of this literature does not refer to the NIHR and continues to be generated outside of England.

2.3 The continued evolution and development of the clinical research nurse role

As time progressed beyond the mid 2000s, two areas of focus began to form the body of emerging literature related to the CRNurse, the role of the CRNurse and professional issues associated with the role. The tone of this literature was noticeably more positive than the earlier papers of Hunt, Willems and Gumbrell, and Jordan. This newer literature suggested a move away from the CRNurse as a mere data collector and focused on integration within the clinical research study team, describing the CRNurse role as a key coordinator across studies (Green, 2011). This shift in tone could indicate that the CRNurse voice was strengthening, and the community were starting to feel more empowered to advocate for their personal and professional needs.

2.3.1 Delineating the clinical research nurse role from other nursing roles

Several papers were beginning to delineate the CRNurse role from other nursing roles. These mainly comprised narrative accounts or opinion pieces breaking the role down into task-based elements whilst also advocating for the implementation of CRNurse roles, and better support and development for such roles (Perry, 2007). These papers often also articulated the added value of the CRNurse in delivering research studies, yet frequently referred to a sense of CRNs feeling misunderstood by colleagues outside of clinical research structures (Gordon, 2008; Gibbs and Lowton, 2012).

These papers were mainly narrative in nature and generated by individuals or teams in a specific centre or disease specialty. They started to describe the value and positive impact of the CRNurse in contributing to the successful, safe, and ethically sound recruitment of participants into clinical research (Green, 2011; Hardicre 2013). This literature also often referred to recruitment to time and target; one of the key high-level objectives of the NIHR. The beneficial influence of the CRNurse role in achieving patient recruitment targets was noted, though discomfort with balancing their own views about a study with the pressure to approach patients to participate and achieve recruitment to time and target were also noted (Perry, 2007; Hastings *et al* 2012; Camsooksai *et al* 2013).

A range of empirical studies focusing on role delineation also emerged (Mori *et al* 2007; Nagel *et al* 2010; Catania *et al* 2012; Wilkes *et al*, 2012). Four studies, conducted in the US and Canada, Australia, and Italy, attempted to define the details of CRNurse roles and responsibilities by implementing the established and validated Clinical Trials Nursing Questionnaire (CTNQ), originally developed in the US (Ehrenberger and Lillington, 2004). The CTNQ incorporated 149 items across 12 sections to identify the presence, frequency and importance of nursing activities undertaken within the CRNurse role. The Italian and Australian based studies by Catania *et al* (2012) and Wilkes *et al* (2012) respectively, utilised a version of the tool adapted for use outside of the US. Whilst the tool was central to initial work outlining the various elements of the CRNurse role across a range of settings, criticisms of the tool suggested it was unnecessarily lengthy and elements of it were ambiguous in nature (Wilkes *et al* 2012).

In relation to the historical views about the CRNurse role and their position as handmaidens in medically focused contexts, in Wilkes *et al* (2012) study, recruitment was undertaken via emailing 350 medical professors, who were asked to forward the email invitation to CRNurses whom they employed. This approach to recruitment provides evidence of a lack of progression in some settings from a medically focused approach to employing CRNurses more generally. Potential limitations are also evident in this approach to sampling, as the research team's ability to reach all CRNurses, would undoubtedly have been affected by decisions and the potential gatekeeping actions of the medical professors contacted. Wilkes *et al's* study ultimately achieved 67 responses out of the 350 invitations. Whilst the author acknowledged this as a limitation, the sample size was highlighted as similar in number to other studies using the same tool. Results across the studies described here identified that CRNurses were seen to be responsible for the overarching coordination of clinical research studies and highlighted that the role incorporated all domains of the CTNQ.

These studies highlighted the number of job titles and descriptions, adding to confusion in relation to the responsibilities of the CRNurse (Purdom, Petersen and

Haas, 2017). In addition, Mori (2007) reported job satisfaction, effective communication and a sense of acceptance or support from clinical colleagues outside of the research team amongst participants in their US study. This is in contrast to the findings of Catania *et al* (2012) and Wilkes *et al* (2012) set in Italy and Australia. These studies described a sense of dissatisfaction experienced by CRNurses in how they were viewed. Both studies reported that CRNurses felt undervalued, underacknowledged, and poorly developed and advocated for better integration and increased role awareness.

Further work to delineate the role and discrete responsibilities of the CRNurse included international literature reviews and survey studies (Bell, 2009; Brinkman-Denney, 2013). The NIHR-CRN also later published narrative papers on their website, describing the role of the CRNurse ‘in their own words’ with the aim of attracting CRNurses into the role via various campaigns (National Institute for Health Research, 2016). One such campaign was aimed at individuals considering retirement. It attempted to offer them an alternative in the hope of retaining them in the nursing workforce. Whilst this was a laudable attempt to address workforce issues and avoid further losses to the nursing profession, it did little to help perceptions of the role. It suggested the CRNurse role was one which was attractive to those heading into retirement and looking for an easier working life (National Institute for Health Research, 2018).

Most of the literature described above had a focus on demonstrating the unique and fundamental contribution the CRNurse role makes to patient advocacy, safety, ethical decision making and protocol adherence, as expertise in the delivery of a range of studies developed.

In clarifying what exactly it is that a CRNurse does, Table 2.1 (Tinkler, Robertson and Tod, 2022), provides an outline of common tasks associated with the CRNurse role found to be present in a range of literature over recent years. However, this does not represent an exhaustive list and debates continue regarding core elements of the CRNurse role.

Table 2.1 Common elements of the clinical research nurse role

Attracting research to the organisation
Horizon scanning for opportunities and linking with regional network specialty groups
Supporting the identification and development of new Principal Investigators
Supporting expressions of interest
Leading the coordination of Site Selection Visits
Reviewing and amending schedule of events and other study documentation
Leading the delivery of research
Patient eligibility assessment
Patient approach, information sharing, discussion, advocacy, consent, and randomisation
Intervention delivery or coordination
Supporting PI with required documentation
Responding to and reporting of Adverse Events
Collection of samples as required
Coordination of couriers
Data collection from baseline through to follow up
Accurate recording of source documentation
Site File upkeep
Supporting and coordinating monitoring visits
Ensuring all staff are trained and logged within site file
Administration of study drug/investigational medicinal products
End of study activities
Study close down audits
Archiving

Defining the task-based elements of the CRNurse role in the published literature highlighted the relative infancy of the CRNurse workforce internationally. This subsequently created calls to recognise the practice of CRNurses as specialised, and advocated towards improved education, certification, and the establishment of a professional organisation to ensure high standards of practice (Mori *et al* 2007; Gordon, 2008; Nagel *et al* 2010; Hardicre, 2013).

In the UK, the first dedicated Competency Framework for Clinical Research Nurses was published in 2008 (Handley, 2011). This framework was heavily influenced by work led through an earlier Wellcome Trust CRF working group. The framework was viewed as a fundamental roadmap in detailing the knowledge, skills and competence required to perform in the CRNurse role. The competency framework was developed by a range of experts in research delivery and acknowledged significant developments in the research landscape resulting from the Research Governance Framework (2004) and Best Research for Best Health (2006). The implementation of the competency framework, for those who were employed in organisations adopting its use, symbolised a step change in how the role was considered and a recognition of the uniqueness of the CRNurse role. The framework provided governance and structure to support the appropriate training and development of professionals practicing in this clinical domain. The competency framework was updated in 2011, however no further updates are noted.

Since the introduction of the UK Competency Framework, two international competency frameworks have been published. Both were aimed at harmonising competencies for all professionals working in clinical research and were not unique or specific to supporting CRNurse training and development (Sonstein *et al* 2014; The Global Health Network, 2016).

Following the launch of the Joint Task Force (JTF) for Clinical Trials Competency document (Sonstein *et al* 2014), the NIHR promoted a similar version for all clinical research professionals. Indeed, the JTF website refers to this stating:

> *"National Health Service Clinical Research Network (UK) – implemented workforce development effort which aligned competencies for clinical research nurses to JTF Framework."*

(https://mrctcenter.org/clinical-trial-competency/framework/use-of-jtf-framework-2/#1559316675748-622929bd-f2da)

The statement suggests the existence of a unique competency framework for CRNurses, which was not the case. The link, points towards a generic ‘Future Learn’ course aimed at anyone with interest in finding out more about clinical research and not the competency framework referred to.

Reflection point

I remember attending a workshop, where the NIHR version of this framework was tested, I joined others around the tables in colouring in sections to identify domains of practice and levels of involvement with such domains. However, I have been unable to locate the document via online searches most recently, which suggests it is no longer being promoted as a valid tool. A number of informal conversations around the time of writing this chapter, however, suggested the original UK Competency Framework (RCN, 2011), remains in use today in many settings despite its age and potential lack of development alongside the role.

On further investigation, a number of other competency frameworks are in circulation. Some are similar to the original 2008 UK framework, others less so (NIHR Clinical Research Network East Midlands, 2019; UK Clinical Research Facility Network, 2020; Guys and St Thomas’, 2022). The research presented in this thesis does not seek to explore such frameworks as this work has been undertaken many times elsewhere. However, attempting to uncover a definitive framework or pathway in use to support the development of CRNurses across England proved extremely difficult. This provides further evidence of the complexity and variation in the implementation of CRNurse roles and a subsequent lack of understanding of them by those working outside of the field of clinical research.

2.3.2 Professional and practice issues associated with the clinical research nurse role

The second area emerging from the literature in the mid-2000s documents the increasing exploration of professional and practice issues for CRNurses, mainly in relation to the training, development, and career progression opportunities. Ledger *et al* (2008) carried out a piece of work in Sheffield, and later Showalter *et al* (2017) carried out similar work in the US. Both studies provided unique and context specific examples of the development and implementation of frameworks to address CRNurses' training needs. These frameworks incorporated dedicated governance structures, induction, and training programmes. The exploration of professional issues links closely to work on role delineation, and a proportion of this literature overlaps with discussions and comment about the core aspects of the CRNurse role and their experiences of being a CRNurse. Papers debating professional issues also continued to refer to difficulties experienced by CRNurses resulting from a lack of understanding about the role by colleagues outside of research structures (McArthur *et al* 2014).

This literature incorporated expert narrative reviews and opinion pieces discussing recent policy and strategy implementations. It also provided recommendations to ensure the skills and knowledge of the future CRNurse workforce were met (Coulson and Grange, 2012; Hastings *et al* 2012; McDermott *et al* 2013).

Training needs analysis to identify where education should be focused (Hardicre, 2013b), and comparative studies exploring the results of survey data collected over time (McArthur *et al* 2014), concluded that many CRNurses continued to feel isolated. It also identified that CRNurses required clearer and more flexible career structures, with a greater focus on approaches to induction, ongoing training, and continuous professional development.

Boulton and Beer (2018) carried out a mixed methods cross-sectional study aimed at providing better evidence on which to base future decisions about the clinical research delivery workforce. The study unexpectedly concluded that the diversity of the research delivery workforce was greater than had been previously reported and that many more non-clinical research delivery roles existed. Boulton and Beer (2018) went on to suggest this may increase even further due to a shortage of nurses and an increase in studies involving non-clinical interventions. Indeed, there has since been an increase in literature regarding diversity in clinical research delivery roles, including the rise of the Clinical Research Practitioner, defined in a recent paper by Faulkner-Gurstein *et al* (2019).

The importance of informed consent and its associated complexity was highlighted by Creswell and Gilmour (2014). In this qualitative paper, participants identified three key themes associated with achieving valid informed consent. These were ‘preparatory partnerships’, ‘partnering the participant’ and ‘partnership with the project’, highlighting the complexity of delivering a research study and the multiple relationships involved. The CRNurses’ extended role as a patient advocate, and in ensuring patient safety were also discussed in several papers (Choo *et al* 2012; Hyland and Clarke-Maloney, 2016; Beuser and Lawan, 2017; Zucchelli, 2017).

The array and scope of professional and ethical issues associated with the evolving CRNurse role were articulated and debated, again, mainly by CRNurses themselves, either individually or within specific research teams or organisations. This indicates a continuation of a positive shift in CRNurses recognising the value of their contribution, their collective voice in the research landscape, and a growing confidence to highlight both the role itself and associated challenges it brings.

Despite this growing literature during the 2000s, and the many positive developments potentially enabled by new funding and infrastructure in England, an agreed and standardised definition of the CRNurse role has yet to be reached. As a result, CRNurses continued to deliberate, whilst navigating the complexity of defining their own roles. This compounded difficulties in articulating their position, value, and unique contribution to other clinical colleagues. This subsequently perpetuated a continued ambiguity about who CRNurses were and what they did. The next section therefore explores role definitions and their potential contribution to ambiguity within and outwith research structures.

2.4 Complexity in defining the clinical research nurse role

The complexity highlighted by CRNurses in describing and defining themselves, their role, and the composition, geographical spread, and size of the CRNurse workforce, suggests that a significant lack of clarity exists for those outside of research delivery teams.

Clinical Research Nursing was defined by the UK Clinical Research Collaboration (UKCRC) in 2007 as:

> *“a nurse employed principally to undertake research within the clinical environment”*
>
> UKCRC (2007) pg. 32

This definition is less than clear and contributes to a lack of ability for those outside of research achieving an understanding of the CRNurse role. Describing the CRNurse as a nurse who *undertakes* research, risks conflation of the CRNurse role with that of a Nurse Researcher who also undertakes research, albeit their own, rather than supporting the delivery of research designed by another health professional.

The 2008 Irish Health Research Board report on the Role of the Nurse or Midwife in Medical-Led Clinical Research, by the National Council for the Professional Development of Nursing and Midwifery, highlighted role ambiguity, multiple job titles and the resulting confusion and lack of understanding of such roles. The report referred to a baseline survey carried out in 2006, which defined Clinical Research Nursing as:

> *“Nurses or Midwives involved in research for purposes other than Nursing or Midwifery.”*
>
> NCPD Nursing and Midwifery (National Council for the Professional Development of Nursing and Midwifery, 2008) pg. 6

This definition is slightly more helpful than that of the UKCRC, in that it attempts to clarify what the CRNurse role is not, however, it does little to define what it is.

Considering the lack of a clear definition for England, most CRNurses are familiar with the more detailed definition offered by the International Association of Clinical Research Nurses (American Nurses Association, 2016), which articulates the CRNurse role as follows:

> *“Clinical Research Nursing is the specialised practice of professional nursing, focused on maintaining equilibrium between the care of the research participant and fidelity to the research protocol. This speciality practice*

> *incorporates human subjects protection; care coordination and continuity; contribution to clinical science; clinical practice; and study management, throughout a variety of professional roles, practice settings and clinical specialties."*
>
> (American Nurses Association, 2016)

Whilst this definition is more helpful in focussing on what the CRNurse role is, it is very detailed and is open to criticism. It also presents challenges when transferring to any context outside of the US. Firstly, the CRNurse role in the US is recognised and defined as an area of specialised practice (American Nurses Association, 2016). In the UK, the CRNurse role is not defined as specialised practice, nor are there currently plans to explore this further despite lobbying towards this from within the CRNurse community (Whitehouse and Smith, 2018).

Secondly, maintaining equilibrium between the care of the research participant and fidelity to the protocol is not an easy phrase to grasp nor is it a simple balance to achieve. This concept has been referred to in different ways across the literature as an enduring challenge for CRNurses. It is present in a body of literature exploring interventions to improve recruitment and retention in clinical research (Donovan *et al* 2014). The caring-recruiting dichotomy was conceptualised in my first empirical research study, carried out exploring the experiences of CRNurses (Tinkler *et al* 2018). The dichotomy seemed to originate from CRNurses who experienced internal incongruence between a dual responsibility to the studies they were tasked with delivering to time and target, and the potential burden of participation, or their own beliefs about the potential benefit of the study (or lack thereof) for their patients. This research identified how CRNurses had, at times, made conscious judgements not to approach patients about studies they felt were at odds with their ethical assessments of benefit versus burden for those patients. Furthermore, the CRNurses made judgements about the timing of approaching potential research participants and whether it was appropriate to add the extra perceived burden of research participation into an already worrying time for patients. This concept had been identified in the literature as early as 1990, in Willems and Gumbrell's paper describing research in cancer care. Willems and Gumbrell highlighted the difficulties and “*psychological burdens*” experienced by CRNurses in relation to offering drugs with only a small chance of success to cancer patients, stating the CRN’s strong “*desire to protect patients from unnecessary harm*” (Willems and Gumbrell, 1990 pg. 30).

The caring-recruiting dichotomy was later utilised as a heuristic device to explore the relationship between workforce development and the successful delivery of research in social care settings (Biswell *et al* 2021). This research concluded that variations in studies, particularly in out-of-hospital and homeless contexts, led to the CRNurse adopting various manners of emotional labour. This created a range of ethical challenges and pressures, including balancing recruitment to time and target across a range of studies and the challenges of demonstrating equipoise.

Most recently, a study by Hill *et al* (2022) drew links between balancing the demands of clinical research protocols with the provision of clinical care by describing a duality of practice in CRNurse roles. CRNurses described undertaking clinical duties in addition to their CRNurse responsibilities. Participants offered a range of perspectives on their experiences of duality in practice, from negative to positive. Positive perspectives included the CRNurse role enhancing patient care, however, most were relationship focused, in being seen to help out, and in contributing to the accumulation of good will with clinical colleagues in a quid pro quo manner. Participants’ neutral perspectives acknowledged being prepared or happy to help clinically, though being aware of the impact this time would subsequently have on their research duties. Negative perspectives included fuelling perceptions of clinical colleagues that research duties were neither time limited nor to be prioritised and therefore help with clinical care should always come first.

Finally, the American definition does not accurately reflect the terminology used to describe research participants in England. The term ‘human subjects’ is a rather faceless term, suggestive of the patient’s input into research as a mere test subject. The context of research access and participation in the US differs to that in England where the terminology tends to be rather more personable, using terms such as research participants, patients, service users and people, who remain at the forefront of any decisions, which are usually taken in partnership with the patient.

The continued lack of a clear CRNurse definition in England, and the inability to fully align with an appropriate global definition, generates difficulty in articulating a clear professional identity for the CRNurse community. This then presents a concomitant struggle in clearly articulating the value, detail, and impact of the CRNurse role for those Nursing, Midwifery and AHP colleagues practicing outwith research structures. CRNurses have acknowledged this ambiguity for a long time and much literature now exists in relation to their own perceptions and experiences of practicing within the role.

2.5 Clinical research nurse perceptions of the role

Evidence generated from within the CRNurse community has previously highlighted the numerous perceptions of those practicing within the role. This evidence has also increased in volume, enabling much greater visibility of the barriers and facilitators to successfully delivering in role experienced by CRNurses; yet it remains to be seen whether this literature has impacted beyond CRNurse communities to date.

In 2020, the first qualitative evidence synthesis combining literature on CRNurses' experiences of the role was published. Hernon *et al* (2020) reported on 19 studies, identifying three themes of 'identity', 'meeting targets' and 'patient advocate'. They described the combined evidence on identity as challenging, from the early days of embarking on a CRNurse role to the continued relative isolation of the role in comparison to other nursing roles. Whilst the literature on identity presented in the review described an eventual sense of ease emerging with experience, it also highlighted the damaging impact of continued historical negative perceptions of colleagues outwith research structures. It also noted the CRNurse call for increased training and support.

2.5.1 Role transition

CRNurses have historically admitted that the role they transitioned into was not the role they expected. They were not fully aware of what the role might entail when they applied for jobs (Kunhunny and Salmon, 2017; Hernon *et al* 2020; McNiven *et al* 2021). Common barriers to initial role transition, were also said to continue for longer than expected in comparison to transition into other nursing roles, with references made to Benner's Novice to Expert model (Benner, 1982; Tinkler *et al* 2018). These barriers were identified in the literature as:

- The nature of the transition, such as whether the CRNurse moves into a research role whilst remaining within a familiar specialty, or whether they move into a new specialty area whilst also transitioning into a CRNurse role.
- The complexity of research related terminology and overuse of acronyms
- Variations in protocols and the nature of studies delivered (industry or academic) meaning the CRNurse often perceives repeatedly returning to a novice-like status each time a new study is proposed
- The unexpected emotional labour associated with building and maintaining new professional relationships and the experience of gatekeeping behaviours, not previously prevalent in other nursing roles
- Difficulties in aligning personal beliefs and core clinical judgements with the ability to demonstrate equipoise in relation to the recruitment activity of a study, previously identified as the caring-recruiting dichotomy

2.5.2 Practicing within target-based cultures

As the CRNurse develops, challenges associated with a target-based culture are experienced. This challenge associated with target-based cultures appears to overlap in the literature with the previously mentioned caring-recruiting dichotomy.

Working within a target-based culture created discomfort for CRNurses, who felt that the care of patients participating in research was their focus. They articulated a strong sense of advocacy on behalf of patients, putting the patient first before any responsibility to the study, and were frustrated by a focus on study targets, league tables and pressure to double recruitment numbers nationally. Whilst some CRNurses relished what they described as a little healthy competition, some organisations linked recruitment directly to the generation of income to secure CRNurse posts. This left CRNurses feeling undervalued and served only to feed a machine of numbers to enable success within league tables (Tinkler and Robinson, 2020).

Many CRNurses felt that competition for clinical trial recruits at organisational and national levels undermined the collaboration required to succeed across a range of studies (Adams, Caffrey and McKevitt 2015; Tinkler *et al* 2018; Tinkler and Robinson 2020). References were regularly made to the role of a salesperson within the literature, whether describing a study as an 'easy sell' according to Lawton *et al* (2016), or identifying a discomfort associated with professional identity in approaching patients to participate and feeling like salespeople under pressure to recruit (Tinkler, 2018; Tinkler and Robinson 2020; Hernon *et al* 2020; McNiven *et al* 2021).

Hernon *et al* (2020) also highlighted the importance of building relationships with colleagues outside of research structures, identifying how ward-based nurses could act as an active barrier to recruitment. The topic of emotional labour in building these relationships, and finding ways to pre-empt and overcome gatekeeping behaviours, was highlighted as a significant challenge in my two earlier studies (Tinkler *et al* 2018; Tinkler and Robinson, 2020). Later, McNiven *et al* (2021) articulated the impact and internalisation of exchanges with staff outside of research structures. They suggested that CRNurses often felt compelled to prepare stock responses in preparation for difficult conversations or challenges about their role and their presence on clinical units.

Such repeated experiences can lead to discomfort, especially when fellow nurses become viewed as gatekeepers by CRNurses who require support from them to enable them to recruit patients into studies. Finally, in Biswell *et al's* (2020) study, the authors articulated a need to move beyond the prioritisation of recruitment metrics and performance measures that do not take account of the time and skills required to undertake the role.

2.5.3 Benefits and positives of the clinical research nurse role

Whilst the focus of much literature to date has been on highlighting and addressing the challenges of this complex role, there are also many positive perceptions of the role for those practicing within the research community. For example, the CRNurse is clear on their role as a patient advocate, articulating a range of positive elements of the shift in nurse-patient relationship enabled by a CRNurse role. Increased time to care is a significant factor noted by CRNurses in comparison to other nursing roles which may not afford the ability to focus fully on the patient and their needs for as long as is required in a consultation or visit (National Institute for Health Research, 2016; Tinkler and Robinson 2020; Hernon at al 2020).

CRNurses describe gaining job satisfaction, and a sense of making a difference, from their unique contribution to driving improvements in prevention, diagnoses, treatment, and practice. Personal benefits are also derived from the nature of working patterns and shifts, and the flexibility in working enabled by diary autonomy and team structures (Munro and Allison, 2018). McNiven *et al* (2021) described how CRNurses were drawn to the role, attracted by the prospect of a new challenge. Kunhunny and Salmon (2017) described CRNurses as change agents in roles that were key to the success of research.

It is evident therefore, that the collective CRNurse community can confidently articulate a range of positive elements in their own experiences of the role. McArthur and Hill (2022) describe a watershed moment in CRNursing in their editorial piece setting the scene for a special edition focused on CRNursing in the Journal of Research in Nursing. They reflect on an early article they co-authored in 2006 and describe the CRNurse community having come a long way since then. The special edition comprised thirteen papers with international coverage, demonstrating the breadth of research activity ongoing into CRNurse roles, perspectives and impacts. Conversely, however, evidence continues to suggest the role remains broadly misunderstood by clinical colleagues outside of the field of clinical research delivery and this lack of understanding has served as a restricting factor for many years (Jones, 2017; Hill, 2018 Hansen *et al*, 2022).

Drawing on the evidence presented thus far, it is clear that the somewhat reactive and inconsistent variations in implementation of the CRNurse role, a persistent position of poor visibility and awareness, and a perceived separation of the role from routine clinical practice, have contributed to CRNurses reporting feelings of isolation, a tacit lack of value from within their organisation, poor opportunities for progression and a negative impact on relationships with colleagues outside of the immediate clinical research team (Jones, 2017; Kunhunny and Salmon, 2017; Tinkler *et al*

2018; Whitehouse and Smith, 2018; Hill, 2018). CRNurses perceptions of how they are viewed by colleagues outside of research is therefore also worthy of consideration.

2.6 Clinical research nurse perceptions of how they are viewed

The CRNurse community has long acknowledged that complexity exists for those practicing outside of research. This complexity stems from a lack of understanding of the structures and activities within the role. This may subsequently impact individual views of the role (Hunt, 1982; Jordan,1990; Willems and Gumbrell, 1990). Whilst anecdotal evidence of a boost in visibility appears to have resulted from the COVID-19 pandemic, little appears to have changed at a practical level in recent decades (Maxton *et al* 2021).

Clinical colleagues are generally characterised by CRNurses as gatekeepers who display a range of behaviours on a continuum of acting in support of, to acting in resistance to, the delivery of clinical research (Hill, 2018; Tinkler and Robinson, 2020).

These experiences described by CRNurses are apparent almost immediately on transitioning into a CRNurse role, though evidence has suggested the impact is lessened if the CRNurse remains within the clinical area in which they practiced as a staff nurse when moving into a CRNurse role (Tinkler *et al* 2018). CRNurses have described experiencing the attitudes and behaviours of clinical colleagues outside of research structures as often one of disengagement. They are thought to see research as somebody else’s job, one which potentially generates extra, unwanted work for those in busy non-research settings. The role itself is not in keeping with the professional identity of a *real* practicing clinical nurse (Whitehouse and Smith, 2018; Tinkler and Robinson, 2020; Hernon at al 2021; McNiven *et al* 2021). Further evidence suggests the CRNurse role is also viewed by those outside of it as somewhat easy, overly administrative, and one which they would set themselves apart from or are not interested in (Tinkler *et al* 2018; Hernon *et al* 2020).

As described by Hill (2018), Tinkler *et al* (2018) and McNiven *et al* (2021), CRNurses often feel the need to prepare for difficult interactions or conversations with colleagues outside of research structures. To aid this, they may employ emotional labour. Examples include, making an extra effort to remember names, and significant events or physical changes such as haircuts etc., providing incentives to gain trust, such as sweets and biscuits for department staff, and, significantly, helping out in the department when the clinical team appears stretched. Support and help may include taking blood samples, assisting with observations or other clinical tasks. The thinking behind this includes an empathy on the part of the CRNurse for their colleagues who are overstretched and the hope that, in return, those colleagues will be more accepting of their presence and therefore more likely to support with accessing notes or providing a room to consult with a patient.

Reflection point

During my first study (Tinkler et al *2018), CRNurses described sympathising with their clinical counterparts outside of research structures. They understood the difficulties faced, knowing how challenging it was 'out on the wards'. One participant attempted to justify the behaviours described by participants in the focus group, reflecting on a scenario where she had previously, as a ward-based nurse, encountered a CRNurse. She described a wish to assist the CRNurse with her work, thinking the study had sounded interesting. She had enabled the CRNurse to put up posters in the department but admitted she did nothing more to help. In this description, she talked not of value or of understanding the role, not of any in-depth lack of acknowledgement of the work or contribution of the CRNurse, but of simply being too busy and just not having the time within her own structure and role, to think about the research or how she might help to implement it or make the CRNurse's life a little easier (Tinkler* et al *2018).*

The difficulty faced by individuals outside of the research arena in understanding the CRNurse role, results from the same complex and inaccessible terminology associated with the research landscape and the countless variations in tasks involved in delivering clinical research experienced by the CRNurses themselves. For example, the lack of understanding of the differences between the work of a nurse who conducts their own research to further nursing knowledge and practice, and that of a CRNurse, whose role is primarily to care for people who are participating in a clinical research study has been described in the literature, with the aspiration of clarifying the differences (Jones, 2015).

Disappointingly, more than twelve years on from the inception of the National Institute for Health Research Clinical Research Network, repeated strategies and objectives continue to be published, both at organisational and national levels. This indicates a continued need to enable and empower all staff to value research as core in the patients' pathway, and in the role of clinical professionals (NHS England, 2021; Department of Health and Social Care, 2021; The National Institute for Health Research, 2021; Health Education England, 2022).

Enabling patients to benefit from research opportunities and the subsequent results of that research in the future, should be seen as equally important to ensuring there is a bed for a patient requiring admission, or sufficient staff to cover a department. This does not appear to be the case, however, as anecdotal evidence suggests research continues to be viewed as a separate activity in many areas of practice and staffing groups within the NHS. Whilst it is difficult to find empirical evidence to confirm these views, especially in the context of many strategies and directives promoting research activity, anecdotal evidence also suggests that research is often not considered as important as, or on a par with, clinical care and therefore is not prioritised as part of it. The continued cycle of strategies, objectives and calls for such issues to be addressed begs the question as to why work has not been previously undertaken to understand what is causing research to be viewed in this way. It is therefore incumbent upon the CRNurse community to do this, not least to address the issues, but to also ensure their work is not misrepresented as is historically evident within the literature.

The challenges described thus far can also be linked to the set up and implementation of a complex research delivery agenda in an already complex and dynamic context. Organisational culture and readiness is often described in the literature related to clinical academic careers (Association of UK University Hospitals, 2016; Baltrucks and Callaghan, 2018). Whilst clinical academic careers do not form part of this research, organisational culture is an important aspect to explore in relation to research delivery and will be considered next.

2.7 Organisational culture as a mediator in the success of research delivery

Research structures across the NHS are complicated and dynamic. A clear picture of CRNurse roles and team structures is obstructed by the dynamic and constantly evolving nature of contemporary nursing roles. Debates persist about the practicalities of incorporating research into clinical practice in an NHS at the height of a workforce crisis, as we continue to work in the most challenging of circumstances with the added pressure of recovering from a Global Pandemic.

Broader evidence exists, outside of the field of research delivery yet within the NHS, which indicates that culture, job satisfaction and morale can act as a mediator of team success, quality of care provision, patient safety and intention to remain in post. NHS culture has, in recent decades, been the focus of considerable empirical research (West, 2012). Think tanks such as The King's Fund advocate for transformation in leadership behaviours, to enable an entrenched culture of command and control to be replaced with more compassionate structures such as shared and distributed leadership, where each individual's role and views are acknowledged and respected (Turnbull-James, 2011; The Kings Fund 2011; West *et al*, 2017; West, Bailey and Williams, 2020).

Perhaps the most tragic and significant indicator of sub-optimal NHS culture in recent times is present in the Francis report (Francis, 2013). This report, commissioned to investigate significant failings in care at the Mid-Staffordshire Hospitals NHS Trust, identified (amongst a wide range of other issues) that target-based cultures driven by national demands, created a toxic culture in which meeting targets to achieve financial balance, rather than the core NHS business of caring for patients, became the primary focus. A bullying culture was also said to have resulted from this pressure to achieve targets (Department of Health, 2015 b).

In a landmark publication in 2020, the NHS People Plan was launched, marking the first fundamental commitment to address negative behaviours and culture in the NHS. The plan's intention was to shift culture, transforming behaviours in an NHS that would seek to better care for its own staff and promote compassion, inclusion and belonging. A focus on the health and wellbeing of our NHS people, reducing bullying and harassment, and a reflection on how the positive changes resulting from the COVID-19 Pandemic might be sustained, are examples of the ongoing work emerging from the plan. The fundamental and unique role that CRNurses played during the pandemic was also acknowledged within the plan and the impact their work had on improving patient care was noted.

Research delivery structures, as integral elements of NHS service delivery, should be included within the work of the people plan and require the thinking described by The King’s Fund literature to be applied. This is relevant to both the target driven cultures which CRNurses described working in, and to the interaction with colleagues outwith research structures, where negative and gatekeeping behaviours appear prevalent.

A link between organisational culture and the success of research delivery has recently been made in research exploring CRNurses perceptions of their ability to successfully deliver research (Tinkler and Robinson, 2020). The conceptual framework emerging from this research defined a complex interplay between the personal experiences, attributes and tendencies of CRNurses, and the broader organisational culture in which they practiced. These mechanisms were thought to be mediated significantly by national strategies and targets associated with the clinical research agenda; namely the High-Level Objectives (HLOs) associated with recruitment to time and target and the speed of recruiting the first participants into studies. These would then filter through organisational managerial structures to play out at the departmental and team level, creating unnecessary pressure on CRNurses and leaving them feeling like undervalued salespeople.

When situated within the concept of leadership rather than focusing on complex research structures, this study enabled broader potential for understanding the underlying issues, thus increasing the range of possible support mechanisms to improve experiences for CRNurses. The challenges were framed in a way that avoided confusion resulting from the complex research related terminology. The study focused instead, on the basics of human interaction and the structures in which we operate. This enabled the contribution of further new knowledge to the dialogue surrounding perceptions, experiences, and behaviours in clinical research delivery.

2.8 The potential missing puzzle piece

The research presented above explored the views of CRNurses in relation to their experiences of practicing within their roles and the implementation of their work. Such research is growing in volume and more recently forms the bulk of evidence in relation to the CRNurse role and the delivery of research. Whilst this evidence makes regular reference to a discomfort stemming from relationships with clinical counterparts outside of research structures, this evidence is open to criticism as it is subjective in nature and presented only through the eyes of CRNurses themselves.

Nevertheless, this literature is an important and much needed addition to the evidence base related to research delivery and CRNurse roles. It provides a broad range of views, strategies, case studies and points of reflection in a wide number of settings and contexts across the world. It provides evidence on what has been advocated for and what has been tried, as the role and landscape has developed. Furthermore, it demonstrates increased interest in optimising the delivery of clinical research and in positioning the role of the CRNurse with parity of esteem in relation to other roles. Yet, it also demonstrates that little has progressed in terms of the experiences, morale and job satisfaction of CRNurses, particularly where key professional relationships are concerned.

As a result, a lack of understanding of the CRNurse role, and the experience of gatekeeping behaviours in relation to enabling research activity in the clinical setting, appears to endure. There is no clear evidence that the views expressed thus far have been tested with those outside of research delivery structures, aside from a small unpublished study conducted by the Emergency Medicine Research Group of Edinburgh (EMERGE) team in Scotland[1]. This study demonstrated that most staff outside of research in an Emergency Department, did understand the role of the CRNurse. The results of this survey did not, however, reflect the experiences and views of CRNurses in the same department, suggesting a potential divergence between perceptions and the behaviours displayed, and the interpretation of both.

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[1] I became aware of this unpublished work, whilst presenting my research at the Scottish Research Nurse and Coordinators Network conference in Scotland in 2017. I had connected with the authors on twitter, and they had talked to me about their study, which they had not had the time to write up, but had produced a poster.

Maxton *et al* (2021) described a changed landscape in relation to CRNursing as a result of the COVID-19 pandemic, which may influence experiences positively for some time to come. Their editorial piece suggested that, despite documented role misconceptions, CRNurses are arguably legitimate nursing roles and are now enjoying a new status as valued, recognised team members in the midst of the pandemic. They argue that this has likely emerged due to the necessity to change multiple processes across whole health systems, brought about by the pandemic, rather than the actual will of people and systems.

Maxton *et al* (2021) also warn though, of the risk of returning to a sub-optimal status, described as normal pre-covid. They advocate instead for maintaining the flexibility and cohesive teamworking experienced in order to avoid losing the positive shifts gained by CRNurses in terms of their value and status as members of clinical teams. Whilst this is a potential positive impact of the pandemic, and is reported anecdotally by CRNurses, empirical research is needed to explore the longitudinal impacts of COVID-19 further.

As mentioned earlier in this chapter, there is, no evidence to suggest the literature generated thus far is reaching beyond the CRNurse community, leading to a potential echo chamber of opinions and experiences.

Increasing research exists, exploring the views of clinical professionals about research generated by these professionals, and about integrating research activity within their roles (Trusson, Rowley and Bramley, 2019). There remains, however, no empirical research directly exploring the views of clinical professionals who work outwith the delivery of clinical research on the delivery of research, the CRNurse role and how they perceive its implementation.

It is clear from the evidence presented so far that there is still a need to integrate the delivery of research in the NHS into the hearts, minds, and daily routine of professionally registered clinical staff, practicing alongside or in parallel with CRNurses. This challenge has prevailed for many decades and has been the content of much debate. Continued calls seeking to change culture and improve attitudes towards research is a point of frustration for many who have worked hard to raise awareness, visibility, and appreciation of its value.

Whilst every job has expected and unexpected challenges and difficulties, arguably the most important element of nursing work is relationships; yet this appears to present the most significant challenge for those practicing in CRNurse roles. The issues described throughout this chapter, which appear to be prevalent across the literature from Hunt (1983) to Tinkler, Robertson and Tod (2022), present an obvious literature gap yet to be addressed. The perceptions of those healthcare professionals practicing outside of, yet alongside, research delivery structures remain unexplored. This research seeks to address this gap.

2.9 Summary

In this chapter, the background, history, and evolution of clinical research delivery and the CRNurse role in the NHS has been critically analysed. Early evidence of the CRNurse role, building to the current day, the history of the National Institute for Health Research and the resulting changes to England's NHS research delivery structures have been critiqued. The chapter has also analysed the complexity of understanding such roles for those CRNurses practicing within them, whilst also noting their understanding of the difficulties for those outwith research structures in understanding what they do.

The rewarding and beneficial elements of the CRNurse role have been stated, yet evidence has been presented to suggest they are overshadowed by the inherent complexities associated with a shift in professional identity. The positives of the CRNurse role have been defined as the activity of driving forward innovative care within a patient facing role, the increased flexibility of working and the autonomy celebrated within the role. Evidence of a caring-recruiting dichotomy, the challenges of navigating a target driven culture and perceptions about how CRNurses are viewed by colleagues outwith research structures, have been debated as significant challenges for CRNurses.

Clinical research delivery activity has been situated and critiqued within existing NHS structures. Evidence has been offered on how broader NHS structures, strategies, and the historical development of the research landscape within, may have interacted over time to impact on the implementation of the CRNurse role and the successful delivery of research. In addition, the propensity for target-based cultures within the NHS and the tragic consequences of such cultures on staff morale and quality of care have been highlighted.

The chapter has emphasised that understanding how research delivery is perceived by those operating outside of CRNurse teams is an important piece of the puzzle which can no longer be overlooked. To seek out such views will assist in understanding what works, what doesn't work, for whom and in which contexts, with the aim of uniting those perceived separate elements described in chapter one. Chapter three will now set out in greater depth, the chosen philosophical foundations of Critical Realism on which this research is based, before briefly introducing the two phases of the doctoral research: a Realist Review and a Group Concept Mapping Study.

CHAPTER 3. PHILOSOPHICAL FOUNDATIONS AND METHODOLOGICAL APPROACH

3.0 Introduction

In the previous chapter, the background and history of clinical research delivery and the CRNurse role was explored. The exploration framed the evidence base intentionally within the context of relationships as fundamental to success. This is because little research has been conducted in this area and that which is available, suggests much more needs to be done (Hill, 2018; Whitehouse and Smith, 2018; Tinkler *et al* 2018; Tinkler and Robinson, 2020; Hernon, Dalton and Dowling, 2020; McNiven *et al* 2021). Specifically, the recommendations for further research from this prior work demonstrate the importance of exploring the views of those clinical professionals practicing outside of, yet alongside clinical research delivery structures.

Chapter two reflected on the CRNurse role as one which is varied and complex (not unlike other nursing roles). The role has been historically and repeatedly subjected to various attempts at defining, delineating, and deconstructing into tasks and activities. The importance and impact of professional relationships at a range of levels, from simply understanding the role to working cooperatively with the CRNurse, was a key theme apparent across a range of the literature explored.

In this chapter, critical realist thinking will be considered and critiqued as the chosen philosophical framework on which this doctoral research methodology is based. This will be intertwined with other relevant theoretical literature seeking to connect elements of the current body of CRNurse research to broader theories on social structures, politics and behaviours. The intention of these theoretical connections is twofold. Firstly, to assist in understanding the challenges described in chapter two, and secondly; to emphasise the relevance of a critical realist stance, demonstrating why complex roles, such as the CRNurse, require different methods of exploration.

Reflection Point

The adoption of Critical Realism as a theoretical stance for this work, came about during the early pursuit of a pragmatic method of literature review that would enable a wide range of evidence to be synthesised. I was aware that an extensive literature review would be required to enable this research to better determine the existence of, and then explore the challenges being reported by CRNurses. These challenges were evident at the interface between clinical research delivery and clinical service delivery in my previous research and in that of other researchers in this field.

Having worked and researched within the delivery of clinical research for a number of years, I was aware that a lot of the published literature that indicated the challenges my doctoral research would explore incorporated a range of sources and types, some of which were defined as subjective, and none of which were originally aimed at explaining the challenges – rather some happened upon them through the course of their study and later made reference to them in their results.

I had become mildly aware of the term realist research, but did not have a grasp of where it was positioned, the complexity of the paradigm in which different types of realism sit, nor the key tenets of the philosophy of critical realism. What I had heard about it however, led me to think it might be a helpful approach to adopt. As I then started to read about realist review as an evidence synthesis method, during early discussions with my supervisors about the most appropriate approach to the literature review, I realised that the foundations of critical realism were highly aligned with my thinking.

The approach to accepting and exploring complexity, the acceptance of open and social systems and the commitment to pragmatism (uncovering what is happening and why it might be happening in one place yet not another) within approaches to critical realist research, led me to believe that I had found my own philosophical stance captured in hundreds of texts – albeit incredibly complex in their writings.

This doctoral work seeks to go beyond adding to the bounded body of CRNurse related research by making these links to broader literature exploring social structures, politics and behaviours. In doing so, it aims to shift current thinking from an individual role perspective to practicing within a system level perspective.

The chapter closes by briefly introducing the two phases of the doctoral research which comprise a realist review and a group concept mapping study. The work of these two phases will not be covered in detail in this chapter. The realist review is presented fully in chapter four, including the paper published from this phase in 2022. Chapter five then presents the group concept mapping study which was informed by the results of the realist review. Chapter five also describes several important methodological contributions which have arisen as a result of conducting the GCM study from a critical realist perspective.

This chapter begins by exploring positivist philosophy, apparent in a large amount of healthcare research. The exploration uses an example of research on research where a focus on deconstructing elements of clinical trial recruitment into separate variables contrasts with the inherent involvement of people in the research. The exploration will therefore illustrate why positivism is not practical to adopt as a philosophy in this doctoral work. Again, personal reflection points, situated within separate text boxes, have been offered throughout the chapter, where felt to be relevant to the topic being discussed.

3.1 Positivism and people, a mismatch in philosophy?

The literature on optimising recruitment and retention in clinical research is aimed at maximising the success of research. The foundation of health research is to improve the health and wealth of the nation, yet messaging which focuses on achieving target recruitment numbers in clinical trials may not align with such values (Tinkler and Robinson, 2020). The evidence base concerned with research on research is broadly made up of qualitative studies that record and deconstruct recruitment conversations and informed consent processes (Donovan *et al* 2016; Mills *et al* 2018). These studies are often nested within randomised controlled trials. All involve people, the researchers, or members of the research delivery team, who are defined as the investigators, and the people who are participants in the research. These studies generally explore and seek to optimise the investigator's ability to demonstrate equipoise; the approach to recruitment conversations and the transactional process of information giving and receiving (Rooshenas *et al* 2018; Rooshenas *et al* 2019).

Alongside this qualitative work, quantitative studies investigate the optimisation of specific trial designs, recruitment strategies and distinct interventions. Again, these are often designed and implemented by people as investigators, with people as participants and recipients in the research (Kearney *et al.*, 2018; Treweek *et al.*, 2018). The intentions of optimisation research are to test and implement a range of interventions to improve recruitment and retention in clinical research.

As suggested in chapter two, this body of evidence generally adopts a traditionally positivist approach. That is, it seeks to break down the delivery of research into simple, individual, observable and measurable tasks and variables. The view is that these variables might be enhanced by observing and refining each one, through removing any perceived bias, testing and retesting (Emmel *et al.*, 2018). These interventions may each demonstrate some success, recognising that no single intervention would ever serve as a panacea (Gardner, 2018). Such research, however, falls short of acknowledging how different facets of research delivery activities, and the contexts in which they operate, may act upon each other and the study as a whole, as part of a chain. To support the optimisation of research on research, the complexity of people and their individual contexts, the structures within which they act, and their relationships, behaviours and individual beliefs and needs should not be overlooked (Emmel *et al* 2018).

At the very heart of the intended outcomes of clinical research activity, are people. People are the intended beneficiaries of the research, and people are essential to its design, set up, delivery, and many other activities such as analysis, interpretation, write up, dissemination, adoption, and thereby its overall success.

Yet, people are not merely variables or tasks that can be separated, broken down and analysed in the positivist sense. People are complex and unpredictable, intertwined within relationships, contexts, social structures, beliefs, and past experiences (Alderson, 2021). Positivist approaches to research generate theories about what is happening by explaining only empirical data, that which can be defined and separated as a variable, then observed and measured. Positivist philosophy does not seek to understand why something is the way it is or if something unseen is causing a particular outcome. For this reason, there exists a potential mismatch between the nature of people within broader social structures as research participants and positivist approaches.

The nature and activity of delivering research in complex healthcare settings, is likewise not something that should be broken down and separated into variables. Implementation of the CRNurse role requires exploration in a way that enables the range of influencing factors to be considered as a whole. As a key intervention within research delivery, understanding is required about how the role is viewed what the perceived blockers are and how they can be removed. Indeed, Tramm, Daws and Schadewaldt (2013) suggest that clinical trial recruitment itself should be defined as a complex intervention. Their research concluded that recruitment activity is, by its very nature, complex and open to a range of threats, inherent in the planning and delivery of studies. They further suggested that existing nursing theories and models may fail to consider threats to recruitment in a holistic way. They suggest complex intervention frameworks may hold the key to improving recruitment rates and subsequently the success of clinical trials. This evidences the need for CRNurse and research delivery related literature to be positioned and considered wider than within one professional discipline and rather considered as part of a broader evidence base. Critical realist philosophy accounts for the complexity in a way that positivism does not. Critical realism may therefore provide an alternative and holistic approach to exploring how research delivery by CRNurses is viewed by those practicing outside of research structures.

The foundations and detail of critical realist philosophy will now be discussed in more detail.

3.2 Critical realist philosophy

To enable an exploration of critical realism, it is important to highlight its position within a wider realist philosophy. Overarching realist philosophy itself is complex to unravel. Various authors continue to debate its unique characteristics, comparing and contrasting it with other philosophies and offering various forms of ‘realism’. Maxwell (2012) identified that his adoption of the term critical realism in his text on realist approaches to qualitative research, encompassed numerous versions of realism across the realist philosophical evidence base, such as ‘experiential’, ‘constructive’, ‘subtle’, ‘natural’, ‘innocent’, and ‘agential’ realism. As Maxwell (2012) demonstrates, each of these terms were posed and debated by numerous authors, from the early 1970s to the 2000s.

Critical realism is defined as a philosophy of the natural and social sciences. It is described as a unique paradigm, positioned on a scale between the extremities of Interpretivism/Constructivism and Positivism (Taylor, 2018). As described above, Positivism seeks to objectively identify an independent factual reality that can be applied universally. Interpretivism and Constructivism by contrast, focus on interpreting and constructing the discourses, meaning and experiences of people, accepting the existence of a subjective reality (Koopmans and Schiller, 2022).

Critical realism combines both structure and interpretation, seeking to achieve ontological depth, i.e., a deeper understanding of what is real, what exists and why.

Critical realism is a way of thinking that can inform our explorations of reality and what is happening beneath the surface to cause what is observed and experienced (Koopmans and Schiller, 2022). It does not seek to achieve uniformity in method or outcomes, nor to construct a subjective reality entirely from the accounts of people. It rather seeks to aid an understanding of what works or does not work, in some contexts yet not in others and why (Alderson, 2021).

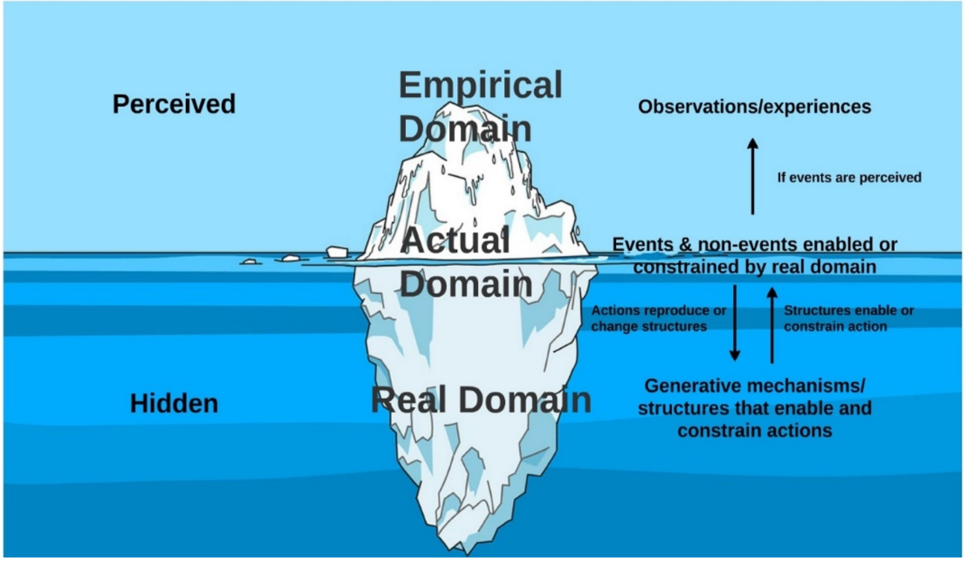
The foundations of the critical realist philosophy on which this work is based, were originally developed, and advocated by the philosopher Roy Bhaskar (Bhaskar, 2008). This philosophy is thought to have developed from, or rather is reflective of, other established sociological theories and work in different philosophical fields. For example, some texts published within Marxist philosophy were later considered to be of a critical realist nature or methodological approach, before the term critical realism was first created (Ehrbar, 2007).

3.2.1 The foundational concepts of critical realism

Critical realism has a structured ontology which incorporates three domains, also known as depth ontology. According to Bhaskar (2008) these three domains, or rather features of the world, are key to understanding critical realist thinking. The belief is that causal powers exist independently of where they occur, regardless of whether they can be observed or experienced where they are happening. This is essentially accepting that there are unseen and unobservable powers that lead to observable events. The three domains are described as that which can be observed or experienced - *the empirical domain*; that which exists, whether it is possible or not to observe or experience it – *the real domain*; and that which occurs when the causal powers of the real are activated and produce events or change – *the actual domain*.

According to Bhaskar, that which is real, is said to also incorporate the empirical. In addition, the actual incorporates that which is real in considering what causes things to be the way they are in their existence or empiricism. This feature sets critical realism apart from other forms of realism, yet accepts that not everything that is real, and therefore happening within a particular structure, can be empirically observed or measured. Thus critical realism has a focus on ontology rather than epistemology (Koopmans and Schiller, 2022). Figure 3.1 illustrates the three domains and how they interact and overlap.

Figure 3.1 Critical realism's stratified reality



(Anderson, B. C)

Critical realist philosophy postulates that it is impossible to be certain about some aspects – *being* or phenomena - of the world. These aspects may exist outside of our knowledge of their presence and are referred to as the intransitive. What is intransitive does not change. Knowledge in contrast, is transitive and subject to change. Therefore the possibility of alternative, growing, changing or incomplete knowledge of the world or phenomena that exist must be accepted (Maxwell, 2012). This feature also makes use of the concept of the epistemic fallacy, whereby ontology – *what is* - can be confused with, reduced to, or attempted to be fully explained only by epistemology – *what is known about it*. The underpinning philosophy of critical realism is therefore via ontological realism - an acknowledgement of the existence of an external world as well as a socially constructed one.

Another key tenet of critical realism is related to transfactuality and open systems (Bhaskar, 2008). In seeking out what works or does not work in some contexts yet not in others, critical realism accepts the permanence of the intransitive and commits to the belief that events occur in open systems (social structures with a range of causal mechanisms at play in different layers at any one time), hence the acceptance that regularity is not the focus. This relates to the inherent involvement of people and the potential mismatch described within a positivist philosophy. The notion of open systems is in contrast to the positivist position that independent variables can be manipulated and observed within closed systems, as phenomena act upon the dependant variable that is isolated for the purposes of the research.

In its acknowledgement of these external and socially constructed worlds, critical realism also accepts that there are lots of ways of knowing. Critical realism therefore commits to both epistemological relativism and judgemental rationality (Buch-Hansen and Nielsen, 2020). Epistemological relativism incorporates a recognition that knowledge is socially produced and is therefore transitive, fallible and subject to limitations. This means that some ways of knowing may be judged to be better than others, or subsequently replace previous ways of knowing as more knowledge is generated about a particular phenomenon.

Judgemental rationality is the belief that one may reasonably select between theories or statements about the phenomena being explored, based on judgements of its practical adequacy in explaining the phenomena in a particular context (Buch-Hansen and Nielsen, 2020). Such judgements are accepted, because, even when the evidence selected is subjective in origin, it may still help explain and shape that which is observable on the surface of that structure (Emmel *et al.*, 2018). The acceptance of judgemental rationality forms an important basis for understanding how and where subjective accounts and input are both important and valid in terms of research methods. Critical realism's commitment to judgemental rationality is therefore important in relation to the approach to this doctoral research.

3.2.2 The application of critical realism in research methods

As described, critical realism is a paradigm, interested in the generation and analysis of theories. Critical realism, poses, and debates philosophical questions and concepts and explores frameworks of analysis (Alderson, 2021). Critical realism is not a research method, rather it is adopted as a position in the pursuit of knowledge

– often to answer complex questions or address complex issues, that may be explored via research. Alderson (2021) highlights that critical realism, in its focus on theories, can have utility in a range of different research methods. Complexity is inherent in the implementation of every role, treatment, intervention, policy, strategy, or programme. This is the case whether it is a programme aimed at staff or patients, whether it is about achieving behaviour change (for example smoking cessation), illness prevention (concerned with vaccination uptake) or health improvement (implementing specific treatments, drugs, or physical interventions) in the NHS. This is largely due to the fundamental involvement of people and the open nature of systems. Complexity also results from the individual characteristics, beliefs, values and attitudes each person brings to either the design of the programme, policy, or strategy, or to the implementation, interpretation, or uptake of the same.

Drawing on critical realist epistemology, the early work of Pawson and Tilley (1997) provides a history of what they describe as realistic evaluation - an approach to evaluating the implementation and outcomes of programmes, policies and strategies such as those explored thus far. In describing their approach to realist evaluation at the time, Pawson and Tilley (1997), claimed that the successful implementation of any programme, intervention, policy or strategy relies on the very minimal requirements of cooperation and non-disruption. Pawson and Tilley (1997) also stated that the perceived relevance of a programme, intervention, policy or strategy is an important marker of whether an individual person will be drawn to, act in support of, resist, or subsequently experience change, as a result of its implementation. Non-disruption and cooperation are arguably driven by whether an individual recognises a programme, intervention, policy, or strategy as relevant to them - in the case of this research, the CRNurse role and the delivery of research.

Since Pawson and Tilley's 1997 text, Pawson has further expanded on these ideas (Pawson, 2006; Pawson, 2013). In his 2006 text entitled Evidence-based Policy, Pawson discusses complexity in evaluating programmes and described open and social systems as products of endless influences. Such influences range from the perspective of what has happened in the past within a system, to the forces working on such a system in terms of institutional arrangements, rules, regulations and intended outcomes. Each of these elements is also open to the influence of behaviours within open systems, which Pawson points out are affected or driven by the choices of people within them (Pawson, 2006). Pawson goes on to describe - in relation to empirical research - the almost impossible task of identifying and isolating everything acting upon, and within the system. Therefore, finding a single truth, in relation to why something works in one setting yet not another may link back to the views of individuals within the system and their perceived relevance of a programme or intervention driving their propensity to enable or disrupt.

Pawson (2006) also discusses the existence of what are termed demi-regularities, where the existence of some patterns or regularities within what is being observed may be seen. Whilst these demi-regularities may indicate outcome patterns that may inform the implementstion of programmes, they cannot be relied upon, nor isolated as evidence of a single definitive, reproducible outcome, certainly not from one setting to another.

Pawson (2006) goes on to describe four contextual layers thus:

- **Individual** capacities and tendencies of key actors to make a programme successful
- **Interpersonal** relationships, which may support or disrupt the programme as it is implemented
- **Institutional** culture, focus and strategy, and its ability to influence the success of a programme or lack thereof
- **Infra-structural** political support and required resources

In the context of such a complex and layered system Pawson (2006) acknowledges difficulty exists in producing any sort of transferrable knowledge from one programme to another due to the likelihood of each being embedded in diverse contextual settings.

It is important to note here that in adopting a critical realist stance for this research, it does not follow that this work is a realist evaluation. However, in recognising layers of context and complexity the levels of micro, meso and macro described by Emmel and colleagues (2018) and referred to by Pawson, (2006) and Pawson (2013) have been adopted at points to assist in making sense of where mechanisms may be triggering in the system.

Reflection Point

This doctoral research is not a realist evaluation, nor am I conflating Pawson and Tilley's work on realist evaluation methods with the philosophy of critical realism. I did, however, spend a lot of time looking at Pawson and Tilley's work in the early days of my PhD. This was as I tried to make sense of critical realist literature and clarify my own philosophical stance. Pawson and Tilley criticise a number of realist philosophers, including Bhaskar and Campbell's interpretations of critical realism. In wrestling with the discourse on realism as a wider school of thought, I did feel as though I was journeying down a rabbit hole, which created some difficulty in separating and clarifying where my work was positioned. Although it felt appropriate to adopt a critical realist philosophical stance, yet not seek to undertake a realist evaluation, I was drawn to Pawson and Tilley's narrative on cooperation and non-disruption. I felt it was an important claim, applicable globally, regardless of whether or not it is adopted within the boundaries of a realist evaluation approach.

The claim that the success of any programme relies on the very minimal requirements of non-disruption and cooperation, triggered a profound realisation when exploring potential research methods and philosophies early in my doctoral studies.

This claim made by Pawson and Tilley led me to think about what might be behind the issues being reported in my earlier research, and in large portions of the CRNurse evidence base. It seemed various manifestations of the opposite of cooperation and non-disruption were present as factors impacting on the CRNurse role in the literature. The concept of those two minimal requirements has stayed with me throughout the research. Understanding what is causing disruptive or uncooperative behaviours requires a critical realist approach, and therein lies the link to Pawson and Tilley's claim.

Critical realist approaches have emerged as well suited to research exploring health policy and systems in recent decades (Emmel *et al.*, 2018). The increased adoption of critical realist thinking within research methods resulted from growing demand for research and evaluation methods capable of handling the inherent complexity within health contexts. As researchers began to acknowledge the social and therefore complex nature of health systems, the resulting uncertainty, arising from such dynamic relationships, meant that methods from the social sciences were increasingly adopted (Emmel *et al.*, 2018).

Critical realist research methods focus not on a solitary question of whether something works or does not work, is successful or unsuccessful in the positivist style associated with the classic experimental design. Instead, critical realist research is concerned with uncovering the underlying, and often unseen, causal mechanisms at play that lead to a particular outcome, depending on the context in which a particular programme, policy, strategy or intervention is implemented (Pawson, 2013; Edwards, O'Mahoney and Vincent, 2014; Emmel *et al.*, 2018). According to Ackroyd and Karlsson cited in Edwards, O'Mahoney and Vincent (2014), the aim of critical realist driven research is to combine available data and theories into an account of what *is* or *might* be happening to the social mechanisms and processes in a particular area. This activity connects the observable world with the unobservable mechanisms that generate what is seen on the surface. Critical realist approaches in their focus on ontology, usually involve first locating or generating theories about what programmes are and how programmes should or were designed to work. Such questions might involve asking for example, what is the CRNurse role and what does it do, before focusing on epistemological questions that generate theories on what might be happening, such as how does it work, why do we see different outcomes in different contexts. (Edwards, O'Mahoney and Vincent, 2014).

These theories are generated or located and subsequently tested to confirm or refute through the identification of rival theories. This is achieved via a mixture of data collection. This may involve reviewing documentary evidence, for example a strategy, policy, or other relevant published literature. It may also involve interviewing key actors within programmes, observing a programme in action and or reviewing outcomes. The critical realist driven approach to evidence gathering takes account of the context in which it is present. It is then used to drive inductive reasoning on whether the programme works (delivers its intended aims), does not work, in which circumstances and why. This is achieved specifically through the exploration of human actions within the programme, or reactions to events, interventions, policies, strategies and or structures. Critical realist thinking recognises that if intervention A is implemented with group of people B, it does not necessarily lead to the same outcome as if intervention A is implemented with group of people C, D, or E. Indeed, if intervention A is implemented with group of people B in a different context, then again, the outcome would be different.

According to Bhaskar (2014) cited in Edwards, O'Mahoney and Vincent (2014) the foundations of critical realist research are: "*based on the primacy of ontology in the research process, whereas for its irrealist rivals, such as positivism and social constructionism, epistemology is primary*" (pg. vi). Translated into accessible language, critical realist research is most interested in reporting on what is or might be happening underneath the surface to explain the outcomes observed and why, rather than focusing on proving how we know for certain what is happening and how that knowledge is generated.

Critical realist research, in its activities to uncover, discover and test, is interested in structures, blockers, facilitators and causes, and how they may interact to generate outcomes in different spatial or time-based contexts.

Critical realist research is fundamentally aimed at explaining what is happening and why, with a focus on the social structures present where programmes are implemented and the mechanisms that generate outcomes. Critical realism is not necessarily about finding patterns in events, rather abduction and retroduction are key terms describing distinct yet linked activities within critical realist research. Abduction involves reframing a particular proposed causal mechanism to explain an outcome, whilst retroduction involves generating a theory, which if it were supported, may explain an outcome. Both abduction and retroduction may be based on observation, lived experience, expertise within the area of interest, other evidence gathered that is of relevance to the specific area being researched - hence judgemental rationality applies - or a combination of some or all (Edwards, O'Mahoney and Vincent, 2014). The identification of mechanisms is fundamental to critical realist research approaches. Mechanisms will now be explored in more detail.

3.2.3 Mechanisms and their importance in critical realist research

The consideration of what may cause things to be the way they are involves retroductive or abductive thinking. Retroduction and abduction are the activities that seek to identify a mechanism; they are a key to helping understand, unlock, and link the three domains of structured ontology in critical realism.

Mechanisms are the units of interest within critical realist research. Mechanisms are real, by nature of the fact that they are causative and so lead to an effect. Mechanisms are the things that lead to observable outcomes, whether these are positive or negative outcomes. Mechanisms enable theories to be generated about what is happening and why, yet they themselves, may not be observable. In fact, mechanisms are often described as underlying, suggesting they, by their very nature, are not seen. Mechanisms may be the outputs of abduction or retroduction and are usually described as ‘triggered’ within or by specific contexts. This is because the context is often the changeable element of why something does or does not work in a particular way. What leads to the identification of a mechanism, and often what therefore triggers it, is the context. Context is key in identifying a mechanism, as it appears to be impossible to identify and define a mechanism without also identifying the context in which it operates or triggers. This is where the premise of exploring and uncovering what works (and does not work) for whom and in which circumstances originates from (Edwards, O'Mahoney and Vincent, 2014).

Mechanisms are said to be present and to operate at a range of levels, usually distinct from those levels where the outcomes are generated, however, they do rely upon interactions between elements of the system (Emmel *et al.*, 2018).

It is important therefore to consider the mechanisms potentially operating at a range of levels in relation to the CRNurse role. This is in addition to investigating the interactions between many elements of the system which ultimately influence the ability of the CRNurse to be successful within their role.

Applying the CRNurse role as an intervention to an example illustrated by Ackroyd and Karlsson cited in Edwards, O’Mahoney and Vincent (2014), the CRNurse role was implemented into an already existing social context. The relationship between that context and the mechanism the role subsequently triggers is where the explanation can be located of what might be happening to generate avoidance and resistance behaviours. The mechanism itself may have different effects, in different contexts, and the context itself may act as an enabler or constraint to the effects of the mechanism. This is how the success or failure of programmes can be better understood (Edwards, O'Mahoney and Vincent, 2014). Interventions are often introduced with the aspiration of addressing problems (usually another mechanism that is causing the problem), hence the implementation of the intervention as a mechanism to block the problem causing mechanism. This complex interaction between context, mechanism and outcome is therefore the focus of critical realist synthesis.

Amidst the previously described philosophical debate in relation to the overarching realist philosophy, critical realism is often described as an emerging philosophy. This is due to its relative infancy in contrast to traditional positivist vs constructivist philosophies. Within such debate, three main criticisms of critical realism are apparent, one of these is the complexity of the theory itself and the overly dense and complicated vocabulary associated with it (Hammond, 2019). The remaining two; reproducibility of critical realist research and the value of judgemental rationality will be explored briefly next.

3.2.4 Criticisms of critical realism

Critical realism is at its core, a philosophical stance. In keeping with the acknowledgment of the complexity of social structures and systems, the community has thus far generally avoided stipulating a specific set of rigid instructions for the methodological conduct of critical realist research. Instead, It has sought to debate and publish literature outlining the approaches and methods adopted and applied in different studies (Alderson, 2021).

Often available resources and accounts of research approaches are adopted, adapted and critiqued within the broader realist literature as critical realism's application to research continues to develop and mature. What exists is often challenging to translate. The complexity of writings on critical realism, can leave naïve critical realist researchers (who are at least certain of the relevance of this philosophy in their work), unsure as to whether their approach is of a sufficient standard and indeed in keeping with core critical realist philosophy. Critical realists, however, accept there is little guidance on how best to proceed. The only clear guidance is that the researcher should reflect on the implications of their knowledge of the area being studied, and carefully consider what other information might be required to provide increased insight (Edwards, O'Mahoney and Vincent, 2014).

Additionally, critical realism by its very nature acknowledges the involvement of agency within structure. As such, it follows that the research methods adopted, and subsequent outputs may not necessarily be reproducible. According to Roberts (2014), critical realists view the social world as what is termed an open system. This implies that researchers may adopt critical realism within a methodology and thereby generate numerous conflicting accounts of what may be happening in a particular area of interest. Roberts (2014) further suggests that open social structures will be subject to a range of causal mechanisms interacting with one another and it is this infinite interaction that can potentially lead to numerous structural accounts of the same social phenomenon.

The dilemma described above links to a further criticism of critical realism. This relates to explanations of a particular social structure, programme, or intervention, often relying upon the existing knowledge, expertise or experiences of the critical realist researcher. Such expertise usually results from their knowledge or lived experience of the area of interest (Roberts, 2014). There is an argument that it is appropriate and necessary to use one’s own experiences and knowledge to assist in generating theories about the existence of mechanisms within structures where one operates. This is indeed one of the elements of critical realist research that was attractive to this research, though reflexivity is therefore an important concept to consider in presenting, evidencing and balancing theories. Indeed, theories should not be generated from personal knowledge or experience in isolation, rather judgemental rationality should be adopted, and a range of relevant evidence should contribute to the generation of rich theories which should then be tested. Kemp and Holmwood (2014) cited in Roberts (2014) pg. 14., suggest, however that the utilisation of lived experience is potentially problematic due to the critical realist’s reliance on prior information about how structures operate. It is therefore imperative to be open to the possibility that how structures operate may be perceived differently depending on the context and personal views of those contributing evidence. It is important also to remember that such knowledge is positioned within the transitive domain and in the commitment to epistemological relativism, different ways of knowing are possible.

An awareness of the common criticisms of critical realist approaches to research, in addition to the beneficial elements of the approach, enables a comprehensive and realistic understanding of the potential value and contrasting disadvantages or risks of adopting the approach. Embarking on critical realist research requires a pragmatic view of the system in which the research will be conducted, clarity on the key markers of critical realist research and an awareness of the potential of criticism of the approach taken. This rounded view has enabled a critical reflection on the value of this approach and clear justification of the choice. The relevance of critical realism specifically within this research will be explored next.

3.3 The relevance of critical realism in this research

The critical realist ontological and epistemological position is a particularly useful locus from which to explore how the role of the CRNurse is viewed by those practicing alongside yet outside of research delivery structures. This is due to the inherent complexity and social nature of research delivery structures within the NHS. In such an open system, many internal and external stakeholders, actors, participants, policies, and strategies will influence the success of the role. The numerous levels present within such a system will be susceptible to a range of mechanisms, operating across and within the structures, thereby generating a range of outcomes. Critical realism is relevant because it seeks to generate an understanding of what interventions and events cause the outcomes observed and reported. This is achieved by going beyond observing, measuring, and describing merely *what* is happening, to developing a deeper understanding of *why*.

Perhaps most important and relevant to this viewpoint is the nature of people, and the human relationships that are fundamental in the successful delivery of research. The afore-mentioned minimal requirements of non-disruption and cooperation described by Pawson and Tilley (1997) are relevant at various levels. Firstly, in influencing whether the CRNurse will support and value a particular study, thereby feeling congruent with demonstrating equipoise in recruitment conversations. Secondly, these two requirements are applicable to whether patients will be drawn to participate in the research. Thirdly, and most relevant to this research, is the perceived relevance and value of research to stakeholders outwith the research team. This may influence whether they will be drawn to support or resist research activity and the CRNurse. This ultimately leads to behaviours (generates mechanisms) which will impact relationships at the interface between research delivery and clinical service delivery. Ultimately, the relevance of research to people within an organisation as a whole (organisational culture) will be a factor in whether that organisation is ultimately changed, or influenced, through particular studies or by a research active culture in general.

The challenges explored thus far in the CRNurse related literature, reflect multiple layers of complexity in successfully implementing the CRNurse role. The CRNurse role, and what it is intended to deliver on a superficial level, is just one element of a larger programme of work, spanning a range of structures, teams, and individuals within a complex NHS system. The complexity does not stop at any given NHS boundary even if such a boundary were possible to clearly define. Rather it crosses into academia, industry sectors, arm's length bodies and far beyond into the patient communities it is aimed at benefitting.

The layers of complexity involved in the CRNurse role and the wider delivery of research in our healthcare system, are reflective of those apparent in large-scale interventions. Large scale interventions can involve multiple people (often termed actors in critical realist philosophy), in different sectors of whole systems. They are aimed at improvement and benefit, whether health related; a particular approach to organisational service delivery; outcomes in a particular population; or regeneration of social settings etc. They benefit from, and yet are equally obstructed by, permeable and moving boundaries. Hence, influencing factors operate in many different directions, with the potential to be negative, positive and neutral in nature (Emmel *et al.*, 2018).

Defining boundaries in complex systems where such interventions are implemented is difficult. According to Cillier (2018) cited in Emmel *et al* pg.96 (2018) social systems do not conform to a concept that aligns with our preference for defining most boundaries in a spatial manner. As such, there is no clear way to define what is within or outwith a social boundary, as everything interacts and multiple interfaces are apparent.

Boundary spanning, whether socially or spatially, within a particular NHS setting, is a common facet of the CRNurse role (Tinkler, Robertson and Tod, 2022; McNiven *et al.*, 2021). Yet the boundaries that the CRNurse operates across are moveable from study to study. They are subject to a range of barriers and enablers, many of which are based on relationships with actors outside of the CRNurse's immediate team.

This boundary spanning work, how it is directed by the structures within which the CRNurse operates, and to a large extent, how it is approached by the CRNurse, may serve as one mechanism in generating territoriality. Territoriality has its roots in anthropology and is an observable behaviour. It is often described as a non-verbal communication, where a particular space is dominated or controlled by an individual or group. Individuals or groups perceive they have ownership, or increased rights to exert power over that space, and seek to limit access to another. Territoriality can be fluid, and long or short term. It is found in settings where control can be exerted over spatial boundaries, people, resources and relationships (Gallaher *et al.*, 2009). This concept is reflective of the gatekeeping behaviours observed in wards and departments and subsequently portrayed in the CRNurse literature. Territoriality links to 'othering' behaviours (Gallaher *et al.*, 2009).

Othering is defined as the action of locating a person or group of persons on the margin of a given social structure where power is retained at the centre. This suggests the other is excluded, marginalised, and often labelled as deviant, because they do not fit the accepted societal norm within the given social structure (Gallaher *et al.*, 2009). The links between othering behaviours and territoriality over spatial boundaries are important to consider when researching behaviours and relationships as key factors in successful delivery of the CRNurse role.

It is possible to coalesce and apply these diverse concepts to the potential exploration of perceptions and relationships as influencing factors at the interface between clinical research delivery and clinical service delivery. These concepts suggest the need for an approach that enables each layer to be investigated and therefore understood holistically. For example, the exploration throughout chapter two analysed how the CRNurse generated literature positions and presents the CRNurse role. Predominantly, this is as one experiencing perceived inferiority, lack of understanding, and a lack of value placed on it by individuals who have power in the spaces in which the role needs to operate. How the role is perceived by those practicing within it, and how CRNurses themselves think they are viewed by those outwith research delivery structures, has mainly shaped the evidence base thus far. Chapter two also identified that little literature exists to link these experiences and perceptions to other broader social structures. Furthermore, evidence which directly reports the views of those described by CRNurses as gatekeepers cannot be located. Such gatekeepers are accused of adopting territoriality and acting to ‘other’ the CRNurse, exerting power or control over what they can or cannot access to carry out their work.

Separately, literature identifies additional factors that have the potential to impact on the role and therefore the success of research being delivered in the NHS. These factors include broader culture and leadership and how research is conducted. However, none have yet been explicitly explored within or linked to the CRNurse literature. In further building a case for the chosen philosophical foundations of this research, links can be drawn between the facets of the broader evidence base described above and the CRNurse literature.

The appropriateness and value of adopting critical realist methods in this research has been established through exploring critical realist philosophy, with some comparison to positivist, interpretivist, and constructionist philosophy. The complexity of research delivery and the implementation of the CRNurse role within this complex intervention is a fundamental reason to consider innovative and holistic research methods. The overarching methodological approach of this doctoral work will now be introduced by briefly outlining the two phases: a realist review and a group concept mapping study.

3.4 Methodological approach

As discussed earlier in this chapter, critical realist thinking is particularly relevant in complex and large-scale interventions. For the purposes of this research, the CRNurse role is defined and viewed as a complex intervention (programme of work) aimed at implementing and delivering multiple, yet distinct packages of research at the frontline in the NHS. This approach enabled the use of critical realist thinking to explore the literature and thus generate programme theories about what the role (programme) is aiming to achieve, what is thought to work well and work less well, and what may be causing things to work or not work.

These programme theories were generated through phase one of this doctoral research via a realist review. A realist review, whilst subject to a number of key principles and recommendations, is pragmatic in its approach, going beyond the methods of a standard systematic review. In keeping with the critical realist philosophy, realist review enables an iterative, flexible, snowball approach to exploring mainly documentary evidence. It incorporates a wide range of sources, including those more traditionally accessed via electronic database searching. The data included in realist reviews are selected based on whether they are considered relevant to the area of interest by the researcher. To decide on relevance, the researcher assesses to what extent the data, or indeed sections of the data located, are able to assist in developing, substantiating, refining or rejecting whole or sections of programme theories (Emmel *et al.*, 2018).

This flexibility is broad and facilitative. This stands in contrast to the relative rigidity of systematic reviews or meta-analyses, where strict inclusion and exclusion criteria are applied and adhered to from the outset. The complexity and breadth of factors involved in delivering clinical research, and its position within a complex healthcare system and culture, mean that, in this research, a broad range of evidence exists that may not be linked, yet is of relevance or would provide enlightenment to the research question. The aim of the initial critical realist review was, as described earlier in the chapter, to first provide clear and structured theories about the CRNurse role, theorising what may and may not work, in which circumstances and why.

Due to the complexity of the subject matter and the range of literature available, many theories were generated (13 in total). Following the realist review, an ethnographic study was to be the next stage. This would enable the direct observation of behaviours and interactions between clinical staff at the interface between clinical research delivery and clinical service delivery. A critical realist ethnography had been considered the most appropriate approach to support the direct testing of a number of theories generated from the review. The plan was for it to be conducted within the context of a large NHS Foundation Trust selected as a site.

The COVID-19 Pandemic developed in the months following the realist review whilst the ethnography protocol was being written and taken through relevant approvals. The impact of the pandemic unfortunately rendered the ethnography impossible, both from a clinical and a research perspective.

A number of potential alternative methods were considered, whilst also considering whether it would be wise to take a pause from the research, restarting when the pandemic had settled.

An online survey design may have enabled the relatively straightforward collection and analysis of responses from diverse groups of staff, however there was a risk that survey data may not provide the level of detail to enable the testing of the theories generated. This was especially relevant as the theories may create some difficulties in posing direct questions to test the mechanisms being triggered beneath the surface, In addition to this, survey designs are commonplace in the literature so would not have supported an original contribution to knowledge from a methodological perspective.

Semi-structured interviews may also have been possible to undertake, via video or telephone call, however much previous research in this field has been undertaken using survey designs, semi-structured interviews and focus groups. The potentially contentious nature of the theories to be tested, again may have proven difficult to research via direct questioning, and similar to a survey design, may have been open to responses that reflected neither an acknowledgement of the existence of resistance or avoidance behaviours, nor uncovering the mechanisms and contexts driving such behaviours.

The aim was to find a method that would not only enable data collection that complied with COVID legislation at the time, whilst also enabling as direct an approach as possible to test theories via the exploration of mechanisms, but would also provide an original contribution to knowledge in this area. Group Concept Mapping was therefore considered following some exposure to it as a method in a different setting. This method will be set out in more detail in chapter five, however the decision to proceed with this approach was in part due to its ability to enable the views of all participants to be collected, mapped and heard through collecting, sorting and rating views about a particular topics. The approach would enable the testing of one theory directly, with participants sharing their views, thematically sorting them, and then rating according to their perceptions through a set of rating scales.

Of the 13 theories generated by the realist synthesis, one was selected which most closely aligned with the overarching aims of this research. This theory was then taken into the second stage of this research – a group concept mapping (GCM) Study (Kane and Trochim, 2007).

This second stage enabled a deeper exploration of the selected theory, in order to test the extent to which causal mechanisms are at play in different contexts and at different levels of the system. The focus was on identifying which mechanisms were perceived as likely to generate resistance or avoidance behaviours (linked to theories of territoriality and othering) at the interface between research delivery and clinical service delivery. The empirical GCM phase then identified the mechanisms perceived as most important to address and provided recommendations as to what could be implemented to address them.

As the selected theory generated was tested and refined, a greater understanding of what works and does not work, for whom, and in which circumstances, in relation to the delivery of clinical research through CRNurses in the NHS was enabled (Edwards, O'Mahoney and Vincent, 2014; Pawson, 2013; Emmel *et al.*, 2018).

3.5 Summary

In this chapter, critical realist thinking and methodology has been described and critiqued, demonstrating its relevance as the chosen philosophical framework on which this doctoral research methodology is based. Other relevant theoretical literature, such as the concepts of territoriality and othering, have also been introduced as useful heuristic devices to connect elements of the current body of CRNurse literature to broader theories on social structures and politics. These theoretical connections have assisted in understanding the challenges described and shifted current thinking from an individual role perspective to practicing within a system level perspective. This chapter has sought to justify the relevance, suitability, and value of a critical realist philosophy in exploring factors which may generate behaviours at the interface between research delivery by CRNurses and clinical service delivery, and why.

Exploring the structures described thus far through a critical realist lens enables an understanding of the behaviours, mechanisms and contexts that lead to the range of outcomes observed. Whilst these differ across teams, within organisations, and across organisations nationally, this provides a richer data set than traditional methods of measurement, categorisation and inductive or deductive reasoning.

The chapter briefly introduced the two phases of the doctoral research comprising a realist review and a group concept mapping study, both conducted whilst adopting a critical realist stance. The full methods and findings of these two phases are presented in chapter four and five respectively. The next chapter will present the first stage of this doctoral work, the realist review.

CHAPTER 4. REALIST REVIEW PHASE

4.0 Introduction

This chapter presents the methodological approach and results of the realist review. This phase of the doctoral research generated the theory taken forward for testing in the subsequent group concept mapping (GCM) empirical phase. The staged process of conducting the realist review will be explained, drawing on relevant epistemological foundations and didactic training undertaken during the review.

The chapter will present a critical analysis of the literature selected as part of the review. The chapter will then explain the stakeholder engagement work undertaken during the review and how this enabled the selection of the final theory taken forward for testing in the GCM phase. The thirteen theories generated by the realist review data analysis will be reported, including their corresponding context, mechanism and outcome configurations. The relevance and value of this methodological choice will be reflected upon throughout the chapter in relation to its utility in providing the foundations of the GCM phase. In keeping with previous chapters, personal reflection points, situated within separate text boxes, have been offered throughout the chapter, where felt to be relevant to the topic being discussed.

4.1 Initial discussions and reflection

At the outset of the review activity, the common typologies of literature reviews were discussed, compared, and contrasted (Grant and Booth, 2009). A critical analysis of the suitability of each approach, and its relative value in informing this work, took place. This analysis was supported by a range of reflective discussions and writing, prior to the eventual confirmation that a realist review was the most appropriate approach based on intended outcomes (Kulviwat, Guo and Engchanil, 2004; Jesson and Lacey, 2006; Peters *et al.*, 2015). Appendix 2 provides evidence of early discussions related to the selection of the evidence synthesis approach. Reflective discussions centred around the aspiration to find and select a methodology that would provide a pragmatic and meaningful evidence synthesis. The pursuit of this pragmatism was partly based on knowledge of previous research and other key literature in this landscape, and partly based on the complexity of the focus of the review. The aim was to avoid the rigidity of a positivist approach which would, by nature of such methods, risk the exclusion of key data.

The evidence synthesis would need to account for the complexity of the subject area, as indicated in chapter three. This would require the inclusion of a range of data, not necessarily eligible for inclusion within a standard systematic review approach and associated, tight, inclusion and exclusion criteria. As described in chapter two, data such as editorials, opinion and narrative pieces, case studies and media generated by CRNurses with lived experience of practicing within their roles, formed a large section of the evidence base. This data was important to consider, as it may provide evidence of underlying mechanisms at play that had not previously been included in any synthesis. Excluding such evidence and working only with empirical data would arguably risk a level of epistemic fallacy and lead to a limited, inaccurate and potentially superficial perceived ontology of this broad landscape. As described in chapter three, critical realist approaches acknowledge such external and socially constructed worlds, enabling epistemological relativism and judgemental rationality. As such, these concepts were critical to this evidence synthesis and indeed the study as a whole.

The early scoping exercise included an examination of literature previously collected through earlier research activity, in addition to further scoping of the literature. These initial discussions informed the selection of a realist review approach and served to confirm the appropriateness of this methodology.

The aims of the realist review were to identify factors that influence how clinical research is perceived by healthcare professionals operating outside of clinical research teams within NHS organisations. It further aimed to consider how such perceptions, and the resulting behaviours, have the potential to subsequently impact on the experiences of CRNurses and the organisation’s ability to successfully deliver research.

4.2 Realist review methods

As identified in previous chapters, the CRNurse role can be defined as a complex programme of work, operating at a range of levels and across a range of structures and systems. The complexity of the role, and the range of layers involved in its implementation, lends itself to exploration through a critical realist lens. Critical realist methods are relevant here because they enable the generation of theory(ies) about potential causal mechanisms, underlying both intended and unintended outcomes observed and reported in relation to interventions or events. This is achieved by going beyond describing merely what is happening to developing a deeper understanding of why. This approach is particularly relevant where people and behaviours are involved; a key element of this research (Vincent and O'Mahoney 2016, cited in Cassell, Cunliffe and Grandy 2016; Wong *et al* 2013).

Realist review has been described as a theory driven, interpretive model of evidence synthesis, designed to work in complex social interventions or programmes (Brennan *et al.*, 2014). Realist review enables the inclusion of evidence that is qualitative, quantitative and mixed methods. Evidence such as strategies, opinion pieces, commentaries and other documents may also be considered within a realist review, if felt to be of relevance to the research. Whilst it is pragmatic in its approach, accounting for the complexity within open systems, realist review does not reduce complex questions to simple answers. Rather it provides a richer, deeper level understanding of what is happening and why within a social system. This ontological depth provides greater utility in the forward planning and subsequent implementation of programmes and interventions at a range of levels (Pawson *et al.*, 2005).

Increasing interest in realist review in the early 2000s led to calls for greater transparency in the reporting of such work. Gilmore *et al* (2019) argued that procedures applied within realist methods were often ambiguous, leaving those seeking to replicate or adopt such approaches uncertain in relation to how, practically, to undertake such syntheses. Meanwhile, work was underway to develop a set of preliminary publication standards in relation to realist synthesis (Wong, 2013). The Realist and MEta-narrative Evidence Synthesis: Evolving Standards (RAMESES) project intended to provide a preliminary resource to those undertaking realist evidence synthesis, whilst improving the reporting of the same (Wong, 2013).

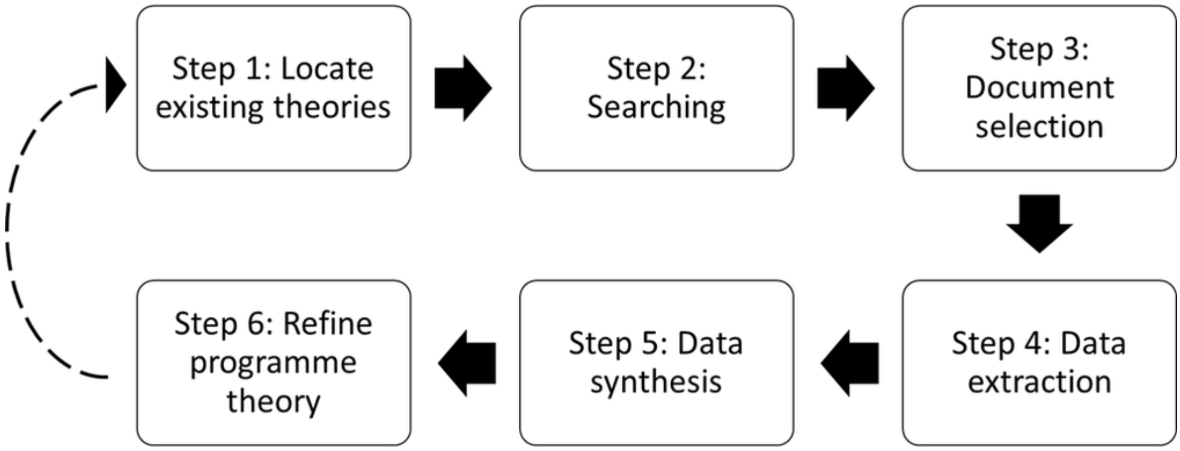
Those standards were adhered to in the publication of the realist review reported here.

The realist review carried out for this doctoral research utilised the six stages described by Weetman *et al*, (2017). These six stages are:

- Locating existing theory(ies)
- Searching the literature
- Document selection
- Data extraction
- Data synthesis
- Refining the theory(ies)

It is important to acknowledge that although the steps in a realist review are represented in a sequential fashion in figure 4.1, the process is iterative and often overlapping, as the researcher moves back and forth between stages (Pawson *et al.*, 2005).

Figure 4.1 Realist review design according to Weetman *et al (2017)*



4.2.1 Locating existing theories (Stage 1)

During the iterative dialogue related to the selection of an appropriate review typology, early scoping searches were conducted. These initial scoping searches, conducted during January and February 2019, enabled the location of existing theories about the CRNurse role. These searches utilised defined keywords, discussed and agreed with the doctoral supervisory team. Table 4.1. Illustrates the search strategy.

Table 4.1. Scoping review literature search strategy template

<table>
<tr><td>Search Question</td><td><i>What is known about the understanding of Clinical Research Nurses and its impact on recruitment and retention of patients to studies?</i></td></tr>
<tr><td>Initial Search terms</td><td>
<table>
<tr><td><i>“Clinical Research Nurs*”</i></td><td><i>“Clinical Trial*”</i></td></tr>
<tr><td><i>“Clinical Research”</i></td><td><i>“Research Nurs*”</i></td></tr>
<tr><td><i>“Clinical Trial* Nurs*”</i></td><td><i>“Research Pract*”</i></td></tr>
<tr><td><i>“Research Delivery”</i></td><td><i>Research AND Nurs*</i></td></tr>
<tr><td><i>“Patient recruitment”</i></td><td><i>“Patient retention”</i></td></tr>
<tr><td><i>“Trial retention”</i></td><td></td></tr>
</table>
</td></tr>
<tr><td>Then search separately for:</td><td>
<table>
<tr><td><i>“Professional Identity”</i></td><td><i>Attitude*</i></td></tr>
<tr><td><i>Understand*</i></td><td><i>Perception*</i></td></tr>
<tr><td><i>Awareness</i></td><td><i>Behaviour</i></td></tr>
<tr><td><i>Development</i></td><td><i>Experience*</i></td></tr>
</table>
Combine each with the initial search terms</td></tr>
<tr><td>Sources to be searched/explored</td><td>Databases to include
Cochrane Library
Healthcare Databases Advanced Search (HDAS) including CINAHL, HMIC, BNI, PubMED
Grey Literature
British Library ETHOS (e-theses online service)
Health Foundation
NIHR Website
The King’s Fund
Key contacts (using known networks of other researchers undertaking relevant work)</td></tr>
<tr><td>Part of journals to be searched</td><td>Title & Abstract
Keywords</td></tr>
<tr><td>Years of search</td><td>No limits initially
Papers will be ordered chronologically, and review will take account of key changes in policy over time e.g., introduction of NIHR</td></tr>
<tr><td>Language</td><td>English</td></tr>
<tr><td>Types of studies to be included</td><td>
<table>
<tr><td>Qualitative</td><td>Quantitative</td></tr>
<tr><td>Mixed Methods</td><td>Policy/strategy documents and frameworks</td></tr>
<tr><td>Narrative and opinion pieces</td><td>Editorials</td></tr>
</table>
</td></tr>
<tr><td>Inclusion criteria</td><td>Includes reference to nursing as key part of trial/study delivery
Related to delivery of clinical trials/research for others
Papers describing single study teams or broader organisational work
UK based mainly, however, international papers will be included for context and background depending on setting and health system
Primary, Secondary, Tertiary and Industry settings
References recruitment of patients to studies</td></tr>
<tr><td>Exclusion criteria</td><td>Nurses conducting own research
Non nursing related studies</td></tr>
</table>

The early scoping work, whilst not designed to be exhaustive, enabled a greater understanding of the breadth, depth and type of literature reporting on perceptions of clinical research delivery and the CRNurse role. Iterative scoping of the literature assisted in sifting out inappropriate keywords and enabled the identification of epistemological assumptions, highlighting gaps within the literature.

Early theories and associated context, mechanism, outcome configurations were developed from this initial scoping work. In realist review methodology, theories are designed to include “if… then” statements which identify the intended outcome by expressing “if we do x then the outcome will be y”. Pawson *et al*, (2004) articulate that the data to be collected in this stage should not relate to the *“efficacy of the intervention but to the range of prevailing theories and explanations of how it was supposed to work – and why things “went wrong””* (pg. No 16.). This is often termed the middle range theory related to the intended workings of the programme (Weetman 2017).

Data collected through the initial scoping exercise therefore included information on what the role of the CRNurse is intended or perceived to be by those in the role, how it has evolved over recent years (in the UK), how the CRNurse as an intervention is aimed at supporting and positively impacting on the delivery of research in healthcare, and the challenges described by CRNurses in practicing within their roles.

The initial scoping exercise uncovered evidence of the presence of potential mechanisms likely to impact on the perceptions, experiences and practice of CRNurses. These were attributed to corresponding layers of theory related to individual (micro) behaviours (Tinkler, Robertson and Tod, 2022), interpersonal relationships and the context in different clinical settings (meso), and institutional, infrastructural, and cultural (macro) level challenges. Mapping the potential mechanisms across these three layers of theory, served as a useful heuristic device, because of its ability to illustrate varying levels and types of interaction within their contextual setting. This is a common, well recognised and long debated analytical framework in the social sciences (Serpa and Ferreira, 2019).

The theories emerging from the literature, located through stage one, appeared to relate to three categories of influencing factors that have the potential to impact on the success of the CRNurse in undertaking their role and delivering research. These three categories are defined as social, emotional, and physical influencers. These influencing factors are referred to both implicitly and explicitly across the literature. Table 4.2 illustrates these categories, and they are discussed in more detail below.

Table 4.2. Influencing factors with the potential to impact on the clinical research nurse role

Social Influences	Emotional Influences	Physical Influences
Approaches to communication Concept of etiquette Incentives culture Emotional Labour Gatekeeping behaviours	Perceptions of target-based culture Job satisfaction Morale Concept of resilience	Trial complexity Lack of access to or sharing of facilities, rooms, and equipment The transient nature of the CRNurse role and related research studies Physical separation from clinical teams

(Spilsbury, Petherick and Cullum, 2008; Stobbart, 2013; National Institute for Health Research, 2016; Jones, 2017; Kunhunny and Salmon, 2017; McFadyen and Rankin, 2017; Gardner, 2018; Hill, 2018; Tinkler *et al.*, 2018; Tinkler and Robinson, 2020)

Social influences

In this study, social influences include approaches to communication between CRNurses and healthcare professional colleagues practicing outside of research; the concept of etiquette, including incentives culture, emotional labour and gatekeeping behaviours arising from the perceptions of colleagues described above (Kunhunny and Salmon, 2017; Hill, 2018; Tinkler *et al.*, 2018).

The perceptions of healthcare professionals and their behaviours towards CRNurses are thought, yet not proven, to incorporate a range of potential influences and factors. Table 4.3 outlines those described in the literature.

Table 4.3 Social influences that may mediate perceptions and behaviours of healthcare professionals outwith research delivery structures

Personal values
Preferences and beliefs about research
Previous experiences of or opinions about research
Understanding of the importance of and ability to remain in equipoise
Impacts arising from own workload or agenda
Fear of increased workload
Fear of ‘unknowns’
Fear of perceived risk to patients
Lack of awareness of the importance of research displayed at individual and team level despite organisational messages to the contrary
Level of visibility (individual, team, organisational)
Organisational culture in relation to research

(Gordon, 2008; Akerjordet, Lode and Severinsson, 2012; Donovan *et al.*, 2014; Donovan *et al.*, 2016; Jones, 2017; McFadyen and Rankin, 2017; Brown *et al.*, 2018; Hill, 2018; Tinkler and Robinson, 2020).

Emotional influences

In addition to the social influences experienced by the CRNurse, a broadly target-based culture in relation to research delivery appears to impact on the morale and job satisfaction of CRNurses (Tinkler and Robinson, 2020). This culture results from a combination of the inherent requirement to meet the calculated research sample size in order to successfully answer the primary outcome measure arising from the research team/sponsor (Gardner, 2018), and the strategic (NIHR and Department of Health) measurement of success of research delivery based on this outcome within a certain timeframe (Spilsbury, Petherick and Cullum, 2008; National Institute for Health Research, 2016; Jones, 2017; Hill, 2018). Although CRNurses acknowledge, and can articulate, the importance of targets, the link made at an organisational and strategic level between recruitment targets, finance and job security induces unnecessary anxiety for some CRNurses, especially where employed on temporary contracts (National Institute for Health Research, 2016; Hill, 2018; Tinkler and Robinson, 2020).

Physical influences

Physical influences on research delivery experienced by both the CRNurse, and arguably by their healthcare colleagues outside of research, include trial complexity, a lack of access to, or sharing of facilities, rooms, and equipment to enable the CRNurse to plan and execute a research appointment. They also include the transient nature of the CRNurse role and research studies meaning that the presence of a CRNurse in a particular area may be sporadic. The CRNurse is also often physically separate to the clinical teams they work closely with (Stobbart, 2013; Jones, 2017; Tinkler *et al.*, 2018; Hill, 2018; Tinkler and Robinson, 2020)

The evidence located through stage one assisted in clarifying what the CRNurse role is intended to be, what the indented outcomes are, and what does not seem to work in terms of its implementation in practice. The iterative process of searching and refining theory was continued through to stage two, following the agreement of an initial draft middle range theory, which will be described next.

4.2.2 Search strategy (Stage 2)

The aim of the search at stage two was to test the following middle range theory generated by the scoping searches in stage one:

> ***If*** *physical, social and or emotional barriers exist in the wider clinical environment,* ***then*** *this may impact on the ability of key colleagues to enable, support and promote research in their clinical area. This could negatively impact on the morale and job satisfaction of CRNurses and affect working relationships at the interface between the CRNurse and key colleagues outwith the research team. This could lead to reduced capacity to deliver research and reduce research opportunities offered to patients as part of their clinical pathway.*

Utilising the initial scoping searches, informal discussions that had taken place with experts in the field and with key stakeholders, searches were *"progressively extended and refocused based on the identified sources"* (Brennan *et al.*, 2014). The individuals referred to as experts in the field and key stakeholders comprised other researchers active in the field at the time, senior NHS staff with an interest or insight into the interface between clinical service delivery and clinical research delivery, and individuals who held senior strategic roles in the research landscape. To maintain confidentiality these individuals will not be named, however discussions with them contributed to the development of further searches and the eventual refining of the data. Specific articles identified in reference lists and "cited by" searches enabled the refinement of the initial scoping review to a manageable and specific data set. Two key words were found to yield the most relevant literature in search activity: *"Clinical Research Nurs*"* and *"Research delivery"*. According to Weetman *et al* (2017), comparable to stage 1 searching, the searches and other labour carried out during stage 2 are not intended to be exhaustive. This activity should, however, provide a sufficiently detailed overview of the literature to enable the further development and refining of theories throughout the review.

Whilst the document searching and retrieval process is a key element of the realist review approach, other relevant data can be included if identified from sources such as social media, dialogue with experts, TV and radio programmes, online information held in relevant websites and newspaper articles (Emmel *et al.*, 2018). This approach enabled the identification of two further articles held on the NIHR website, and a set of videos forming an online resource aimed at sharing the experience of nurses, midwives and allied health professionals (NMAHPs) involved in research and research roles (University of Oxford, Health Experiences Research Group 2019).

4.2.3 Document selection (Stage 3)

In line with the realist review approach, documents and data were selected based on two key indicators in addition to the initial eligibility criteria defined in the search strategy (Table 4.1):

1. Their relevance and ability to inform the aims of the review

2. The potential of adding understanding to the existing knowledge base about the intended impact of the CRNurse role and what does or does not work in its implementation

In assessing the relevance of a particular piece of evidence, it is not necessary to base this on the entirety of a document. Sections or extracts from whole documents may be judged relevant and therefore selected for data extraction (Brennan *et al.*, 2014).

Documents and data included empirical studies, (Qualitative, Quantitative and Mixed Methods), narrative opinion pieces and individual commentaries. Several policy and strategy documents and frameworks were also collected and reviewed. Whilst these were not deemed appropriate to take forward into stage four data extraction, they were considered useful and therefore retained in order to inform the background and foundations for the overarching study. Searching did not identify any relevant social media dialogue, TV reports or newspaper articles. However, discussions with key stakeholders and experts (regional and national NIHR Network staff, CRNurses and other researchers in this field) did contribute to this stage of the review and directed some of the searching to include specific papers and viewpoints.

4.2.4 Data extraction (Stage 4)

Data were extracted via an iterative combination of reflective notetaking, highlighting and annotation of sections, and recording document characteristics using Quirkos$^{©}$ software. Papers were categorised by evidence type, main theme of paper, country and setting, and the approach or methodology. Weetman *et al*, (2017) describe this approach as useful in collecting descriptive information to enable the grouping of documents during review, whilst utilising recognised realist note-taking techniques to achieve data extraction.

During the review, theories were extracted in relation to how the CRNurse role is intended to work; the perceived characteristics required to be successful as a CRNurse; the views of stakeholders the role is required to interact with, and factors that appear to demonstrate success and failure, and why. Extracts of text related to these subject areas were highlighted, annotated, and labelled thematically.

Throughout data extraction, documents were considered in relation to the quality of the evidence they presented (Pawson *et al.*, 2004). Realist review approaches support the fundamental principle of confirming the quality of data in the pursuit of high quality reasoning, however, reject the traditional approach privileging the hierarchy of evidence and making judgements about the inclusion or exclusion of evidence based on a quality appraisal alone. Pawson (2013) discussed the implications of seeking to achieve objectivity, when searching for and including a wide range evidence and the subsequent approach to assessing quality. The inclusion of multiple types from qualitative, quantitative, and personal accounts, described by Pawson (2013) as gossip, were all deemed acceptable, yet, challenges should be considered in achieving a single objective truth, due to the many ways in which data may be interpreted and therefore acted upon. The use of the CASP framework for example, may be appropriate for certain evidence types, however, not for others and therefore treating the evidence equitably presents the researcher with conundrum in confirming the quality, relevance, and truth of what is available to assess and synthesise. Pawson (2013) therefore suggests that in the impossible pursuit of objectivity, the key is seeking out and testing the quality of the reasoning and inferences drawn in the evidence, rather than the quality of the data alone. The importance of hypotheses and inferences being tested, debated, confirmed or rejected is what drives the collective approach to assessing and confirming quality. It is also important to note that although rigour and relevance were assessed, the exclusion of an entire document based on rigour alone is not advised due to the ability of different sections of different documents to contribute to the evidence base for theory testing and refinement (Pawson *et al.*, 2004).

4.2.5 Data synthesis (Stage 5)

Data synthesis was undertaken using the approach described by Pawson *et al*, (2004) which aims to refute or support theory integrity and search for rival theories. This approach enabled a focus on specific influencing factors in the implementation of the CRNurse role in relation to the aims of the study and the draft middle range theory defined in stage two. Data were synthesised to question the integrity of current approaches to implementing the role in the NHS. This included the social, physical and emotional influences emerging from the literature. The review was therefore conducted via a retroductive approach to propose what it is about the implementation of the CRNurse role that works (or does not work), for whom, in what circumstances, and why. Data extracted from the included sources were used to test and refine the initial middle range theory and to seek to identify the potential causal mechanism(s) and the context(s) in which those mechanism(s) might be triggered (Brennan *et al.*, 2014).

Reflection Point

During data synthesis, I attended a summer school in realist review methodology at Solent university. The summer school ran over four days. It was delivered via a mixture of theory based didactic sessions exploring the use of realist methods, alongside dedicated self-directed time for developing one's own work and 1-1 sessions with experts in the field of realist review methodology. During 1-1 sessions I was able to discuss and verify the suitability of the approach taken so far and share progression of the realist synthesis stages.

Group and self-directed sessions enabled the development and refinement of programme theories and related "Context Mechanism Outcome" configurations from the data collected so far. The learning undertaken through the summer school shifted my mindset from some rather positivist concerns I was feeling related to being able to justify my approaches. This included handling potential criticism from those of a more positivist mindset who may require the production of empirical evidence to demonstrate or back up the theories I was developing about the challenges of implementing the CRNurse role.

As the data synthesis activity progressed, and retroductive thinking was supported through the attendance at a Realist Summer School, it became possible to translate the themes generated into a range of programme theories with associated Context, Mechanism, Outcome configurations.

A total of 11 separate programme theories at micro, meso and macro levels with associated CMO configurations were developed during the data synthesis stage. These were discussed, reflected upon and refined during the learning that took place via a realist summer school with a range of experts in the field and other novice realist synthesis students. A further two programme theories were developed later, as the iterative process of reviewing and reflecting on the data continued. The 13 eventual theories are illustrated in Table 4.4.

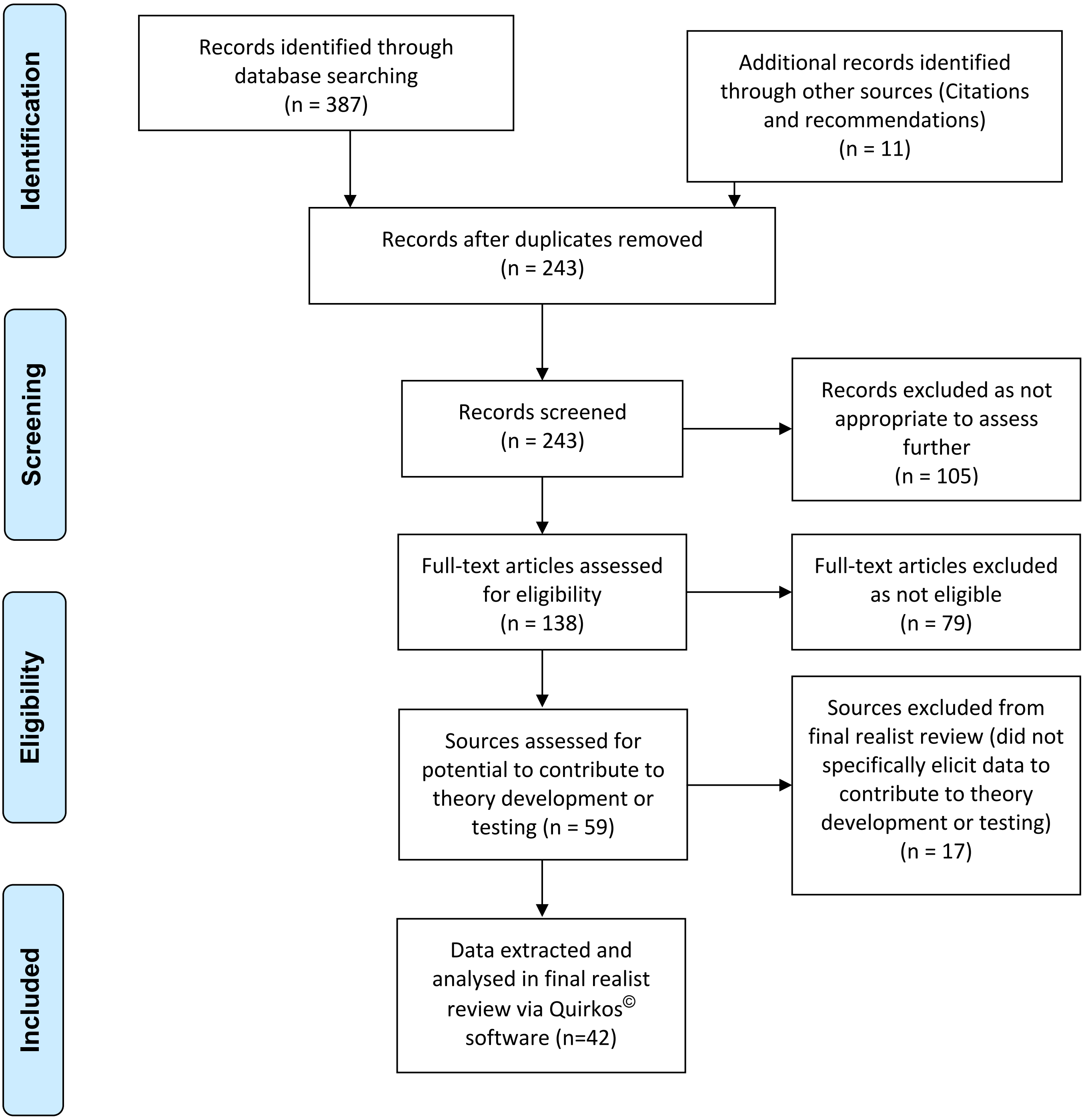
4.3 Findings

Figure 4.2 provides a PRISMA flow diagram to illustrate the final searches undertaken at stage 2 and the selection and exclusion of sources for the review. Appendix 3 illustrates the document characteristics of the coded papers. A total of 59 papers and data sources were initially located during scoping. During data extraction, all 59 were read, however 42 were transferred into the Quirkos© software, coded and annotated for the purposes of the realist review. The remaining papers were retained for interest, future reference, background relevance, or further analysis, as the work progressed.

Initial coding generated 3,644 extracts of text coded against 160 themes (called "quirks" in Quirkos© software). Themes were further refined and merged, reducing this number to 124 overarching themes. Larger overarching themes were generated in relation to defining the CRNurse role, the required skills and competencies, influencing factors in relation to the success of the role, and the research perceptions of the CRNurse and other staff.

A theme with a patient focus was also generated, containing sub-themes of how patients benefit from research, the nurse patient relationship, and the CRNurses' perceptions of patient motivations to participate in research. Themes were also generated in relation to the overarching research culture and attitudes to research in the NHS, target driven cultures and specific training for the CRNurse role.

Figure 4.2 PRISMA flow diagram



A handful of empirical studies were found relating to CRNurse perceptions and experiences. These built on existing narrative accounts and provided observed evidence of the experiences described by CRNurses. As outlined in chapter two, research carried out by Kunhunny and Salmon (2017), Hill (2018), Tinkler et al (2018), Tinkler and Robinson (2020) and McCabe et al (2019), reported a range of positive experiences in relation to the CRNurse role. The most significant of these included: being at the forefront of improving and changing practice, care and patient outcomes; increased autonomy; the development of specialist clinical or research related skills; and the increased amount of time they perceived they were able to afford to patients when practicing in their role.

The realist review identified the key elements of the CRNurse role as one of a communicator, boundary spanner, advocate and influencer, in addition to the varied nature of the clinical demands associated with the range of research being delivered. To be successful, the CRNurse is required to influence across departments and professions whilst advocating on behalf of patients and carers, thereby balancing the preferences of patients with the complexities of implementing discrete research studies across different teams and departments. This has most recently been supported by McNiven *et al* (2021) who described an essential part of the role as *“connecting with and between important groups in research.”*

As the data synthesis progressed, the themes generated were translated into a range of theories with associated context, mechanism, outcome (CMO) configurations. The micro, meso, macro contextual level framework outlined earlier was then used to structure the presentation of these theories.

A total of 13 separate theories with associated CMO configurations were eventually generated and refined during the realist review. These are illustrated in Table 4.4 and are discussed further in the next section

Table 4.4. Theories and context, mechanism, outcome configurations

No	Contextual Level	Theory Statement (If-Then)	Context, Mechanism, Outcome Configuration
1.	Micro	*If the CRNurse is an* ***effective communicator*** *(influencing, motivational, change management, leadership skills etc.) then he/she may be more successful in engaging key colleagues in supporting or enabling research to take place. This is because positively influencing clinical colleagues can lead to enhanced shared purpose associated with the role of clinical research delivery, subsequently increasing opportunities for patients to be offered research as a core part of their clinical care*	A CRNurse who is an effective communicator will possess a range of skills to draw on to influence, educate and engage staff in supporting or enabling research to take place, because positively influencing key clinical colleagues through a positive approach, communication style and self-confidence, will lead to a shared understanding and purpose associated with clinical research delivery in the clinical area. This may subsequently increase job satisfaction for the CRNurse, foster closer working relationships with key colleagues, increase the levels of research related knowledge and confidence in key colleagues and ultimately lead to increased opportunities for patients to be offered research as part of their clinical care
			A CRNurse who does not possess effective communication skills may inadvertently disengage key staff in relation to the value and utility of supporting clinical research delivery in the clinical area. This may subsequently damage potential for team working, decrease job satisfaction for both the CRNurse and their key colleagues and lead to decreased opportunities for patients to be offered research as part of their clinical care

			A CRNurse who is familiar with the clinical area or staff in the area in which she/he is delivering research, may possess key soft intelligence and benefit from established relationships or knowledge of successful approaches to influencing which may lead to a greater shared understanding and purpose associated with clinical research delivery in the clinical area. This could subsequently increase job satisfaction for the CRNurse, foster closer working relationships with key colleagues, increase the levels of research related knowledge and confidence in key colleagues and ultimately lead to increased opportunities for patients to be offered research as part of their clinical care
2.	Micro	*If the CRNurse has* ***high levels of resilience,*** *then he/she may more effectively cope with and or overcome the challenges associated with transitioning into the role, leading to increased productivity and confidence in practice, increasing opportunities for patients to be offered research as part of standard care and delivering more studies to time and target.*	A CRNurse with high levels of resilience may more effectively manage the challenges associated with transitioning into the role, leading to increased productivity and confidence in practice, increasing opportunities for patients to be offered research as part of standard care and successfully delivering more studies to time and target
			A CRNurse with low levels of resilience may less effectively manage the challenges associated with transitioning into the role, leading to decreased productivity and lower confidence in practice, decreasing opportunities for patients to be offered research as part of standard care and reducing potential to deliver studies to time and target

3.	Micro	*If the CRNurse **feels adequately supported** in the role then he/she may experience an increased sense of fundamental value associated with their role in delivering research, leading to greater confidence, intrinsic motivation and effort to successfully deliver in the role*	In a context of feeling adequately supported in the role, the CRNurse may experience an increased sense of value leading to greater intrinsic motivation and effort to successfully deliver in the role
			In a context of feeling adequately supported in the role, the CRNurse may be more likely to have higher levels of self-efficacy and confidence, enabling more effective communication with key colleagues, fostering a research aware and active culture, ultimately increasing opportunities to introduce research opportunities to patients
4.	Micro	*If the CRNurse **does not feel adequately understood or supported** in the role then he/she may experience a reduced sense of fundamental value associated with their role in delivering research, leading to increased isolation, lower confidence levels, reduced intrinsic motivation and reduced job satisfaction. This could impact on subsequent potential to successfully deliver in the role*	In a context of feeling inadequately supported in the role, the CRNurse may experience a reduced sense of value leading to lower levels of intrinsic motivation and effort to successfully deliver in the role
			In a context of feeling inadequately supported in the role, the CRNurse may develop lower levels of self-efficacy and confidence, hindering the ability to effectively communicate with key colleagues. This may impact on the ability to foster a research aware and active culture and may ultimately decrease opportunities to introduce research opportunities to patients and deliver studies to time and target

5.	Meso	*If key colleagues* ***do not understand the importance, value and utility of research to their role, their patients, or the wider NHS agenda*** *then they may* ***inadvertently*** *display avoidance of or resistance to research being delivered in their clinical area, thereby hindering positive working relationships with CRNurses and reducing access to research opportunities for patients*	In the context where key colleagues are not aware of the importance, value and utility of research to their role, the patients in their care, or the wider NHS, then they may be unaware of the impact of their behaviours on the CRNurse and the wider research agenda, leading CRNurses to feel undervalued, unwelcome and invisible, thereby hindering positive working relationships with CRNurses and reducing access to research opportunities for patients
			In the context where key colleagues do not understand the importance, value and utility of research to either their role or the patients in their care, then they may display active resistance to research being delivered in their clinical area, this leads CRNurses to feel undervalued, unwelcome and invisible, thereby hindering positive working relationships with CRNurses and reducing access to research opportunities for patients
			In the context where key colleagues do not understand the importance, value and utility of research to either their role or the patients in their care, then they may display avoidance in relation to research being delivered in their clinical area, this leads CRNurses to feel undervalued, unwelcome and invisible, thereby hindering positive working relationships with CRNurses and reducing access to research opportunities for patients
6.	Meso	*If key colleagues* ***do not understand the importance,***	In the context where key colleagues may not understand the importance, value and utility of research to either their role or the patients in their care, then they may

		value and utility of research to their role or their patients *then they may* ***knowingly*** *display avoidance of or resistance to research being delivered in their clinical area, thereby hindering positive working relationships with CRNurses and reducing access to research opportunities for patients*	knowingly display avoidance of or active resistance to research being delivered in their clinical area, this will lead CRNurses to feel undervalued, unwelcome and invisible, thereby hindering positive working relationships with CRNurses and reducing access to research opportunities for patients
7.	Meso	*If key colleagues* ***are not interested in (intrinsically motivated by) research*** *then they may* ***display gatekeeping behaviours of avoidance of or active resistance to research*** *being delivered in their clinical area, thereby hindering positive working relationships with CRNurses and reducing access to research opportunities for patients, impacting on organisational performance in*	If key colleagues are not interested in (intrinsically motivated by) research then they may display avoidance of or active resistance to research being delivered in their clinical area. This will lead CRNurses to feel undervalued and unwelcome thereby damaging positive working relationships and reducing access to research opportunities for patients, impacting on organisational performance in relation to research activity and culture In the context of a lack of interest in research from key colleagues, the CRNurse may deploy tactics to incentivise colleagues to support them in gaining access to space, facilities or patients in the clinical area. The need to deploy such tactics may lead CRNurses to feel undervalued and unwelcome thereby damaging positive working relationships and reducing access to research opportunities for patients, impacting on organisational performance in relation to research activity and culture

		relation to research activity and culture	
8.	Meso	*If key colleagues are* ***fearful of increased workload*** *as a result of research activity in their clinical area, then they may* ***avoid*** *communicating with the CRNurse or* ***actively prevent access*** *to facilities or patients, thereby reducing opportunities to introduce research as part of standard care and affecting the CRNurses ability to deliver a study to time and target*	If key colleagues are fearful of increased workload as a result of research activity in their clinical area, then they may avoid communicating with the CRNurse. This may lead CRNurses to feel burdensome, unwelcome, ostracised and undervalued, reducing opportunities for shared learning in relation to research delivery within clinical practice and also affecting the ability to introduce research to patients as part of standard care
9.	Meso	*If key colleagues are* ***fearful of risk to their patients*** *as a result of research activity in their clinical area, then they may* ***avoid*** *communicating with the CRNurse or* ***actively prevent access*** *to facilities or patients, thereby reducing opportunities to introduce research as part of*	If key colleagues are fearful of risk as a result of research activity in their clinical area, then they may, **avoid communicating with the CRNurse**. This may lead CRNurses to feel burdensome, unwelcome, ostracised and undervalued, reducing opportunities for shared learning in relation to research delivery within clinical practice and also affecting the ability to introduce research to patients as part of standard care
			If key colleagues are fearful of risk as a result of research activity in their clinical area, then they may **actively prevent CRNurses from accessing facilities or patients.** This may lead CRNurses to feel burdensome, unwelcome, ostracised and

		standard care and affecting the CRNurses ability to deliver a study to time and target	undervalued reducing access to the ability to introduce research to patients as part of standard care
10.	Meso	*If Clinical Research is (seen as) a* ***priority*** *for senior management then support for the CRNurse including development and progression opportunities in relation to the role will be integral to the trust's ongoing research strategy, leading to better working relationships with key colleagues and increased research capacity*	In the context where Clinical Research is (seen as) a priority for senior management then support for the CRNurse including highlighting the importance of the role, development and progression opportunities will be integral to the trust's ongoing research strategy. This will then lead to increased visibility and awareness of the role in key colleagues enabling greater capacity to deliver research and offer more opportunities to patients to participate in research
11.	Meso	*If the CRNurse role is* ***clinically embedded or is co-located*** *with the clinical team then shared purpose and joined up working is more likely, enabling higher levels of research capacity within the team, greater understanding of the role of the CRNurse and a*	If the CRNurse role is clinically embedded or is co-located with the clinical team then joined up working is more likely, this then leads to a greater understanding of the role of the CRNurse enabling higher levels of research capacity within the team and fostering a culture of offering research opportunities to patients where possible

		culture of offering research opportunities to patients where possible	
12.	Macro	*If the National focus (message) is on* ***achieving targets*** *and subsequently attracting funding then trust between individual, organisational and regional/national levels may be eroded and morale may be affected because CRNurses feel the focus on patients is lost, leading to lower levels of intrinsic motivation which may impact on productivity in relation to delivering research*	In the context where the national strategic focus is on achieving targets and resulting funding then trust is eroded, and morale is affected because CRNurses feel the focus on patients is lost leading to lower levels of intrinsic motivation which may impact on productivity in relation to delivering research
			In the context where the national strategic focus is on achieving targets and resulting funding then CRNurses identify with the negative elements of their perceptions of the role of the salesperson, leading to lower levels of intrinsic motivation altered professional identity and reduced morale which may impact on productivity in relation to delivering research
13.	Macro	*If the National strategic focus is on* ***promoting the value and potential of research to patients as an integral element of the care pathway,*** *CRNurses*	In the context where the national strategic focus is on promoting the value of research to patients, then trust and morale are increased because CRNurses feel the focus on patients is strong, leading to higher levels of intrinsic motivation which may impact on productivity in relation to delivering research

		will feel the focus on patients is strong, leading to higher levels of intrinsic motivation which may impact on productivity in relation to delivering research	In the context where the national strategic focus is on promoting the value of research to patients, then CRNurses identify with the positive elements of the role of advocate and the nurse patient relationship, leading to higher levels of intrinsic motivation and improved morale which may impact on productivity in relation to delivering research

4.2.6 Refine theory (Stage 6)

The final stage of the realist review involved a stakeholder engagement activity to support theory refinement. Stakeholder engagement is a key activity to ensure theories derived from the synthesised data are reflective of stakeholder perceptions. Seeking stakeholder perspectives in this realist review provided the opportunity to access expert knowledge of the content through a process of checking that the theory(ies) arising from the review were congruent with the experiences of CRNurses and their leaders in practice (Weetman *et al.*, 2017). The stakeholder engagement undertaken in this realist review also supported preparation for the GCM phase of the study, by supporting the selection of a single theory to take through into the GCM phase.

Stakeholders for the synthesis were engaged through an opportunity to undertake a Visual Presentation with Expert Review (ViPER) session at the Royal College of Nursing International Nursing Research Conference in September of 2019. Appendix 4 outlines the main elements of the ViPER session according to the Royal College of Nursing. A ViPER session is described by the RCN as a novel approach to delivering research presentations, to aid with networking. ViPERs involve the appraisal of a visual presentation with expert review. This means the researcher is usually accompanied and supported by an expert in the field. The approach enables an interactive and discursive approach to the presentation of research data, in contrast to established didactic approaches to conference presentations.

The ViPER involved producing an academic poster for display, critically presenting the main elements of the poster and work undertaken, and responding to questions from an expert reviewer, before opening up to the room to respond to questions and gain feedback. An information leaflet (Appendix 5) was produced and handed to every delegate to explain the overarching ongoing research and invite them to offer their feedback on the data presented. A smaller version of the poster (Appendix 6) was also provided to delegates attending the session. The session was attended by more than fifty conference delegates, most of whom were managing, working as, or practicing alongside, CRNurses. Due to the time and poster display constraints associated with such a session, the poster was limited to one programme theory. Appendix 7 illustrates the broad plans and subjects covered during the ViPER session. Whilst the discussion related mainly to one programme theory, data and views related to the other programme theories naturally emerged, providing validation of the continued direction of the research.

The opportunity to share early findings and enable questions and clarification from stakeholders at a single point in time via presentation in a conference setting, provided an excellent opportunity to influence interpretation and refinement of the findings. This approach served to optimise the relevance and specificity of the review recommendations and was particularly advantageous in relation to agreeing the overarching theory to be taken forward into the empirical element of this work, the group concept mapping phase.

4.4 Discussion

The research related perceptions of healthcare professionals practicing outside of research roles identified in the literature mainly related to the concept of nurse-led research and the demands of fitting research into one’s own clinical practice. Little was identified in relation to specific views of research delivery, or the CRNurse role outwith the views of research teams and CRNurses. This demonstrates a clear research gap and suggests the urgent need to explore these currently absent views to enable a deeper understanding of the experiences described by CRNurses.

The four micro level theories generated by the review assist in confirming previous reports of a combination of intrinsic factors directly affecting the success of the individual within the role. These factors include communication skills, resilience, and perceptions of feeling supported and valued within the role (Tinkler *et al.*, 2018; Tinkler and Robinson, 2020). Whilst these factors have been reported in the literature elsewhere, the review enabled them to be situated within a framework of context, mechanism and outcome, facilitating further consideration of their importance in relation to the delivery of research in the NHS. Whilst resilience is the subject of ongoing debate in nursing, evidence emerging from the empirical data reviewed throughout the review suggests that those CRNurses possessing higher levels of resilience may more effectively cope with, and/or overcome, the challenges associated with transitioning into the role (Traynor 2018; Tinkler *et al* 2018).

The seven meso level theories highlight a multifaceted range of potential mediators of success, ultimately generated by human agency. The term ‘human agency’ was defined by Bandura (Bandura, 1989; Bandura, 2001) as the capability of humans to be able to influence one's own functioning and the courses of events through one's own actions. Bandura describes the four functions through which human agency is exercised as intentionality, forethought, self-reactiveness and self-reflectiveness.

When the concept of human agency is considered specifically in relation to the CRNurse role and its implementation, a range of factors can be considered relevant. These include individual beliefs, past experiences, environment, organisational culture, and decisions made by actors within and outside of the role. All have the potential to interact and impact, through the visible behaviours displayed at the interface between research delivery and clinical service delivery. These challenges can be better understood when viewed through the lens of social structures. As such, interactions between, and impacting on, the CRNurse and colleagues outside of the research team can range from choosing to embrace and promote research, to avoidance, displaying scepticism, and exhibiting gatekeeping behaviours in relation to the role. These directly impact on the CRNurse and affect their subsequent behaviours in relation to such interactions. In addition to this, emotional influencers present at an underlying level, such as anxiety linked to workforce pressures and job security resulting from the target driven, task focussed culture in research and healthcare, can also impact on the individual CRNurse, mediating morale, job satisfaction and intention to remain in post (Tinkler *et al.*, 2018; Tinkler and Robinson, 2020).

The recent work of McNiven *et al* (2021) supports these findings, building a strong link between the articulated professional identity of CRNurses, Midwives and AHPs (R-NMAHPs) and the wider contexts in which they work. This includes groups of individuals such as non-research active clinical colleagues. McNiven *et al* (2021) describe a sense of alienation and rejection from clinical colleagues, which affects their ability to absorb boundary spanning activities, despite the positive potential of this key element of the role.

A key statement which has informed the theoretical considerations of this doctoral work, as described and expanded on in chapter three, is offered by Pawson and Tilley (1997). They suggest the successful implementation of any '*programme*' relies on the very minimal requirements of cooperation and non-disruption. The perceived relevance of a programme, intervention, policy, or strategy to an individual is also an important marker of whether they will be drawn to, act in support of, or experience change as a result of its implementation. That is to say that programmes will only be successful if the people involved see value in the programme and act to make it a success (Pawson, 2006). Using Pawson and Tilley's theoretical proposition helps to explicitly link the notion that individuals outwith research teams need to, as a minimum, demonstrate cooperation with research teams to enable the successful delivery of research. Where cooperation as a bare minimum does not exist, the chances of success are reduced, regardless of the resources supplied or withdrawn in order to make a programme work (Pawson, 2006). In a study exploring gatekeepers in research, McFadyen and Rankin (2017) referred to the complexity of achieving this, suggesting that access to a particular department to deliver research needs not only approval but also cooperation. A key inference from this review is therefore that interactions at the interface between research delivery and care delivery, and leadership and organisational culture, may act as mediators in the potential success of research delivery in the NHS.

Leadership and culture are terms used regularly in discussion and debate related to the NHS, the quality of patient care, and its performance in relation to government targets. A range of evidence describes the impact of leadership and culture on the cohesiveness of teams, the behaviour of NHS staff, and the resulting quality of care (Turnbull-James, 2011; West, 2012; Francis, 2013). In previous work, Tinkler *et al* (2018), and Tinkler and Robinson (2020), identified the impact of culture and leadership specifically in relation to the delivery of clinical research. This previous work suggested that visibility, awareness, value and organisational context have the potential to impact on both staff within and outside research delivery teams, ultimately mediating attitudes towards research and the resulting "research culture". The meso level theories generated by this review provide insight into the key interactions required for the success of research delivery and correlate with evidence of leadership and culture as mediators of success.

At a macro level, in the context of continued nursing shortages and wider workforce challenges in the NHS, maintaining adequate research delivery capacity presents a significant challenge, inevitably affecting the recruitment and retention of CRNurses (Faulkner-Gurstein, Jones and McKevitt, 2019). The NHS People Plan identifies the nursing shortage as both the most significant and most urgent of the challenges faced, and importantly outlines the key part the nursing role plays within the *"multiprofessional team needed to deliver the NHS Long Term Plan..."* (NHS England, 2019). The plan acknowledges the need for a "*multifaceted and carefully coordinated strategy"* (pg. 20) to include, amongst other key ingredients, improved retention of nurses and the clear provision of equitable career development opportunities to meet the needs of both the workforce and the changing requirements of our patient populations. Research and effective research delivery remain integral to these aims, though are not forefronted within the plan.

Weaved throughout the NHS People Plan is a fundamental thread; a commitment to making the NHS the best place to work through inclusive and compassionate leadership. The plan identifies the importance of the right type of behaviours expected in our interactions with each other, and across the system. A link can be made here between the NHS People Plan's commitment to inclusive and compassionate leadership, and the potential influence of culture, leadership and the resulting behaviours displayed during interactions between CRNurses and colleagues outside of the research team.

Adding to the omnipresent workforce issues is continued evidence that few trials are able to recruit and retain the required number of participants within the planned timeframe in order to address the primary outcome measure and answer the original research question (Campbell *et al.*, 2007; Donovan *et al.*, 2014; Gardner, 2018; Treweek *et al.*, 2018; National Institute for Health Research, 2020). Increasingly, "research on research" is being undertaken to explore what is termed *'recruitment to time and target'* and the efficiency of clinical trials in answering research questions (Preston *et al.*, 2016; Skea, Treweek and Gillies, 2017; Gardner, 2018). The focus of this emergent evidence base is mainly related to the practicalities of trial design, methodology, and approaches to training site investigators (Donovan *et al.*, 2014; Mills *et al.*, 2018; Gardner, 2018; Rooshenas *et al.*, 2019; Rooshenas *et al.*, 2019b). Within this field there remains relatively limited acknowledgement of the complexity of human agency and the wider context-related complexities of implementing a study protocol which is designed at one site (in a specific context) but then delivered at other sites through different teams with different challenges.

Such macro level challenges impact on the individual CRNurses at micro levels in relation to morale, job satisfaction and intention to remain in post. They also have the potential to influence the organisational capacity to offer research opportunities to patients and the resulting success of research projects delivered within the clinical area. This poses a significant risk in relation to the wider government ambition to ensure the UK has a flourishing life sciences industry and that the UK is seen as a preferred location in which to undertake clinical research. There are also further reputational consequences in relation to research and clinical care related league tables and their associated quality ratings (Department of Health, 2012; National Institute for Health Research, 2016; National Institute for Health Research, 2020).

Finally, in an online blog written for the British Medical Journal, Leary (2019) stated that *"healthcare is a human activity delivered by humans... and trying to model skills, task delivery, or any other abstraction of the work is unlikely to meet with success."* Leary suggested there is a necessity to explore workforce needs in relation to the populations they serve, with workforce design driven by that demand. Leary also stated that courage is required to enable emancipation from 'activity' being the primary measure of success in health and suggesting that outcomes for patients and workers should also be considered when thinking about workforce planning.

The realist synthesis has enabled a range of theories at micro, meso and macro levels to be generated in relation to the causal mechanisms influencing how Clinical research delivery is perceived by healthcare professionals. It has enabled retroductive thinking to suggest how these perceptions impact on CRNurse experiences, practice and capacity to ensure successful patient recruitment to research in the NHS. The following overarching theoretical proposition, resulting from meso level theory, was developed and selected to form the foundation of the empirical data collection in the Group Concept Mapping phase:

> *If key colleagues are **not interested in, aware of, or do not understand** the importance, value and utility of research to their role, their patients, or the wider NHS agenda, then they may **unintentionally or intentionally** display*

avoidance of or resistance to research being delivered in their clinical area. This presents a risk to positive working relationships with CRNurses and access to research opportunities for patients. Consequently, this could impact on organisational performance in relation to research activity and culture.

4.5 Strengths and limitations of the realist review

The aim of this review was to draw out the underlying mechanisms that may shed light on the experiences described by CRNurses, the perceptions they articulate about practicing within their roles, and their interactions with other professionals as they go about their work. The majority of literature relating to perceptions of the CRNurse role, and research delivery in the NHS, is understandably presented by CRNurses, sharing their passion for the role, aiming to create debate, raise awareness and visibility, and attracting others into the role by highlighting the main elements of the work. The lack of literature regarding views of health professionals outside of the role is not surprising. However, it must be acknowledged that the perspectives of these individuals are currently absent and a more balanced view of the context in which research is delivered in today's NHS should be sought.

The majority of literature generated by CRNurses thus far has historically been subjective in nature, or generally specific to single research studies or discrete clinical specialties. Case studies, narrative discussion pieces and reflective accounts form the majority of the evidence base accessed for this review (Gordon, 2008; Hardicre, 2013; National Institute for Health Research, 2016). Whilst this could be viewed as a limitation, as described previously in relation to judgemental rationality and epistemological relativism, in critical realist approaches the lived experience and therefore expertise of those embedded in a particular context has the potential to uncover key clues as to why something works or does not work, for whom and in what circumstances. Such evidence would not have been acceptable to include in a standard systematic review approach.

The approach to data extraction in this review included conventional methods of extracting, categorising and annotating excerpts of text from the sources selected. This supported the process of theory extraction. The literature associated with approaches to realist synthesis has reported that many realist syntheses demonstrate low levels of uniformity and transparency, with recommendations that further specific methodological guidance would be beneficial to improve this (Berg and Nanavati, 2016). The realist review reported here aimed to promote transparency by following the RAMESES publication standards for realist review (Wong, 2013). However, as the methodology and literature related to realist reviews continues to evolve, it is important to note that this realist review could have been improved. For example, Cooke *et al* (2018) conducted a realist review, generating indicative 'if then' statements for each paper analysed. This approach may have been useful to adopt in the current review and could be considered in the future.

4.6 The utility of the realist review in supporting the empirical phase

The range of challenges with the potential to impact on the success of research delivery in the NHS remains wide and varied. The review conducted here suggests extensive work is required to optimise research delivery and to reduce the manifestation and complexity of the challenges described as impacting on successful research delivery. A key contribution to optimising research delivery potentially lies in the decisions made by actors both within and outside the research arena. These are often played out through the visible behaviours displayed at the interface between research delivery and clinical practice and care provision. This review has identified a gap in the literature in relation to the perceptions of stakeholders external to the research team. By exploring these views, the theories generated can be tested and either confirmed or refuted, enabling clear recommendations to be made in relation to the future of research delivery roles in the NHS.

4.7 Summary

The novel and broad nature of a realist review in the subject area of clinical research delivery, provided a unique opportunity to utilise critical realist thinking to contribute to what is known in this area. The realist review enabled the analysis of a variety of literature, both empirical and non-empirical, in relation to the CRNurse role. The nature and range of the theories extracted from the review provided an in-depth insight into the complex and layered reality of implementing the delivery of research in the NHS. This helped identify what works, and what is perceived to not work, and the contexts in which such mechanisms are thought to be triggered.

Social, emotional, and physical influencers identified in the early stages of the review, enabled the generation of a middle range theory, which was tested in the later stages of the review. Attendance at a methodological summer school during stage five was timely in enabling the exploration of the realist review methods employed, and their congruence with available guidance and literature. Access to experts in the field at the realist methodology summer school, further enhanced the work by enabling the generation of and reflection on a number of programme theories, which were then iteratively developed over subsequent weeks.

After consideration and refinement, the review produced thirteen programme theories in total, one of which was further refined during stakeholder engagement. This programme theory was then selected to form the basis of the empirical group concept mapping phase. The opportunity to explore and refine theories via stakeholder engagement at an international conference, provided additional richness and rigour to the review methodology.

The next chapter will set out the empirical, group concept mapping phase, reporting the findings at each stage of the process.

CHAPTER 5. GROUP CONCEPT MAPPING (GCM) PHASE

5.0 Introduction

This chapter presents a detailed and sequential account of the work undertaken and the results generated during the empirical phase of the doctoral research. The methods and results will be presented in a stepwise approach, reporting in detail the distinct activities completed during each stage of the study.

Each stage builds on the previous stage and is situated within the critical realist paradigm articulated in previous chapters. Evidence of the complementary nature of GCM within a critical realist paradigm will be offered, providing justification of this methodological choice. In keeping with previous chapters, personal reflection points, situated within separate text boxes, have been offered throughout the chapter, where felt to be relevant to the topic being discussed.

This chapter begins by briefly summarising the narrative developed within the thesis so far before outlining the aims and objectives of the empirical phase.

In the previous chapters, a narrative has been developed and debated in relation to the need for this research into factors affecting healthcare professional views of clinical research delivery and the CRNurse role. The realist review reported in the previous chapter (Chapter four) provided supporting evidence of the developing narrative by presenting a critical analysis of relevant literature. The realist review generated theories at micro, meso and macro levels about the causal mechanisms influencing how clinical research delivery is perceived by healthcare professionals practicing outwith clinical research delivery structures. The theories generated provide insight into how such perceptions may impact on CRNurse experiences, practice and capacity to ensure successful patient recruitment to research in the NHS.

The results of this work so far appear to support the view that a range of behaviours are present at the interface between research delivery and clinical service delivery. These behaviours may be viewed as mechanisms, triggered by a range of contexts which then lead to events that impact the success of research delivery and the CRNurse role. The available evidence referring to these behaviours is largely made up of the perceptions of CRNurses and does not appear to include the views of healthcare professionals practicing outside of clinical research delivery structures. Little is known about how healthcare professionals practicing outside of clinical research delivery structures perceive research being delivered in the NHS and therefore the CRNurse role. The narrative so far advocates that an opportunity should be provided to those practicing outside of clinical research delivery structures to share their views on research delivery and the CRNurse role in the NHS. This will enable a more balanced view by uncovering other potential perceptions.

The overarching programme theory below resulted from meso level theory generation during the realist synthesis. This theory was selected as the foundation for the empirical data collection presented in this chapter:

> *If key colleagues are **not interested in, aware of, or do not understand** the importance, value and utility of research to their role, their patients, or the wider NHS agenda, then they may **unintentionally or intentionally** display avoidance of or resistance to research being delivered in their clinical area. This presents a risk to positive working relationships with CRNurses and access to research opportunities for patients. Consequently, this could impact on organisational performance in relation to research activity and culture.*

Reflection point

The original intentions of this work were to undertake a critical realist ethnographic study. The plan was to use non-participant observation and stakeholder engagement, working from a critical realist theoretical position to collect and then subsequently evaluate data to address the aims and objectives.

Ethnography, a sociological practice, rooted in anthropology, is particularly suited to critical realist thinking. As such critical realism and Ethnography can enjoy a mutually beneficial relationship supporting the researcher in retroductive practice (Rees and Gatenby, 2014). Ethnography enables the direct observation of behaviours, cultures and social structures through integration within the community of interest for a period of time (Hammersley and Atkinson, 2019). Directly observed evidence and other relevant data derived from such integration is informative in ways not enabled by approaches that focus on direct questioning only. This was felt to be congruent with the critical realist philosophy of going beyond that which can be measured in a positivist sense alone.

A protocol had been written. Research ethics committee approval was obtained. I had identified and agreed an NHS site to undertake the Ethnography and was going through the final Health Research Authority Approvals process, when the COVID-19 Pandemic hit the UK.

As a result, face to face data collection was stopped and the site was pausing all research other than urgent public health (COVID related) studies. I continued with approvals and preparation in the hope that the pandemic would soon be over, however, it became increasingly clear that a change in methodology was required to maintain momentum with the doctoral research.

Around this time, I was involved in some evaluation work in my own NHS trust using a group concept mapping approach. As I learned more about the methodology, it became apparent that this approach would be a highly suitable alternative to the planned ethnographic study. It would provide the flexibility to collect a range of data from a broad sample and would enable a critical realist philosophy to remain at the forefront of the research. The web-based approach to GCM was particularly useful in the context of COVID-19 where social distancing was essential and face to face data collection enabling real-time observation of phenomena was not feasible.

5.1 Aims and objectives

The purpose of the empirical phase of this work was to seek out and analyse the views of healthcare professionals practicing outside of, yet alongside, clinical research delivery structures in the NHS. The aims of the doctoral research were:

a) To understand how clinical research nursing and research delivery is perceived by healthcare professionals operating outside of clinical research teams within NHS organisations

b) To understand what is required to improve the relationships and interactions integral to successful clinical research delivery

c) To identify implications for future research to inform practice

The specific objectives of this study were:

a) To use the selected programme theory to enable the collection of multiple views on clinical research delivery at the interface between research delivery and clinical practice

b) To use group concept mapping (GCM) methodology to first collect and then subsequently organise a range of views, before exploring the perceived likelihood of each view in generating avoidance or resistance behaviours at the interface between clinical research delivery and clinical service delivery

c) To assess the perceived level of importance of addressing each view explored through rating and interpretation activities.

5.2 Group Concept Mapping philosophy and methodology

This study used group concept mapping (GCM) (Kane and Trochim, 2007), working from a critical realist theoretical stance, to collect and then subsequently interpret data to address the aims and objectives. Group concept mapping is defined as:

> *“… a methodology that creates a stakeholder-authored visual geography of ideas from many communities of interest, combined with specific analysis and*

> *data interpretation methods, to produce maps that can then be used to guide planning and evaluation efforts on the issues that matter to the group."* (Kane & Trochim, 2007 pg.1.)

GCM is also described as *"an architecture for ideas, a structure for the building blocks of knowledge"* and noted to be a practical and efficient method of developing theory and or strategy (Kane and Rosas, 2018 pg. 3). The ability to inform a specific topic comes from the potency of the group involvement, the views of a range of stakeholders, and the multiple perspectives enabled by the approach (Kane and Trochim, 2007).

GCM has evolved since the 1980s from the early concept mapping work of William Trochim, who initially developed a software-based approach to articulating the differences and commonalities amongst individuals working on a common issue (Kane and Rosas, 2018). Other concept mapping approaches emerged around this time (Novak and Gowin, 1984 cited in Kane and Rosas, 2018). GCM, however, is said to have evolved as distinct from early work due to two characteristics. The first is the active engagement of many individuals as knowledge sources. The second is the emergent, rather than hierarchical, approach to both process and outputs, combining ideas in a context specific way. These two characteristics set GCM apart from other concept mapping approaches and both are fundamentally group processes.

GCM is an integrated mixed methods approach, enabling the quantitative analysis of qualitative data, ultimately producing visual representations (maps) of socially constructed theories and ideas about a specific topic, programme, or intervention. Researchers have used GCM to understand social and behavioural phenomena in a range of disciplines, with context seen as key to defining the world in which those who are sources of knowledge or opinion operate (Kane and Rosas, 2018).

It is possible to theoretically align GCM as a method with critical realist philosophy, partly because it's methodological approach is arguably positioned on a scale between interpretivism/constructivism and positivism. Through combining both structure and interpretation, producing a visual framework on which the views of multiple stakeholders are mapped and interpreted in a structured manner, GCM enables the pursuit of a deeper understanding of what is real, what exists and why.

Furthermore, GCM does not seek to achieve regularity, uniformity, or consensus in its approach. GCM instead, seeks to illuminate equally, the views of all participants, engaging multiple voices and visually mapping where such voices are similar and where they are different (Kane and Trochim, 2007). This method provides a richer understanding of how different people may view and interpret the same phenomena, from their own contextual position. This is highly advantageous for those designing and implementing programmes, strategies, or roles, in understanding how they might work in some contexts but not in others.

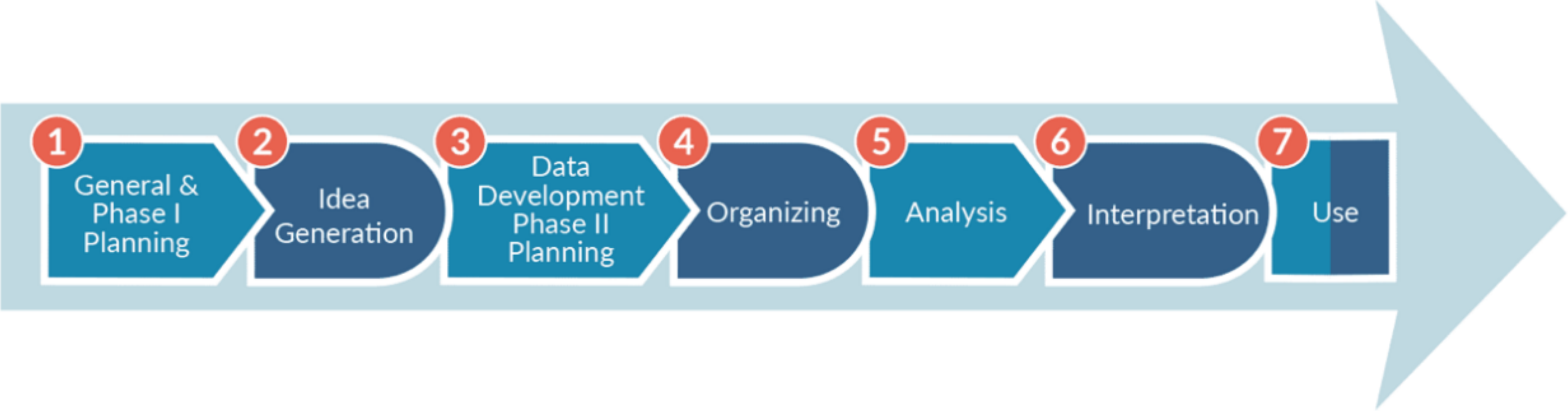
In relation to the open systems and social structures acknowledged in a critical realist philosophy, GCM accounts for the complexity of relationships within and across systems, while acknowledging that humans naturally seek meaning from connection to others as part of a group (Kane and Trochim, 2007). Furthermore, the pursuit of mapping is an inherently human activity because, as humans, we often seek to achieve clarity by mapping out ideas, spaces, and territories. This inclination towards mapping activity assists us with awareness of a given position, whether this is physical, social, or emotional in nature, thus enabling the assessment of what is currently happening and the planning of where to next. In direct relation to this, healthcare can be considered a social interaction between clinicians and patients, and also between clinical teams interacting with each other throughout the course of their work. Exploring the views of a range of individual clinicians specifically in relation to clinical research delivery, through a process of group concept mapping, will enable a deeper understanding of the mechanisms triggering the behaviours reported in the literature and the contexts in which they occur.

Although neither explicit nor proven empirically, it is possible to argue that the structured ontology of critical realism is respected by the GCM approach. It is possible to make such links because mapping activity seeks out data within the empirical domain - *that which can be observed*, by collecting multiple views about a specific programme or phenomena in order to observe and understand it. GCM also enables the exploration of views on what is, or what might be, happening within the real domain through combining the collection of participant views with subsequent participant led sorting and rating activities – *that which exists*, whether or not it is possible to observe or experience it. The exploration and mapping of such views, including stakeholder driven interpretation, has the potential to then provide insight into the actual domain – *that which occurs when the causal powers of the real are activated and produce events or change* (Bhaskar, 2008). Furthermore, the activity of initially agreeing a focus prompt enables retroductive thinking as the draft prompts are tested and refined.

In GCM, individuals and their perspectives are the units of interest. In critical realism, mechanisms are the units of interest. GCM enables the exploration of potential mechanisms through the perspectives of individuals in the three critical realist domains as described above. This provides a unique opportunity for participants to influence change from what is, to what it could or should be in a specific context (Kane and Trochim, 2007). Further justification of the potential complementary relationship between GCM and critical realism, will be offered later in the chapter as the approach to the GCM study is reported.

Figure 5.1. provides a visual illustration of the six main steps involved in the GCM process prior to the final seventh step where the results are used. The six stages used in this doctoral study will now be reported.

Figure 5.1. The seven steps of Group Concept Mapping



5.2.1 Planning

As illustrated in figure 5.1, Planning is the first step in developing and undertaking a GCM study. The planning phase includes the work of identifying who will be invited to participate and the development of a robust statement to enable the collection of appropriate and relevant views on the topic of interest. This statement is called a “focus prompt” and takes the form of an open-ended sentence which participants complete repeatedly until they feel their views have been expressed in entirety in separate statements. Developing the focus prompt is an important element as it is the foundation of collecting the views of participants and therefore needs to be as specific and clear as possible to enable the collection of meaningful data. In the pursuit of upholding a critical realist theoretical position in this research, the focus prompt was designed to reflect the content of the theory taken forward for testing, this process will be described further next.

5.2.2 Developing the focus prompt

During planning, four separate, short, focus prompts were developed in partnership with the supervisory team. Each was developed based on the programme theory selected following the realist review. A reminder of that theory is below:

> *If key colleagues are **not interested in, aware of, or do not understand** the importance, value and utility of research to their role, their patients, or the wider NHS agenda, then they may **unintentionally or intentionally** display avoidance of or resistance to research being delivered in their clinical area. This presents a risk to positive working relationships with CRNurses and access to research opportunities for patients. Consequently, this could impact on organisational performance in relation to research activity and culture.*

The intention was to develop a focus prompt broad enough to elicit a range of authentic views about research delivery without making any inferences that might influence a particular response. Developing a focus prompt that would enable this effectively was a challenge. The focus prompt would need to capture views about the relevance of research to a participant’s role (whether negative or positive) yet be open ended enough to also provide insight into the behaviours present at the interface between clinical research delivery and clinical service delivery.

The four draft focus prompts below were tested over a four-week period between November and December 2020. This involved emailing the draft prompts to 15 healthcare professional volunteers, aligned with the intended sample, and geographically spread across NHS trusts in England:

a) *A specific view I have about the work of Clinical Research Nurses in the NHS is...*

b) *A specific view I have about my role in relation to the delivery of clinical research in the NHS is…*

c) *Health professionals could support clinical research nurses in the delivery of clinical research by…*

d) *My role in supporting the work of clinical research nurses is…*

Responses to the four draft prompts revealed an increased number of responses to prompt b, in comparison to any other, despite all four being sent to an equal number of individuals (2 - 3 people per prompt). No responses were received to prompt a. This may have been due to time constraints for those invited to respond, a perceived lack of clarity of the statement, or a perceived lack of understanding of, or absence of, views on the CRNurse role. A small number of responses to prompt b and d appeared to relate to the role of a Nurse carrying out their own research alongside a clinical role, as opposed to the role of the CRNurse. This suggested the Participant Information Leaflet would need to be explicit regarding the focus of the topic. Following discussion with supervisors in response to the statements received, the following focus prompt was selected for use in this study:

A specific view I have about my role in relation to the delivery of clinical research in the NHS is…

5.2.3 Sampling and recruitment

Whilst Kane and Trochim (2007) suggested no strict rule with regards to participant numbers, consideration should be given to the possibility of diminishing returns and data saturation where numbers become too large. The aim of this study was to recruit a minimum of 50 participants to the first phase of the study (ideas generation). The minimum figure of 50 participants is recommended by Rosas and Kane (2012), to enable sufficient diversity of ideas and adequate richness of data. Participant recruitment was opened at ideas generation, then re-opened at sorting and rating, to enable additional individuals to join the study at any stage. Again, this is supported by Kane and Trochim (2007) to maximise participant voice and opportunity to contribute. Table 5.1 provides information on participant numbers and involvement at each stage of the study.

An invitation to participate in the study was circulated by email to a number of professional forums to disseminate the opportunity to their members. A number of opportunities to participate were also posted via the social media platform Twitter. The professionals invited to participate were nurses, nursing associates, midwives, and the fourteen allied health professions defined by NHS England. Table 5.2 illustrates the range of participant recruitment routes and the rationale for the sampling approach.

The invitation contained a direct web link to the Participant Information Leaflet (PIL) which was held securely on the Sheffield University Strategic Research Alliance webpage. Individuals reading the PIL who then opted to participate, were able to follow a direct web link to the GCM website, where they were asked to provide consent prior to data collection. The PIL can be found at Appendix 8.

Table 5.1 Participant recruitment and flow throughout study

Ideas Generation		**Sorting and Rating**		**Interpretation**	
Consented	40	Assigned from ideas generation	32	Invited	38
Commenced	38	Commenced sorting	10	Accepted	5
Completed	32	Completed sorting	7	Attended	3
Did not complete	6	Commenced rating	8		
		Completed rating	6		
		Additional recruits consented at sorting/rating	10		
		Commenced sorting	10		
		Completed sorting	3		
		Commenced rating	5		
		Completed rating	3		
Total contributing ideas	**32**	**Total completing sorting and rating**	**19**	**Total attending**	**3**

Table 5.2 Sampling routes and rationale

Route	Rationale
Twitter social media platform using the following recognised healthcare hashtags #WhyWeDoResearch #MakeSpace4Research #ClinicalResearch #NHS A new and dedicated study hashtag: #RepresentCRNStudy was used to enable a focused thread for interested parties to follow.	The researcher was fortunate to be well connected, through Twitter, to a range of professional groups and networks who were able to circulate the opportunity both personally and within their own networks. Hashtags are an effective way of sharing information related to a specific topic.
The Royal College of Nursing (RCN) Strategic Research Alliance and the RCN Research Committee were asked to circulate the invitation via their regular communications and research roundups (email)	To maximise support through the strategic research alliance and to utilise links with the RCN Research Society.
Professional Associations such as Lung Cancer Nursing UK, The Association of Respiratory Nurse Specialists, The Stroke Nursing Association and similar AHP associations (email and twitter)	To maximise the potential of broad and varied participation via a range of specialisms and professional networks

5.2.4 Ethical considerations and Informed consent

This study involved primary data collection from professionals employed in the NHS. The study received a favourable ethical opinion from The University of Sheffield, and due to the recruitment approach taken, governance approval from the Health Research Authority was not required. This is because NHS sites were not being directly approached to identify participants for the purposes of this research.

Confidentiality was safeguarded for all participants via a range of measures. The demographic data collected at the study outset did not constitute identifiable data, however, participants were informed that if they chose to enter the study using their NHS email address, this may constitute identifiable data due to the first name/initial – surname approach to the NHS email system. The study database is hosted in Germany, within the EU and privacy policies are such that the hosts have no direct access to participant information or email addresses if entered. The email addresses collected were stored on the study database only and were only used to invite participants to the various stages of the study, via the study database. Participants were advised not to disclose any identifiable information during data entry, and the general nature of the focus prompt did not risk the generation of such data. The Data Protection Act (2018) and the UK Policy Framework for Health and Social Care Research (2017) were adhered to throughout this study. For the final interpretation step of the study, participants were informed at invitation, that they would be participating in an online meeting where they would meet and see/hear from other participants within the study.

Consent was received from all participants via the GCM web-based platform prior to any data being collected at any stage of the study. During the process, participants were asked to confirm they had read and understood the PIL, to confirm they had been given the opportunity to ask further questions, and had any questions answered satisfactorily. Participants were asked to confirm they were happy to proceed with study participation. The specific consent statements completed on the GCM web-based platform, and a copy of the consent form, which participants were able to download, can be found in Appendix 9. No additional questions or queries were received by participants during recruitment and participation.

Screenshots of the web-based platform, illustrating the participant interface at each stage of the GCM phase can be found in Appendix 10.

The sections set out below will describe the linked and sequential collection and parallel analysis of the data generated during the GCM phase. This commences with the process of ideas generation.

5.2.5 Ideas generation

Participation in this step of the study was undertaken via a web-based interface. Participants completing the ideas generation activity were asked to provide an email address of their choice to enable them to be invited to subsequent steps in the study. All consenting participants were asked to provide minimal demographic data prior to ideas generation. The collection of demographic data can be useful in enabling potential subgroup analysis, especially if there may be perceived differences in priorities or perceptions between participant groups. Subgroup analysis was not possible in this study due to the relatively small numbers of each profession participating in the different steps of the study. It was also not feasible to undertake sub-group analysis because not all individuals contributing ideas continued on to participate in sorting and rating. Whilst some did continue on, additional participants were recruited at this step and not all participants completed the demographic data collection. Demographic data requested included profession, agenda for change (Pay scale) banding, level of awareness of research being delivered in the clinical area and highest level of qualification. Demographic data are presented below in table 5.3.

Table 5.3 Participant demographics

Profession	No.	Highest Level of academic qualification	No.	Awareness of Research Delivery activity in clinical area	No.	Agenda For Change Banding	
Art Therapist	0	Level 5	3	Not aware	8	Band 4	0
Chiropodist/Podiatrist	2	Level 6	8	Aware of current	25	Band 5	6
Dietitian	2	Level 7	23	Aware of previous	5	Band 6	8
Drama Therapist	0	Level 8	4	Did Not Respond	12	Band 7	12
Midwife	0	Did Not Respond	12			Band 8a	6
Music Therapist	0					Band 8b	4
Nurse	27					Band 8c	2
Nursing Associate	0					Band 8d	0
Occupational Therapist	1					Band 9	0
Operating Department Practitioner	1					Did Not Respond	12
Orthoptist	0						
Osteopath	0						
Paramedic	0						
Physiotherapist	4						
Prosthetist/Orthotist	0						
Radiographer	1						
Speech and Language Therapist	0						
Did Not Respond	12						
Total	**50**	**Total**	**50**	**Total**	**50**	**Total**	**50**

Consenting participants were asked to complete the following focus prompt:

> *A specific view I have about my role in relation to the delivery of clinical research in the NHS is…*

Participants were encouraged to respond to the focus prompt, repeatedly completing sentences in order to submit as many views/responses as they felt able to during this activity. Participants were able to see the anonymous responses of other participants contributing to the ideas generation activity. Access to other statements being generated is thought to assist in developing ideas or building on those of others. Furthermore, the risk of duplication of ideas is also reduced (Kane and Trochim 2007).

A total of 101 statements were generated by the 32 participants between the 27th of January 2021 and the 30th of April 2021 in this initial step of the study.

5.2.6 Data development (ideas synthesis) and phase 2 planning

Following completion of ideas generation, all statements were reviewed, supported by discussion with the supervisory team. A structured process called ideas synthesis, recommended by Kane and Trochim (2007), was used to remove duplicate statements and to ensure the views submitted were clearly articulated. The aim of this step in GCM is to consolidate the range of statements into a manageable set, ensuring all views collected are represented, without duplication. This is beneficial for the subsequent sorting and rating activities providing a condensed data set, which remains substantial enough to ensure saturation of the themes generated during ideas generation.

The process of ideas synthesis included removing statements not deemed to contain responses that were relevant to the research aims; removing duplicate statements; and splitting statements with more than one theme or focus. During ideas synthesis, statements were also refined and checked for composition, grammar, and flow to ensure they clearly articulated the voice of the participant. For example, one participant completed the focus prompt as below:

> *"My clinical role is not a research post and as a second year PhD student I am studying in my own time. I think this is unfair and all MSc and PhD students who work clinically should be given study time, a day a week."*

This statement provides important insight into the challenges of balancing clinical and research activity in the NHS, however, it neither relates to the participant's views of clinical research delivery in the NHS, nor the CRNurse role. For this reason, it was removed from the statement set. Another example is as follows:

> *"There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched, and they don't feel the results will have a direct impact on their work."*

This statement relates directly to clinical research delivery and is relevant to the research aims, however, it contains more than one theme; limited motivation amongst staff due to feeling overstretched, and the view that research results will not have a direct impact on their work. This statement was therefore split into two separate statements to enable both elements to be equally voiced and analysed. The manner in which statements are split into separate themes is essential to ensure the participant voice is not lost. This statement was therefore broken down as follows:

> *"There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched."*
>
> *"There is limited motivation amongst staff to take an active interest in clinical research delivery because they don't feel the results will have a direct impact on their work."*

In deconstructing statements, it is important to avoid over sanitisation of participant voice. This is to ensure the meaning of a given statement is not lost. This is particularly relevant from a critical realist perspective, to ensure the complexity of views that are intertwined with contexts, social structures and beliefs are not separated and deconstructed too heavily (Alderson, 2021). This was also important for the subsequent sorting and rating activities which will be described later.

The resulting set of 99 unique statements was prepared for the next phase where it was then shared with participants separately to enable them to undertake two further activities. These were sorting and rating activities. The final statement set submitted for sorting and rating can be found in Appendix 11.

5.2.7 Organising and structuring activities (sorting and rating)

All participants involved in the ideas generation phase were invited to continue their involvement into the organising and structuring phase. Ten further participants were also recruited exclusively into this phase, to maximise diversity of ideas, richness of data, and opportunity to participate (Kane and Trochim, 2007). As described previously, Table 5.1 provides information on recruitment and activity in each phase.

Participants were invited to complete two activities sequentially during this phase: sorting, followed by rating. The sorting activities (completed prior to rating activities) were aimed at enabling participants to organise the statements generated in phase one, based on their personal interpretation of the statements and how they viewed them in their own context. Kane and Trochim (2007) describe this approach as enabling stakeholders to organise disparate ideas into groups. This activity subsequently provides insight into participant views of the interrelationships between ideas based on their themes. It is recommended that participants complete sorting, before undertaking rating activities (Kane and Trochim 2007). This is because, the sorting of data supports participants to focus on similarities and differences between statements, without involving on any emotional judgement of value or priority in relation to each statement. Rating activities in comparison involve making judgements about each statement based on the scales provided. This activity is thought to be subject to a wider range of views and experiences and, if done first, may risk influencing the later sorting of statements by some sort of priority measure rather than semantically (Kane and Trochim, 2007).

Sorting activities

Sorting activities involved participants first examining the finalised statement set and then sorting all statements into groups of their choosing using the same web-based platform. Participants were asked to sort statements thematically, based on the content, and their assessment of each statement in terms of how similar or different each was to another. Participants were advised there was no set (right or wrong) approach to this, they were free to sort as they saw fit, into many or few groups. During sorting, participants were also asked to label each group of statements with “cluster names”. This provided a thematic title and further insight into how participants had viewed and subsequently sorted the data, based on how they thought ideas connected (Kane and Rosas, 2018). These thematic titles were important for later data analysis.

Kane and Trochim (2007) advocate three rules should be applied in relation to the sorting of data. The first two of these are that the finalised statements should not be sorted into one single group, nor should statements be sorted into (in this case 99) separate groups. These rules apply because sorting in either of these manners would provide no insight into the perceived interrelationships of the data. The third rule is that each statement should only be placed in one group, compelling participants to decide where it would best fit, rather than enabling a single statement to be sorted multiple times with other statements (Kane and Trochim, 2007).

Following sorting activities, participants were invited to continue, and to undertake rating.

Rating activities

The activity of ideas synthesis and the iterative process of reflecting on the aims and objectives of this doctoral work throughout supervision meetings, led to discussions about the subsequent planned rating activities. A large number of the statements generated appeared to be reflective of behaviours either perceived or experienced by participants, and although further analysis had not yet taken place, it became clear from the data that the original planned rating scale would require amending to optimise the insight gained from the data. In GCM studies, the majority of rating scales tend to focus on some combination of impact and importance or presence and importance (i.e., impact or presence of a particular phenomenon described by participants in ideas generation and the importance of either addressing or including this in the recommendations/planning etc.). These types of scales enable analysis and future planning to take account of indicators of relevance and importance to participants (Kane and Trochim, 2007; Kane and Rosas, 2018).

The initial plan for rating in this study was to ask participants to rate based on two indicators. The first was perceptions of how important each statement was relative to the success of clinical research delivery in their organisation. The second was the potential impact of each statement on successful delivery of clinical research, i.e. *How important is each of these views, and what is the potential impact of each view on the success of research delivery in my organisation?*

Further reflection on the data generated through ideas generation, continuous reflection on the aims of the study, and efforts to maintain a critical realist stance led to the consideration that the initial rating scales may require some adaptations to optimise their relevance and potential. Discussion regarding this took place with the supervision team followed by email correspondence with the university ethics team. The rating scales were subsequently amended. Appendix 12. contains the email correspondence regarding amending the rating scales in response to data collected.

Firstly, ratings would be set according to likelihood of generating avoidance or resistance behaviours at the interface between clinical research delivery and clinical service delivery. Secondly, ratings would be set according to participant views of importance to address.

Following the activity noted above in response to the data collected at ideas generation, participants were then asked to rate each statement on the two scales agreed. Each rating activity was completed using a 4-point rating scale defined in table 5.4. As outlined previously, screenshots, illustrating the web-based participant interface can be found in Appendix 10.

Table 5.4 Rating Scales

Likelihood of generating resistance/avoidance behaviours in relation to clinical research delivery	Importance to address
1 = Not at all likely	1= Not very important
2 = somewhat likely	2= Somewhat important
3 = Likely	3= Important
4 = Very likely	4= Very important

The outputs resulting from both sorting and rating activities were expected to differ between participants due to the nature of context and the subjectivity through which the participants respond. At the end of this phase, a complete dataset was checked for quality prior to being moved into the analysis phase. This is called a quality review.

5.2.8 Quality review

Reviewing each participant's contribution to sorting and rating is an important step in the research process. This links to judgemental rationality in a critical realist philosophy, as judgements are made during the review about the adequacy of each dataset in enabling an accurate and representative analysis. Checking the data enables the researcher to ensure the data from this phase has utility in the analysis and matches the intentions of the study. The level to which participants undertook the sorting and rating based on the instructions given by the researcher can be assessed by reviewing every dataset generated by each participant. In the web-based platform, this enables the approval or rejection of data at both sorting and rating stages separately. The web-based platform also allows the researcher to see how much time has elapsed for each participant in each distinct activity. For example, one might expect to see a shorter total amount of time spent from start to finish on rating activities in comparison to sorting, where much thinking and organising of statements is required. These additional data are helpful when making judgements about the quality of the data.

Of the ten participants completing sorting activities, nine datasets were confirmed as suitable to take through to analysis. One dataset was rejected because it contained data that had been sorted and labelled categorically based on decisions other than relative meaning or concepts. One participant had labelled their completed sets of statements as "*agree"*, "*disagree"*, "*true in practice I've seen",* and "*no experience of this so unable to make a judgement".* The fundamental analysis structure for GCM is based on a similarity matrix used for each sort activity. Where data are not sorted conceptually, it may affect the analysis and hamper interpretation. In short, the highest level of data quality prior to analysis will ensure that the subsequent analysis is of the highest quality (Kane and Rosas, 2018).

One dataset contained two unlabelled/unnamed groups of statements from a total of five. Checking the statements across this whole dataset confirmed the participant had sorted statements conceptually, however had omitted labelling two groups. Although reminders were sent to all participants with regards to the importance of labelling grouped statements, these two groups generated by this participant remained unlabelled. This was not however, a reason to exclude data, as the software would account for unnamed groups during the analysis.

Finally, one dataset contained three unsorted statements. As the remainder of the statements were considered to be appropriately and thematically sorted, this dataset was approved. In relation to unsorted statements, Kane and Trochim (2007), suggested a minimum of 75% of statements within a given statement set should be sorted to confirm the quality of that dataset. As 96 sorted statements constitute almost 97% of the dataset, it was therefore considered appropriate to retain the dataset for analysis.

There is, however, a further quality measure available, which tests the likelihood of statements being sorted randomly rather than thematically, regardless of the percentage eventually sorted per participant. A measure, which considers this, called the 'stress value' is commonly seen in multidimensional scaling (Kane and Rosas, 2012). In judging the relevance and impact of a stress value, Sturrock and Rocha (2000) reported that there is less than a 1% chance the sorting of statements has been completed randomly (rather than thematically) if the stress value is below an upper limit of 0.39. The stress value noted in this study, following sorting activities was 0.27, which falls sufficiently below the recommendation of 0.39.

Reflection Point

I was able to discuss the potential impact of unsorted statements and the stress value resulting from the sorting activities during a GCM methods training course led by Mary Kane and Scott Rosas in late 2021. The discussion confirmed the appropriateness of the decision to retain the dataset where three statements had remained unsorted, and highlighted again the relevance of adopting a critical realist perspective in the analysis and interpretation of the approaches by participants to each stage of the study.

Quality review of rating data includes considering to what extent participants reasonably utilise the whole range of the provided rating scale. In this case a range of between 1 and 4 was available on both scales. The appropriate use of the whole rating range is important in producing meaningful analysis of the dataset. For example, a participant rates all statements as “likely” (3) on the scale of likelihood of generating avoidance/resistance behaviours, and then again rates all statements as “very important” (4) on the scale of importance to address. The results of this dataset would have no effect on average rating scores and therefore would not provide a meaningful contribution to the rating maps (Kane and Rosas, 2018).

The review of rating data revealed participants had used the full range of rating across both scales, indicating the data were appropriate to include in the analysis. The full data analysis will be reported next.

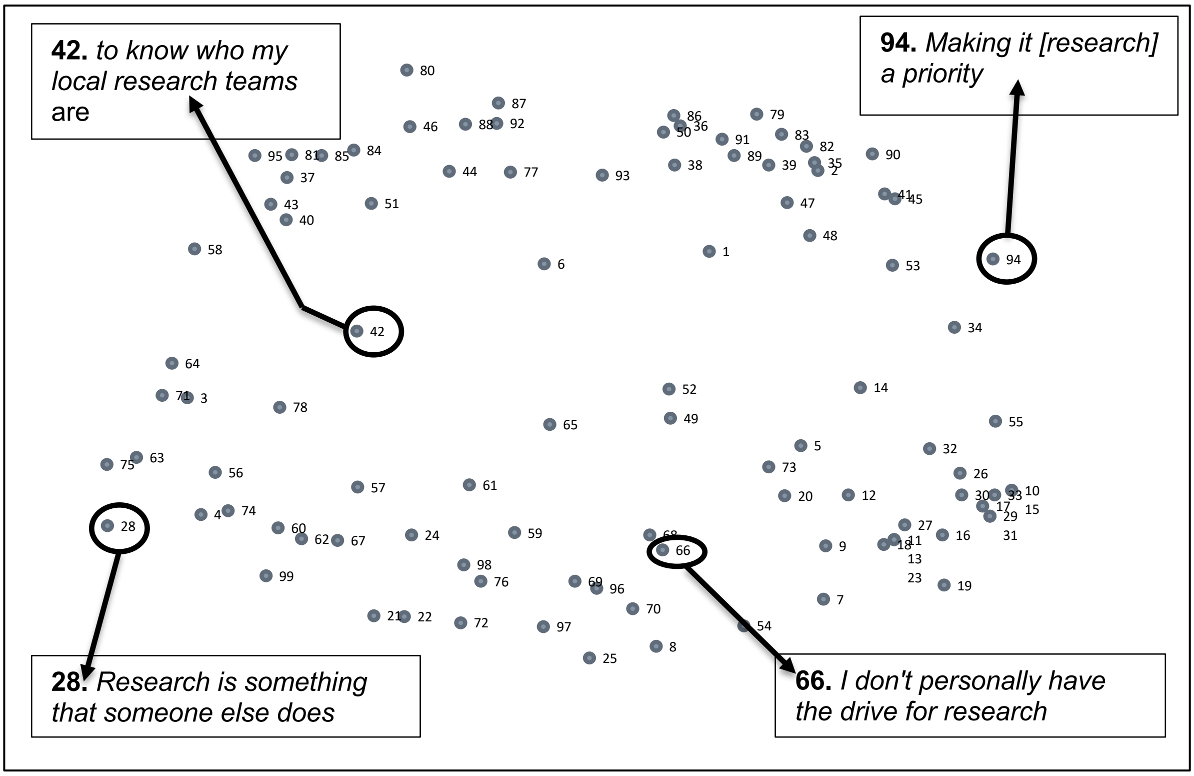
5.3. Data Mapping

According to Kane and Trochim (2007), the sequence of analysing, mapping and reviewing the data generated during sorting and rating, is fundamental to the subsequent interpretation activity. The data gathered during sorting and rating was therefore used to construct a range of visually accessible representations (maps). Each type of map serves a slightly different purpose and will be explained sequentially in the following sections. The analysis and representation were undertaken using the Group Wisdom, Concept Systems Global© online software package. Whilst the software enables several ways in which to represent the data, Kane and Trochim (2007) emphasise that all visualisations produced are interrelated, and are simply different ways of reflecting the views of participants on the same phenomenon.

A similarity matrix is produced first. This is a table of values demonstrating the number of times each statement was sorted together with each of the other statements. The similarity matrix for this study has 99 points on each axis, representing the final 99 statements. A similarity matrix of this size is therefore challenging to interpret as a whole, and too large to include visually here. A condensed extract of the similarity matrix can be found in Appendix 13, to aid in understanding how the subsequent data were mapped. For the purposes of reviewing with ease, the data is therefore more appropriately represented initially as a point map (Figure 5.2).

The values generated by the similarity matrix were used to create a point map, through a process called multidimensional scaling. The statement point map can be seen in figure 5.2 below.

Figure 5.2 Statement point map



42. *to know who my local research teams are*

94. *Making it [research] a priority*

28. *Research is something that someone else does*

66. *I don't personally have the drive for research*

The statement point map shows the data represented at a statement level. The distance between points is a key factor in the point map. Each point on the map represents a numbered participant response to the focus prompt. Points are positioned on the map in relation to how participants viewed them as conceptually similar or disparate to other points during the sorting exercise. Those points closest to each other on the map represent statements that were sorted as closely linked conceptually by participants. Those points further away from each other depict responses that were distinct from each other and therefore less linked.

The resulting map illustrates where conceptually similar ideas appear closer together (if viewed as so by participants). The position and proximity of each statement is so, because of how each was sorted in relation to others.

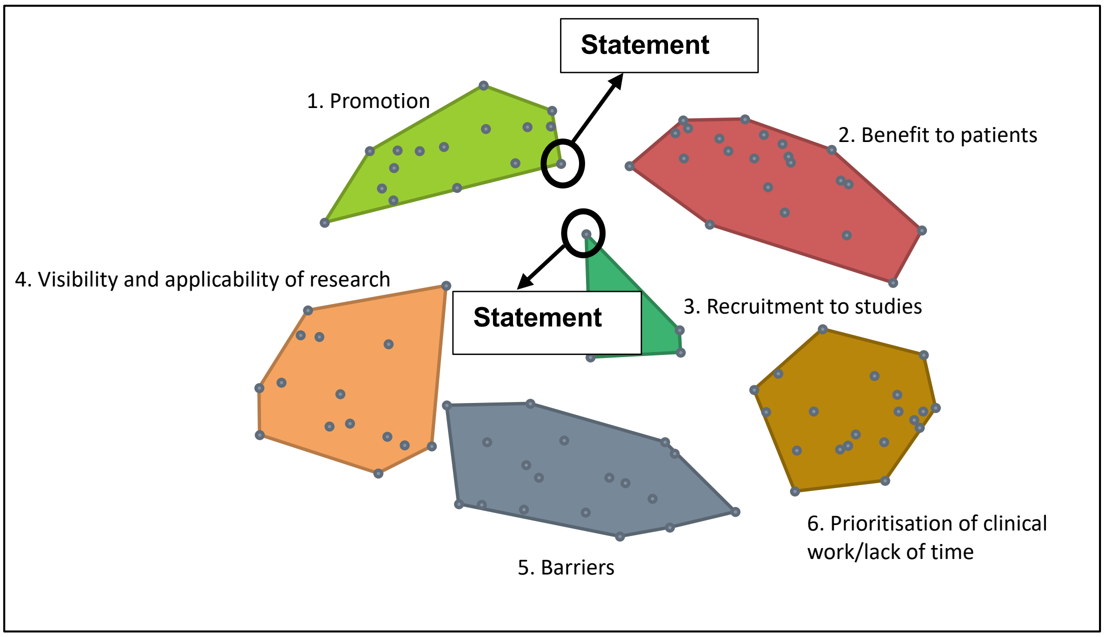
Following the generation of the point map, a process called hierarchical cluster analysis was undertaken to produce a cluster map. Hierarchical cluster analysis utilises Ward's minimum variance method (Glen, 2022) to create clusters of statements using the coordinates generated through multidimensional scaling. Clusters are generated by grouping points together where they are sorted in closest proximity to each other, representing a set of ideas that together reflect a shared understanding. The cluster map produces a number of coloured shapes based on the proximity of points (statements) and these are then populated with the best fit labels/titles to define the themes. In this method, each statement in isolation can be viewed firstly as a single cluster (depicted by the point map). Recognising that 99 individual clusters, comprising a single statement will provide little thematic value, statements are progressively grouped together by the software through repeatedly selecting the two clusters which have the shortest distance between their central points. This manner of cluster analysis continues until there is only one cluster left.

It is important to note that there is no right or wrong number of clusters, however, the researcher is advised to consider the most appropriate number of clusters, in order to reasonably represent the data in sufficient detail with thematic clarity. This is often dependant on how much information the researcher is interested in seeing (Kane and Trochim, 2007). The aim is to produce the best and most accessible explanation of the data and therefore appropriately represent the views of participants.

Cluster maps comprising of between 15 and four clusters were therefore considered. These were reviewed sequentially, gradually merging clusters together (similar in approach to the generation of a coding tree, seen in qualitative thematic analysis). This approach enabled a comprehensive, manual review of the cluster content and related boundaries. Data automatically produced by the software, illustrating the merging of statements from 15 clusters down to four can be found in Appendix 14.

The goal of gradually merging clusters together was to arrive at a cluster solution which balanced the most useful detail between clusters, whilst combining those which appeared practically adequate to merge together (again, linking the process back to the critical realist concept of practically adequacy). The activity of combining clusters continued until there were as few as four clusters. The statements within each cluster boundary were assessed to ensure the content of each cluster reflected an overall theme for the given cluster composition. The assessment of and arrival at a preferred cluster solution is a qualitative judgement based on content and fit. As the cluster merges moved closer towards four clusters, it became apparent that the contents of any further merging of clusters would risk an overly broad conceptual frame within each cluster. This is why the final cluster solution was agreed as six. Figure 5.3 depicts the original selected cluster solution of six clusters, including the titles suggested by the software. These titles were based on an average of those provided by participants during sorting.

Figure 5.3 Original cluster solution



At this point a more detailed review of the agreed cluster solution took place. The position of the statements on the map does not change, however, it is possible to change the shape of a cluster manually, by excluding or including statements from within or outwith a given cluster. This is described as moving a cluster boundary. Moving cluster boundaries is an accepted practice, which again is subject to the researcher's judgement on the practical adequacy of the cluster solutions in reflecting the content and themes derived. Discussions took place with the supervisory team regarding the positioning of statement number six, creating an irregular shape for cluster number three, and positioned relatively centrally on the point map. A further reason to look at this cluster more closely was the small number of statements and the ambiguous cluster title suggested by the software in relation to the content. The content of this cluster was as follows:

6. *I keep thinking of ways to facilitate research as 'everyone's business' but it is hard.*

49. *There are frequently missed opportunities for district nursing staff to identify and signpost potential research participants toward appropriate studies.*

52. *We were asked to treat research as a 'business'.*

65. *Nurses should know about research in their area, but we don't.*

The cluster title of "Recruitment to studies" was felt to be vague and a poor reflection of statement content. On exploring the position of statement number six, relative to others, it was evident that it had – on average - been sorted closest to statement number 77. "*The training I have received in order to undertake the clinical interventions for research trials has been beneficial to my clinical role."* Statement number 77 was positioned within cluster one. Moving statement number six into cluster one however, did not improve the perceived fit of statement number six, nor did statement number six appear to be conceptually linked to statement number 77. A range of cluster solutions were therefore subsequently attempted in order to find a best fit for the four statements positioned within the third cluster. These are illustrated below in figures 5.4 to 5.5. The final cluster solution is depicted in fig 5.6, where statement number six was considered to be worthy of a cluster on its own. The nature of this decision will be discussed next in relation to bridging and anchoring of statements.

Figure 5.4 Amended cluster solution 1

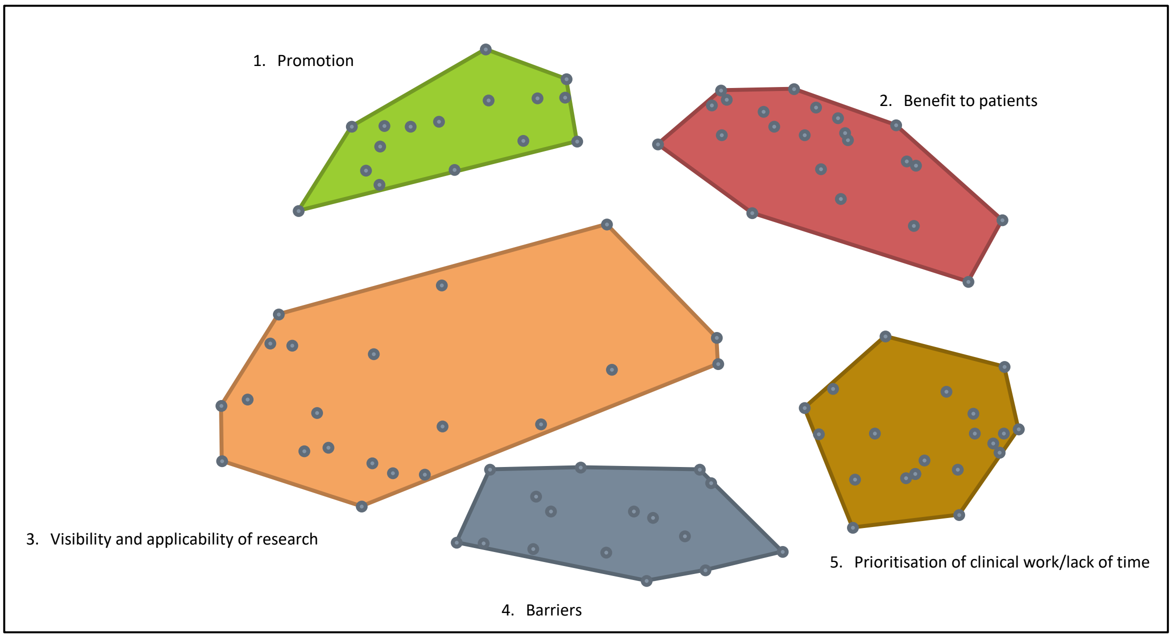


Figure 5.5 Amended cluster solution 2

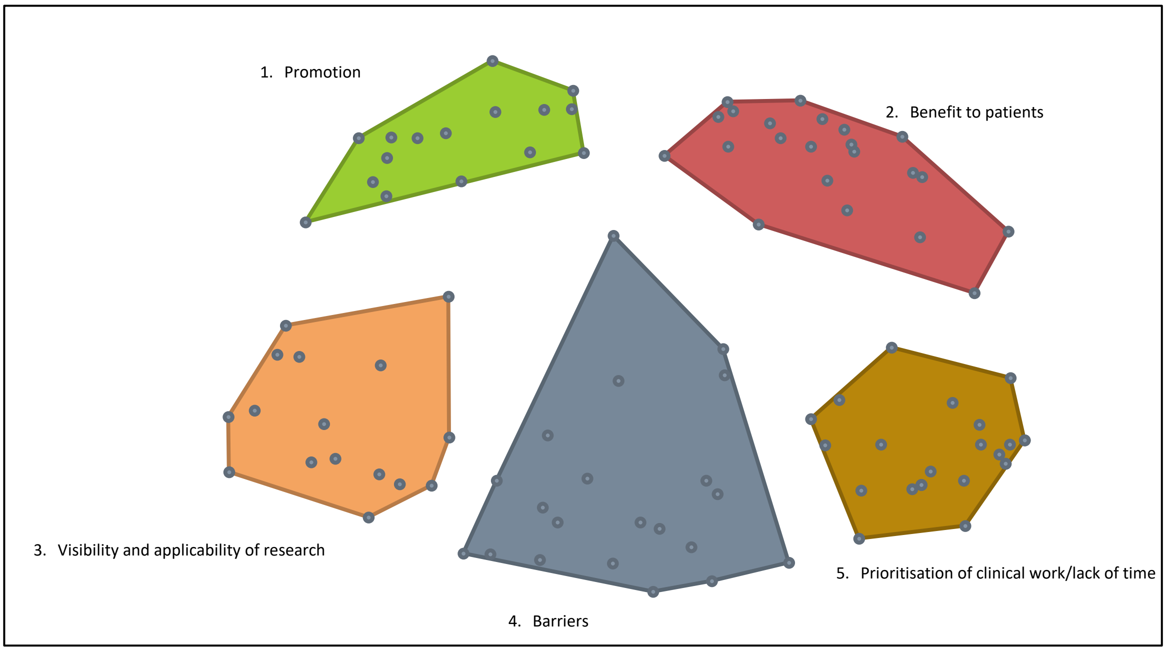
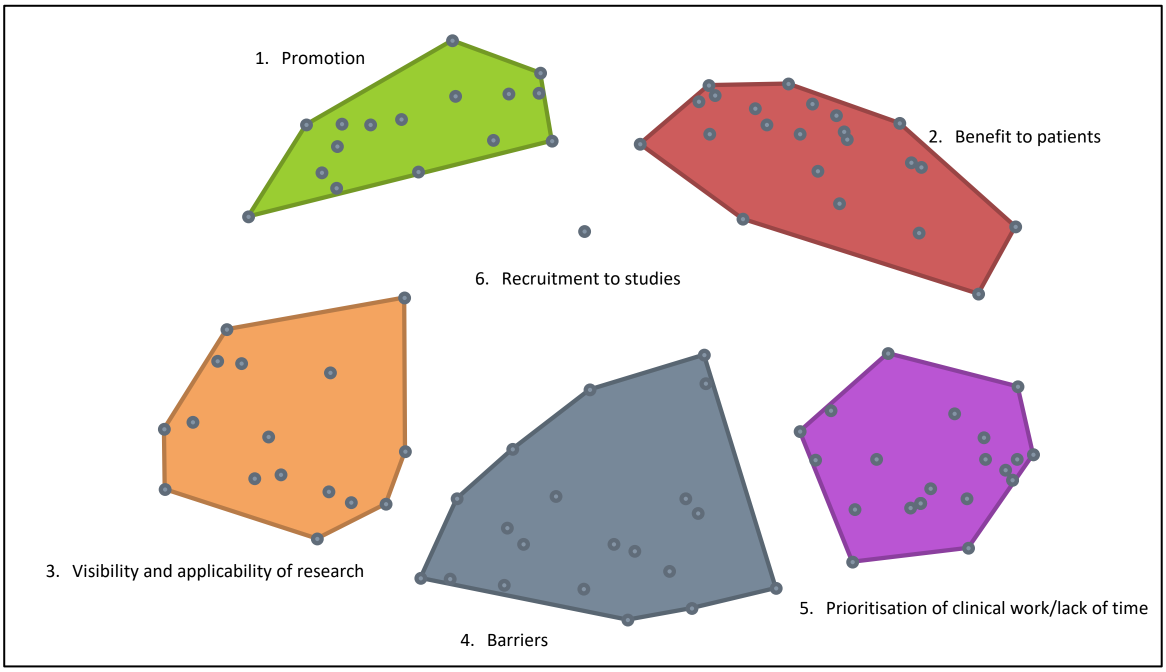


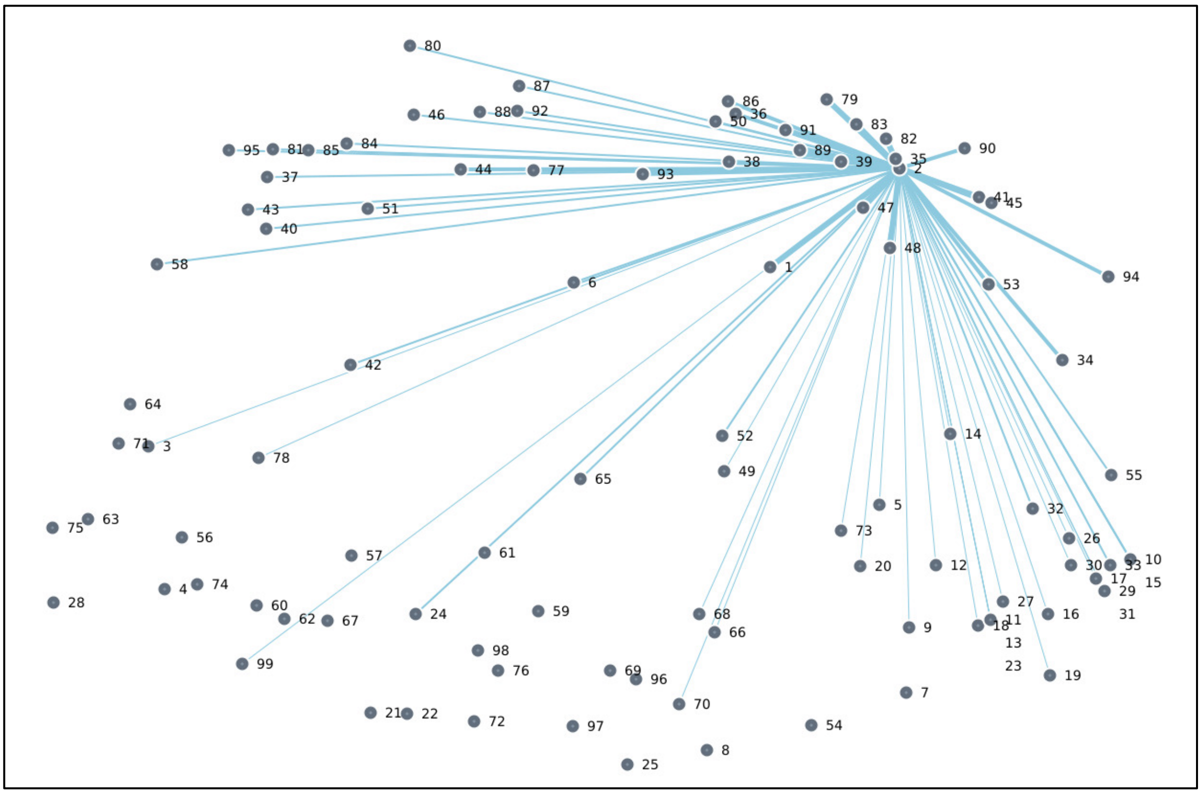
Figure 5.6 Amended and final cluster solution



Bridging and Anchoring analysis

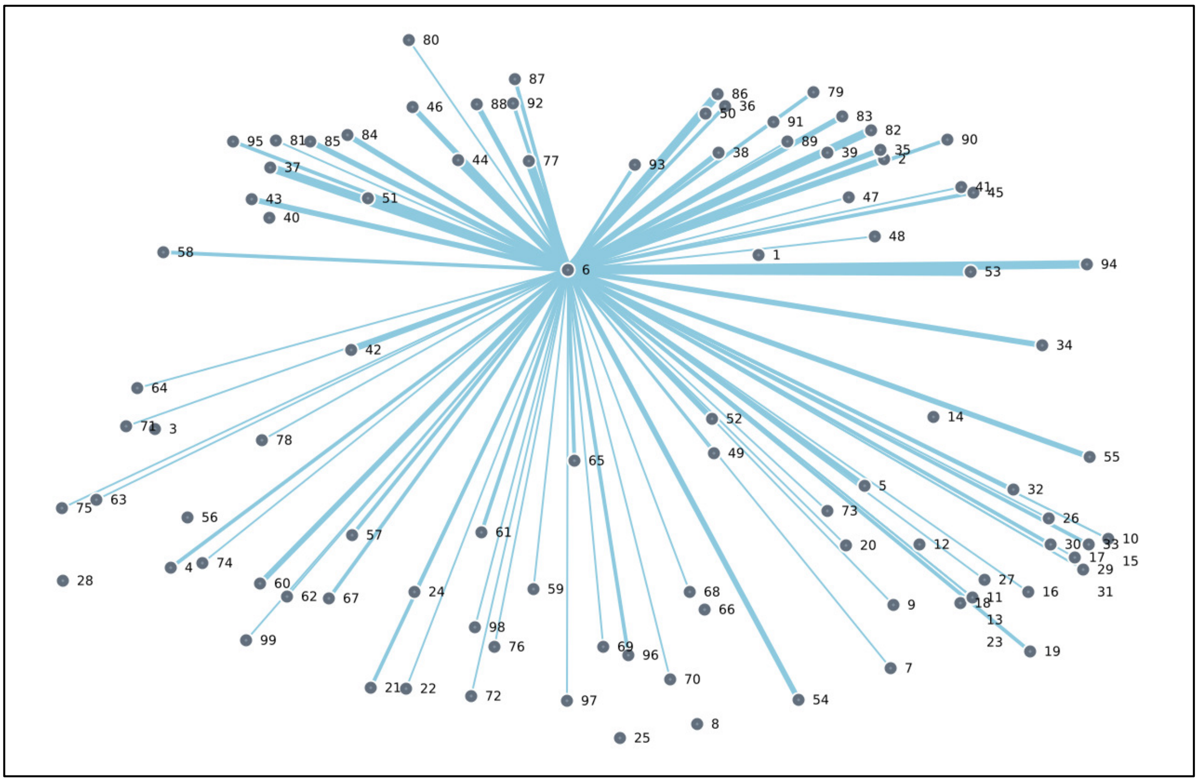
In selecting the final cluster solution, especially where statements are perceived to be outwith a best fit solution conceptually, it is possible to consider the bridging and anchoring of statements. The nature of multidimensional scaling requires that every statement is positioned somewhere on the map. The position of each statement is, as described, a result of how that statement has been sorted in relation to other statements. A statement may be positioned closer to others on the map due to the large number of participants sorting it with other statements, meaning it is then positioned in closer proximity to another. This is known as an anchor statement because the map in the area of that particular statement reflects the thematic content nearby. Figure 5.7 illustrates how statement number two may be considered as an anchor statement, due to its eventual position in close proximity to others of a similar theme. The heavier the blue line, indicates the increased number of times a statement has been sorted with another, thus the tighter cluster in this area of the map.

Figure 5.7 Example of an anchor statement



In contrast, a statement may be positioned as a result of being sorted with a range of statements in many other areas of the map. This is perhaps where participants have sorted it differently and feel it links conceptually across a range of themes in the map, or were unsure where to thematically place it. This type of statement is called a bridging statement because it links with many other areas of the map, yet it does not necessarily fit well into any given cluster (Kane and Trochim, 2007). Analysis of statement number six identified it as a potential bridging statement. This accounted for its somewhat central position on the map and reflected the difficulties in fitting it into an adjacent cluster. Figure 5.8 illustrates the bridging nature of statement number six. Again, a heavier blue line illustrates an increased frequency of the statement being sorted with another. A thinner blue line illustrates it was sorted less with another statement. As figure 5.8 demonstrates, statement six was sorted with many of the other 98 statements. This is in contrast to the example illustrated in figure 5.7. The nature and focus of statement number six will be explored further in the discussion and its importance as a standalone cluster will be analysed.

Figure 5.8 Bridging of statement number 6



Cluster label analysis

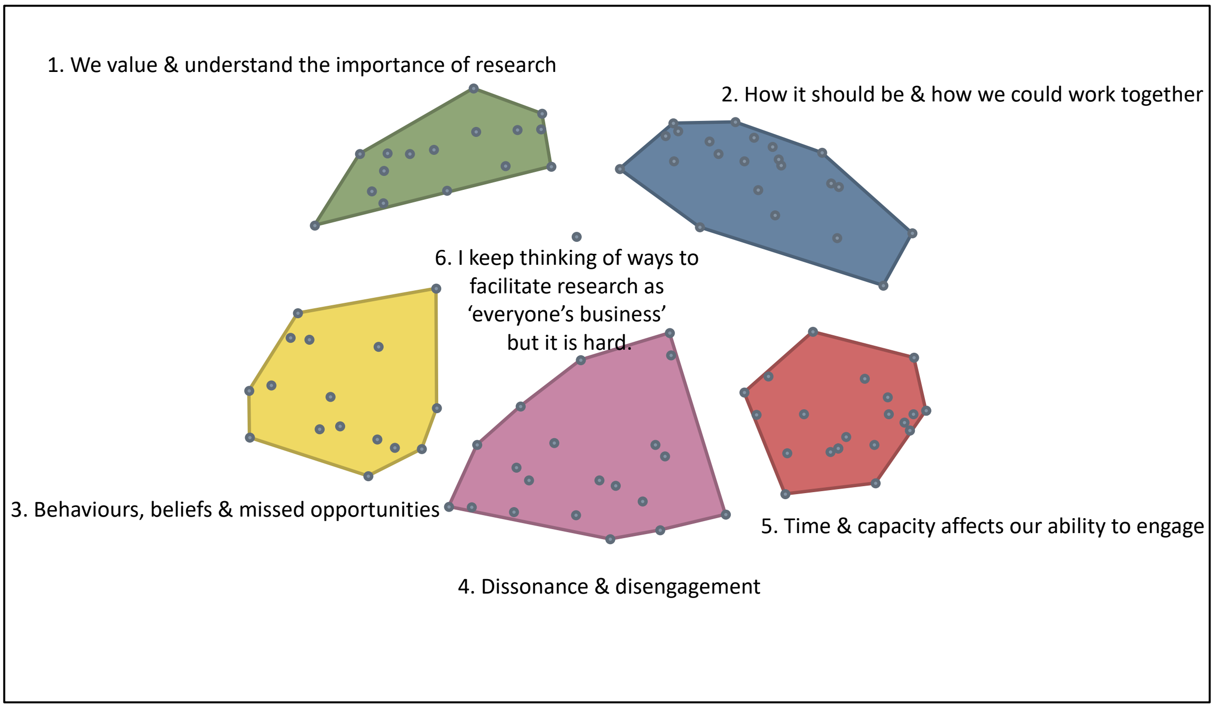
GCM software recommends cluster titles (called labels in GCM) based on those provided by participants for the groups of statements generated in the sorting exercise. The initial cluster labels, illustrated in figure 5.3 were recommended from those suggestions. By examining the content of each statement within a cluster and its relevance to the cluster label suggested, it was possible to thematically assess the relevance of the suggested cluster labels and assign more meaningful labels to each cluster. This was done based on a review of all statements positioned within each cluster. Kane and Trochim (2007) suggest it is appropriate for the analyst or researcher to develop and assign different cluster labels, acknowledging that there is no guarantee that participants are able to provide *good* fit suggestions. However, the suggested labels should be reviewed by the researcher for appropriateness, and should be considered a standard part of the exercise. The activity of thematically reviewing the statements within a given cluster is also beneficial in enabling the researcher to develop a deeper understanding of the contents of each cluster. Figure

5.9 illustrates the final cluster solution with amended labels for five of the six clusters. Because statement number six is a cluster in isolation, the label was not amended, as this would have risked changing the meaning of the statement. Table 5.5 presents a cross section of the range of cluster labels provided by participants during sorting activities. As mentioned earlier, some participants did not suggest cluster labels for all groups during sorting activities.

Table 5.5 Cross section of titles provided by participants during sorting

Time and capacity as barriers	*Positives*
Discordance between research and practice	*Barriers*
Importance of research to clinical care	*Colleagues' misconceptions*
Research as a lesser priority	*Individual responsibility*
Support and Opportunity	*No time for research!*
Communication and dissemination	*Challenges to research*
Visibility and applicability of research	*Research gets a poor rap!*
Need for specialist education and training	*Opportunities research can bring*
Role of non-research clinical staff	*NHS Values*
Belief that research is only medical	*Participation*
Benefit to patients	*Time*
Negative beliefs	*Elitism*
Research is business-focused	*Barriers*

Figure 5.9 Final cluster solution with amended titles



Cluster rating maps

Following generation of the final cluster map solution, rating data were overlaid for both rating scales, producing two cluster rating maps. The cluster rating maps provide a visual representation of the average participant ratings, using the two rating scales of likelihood of generating resistance or avoidance behaviours, and importance to address. This is illustrated by producing layered clusters. A range of between one and five layers is possible. A higher number of layers contained in a cluster indicates a higher average score for that cluster. A lower number of layers indicates a lower average score. Figures 5.10 and 5.11 illustrate these ratings respectively. The average score range influencing layer numbers generated by the software can be found on the left-hand side of each figure. In Figure 5.10 the average participant ratings ranged from 2.13 to 3.20 on a scale between 1 (not at all likely) and 4 (very likely). In figure 5.11 the average participant ratings ranged from 3.01 to 3.26. Again, this was on a scale of between 1 (not very important) and 4 (very important).

Figure 5.10 illustrates that on average, participants felt that statements contained within clusters three, four and five were more likely to generate resistance or avoidance behaviours.

Figure 5.10 Cluster ratings – likelihood of generating resistance or avoidance behaviours

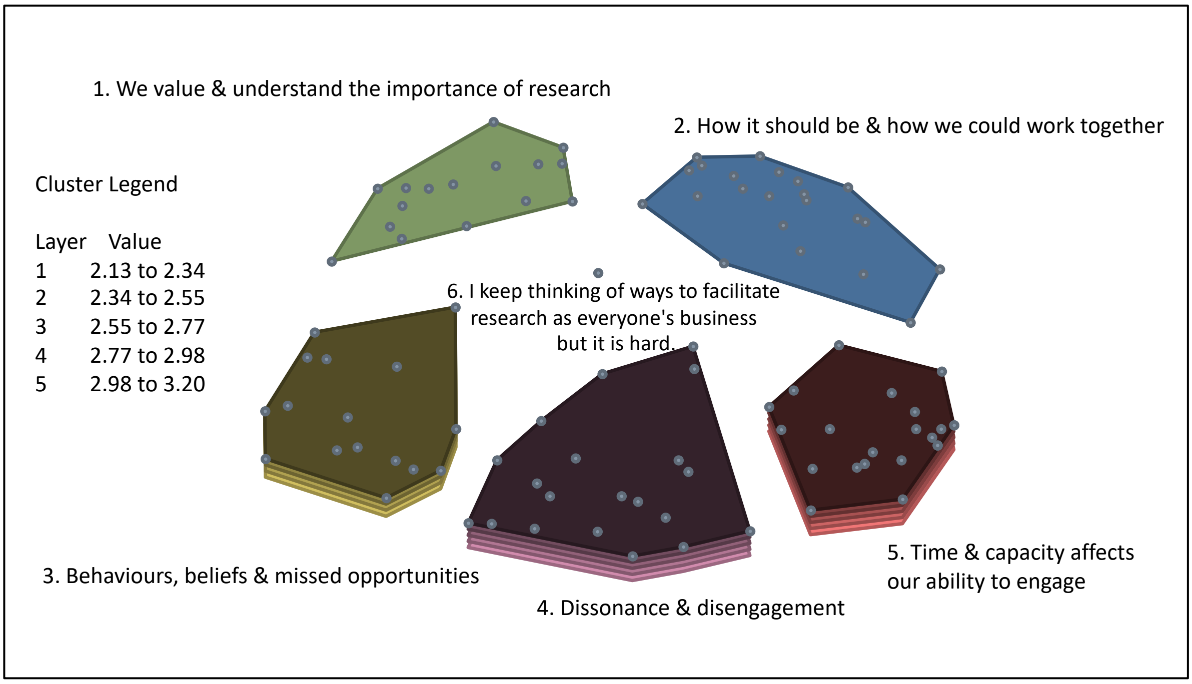
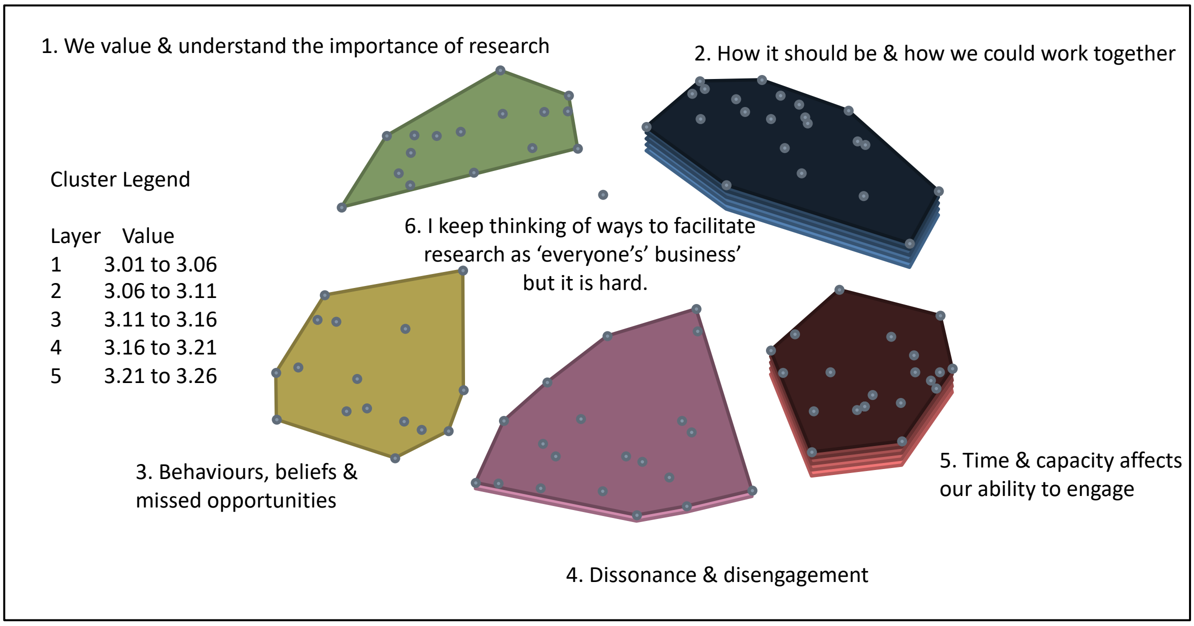


Figure 5.11 illustrates that on average, participants felt that statements contained within clusters two and five were most important to address.

Figure 5.11 Cluster ratings – importance to address



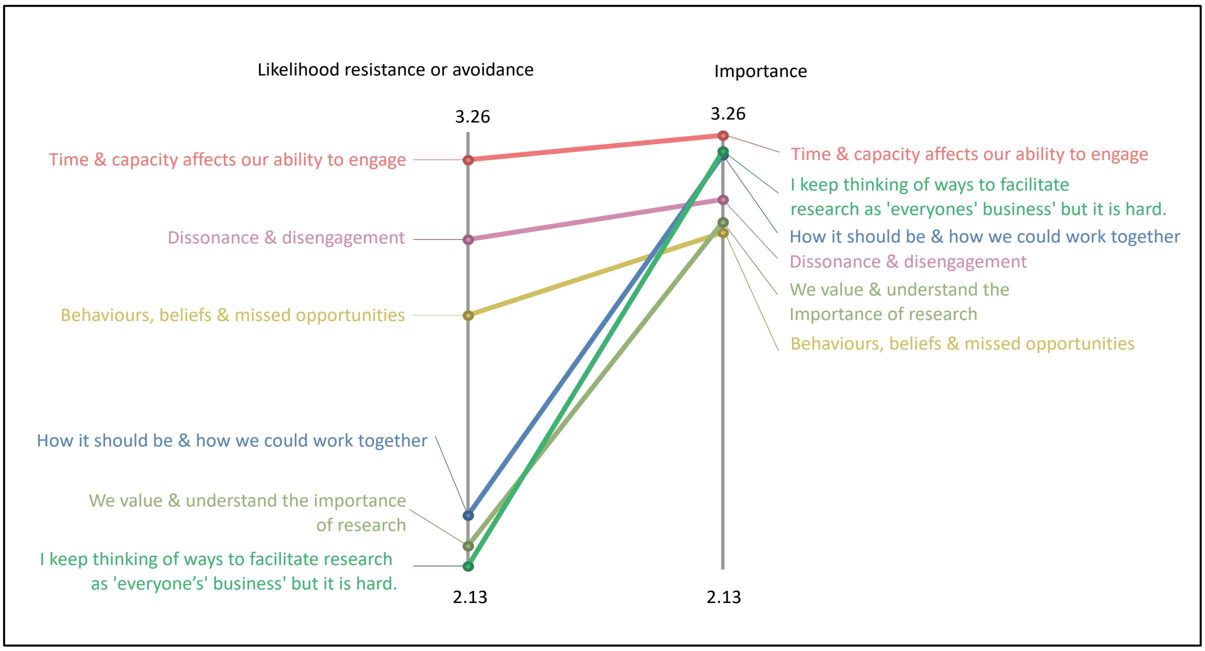
Pattern Matches

Cluster rating maps are a useful visual representation; however, they provide a visual representation of the average rating scales for a single rating only. To enable visual comparisons between both rating scales in terms of likelihood and importance to address, the rating data across clusters can be represented using a process which generates a visual pattern match using a ladder approach.

Figure 5.12 illustrates an absolute pattern match. An absolute pattern match uses the absolute minimum and absolute maximum average scales noted across both rating scales together. The minimum of 2.13 was the minimum average rating noted across both scales and was produced by participants scoring likelihood of generating resistance or avoidance behaviours. The maximum of 3.26 was the maximum average rating noted across both scales and was produced by participants scoring importance to address.

A pattern match provides another method of visualising the rating data at a cluster level. A perfect correlation between importance and likelihood would resemble the straight rungs of a ladder. Whilst there is a difference noted between the two rating scales in terms of importance and likelihood average scores, cluster number five, Time and capacity affects our ability to engage, and cluster number four Dissonance and Disengagement appear to have relatively balanced ratings between likelihood and importance on an absolute scale.

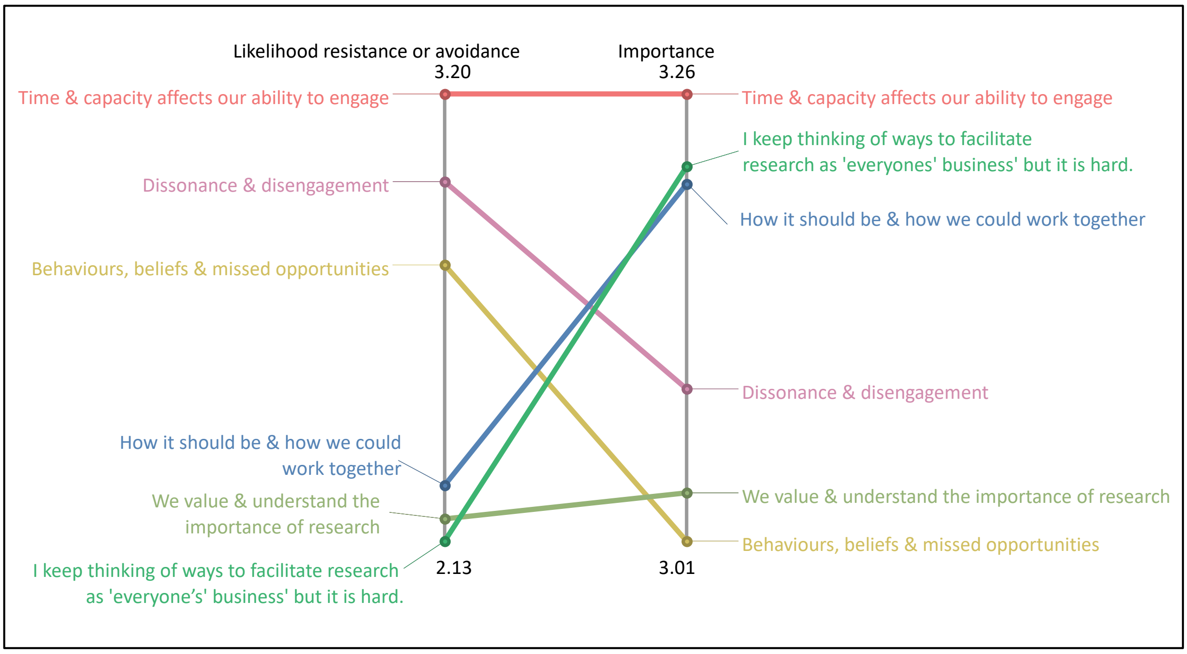
Figure 5.12 Absolute Pattern match



A relative pattern match presents the same rating data as an absolute pattern match, however, the scales are represented relative to each other rather than on an absolute scale. Figure 5.13 illustrates a relative pattern match using the minimum and maximum average ratings noted for both rating activities separately. For likelihood of generating resistance or avoidance behaviours the average ratings were between 2.13 and 3.20. For importance to address the average ratings were between 3.01 and 3.26. These are represented in the ladder graph, producing a very different visual representation for some of the clusters. Cluster number five, however, remains relatively balanced in terms of participant views on both scales.

Pattern matches are beneficial in visualising the average relationship between two rating scales across clusters. It is important, however, to be aware of the implications of visualising the rating scales in either an absolute or a relative manner, as such scales do not provide detail at a statement level and can appear very different depending on approach.

Figure 5.13 Relative pattern match



The cluster maps and pattern match representations have enabled the identification of broad relationships between the clusters and participant perceptions of likelihood and importance. The data presented so far indicate that cluster number five, *Time and capacity affects our ability to engage* was rated by participants, on average, both as most likely to generate resistance or avoidance, and as the most important to address. Of the remaining clusters, less correlation between the two rating scales was noted. For example, whilst cluster number four *Dissonance and disengagement* was rated, on average, as the second most likely to generate resistance or avoidance, it was rated as fourth most important to address. The importance rating of cluster number four was lower, on average, than cluster six, *I keep thinking of ways to facilitate research as everyone's' business but it's hard,* which was rated as second most important to address, but least likely to generate resistance or avoidance. In addition, cluster number two *How it should be and how we can work together*, was rated third most important to address, but fourth in terms of likelihood of generating resistance or avoidance.

Cluster number three, *Behaviours, beliefs and missed opportunities* was rated as least important to address, yet, on average, the third most likely to generate resistance or avoidance. Cluster number one, *We value and understand the importance of research,* was rated, on average, only slightly more likely than cluster six in likelihood of generating resistance or avoidance, and this was balanced with a lower importance rating, being second least important to address.

Go zones

To enable a more detailed analysis of rating data at a statement level, further visualisations called Go zones were produced. This further level of data analysis, built on the previous analysis, gradually increasing the level of complexity of analysis, yet enabling different views of the same data to aid understanding. This informed the interpretation of the data, the testing of the programme theory and the generation of recommendations in partnership with participants.

A Go zone is a bivariate graph, enabling the assessment of statement level values on both likelihood of resistance or avoidance and importance to address, both above and below the average rating noted either for the whole data set or by cluster. This is divided into quadrants plotted on an x and y axis, with a vertical line marking the average likelihood rating and a horizontal line marking the average importance rating. This produces a window like visual. Each quadrant is colour coded, with the top right quadrant coloured green, identifying those statements rated as both most important to address and most likely to generate resistance or avoidance. The bottom left quadrant colour coded grey, represents those statements rated on average as least important and least likely to generate resistance and avoidance. The top left orange quadrant illustrates those statements rated as less likely to generate resistance or avoidance, yet more important to address. The bottom right, yellow quadrant contains statements rated on average as more likely to generate resistance or avoidance, but less important to address. Of note, the ratings are presented as relative to each other and, in keeping with a critical realist acknowledgement of epistemological relativism, it is important to recognise that this knowledge has been socially produced and is therefore transitive, subject to limitations and fallible.

A Go zone was first produced for all statements, this is illustrated in figure 5.14. The statements contained within each quadrant are represented in table 5.6.

The *All Statements* Go zone, statement number 39. *“There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects.”* was rated by participants overall as the most important to address. Statement number 16. *“There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched.”* was rated by participants overall as the most likely to generate resistance or avoidance. Statement number 74. *“It is up to Doctors to recruit patients”* was rated as overall least important to address. Statements number 77. *“The training I have received in order to undertake the clinical interventions for research trials has been beneficial to my clinical role.”* and number 82. *“It's good for my patients to be able to take part in clinical research when they attend for their care.”* were rated as overall least likely to generate resistance or avoidance.

Figure 5.14 All statements go zone

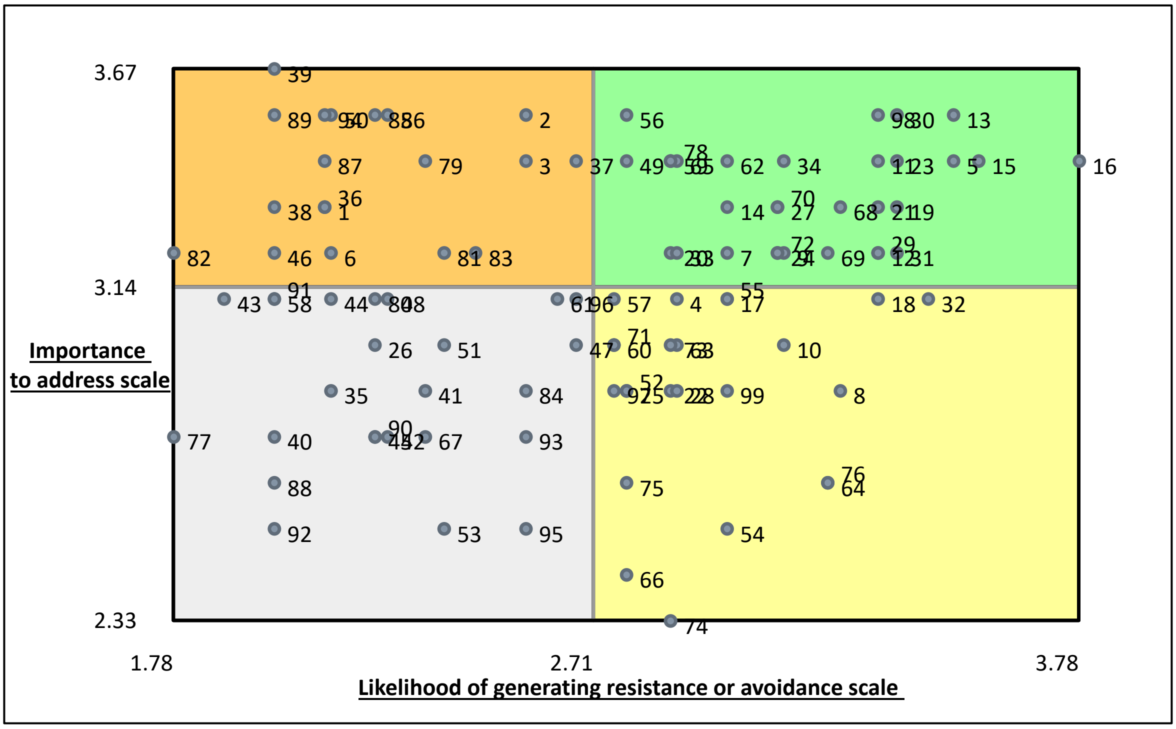


Table 5.6 Statements by quadrant in all statements go zone

1. Effective team working is essential between clinical and research delivery teams *2. Increased collaboration between clinical staff and research staff* *3. There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels* *6. I keep thinking of ways to facilitate research as 'everyone’s' business' but it is hard.* *36. That everyone has a responsibility to enable clinical research to take place in the NHS* *37. The importance of promoting research engagement to other nurses and AHP's* *38. I believe I have a duty of care to at least participate in research as a clinician.* *39. There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects.* *46. To be aware of ongoing research projects* *50. It is important to be involved or advise our patients about clinical research as it improves patient care.* *79. To enable better care for our patients* *81. Research is the key part of how we improve LD services and keep moving forward* *82. It's good for my patients to be able to take part in clinical research when they attend for their care* *83. Clinical research is important to the NHS* *85. That everyone who has clinical contact should have a basic understanding of the principles of clinical research* *86. It should be integral to my clinical work.*	*5. People who do research or bring innovation lack peer support* *7. I have been involved in the delivering the clinical intervention of two different research trials but this has been alongside my own clinical caseload and has caused increased pressure* *9. It sometimes can be time consuming* *11. It is hard to be involved within our working hours.* *12. I lack the time to get as involved in research as I'd like* *13. Time isn't prioritised within clinical working to allow engagement in research* *14. Education isn't prioritised within clinical working to allow engagement in research* *15. We just don't have the time* *16. There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched* *19. Research it is often hard to integrate it into my clinical practice as it is extra to my workload.* *20. Research is not taken into consideration on a day to day basis in a clinical setting* *21. Research is not seen as necessary in Learning Disability services* *23. Because research is seen as 'an add on' instead of part of clinical care, clinicians don't have time to engage in research.* *24. Clinical care and research are seen as separate entities* *27. Research is seen as a bother rather than core business* *29. Often clinical research is not seen as a priority within the department* *30. It is not often considered a priority by managers or heads of services.*

87. Research should be at the core of what we do as nurses *89. Nurses should be supported to be involved in research at all levels of their clinical roles.* *94. Making it a priority*	*31. Clinical research is expected to take a back seat in order for clinical practice to be delivered* *33. I always try to engage and support research activities in the unit but sometimes the need to prioritise patient care limits my capacity* *34. I lack the support to get as involved in research as I'd like.* *49. There are frequently missed opportunities for district nursing staff to identify and signpost potential research participants toward appropriate studies.* *56. Research studies need to explain their purpose in a way that junior and unregistered nurses can engage with.* *59. There is lot of misunderstanding about clinical research in NHS* *62. Research is invisible to nurses* *65. Nurses should know about research in their area, but we don't* *68. Research is seen as elitist* *69. I don't find out the outcome of the research I support* *70. There is limited motivation amongst staff to take an active interest in clinical research delivery because they don't feel the results will have a direct impact on their work.* *72. There is inconsistency of approach* *78. There is a historical belief that clinical research nurse roles can't be undertaken by non nurses (ie AHPs). I think this should be encouraged to change* *98. Lots of community staff believe that research doesn't apply to them*
26. Research is a nice extra *35. As a clinician, I am perfectly placed to work alongside the delivery team. I screen, recruit, take consent and deliver interventions etc with the support of my delivery team* *40. My role supports research in practice*	*4. People who do research or bring innovation are likely to be bullied* *8. Usually laborious and requires heavy admin work* *10. I always try to engage and support research activities in the unit but sometimes time limits my capacity*

41. To help researchers with their projects 42. To know who my local research teams are 43. To ensure my local research teams know me 44. To ensure my local research teams know how I can help 45. To facilitate data collection for research if approached by members of the research team and asked to help with this. 47. To help with identifying appropriate patients if they fit study criteria. 48. It could be part of the routine nurses work to seek out appropriate trials and or patients 51. To play a role in helping the recruitment process to happen. 53. The more 'customers' we recruit, the higher the chances of retaining funding 58. Research should be made more visible and exciting. 61. I am not very well informed about research 67. I do not really have anything to do with it 77. The training I have received in order to undertake the clinical interventions for research trials has been beneficial to my clinical role 80. Research is the key part of how we improve the lives of people with an LD 84. I understand the importance of research 88. My role is pivotal to improve research on the front line 90. It is encouraged 91. It provides an opportunity to work collaboratively with people you wouldn't usually work closely with 92. I think it would be really interesting 93. Being proactive 95. Research in large teaching hospitals is given a lot of credibility 96. Lots of community staff believe that research is a highly technical, advanced activity	17. The delivery of research requires further learning away from patient care 18. The delivery of research requires further time away from patient care 22. Research is not seen as something to make an effort to engage with in Learning Disability services 25. Research is an add on 28. Research is something that someone else does 32. Patient contact is seen to be of more importance than research in a clinical setting 52. We were asked to treat research as a 'business'. 54. Research has become more about money and less about patients 55. The challenges of embedding clinical research in the NHS during various pressures (money, workforce, pandemic etc.) is costing patients opportunities of accessing clinical trials. 57. Junior nurses do not have enough knowledge of ongoing research and the importance of it. 60. I find research dull and difficult to understand 63. Research is invisible to patients 64. I have no idea what research studies are currently being recruited for 66. I don't personally have the drive for research 71. Unaware of any relation of my role to clinical research in the nhs in my current trust 73. The clinical trials associated with the department I work for and the university we are affiliated to are very medically focused 74. It is up to Doctors to recruit patients 75. Do what you are told to do, and support the doctors with their research involvement.

	76. The clinical trials associated with the department I work for and the university we are affiliated to have limited focus on non-pharmacological clinical research *97. Lots of community staff believe that research happens in hospital* *99. The majority of people I know leave clinical roles to work in research*

Subsequent Go zones were produced for cluster numbers one to five. These are illustrated in figures 5.15 to 5.19. Each cluster will be discussed sequentially according to the level of importance rated by participants, starting with most important. Go zone number five. *“Time and Capacity affects our ability to engage”* will be discussed first.

Cluster number 5. Time and capacity affects our ability to engage.

Individuals participating in the rating activity rated cluster number five as the most important cluster to address. Cluster five contained 25 statements. According to participants, statement numbers 30. *“It is not often considered a priority by managers or heads of services.”* and 13*. “Time isn't prioritised within clinical working to allow engagement in research.”* were rated as most important to address.

Statement number *16. “There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched.”* was contained within this cluster. As previously highlighted, this statement was rated the most likely of all statements across the entire dataset to generate resistance or avoidance, however, it was not rated higher than statements 13 and 30 in importance to address. The statements described above, rated highest on both scales were contained within the green quadrant in this cluster, however, it is important to note that statements in the yellow quadrant were also rated high in terms of likelihood and importance. Statements 12, 29, 31 and 32 were of particular interest.

12. *“I lack the time to get as involved in research as I'd like.”*

29. *“Often clinical research is not seen as a priority within the department.”*

31. *“Clinical research is expected to take a back seat in order for clinical practice to be delivered.”*

32. *“Patient contact is seen to be of more importance than research in a clinical setting.”*

Figure 5.15 Cluster 5. Time and capacity affects our ability to engage - go zone

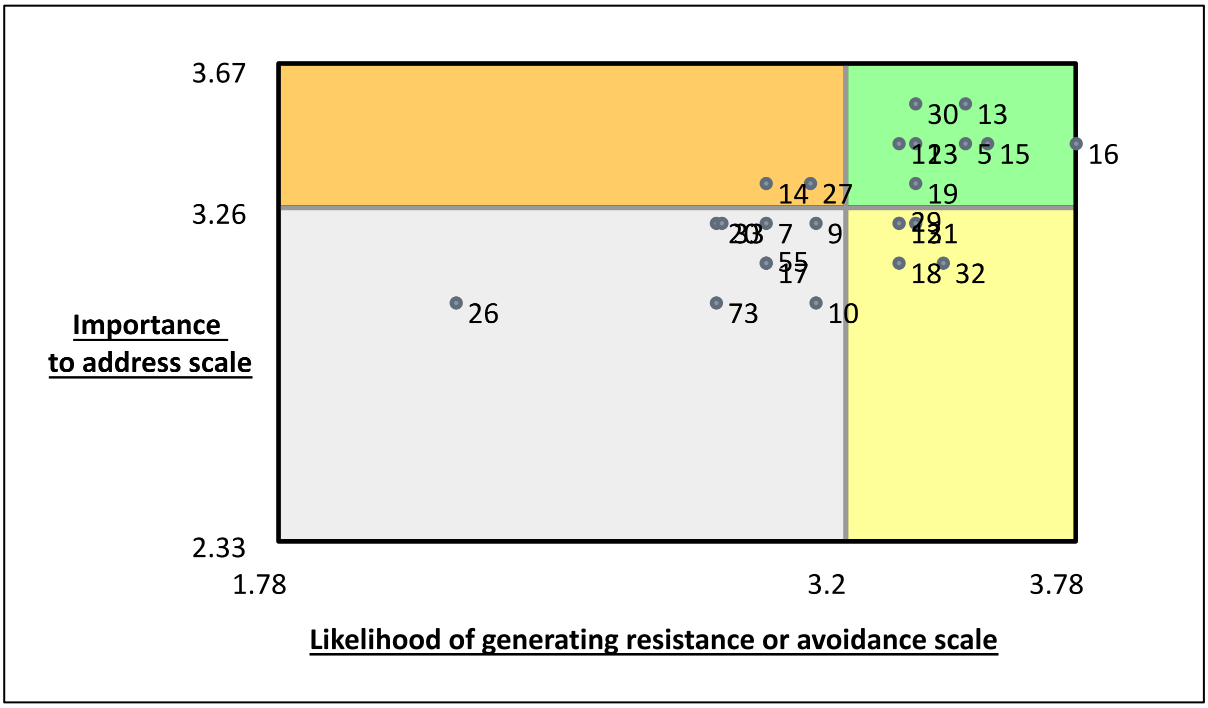


Table 5.7 Statements within cluster 5

14. Education isn't prioritised within clinical working to allow engagement in research *27. Research is seen as a bother rather than core business*	*5. People who do research or bring innovation lack peer support* *11. It is hard to be involved within our working hours.* *13. Time isn't prioritised within clinical working to allow engagement in research* *15. We just don't have the time* *16. There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched* *19. Research it is often hard to integrate it into my clinical practice as it is extra to my workload.* *23. Because research is seen as 'an add on' instead of part of clinical care, clinicians don't have time to engage in research.* *30. It is not often considered a priority by managers or heads of services.*
7. I have been involved in the delivering the clinical intervention of two different research trials but this has been alongside my own clinical caseload and has caused increased pressure *9. It sometimes can be time consuming* *10. I always try to engage and support research activities in the unit but sometimes time limits my capacity* *17. The delivery of research requires further learning away from patient care* *20. Research is not taken into consideration on a day to day basis in a clinical setting* *26. Research is a nice extra* *33. I always try to engage and support research activities in the unit but sometimes the need to prioritise patient care*	*12. I lack the time to get as involved in research as I'd like* *18. The delivery of research requires further time away from patient care* *29. Often clinical research is not seen as a priority within the department* *31. Clinical research is expected to take a back seat in order for clinical practice to be delivered* *32. Patient contact is seen to be of more importance than research in a clinical setting*

limits my capacity *55. The challenges of embedding clinical research in the NHS during various pressures (money, workforce, pandemic etc.) is costing patients opportunities of accessing clinical trials.* *73. The clinical trials associated with the department I work for and the university we are affiliated to are very medically focused*	

Cluster number 2. How it should be and how we could work together.

The cluster rated as next most important to address by participants was Cluster number two, *"How it should be and how we could work together."* This cluster contained a total of 22 statements. This cluster also contained the highest rated statement across the whole dataset in relation to importance to address. This was statement number 39. *"There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects."* Statement number 39, however, was not rated high on the scale of likelihood of generating resistance or avoidance, therefore it was positioned within the orange quadrant. The importance of this statement and the potential consequences of its position within the cluster, due to the rating scales used, will be explored in chapter 6, where a full discussion of the data and its implications and links with the evidence base are presented. In this cluster, participants rated statement number 34*. I lack the support to get as involved in research as I'd like."* as most likely to generate resistance or avoidance. The statement rated most important to address contained within the green quadrant was statement number 2. "*Increased collaboration between clinical staff and research staff."*

Figure 5.16 Cluster 2. How it should be and how we could work together - go zone

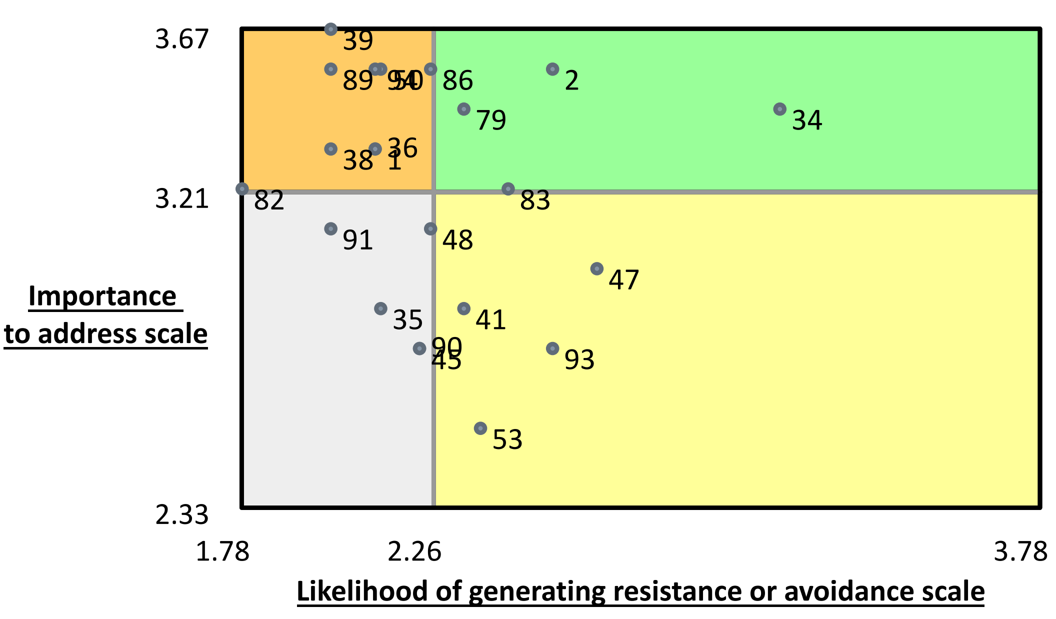


Table 5.8 Statements within cluster 2

1. Effective team working is essential between clinical and research delivery teams *36. That everyone has a responsibility to enable clinical research to take place in the NHS* *38. I believe I have a duty of care to at least participate in research as a clinician.* *39. There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects.* *50. It is important to be involved or advise our patients about clinical research as it improves patient care.* *82. It's good for my patients to be able to take part in clinical research when they attend for their care* *86. It should be integral to my clinical work.* *89. Nurses should be supported to be involved in research at all levels of their clinical roles.* *94. Making it a priority*	*2. Increased collaboration between clinical staff and research staff* *34. I lack the support to get as involved in research as I'd like.* *79. To enable better care for our patients* *83. Clinical research is important to the NHS*
35. As a clinician, I am perfectly placed to work alongside the delivery team. I screen, recruit, take consent and deliver interventions etc. with the support of my delivery team *45. To facilitate data collection for research if approached by members of the research team and asked to help with this.* *48. It could be part of the routine nurses work to seek out appropriate trials and or patients* *90. It is encouraged* *91. It provides an opportunity to work collaboratively with people you wouldn't usually work closely with*	*41. To help researchers with their projects* *47. To help with identifying appropriate patients if they fit study criteria.* *53. The more 'customers' we recruit, the higher the chances of retaining funding* *93. Being proactive*

Cluster number 4. Dissonance and disengagement

The cluster rated as next most important to address by participants was Cluster number four. *Dissonance and disengagement.* This cluster contained 20 statements. In this cluster, the statement rated on average as most important to address was statement number 98. *"Lots of community staff believe that research doesn't apply to them." This statement was* rated on average as equally the most likely to generate resistance or avoidance alongside statement number 21. *"Research is not seen as necessary in Learning Disability services."*

Figure 5.17 Cluster 4. Dissonance and disengagement - go zone

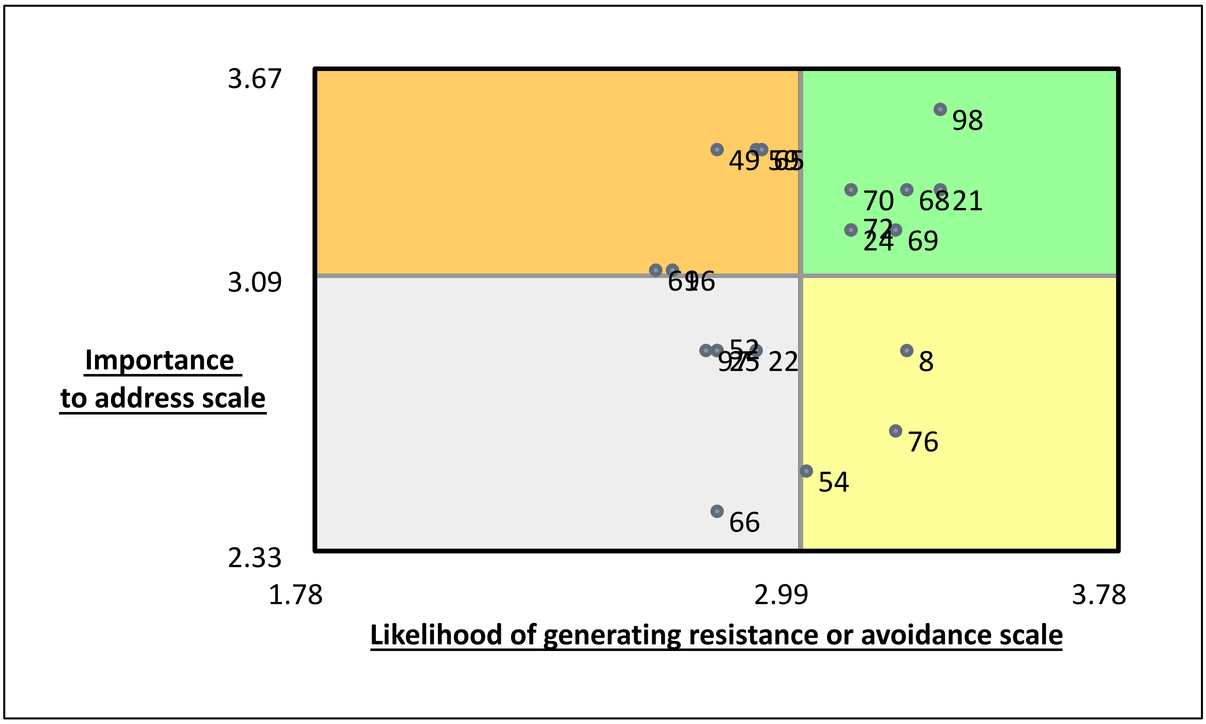


Table 5.9 Statements within cluster 4

49. There are frequently missed opportunities for district nursing staff to identify and signpost potential research participants toward appropriate studies. *59. There is lot of misunderstanding about clinical research in NHS* *61. I am not very well informed about research* *65. Nurses should know about research in their area, but we don't* *96. Lots of community staff believe that research is a highly technical, advanced activity*	*21. Research is not seen as necessary in Learning Disability services* *24. Clinical care and research are seen as separate entities* *68. Research is seen as elitist* *69. I don't find out the outcome of the research I support* *70. There is limited motivation amongst staff to take an active interest in clinical research delivery because they don't feel the results will have a direct impact on their work.* *72. There is inconsistency of approach* *98. Lots of community staff believe that research doesn't apply to them*
22. Research is not seen as something to make an effort to engage with in Learning Disability services *25. Research is an add on* *52. We were asked to treat research as a 'business'.* *66. I don't personally have the drive for research* *97. Lots of community staff believe that research happens in hospital*	*8. Usually laborious and requires heavy admin work* *54. Research has become more about money and less about patients* *76. The clinical trials associated with the department I work for and the university we are affiliated to have limited focus on non-pharmacological clinical research*

Cluster number 1. We value and understand the importance of research.

The cluster rated as next most important to address by participants was Cluster number one. *We value and understand the importance of research*. This cluster contained 16 statements. In this cluster, the statement rated on average as most important to address was statement number 85. "*That everyone who has clinical contact should have a basic understanding of the principles of clinical research"* The statement rated as highest on the scale of likelihood of generating resistance or avoidance was statement number 37. *"The importance of promoting research engagement to other nurses and AHP's."*

Figure 5.18 Cluster 1. We value and understand the importance of research - go zone

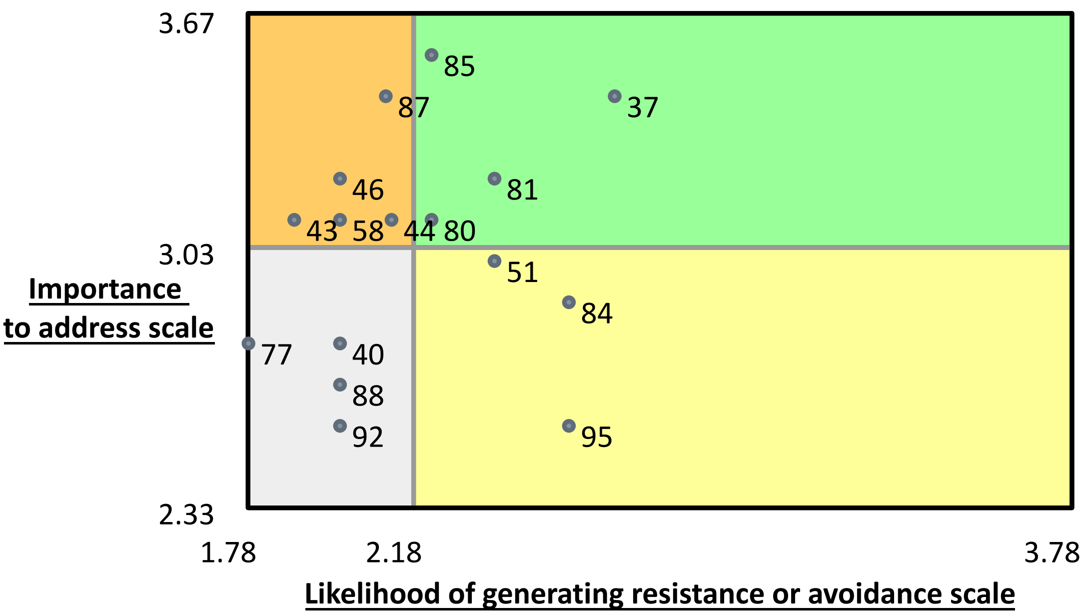


Table 5.10 Statements within cluster 1

43. To ensure my local research teams know me *44. To ensure my local research teams know how I can help* *46. To be aware of ongoing research projects* *58. Research should be made more visible and exciting.* *87. Research should be at the core of what we do as nurses*	*37. The importance of promoting research engagement to other nurses and AHP's* *80. Research is the key part of how we improve the lives of people with an LD* *81. Research is the key part of how we improve LD services and keep moving forward* *85. That everyone who has clinical contact should have a basic understanding of the principles of clinical research*
40. My role supports research in practice *77. The training I have received in order to undertake the clinical interventions for research trials has been beneficial to my clinical role* *88. My role is pivotal to improve research on the front line* *92. I think it would be really interesting*	*51. To play a role in helping the recruitment process to happen.* *84. I understand the importance of research* *95. Research in large teaching hospitals is given a lot of credibility*

Cluster number 3. Behaviours, beliefs and missed opportunities.

The cluster rated as least important to address by participants was Cluster number three *Behaviours, beliefs and missed opportunities.* This cluster contained 16 statements. Statement number 56. *"Research studies need to explain their purpose in a way that junior and unregistered nurses can engage with"* was rated on average as the most important to address, though this was positioned within the orange quadrant. The statement rated as most likely to generate resistance or avoidance was statement number 64. *"I have no idea what research studies are currently being recruited for."* This cluster contained the statement rated as least important to address across the entire dataset. This was statement number 74. *"It is up to doctors to recruit patients."* This statement was however rated above the average rating in relation to likelihood of generating resistance or avoidance.

Figure 5.19 Cluster 3. Behaviours, beliefs and missed opportunities - go zone

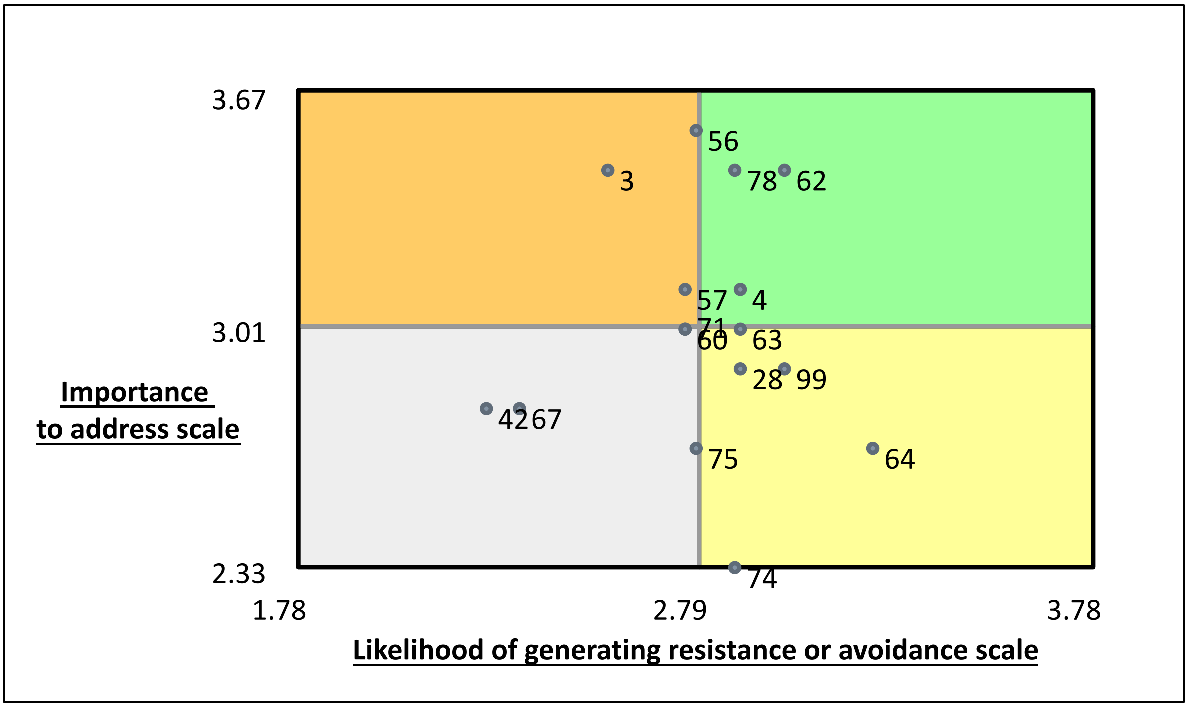


Table 5.11 Statements within cluster 3

3. There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels *56. Research studies need to explain their purpose in a way that junior and unregistered nurses can engage with.* *57. Junior nurses do not have enough knowledge of ongoing research and the importance of it.*	*4. People who do research or bring innovation are likely to be bullied* *62. Research is invisible to nurses* *78. There is a historical belief that clinical research nurse roles can't be undertaken by non-nurses (i.e. AHPs). I think this should be encouraged to change*
42. To know who my local research teams are *60. I find research dull and difficult to understand* *67. I do not really have anything to do with it* *71. Unaware of any relation of my role to clinical research in the NHS in my current trust* *75. Do what you are told to do and support the doctors with their research involvement.*	*28. Research is something that someone else does* *63. Research is invisible to patients* *64. I have no idea what research studies are currently being recruited for* *74. It is up to doctors to recruit patients* *99. The majority of people I know leave clinical roles to work in research*

Cluster number 6. I keep thinking of ways to facilitate research as ‘everyone’s business’ but it is hard.

It was neither possible nor feasible to generate a go zone representation for cluster number six, because it contained only a single statement. *“I keep thinking of ways to facilitate research as ‘everyone’s business’ but it is hard.”* It was, however, possible to locate this statement in the all statement go zone, where it was found to be positioned within the grey quadrant, almost centrally, proximal to the average horizontal and vertical lines. This statement had an average rating of 2.13 in relation to likelihood of generating resistance or avoidance, and an importance rating of 3.22. The significance of this statement, its position on the map and the dialogue it generated during the participant interpretation session will be further discussed in chapter six.

Following the generation and analysis of the range visual interpretations of the data, the final step in group concept mapping is to facilitate participants to interpret the findings from their perspective. The interpretation session follows a specific stepwise approach according to Kane and Trochim (2007) and will be described next.

5.4. Interpretation

To maximise potential participation, and in light of ongoing variations in the global pandemic, a participant interpretation session took place via the secure online platform google meet. All participants consenting to join at any stage of the GCM study were invited to attend. A further reminder invitation was sent approximately four weeks prior to the session. An agenda and joining instructions were sent to participants one week prior to the session. Of the 38 participants invited to join the interpretation session, five individuals responded to express an intention to attend. On the day, three attended and contributed to the session. Two, were unable to attend at short notice due to unexpected clinical pressures. Whilst three could be considered a small number of individuals and a potential limitation of the research, it felt important to progress with the session. Furthermore, the discussion and themes emerging during the session were deemed useful, appropriate, well considered, and relevant to the study. Rosas and Kane (2012) did not assess the validity of interpretation activities in their pooled analysis, therefore it is not possible to predict the potential impact of a smaller group on the research. Rosas and Kane (2012) also state, these sessions are intended to help participants to understand the data and interrelationships between, to add richness to the recommendations. Whilst an important step in the GCM process, interpretation was not considered in the pooled analysis, though it is unclear as to why. The implications of recruitment, and participation in the seven steps within the GCM phase will be discussed in more detail in chapter six, specifically in relation to the strengths and limitations of this study.

To facilitate the interpretation of data generated and collected at the different stages of the study, a number of resources were assembled and presented at the session. A PowerPoint slide deck was created and used to guide participants through the session, generate conversation between participants, and encourage questions throughout.

The presentation firstly reminded participants of the background to the research and the original intentions of the study. Following this, the stages that had taken place to date and the original focus prompt used to generate the statement set were shared. Next, data on participation and the statement list was discussed with participants, with an explanation of the process of ideas synthesis which enabled the refining of the original statement set into the final list.

Following this, the statement point map and the range of cluster solutions was discussed, including the process of arriving at the final cluster solution. There was agreement between participants regarding the final cluster solution, and a thought-provoking discussion took place regarding interpretation of cluster number six, made up of only one statement. This discussion will be explored in more detail in chapter six and reflects the importance of recognising how the same information can be perceived differently by individuals in different contexts.

Following a group discussion about the cluster solutions, the rating maps and further visual representations via pattern matches and go zones were shared. These more detailed maps enabled discussion about the different ways of looking at the same data. A discussion was facilitated regarding the perceived likelihood of generating resistance or avoidance, the perceived importance to address, and a perceived focus on clusters containing positive statements rather than negative ones to bring about change.

Participants attending the interpretation session overwhelmingly agreed that it was reasonable to support the original programme theory based on the data generated throughout the study. Participants agreed there was clear evidence of a range of behaviours and perceptions, likely to generate resistance or avoidance at the interface between clinical research delivery and clinical service delivery.

A discussion took place regarding the concept of discursive distancing noted from the composition of some statements generated. For example, statement number 59. "*There is lot of misunderstanding about clinical research in NHS."* identifies that there is a level of misunderstanding about research. This is widely acknowledged in the literature, as described in previous chapters. Yet whilst the participant generating this statement presented an awareness of the issue, they chose not to articulate it in such a way as to suggest they experienced any misunderstanding themself. Another example of discursive distancing can be seen via statement number 30. which states *"It is not often considered a priority by managers or heads of services."* This statement suggests that research is not prioritised by particular groups of individuals separate to the participant, perhaps reflective of othering. The concepts of discursive distancing and othering will be analysed in relation to these findings in chapter six.

Participants attending the interpretation session agreed, drawing on their own experiences that cluster number five; *Time and capacity affect our ability to engage* was both most likely to generate resistance or avoidance and was most important to address. Participants expressed the notion that focusing on positive aspects, seeking quick wins, or maximising "low hanging fruit", would be an appropriate way forward to change the perceived experiences of CRNurses and the success of clinical research delivery. The contents of cluster number two *How it should be and how we could work together* provided much food for thought in relation to this and is perhaps the reason it was the second highest rated cluster in relation to importance to address.

A number of recommendations were made in addition to the consensus regarding a need to focus on clusters five and two. These recommendations were nuanced and contextually informed. One participant suggested that, at a statement level, statement number 34. "*I lack the support to get as involved in research as I'd like.*" could hold the key to naturally addressing other issues, suggesting support to explore, feel comfortable with, and learn about the positive aspects of research, should begin at an undergraduate level.

There was a discussion about the potential of clusters five and two to address other issues and remove the perceptions or experiences related to cluster number four.

There was also a discussion about the visibility of research as a result of COVID and how the political status of research could be maximised to the benefit of this study.

The interpretation session was a critical activity in consolidating the data collected and analysed prior, enabling a deeper understanding of the collective views and resulting recommendations. The session informed the development of next steps, which will be discussed in chapter six. The findings have enabled an enhanced understanding of the potential underlying mechanisms that may impact relationships at the interface between clinical research delivery and clinical service delivery. This has further assisted in identifying priorities and potential strategies that could improve relationships that are integral to clinical research delivery.

5.5 Summary

In this chapter, the methods and results of the group concept mapping study have been presented. Participants involved included a range of health care professionals across nursing and allied health professions. The data gathered through the GCM process appeared to support the programme theory tested during the GCM study. Working with participants during an interpretation session, recommendations were generated in relation to where a focus is required in order to improve the relationships and interactions integral to successful clinical research delivery.

Chapter six will move on to draw out key themes from the data collected and analysed as part of the GCM phase. This will include constructing a critical discussion of the findings presented within this chapter, making explicit links to relevant literature and to the realist review stage.

CHAPTER 6. DISCUSSION

6.0 Re-stating the aims and intentions of this study

Before describing the structure and flow of this chapter, the focus and aims of this doctoral work will be re-stated due to their central importance in informing the discussion that follows.

The focus of this doctoral work was on uncovering the beliefs and perceptions of those nurses, midwives and AHPs (NMAHPs) not involved in the delivery of clinical research yet practicing alongside teams who deliver clinical research in the NHS. Specifically, the exploration intended to elicit views on the delivery of clinical research and the CRNurse role. The purpose was to provide insights into what may generate avoidance and resistance behaviours reported to be present at the interface between clinical research delivery and clinical service delivery. This would subsequently enable the identification of what works, what could work better, and in which contexts, to improve the success of clinical research in the NHS.

The overarching aims of this doctoral work were:

a) To understand how the clinical research nurse role and research delivery is perceived by healthcare professionals operating outside of, yet alongside, clinical research teams within NHS organisations

b) To identify and characterise factors that may generate avoidance and resistance behaviours towards clinical research nurses, in healthcare professionals practicing at the interface between research delivery and clinical service delivery

c) To understand which factors are perceived as important to address by these healthcare professionals, in order to improve the relationships and interactions integral to successful clinical research delivery

d) To identify implications for future research to inform and improve practice

6.1 Introduction

This chapter will present a critical discussion of the research findings and make comparisons with the existing evidence base. In keeping with previous chapters, personal reflection points, situated within separate text boxes, have been offered throughout the chapter, where felt to be relevant to the topic being discussed.

The discussion is set out in three distinct sections linked to the original aims of the study. The first section will present a discussion of how the clinical research nurse role and research delivery is perceived by healthcare professionals operating outside of, yet alongside, clinical research teams within NHS organisations (aim a.). This will involve a critical analysis of the original statement generation and sorting activities completed during the Group Concept Mapping (GCM) phase.

The second section will critically examine the data related to factors considered by participants to generate avoidance or resistance behaviours towards CRNurses (aim b.) combined with an analysis of the factors participants indicated were important to address (aim c.). This will involve critiquing the data generated during both of the GCM rating activities.

The third section will present the implications and key recommendations arising from this study.

Following the main discussion, a further section will set out critical reflections on this doctoral work, including the perceived strengths and limitations noted across the thesis.

Throughout the main discussion, where there is considered to be an original contribution to knowledge, this will be indicated, though not discussed fully at this stage. A subsequent discussion of the original contribution to the evidence base arising from this work will be unpacked in more detail early in the conclusion chapter.

Before entering into the main discussion, a brief summary of the main findings will be re-stated in order to set the context for the subsequent discussion.

6.2 Summary of main findings

The first Phase, the Realist Synthesis, generated 13 theories. One was selected during stakeholder engagement to form the basis of the group concept mapping (GCM) Phase. The theory taken forward for testing in the GCM phase was:

> *If key colleagues are **not interested in, aware of, or do not understand** the importance, value, and utility of research to their role, their patients, or the wider NHS agenda, then they may **unintentionally or intentionally** display avoidance of or resistance to research being delivered in their clinical area. This presents a risk to positive working relationships with CRNurses and access to research opportunities for patients. Consequently, this could impact on organisational performance in relation to research activity and culture.*

The following focus prompt, used in the empirical study, was derived from the chosen theory:

A specific view I have about my role in relation to the delivery of clinical research in the NHS is…

This focus prompt was completed repeatedly by consenting participants, generating 99 unique statements (Appendix 11). These were sorted by participants into six thematic clusters and subsequently rated according to likelihood of generating resistance or avoidance behaviours and their importance to address.

The six clusters were:

1. We value and understand the importance of research
2. How it should be and how we could work together
3. Behaviours beliefs and missed opportunities

4. Dissonance and disengagement
5. Time and capacity affects our ability to engage
6. I keep thinking of ways to facilitate research as everyone's business but it's hard

On average, the statements contained within clusters three, four and five *Behaviours beliefs and missed opportunities, Dissonance and disengagement, and Time and capacity affects our ability to engage were* perceived by participants as most likely to generate resistance or avoidance behaviours. Participants rated statements within cluster two and five *How it should be and how we could work together, and Time and capacity affects our ability to engage* as most important to address.

6.3 Main discussion

The three sections of the main discussion will now be set out, commencing with a critical examination related to aim a., how the clinical research nurse role and research delivery is perceived by NMAHPs operating outside of, yet alongside, clinical research teams within NHS organisations. This will be followed by a discussion combining aims b., and c. This will incorporate the factors considered by participants to generate avoidance and resistance behaviours, and those considered important to address in order to improve the relationships and interactions integral to successful clinical research delivery.

6.3.1 Perceptions of the Clinical Research Nurse role and research delivery

This section will critically discuss the data collected and analysed during both the initial ideas generation stage and the sorting activities of the GCM phase. The initial ideas were collected in response to the focus prompt and subsequently sorted by participants thematically into the six eventual clusters set out in the previous chapter and briefly reiterated above.

The initial ideas generated by participants in response to the focus prompt indicated a balanced range of views in relation to the CRNurse role and research delivery. Statements reflected a mixture of positive and negative views, combined with suggestions of what needs to change to improve the delivery of research in the NHS. Some reflected on what could be interpreted as lived experiences in relation to involvement in supporting the delivery of clinical research, and some presented their observations of individuals involved in delivering research across the NHS and the behaviours they may be subjected to.

As previously stated, chapter two highlighted how the CRNurse literature has, at times, historically presented the CRNurse role as one of perceived inferiority in comparison to other professions, such as medicine (Hunt, 1983; Jordan, 1990). The significance of these views, if held by colleagues outwith research delivery structures, could be important in relation to the assumed power these individuals may possess in the spaces where CRNurses need to operate. Territoriality, as an observable behaviour that may play out as passive avoidance or active resistance, was linked to these experiences in chapter three. This was in relation to the gatekeeping behaviours and the perceived power imbalance experienced by CRNurses as visitors to departments (Tinkler *et al.*, 2018; Hill, 2018; Tinkler and Robinson, 2020; Hernon, Dalton and Dowling, 2020). Such perceptions were thought, in part, to be due to the liminal state in which the CRNurse practices (Stobbart, 2013).

The statements generated in this study did not provide direct insight into views on the CRNurse role specifically. It follows therefore, that it is not possible to state with any certainty whether NMAHP colleagues view CRNurses as inferior or practicing within a role of less value. There is, however, some potential to offer previously unknown insight into the matter, based on what has been uncovered in this study and the earlier testing of focus prompts. The inferences drawn from the earlier testing of focus prompts will be briefly discussed first.

As described in chapter five, during the development of the focus prompt for the empirical phase, the extent to which views directly related to the CRNurse may be possible to seek was tested. The following explicit open-ended statement was tested for adequacy in generating relevant data:

A specific view I have about the work of Clinical Research Nurses in the NHS is...

This test prompt generated no responses. The lack of response to this test prompt may have been due to time constraints for those invited to respond, or to a perceived lack of clarity of the prompt itself. It is also possible that a perceived lack of understanding of, or an absence of views on, the CRNurse role may be an alternative explanation for the lack of response. Reflecting on this further, however, and acknowledging that all other test prompts received responses, those individuals testing this focus prompt may have provided an indication that there would be reluctance to share views on a specific role, therefore choosing to remain silent rather than expressing views which may pose a personal risk.

Consequently, the pre-study testing of focus prompts indicated a lack of feasibility in seeking explicit views on the CRNurse role, implying it would be more appropriate to elicit broader views on the delivery of research. It would, as a result, be critical to seek views on the perceived likelihood of generating resistance and avoidance behaviours to enable some inferences to be drawn from the data regarding how CRNurses experience and then interpret interactions with other NMAHPs. This was felt to be appropriate because territoriality and othering behaviours may be less likely to be described in relation to an individual or a role. They may instead be present beneath the surface of descriptions of the challenges faced as individuals practicing outside of research.

The views expressed that could be perceived as negative in tone within the empirical GCM phase of this study reflected themes prominent in the literature. This literature has been generated by CRNurses describing their thoughts on how they are perceived (Brown *et al.*, 2018; Alsleben, Alexander and Matthews, 2018; Aksoy *et al.*, 2018). Hernon, Dalton and Dowling's (2020) qualitative evidence synthesis, incorporated 19 such studies published between 2002 and 2018. The synthesis reported a high level of confidence in the notion that CRNurses felt that colleagues outside of research possessed a low level of understanding of their role. This notion, alongside a sense of isolation and of being less supported than other clinical colleagues, is supported by clusters three, four and five *Behaviours beliefs and missed opportunities, Dissonance and disengagement and Time and capacity affects* *our ability to engage*. There also appears to be novel evidence indicating why such perceptions may exist within these clusters, this will be explored next.

The data generated by this study supports the view that some individuals outside of the research arena do not understand the research delivery landscape or the detail of the CRNurse role. This lack of understanding, however, appears to result from a complex range of factors. It seems less related to an individual CRNurse, and more to a mixture of perceptions of what the role itself entails and where it is perceived to be positioned in social and hierarchical structures. The lack of understanding and awareness associated with the multifaceted research landscape generally, a perceived inconsistency in approaches to research, and the alleged dull, administratively focused nature of tasks involved in delivering clinical research were highlighted within clusters three, four and five, as discussed above.

Many statements indicated that participants were cognisant of a range of challenges and complexities within the research landscape in general. The identification of such challenges in participants own words may assist in illuminating how the landscape appears to those outwith, and what might be done to support a better understanding of the landscape. This activity may also help to reassure CRNurses regarding the extent to which their role is valued, addressing some misperceptions that CRNurses feel exist about their role.

A number of statements within clusters three, four and five also indicated difficulties or discomfort in engaging with research activity and appeared more related to the participants' clinical area (context), than any other factor. These statements mainly indicated a lack of opportunity, time, education, or support in relation to individual ability to engage with research. These factors, again, imply less of a focus on not valuing the CRNurse role, and more of a focus on the contextual and systemic factors that actively prevent engagement. It is possible that the resulting behaviours, however, may be perceived as the former by CRNurses.

Lack of time and support to engage with research activity are frequently cited in the broader evidence base related to research. This evidence, however, mostly relates to the development of clinical research alongside one's clinical practice.

Consequently, difficulties with carving out research time within a clinical role is one of the most significant barriers reported and there are often calls for protected time to enable a focus on research within clinical practice (van Oostveen *et al.*, 2017; Caldwell *et al.*, 2017; Baltruks and Callaghan, 2018; Trusson, Rowley and Bramley, 2019; Avery, Westwood and Richardson, 2021).

Whilst studies reporting the experiences and perceptions of CRNurses have indicated that CRNurses are aware of the limited time they perceive their non-research colleagues may have to engage with the research they are delivering, there has been a lack of research exploring the validity of these perceptions until recently (Hill, 2018; Tinkler *et al.*, 2018). The results of this study appear to support the view that rather than an absolute lack of value of the CRNurse role, there is in reality, limited time to think about and engage specifically in the delivery of research. Importantly, these views have now been offered by NMAHPs practicing outside of research delivery teams. These previously unexplored views provide a different and more nuanced perspective to the perceptions offered by CRNurses themselves and therefore make a unique contribution to this evidence base. This insight may provide reassurance to CRNurses that they are not necessarily less valued than their colleagues. Whilst the insight discussed here may offer an alternative view to the historically presented CRNurse perceptions of a lack of understanding or sense of value in their role, views will be discussed later regarding the likelihood of such views generating resistance or avoidance behaviours.

A further complexity to consider relates to a thread discussed in chapter four, regarding the research related perceptions of healthcare professionals practicing outside of research roles identified in the literature. These mainly relate to the concept of nurse-led research and the demands of fitting research into one's own clinical practice. As discussed, little was identified relating to the specific views of research delivery, or of the CRNurse role outwith the views of research teams and CRNurses. Many statements generated during this study were also found to reflect this slightly different evidence base, encompassing what could be interpreted as views relating to the clinical academic landscape and the generation of one's own research alongside clinical practice.

The reasons why statements that might be interpreted in the context of clinical academic careers were generated by participants, and their subsequent interpretation of the statements at the sorting stage, may further indicate a lack of understanding of the broader research landscape and the differences between research delivery and the generation of one’s own research. Such statements may also indicate a veiled aspiration on the part of participants to advocate for change, based on their own experiences of the landscape. The issues described could therefore be interpreted as multidimensional. Responses to the focus prompt and subsequent sorting and rating activities will have undoubtedly been influenced by individual context and personal understanding of the landscape. In addition to these contextual and experiential influences, the approach to GCM enables all participants contributing to ideas generation to see the statements being generated by other participants, albeit anonymously. Therefore, those joining the study at a later stage where they were able to see statements already generated, may have been influenced by the responses present in the software.

In relation to this discussion point, the approach to managing the final statement set for inclusion in sorting and rating activities was discussed in detail in chapter five. Those statements considered to be exclusively related to clinical academic careers or the generation of one’s own research, and not to the delivery of clinical research or the CRNurse role, were excluded. The potential multidimensional way in which some statements could have been interpreted however, and the decisions to exclude those interpreted as focused only on the clinical academic landscape, may present an opportunity to revisit the data generated in this study from a different perspective at a later date. Irrespective of the intended focus of the statements, and the ease with which they could be interpreted and thematically analysed, the data generated in this study indicates clear evidence of persistent complexity in the broader research landscape. This may have affected participants’ ability to distinguish between the different facets of delivery and development activities.

The broader understanding of the research landscape is worthy of further consideration in the current context of an increased number of national strategies and plans related to research in the NMAHP professions (Department of Health and Social Care, 2021; National Institute for Health Research, 2021; NHS England, 2021;

Health Education England, 2022; National Institute for Health Research, 2022). The Chief Nursing Officer's strategic plan for research "*Making Research Matter*" (NHS England 2021), presents a candid title that evokes the view that historically, research for Nurses has been considered less important in comparison to other professions. This requires action to empower nurses to fully embed research within their practice regardless of role. This ambitious five step plan was developed in partnership with key stakeholders involved in different facets of the health research landscape, including the NIHR, which has responsibility for leading on training the research leaders of the future and is also accountable for the delivery of research in England. In addition, the Council of Deans for Health, Health Education England, the Nursing and Midwifery Council and the Royal College of Nursing, have contributed to the plan.

As significant macro level stakeholders in the health sector, each of these organisations has key responsibilities for a range of preparation, training, development, regulation, and representation of Nursing and other professions. Their positional power to influence the landscape will be vital if the CNO's aspirations are to be realised and Nurses are to be truly supported and enabled to implement and drive change through the plan.

In relation to how the CRNurse role is perceived, within the scope of the document, reference is made to the CRNurse workforce, highlighting the importance of their contribution in influencing and promoting positive research cultures. Yet, whilst the plan acknowledges it is relevant to the CRNurse community, it goes on to indicate instead the NIHR's role, responsibility and intention to address the unique contribution the CRNurse makes to the research landscape. Consequently, individuals outwith research delivery structures reading this plan may not achieve any further clarity on how the CRNurse role fits into the system. Furthermore, there is a risk that such a statement may reflect CRNurses and midwives experiences of being in a liminal state, feeling somewhat overlooked in the context of the CNO plan, yet practicing in the absence of an NIHR strategy which focuses on their community, despite such a strategy being signalled since the launch of the CNO plan.

At the outset, the CNO’s plan recognises the need for cooperation and non-disruption, acknowledging that close working and engagement will be required to help organisations understand the benefits of giving nurses time to lead, deliver and implement research. Adequate time to be involved in research was a key theme threading through this study. Yet the complexities of fostering positive attitudes at all levels and changing the views of those individuals who do not prioritise research, will be a complex and multifaceted piece of work to achieve in the current NHS landscape. Considering this in the context of a workforce crisis increases the challenge. Being unable to fill posts, overstretched services, long waiting lists for treatment, a reported sub-optimal and bullying culture in the NHS, all lead to the current low levels of morale and energy reported within the workforce. (West, Bailey and Williams, 2020; NHS England, 2019; NHS England, 2020).

Linked to this point, a small number of statements offered during ideas generation indicated the risk of being bullied for those involved in or *“who bring research”*. It is not possible to define whether the participants generating these statements had themselves experienced a lack of support, or indeed bullying, due to the framing of the statements. On reflection, however, it is conceivable that such statements were more related to the development of one’s own research than the delivery of clinical research. Regardless of interpretation, such statements indicate the continued presence of a sub-optimal culture in relation to the clinical research landscape in the NHS.

In previous research, CRNurses have frequently described what they perceive as the disengaged attitudes and behaviours of clinical colleagues outside of research structures (McNiven *et al.*, 2021; Hernon, Dalton and Dowling, 2020; Hill, Ellis and Irvine, 2022). CRNurses believe such colleagues view research as somebody else’s job, and a role which generates extra, unwanted work for those in busy non-research settings. Previous evidence has also suggested that those practicing outside of research believe the CRNurse role is not in keeping with the professional identity of an authentic and credible clinical nurse (Hernon, Dalton and Dowling, 2020; McNiven *et al.*, 2021). Furthermore, evidence discussed in previous chapters suggested that the role can also be viewed by those NMAHPs practicing outside of research as somewhat easy, overly administrative, and one which they would set themselves apart from or are not interested in (Whitehouse and Smith, 2018). Whilst evidence from this study does not appear to offer any insight as to whether the CRNurse role itself is perceived to be less credible than any other nursing role, a number of statements do support the existence of views related to research being less clinical, bringing additional work, being dull, laborious, administratively focused and something that somebody else does.

A small number of statements also revealed an explicit lack of personal interest or a perceived sense of low value or importance of research, which some participants were prepared to share. Such statements indicate that there are individuals who are not interested in, not aware of, and do not understand the value of research, and who were prepared to voice such views. Interest in, awareness of, and understanding of clinical research were the three key elements proposed to have the potential to generate resistance or avoidance behaviours and incorporated into the theory tested in the empirical phase. Statement 66. *“I don't personally have the drive for research”* provides a rare but clear signal of a lack of interest in research. In addition, statement 71. *“Unaware of any relation of my role to clinical research in the nhs in my current trust”* suggests disengagement, or a lack of awareness. However, the framing of this statement may also indicate a more insidious or cynical undertone, in relation to the culture within their organisation.

In addition to this, a number of statements indicated a perception that the delivery of research required additional time away from patient care. This is in contrast to much of the contemporary literature related to the CRNurse role, which identifies the ability to spend additional time with patients, thereby enabling the provision of a high quality of care and attention. This element of the role is often highlighted as a particular benefit, and one of the most positive aspects that is promoted (Kunhunny and Salmon, 2017; Tinkler *et al.*, 2018; Tinkler and Robinson, 2020). Connecting this example to common perceptions that the role is data heavy, and administratively focused, may provide additional insight as such perceptions may lead to assumptions that data heavy and administratively focused therefore indicates less time for patient interaction, which is not necessarily the case.

Whilst the data generated in this study appear to support the view that variations do exist in the understanding of research delivery and the CRNurse role, there is also, in contrast, much positive evidence of awareness, understanding and a sense of value placed in research delivery within clinical settings. Statements generated by participants and subsequently sorted within clusters one and two respectively *We value and understand the importance of research* and *How it should be and how we could work together*, indicated that many participants could identify and articulate the importance of research within their clinical role. A number of statements provided evidence of broad acknowledgement of the value and benefits of research being delivered in the clinical setting. Statement number 36 reflects the intentions of a range of national strategies and aspirations to embed research as part of the fabric of the healthcare landscape: "*That everyone has a responsibility to enable clinical research to take place in the NHS".* In addition to this, participants acknowledged a duty of care to engage in research as part of their clinical role and were able to articulate the value of offering research opportunities to the patients within their care. This correlates with the messaging within the NHS Constitution which highlights the obligation placed on NHS settings to generate and utilise evidence to improve care, whilst also ensuring patients are made aware of opportunities to participate in research that is relevant to their health (Department of Health, 2015).

Some participants took this rather more positive framing further, by indicating their involvement in or aspirations to support research teams with the delivery of their projects. This ranged from ensuring they knew who their local research teams were, to actively supporting and facilitating data collection. Some were able to refer to research related terminology, identifying an awareness of eligibility criteria, and one participant made a clear statement which directly correlated to the theory being tested 84: "*I understand the importance of research".* This appetite correlates with the intentions of the government's policy paper "Saving and Improving Lives, the future of UK Clinical Research Delivery" (Department of Health and Social Care, 2022). Echoed in the intentions of the CNO plan, this policy paper indicates the government's ambition for clinical research to be embedded in the NHS, through a research-positive culture where all health and care staff are empowered to support and participate in clinical research as part of their role. Other intentions include improving access to participation in research for patients, which was highlighted as an important element of the care pathway by some participants in this study. Statements number 50 and 82 respectively reflect this view: "*It is important to be*

involved or advise our patients about clinical research as it improves patient care.”
“It's good for my patients to be able to take part in clinical research when they attend for their care”

Noticeably in this study, the nature of statements related to the more positive aspects of research delivery suggested a clear sense of ownership, involvement, responsibility and a sense of personal duty and commitment to support. This is in direct contrast to the rather more distanced tone noted in participants’ approaches to articulating the challenges and difficulties of engaging with research, which will be discussed later in the chapter. Participants appeared to align themselves explicitly with the more positive views by preferring the use of “I”, “my” and “me”. This was noted in contrast to the more consciously detached use of terms such as “seen as” and “considered to be” in statements related to the comparatively negative aspects.

A number of statements provided evidence that participants had direct experience of supporting research delivery in the clinical area. The tone of these ranged from articulating the benefits and positive experiences of engagement and involvement in research delivery, to highlighting the real difficulties of managing time, or the subsequent negative consequences of involvement. Consequently, these statements had been sorted across a range of clusters from one to five, in keeping with their specific focus. For example, in cluster one *We value and understand the importance of research,* statements indicated that research was accepted as core within practice and was seen to be beneficial. This was in contrast to statements which were positioned within cluster five *Time and capacity affects our ability to engage*. These statements instead, articulated the pressure, extra workload and limited capacity associated with participants’ support for, or engagement in, research activity within their clinical setting.

Whilst there is minimal published evidence empirically supporting the more positive views expressed in this study, anecdotal reports indicate the potential of the COVID-19 Pandemic in impacting positively on the profile of the CRNurse role (Milne *et al.*, 2022; Gardiner and MacLellan, 2022). Whitehouse *et al* (2022) utilised a reflective model to share perspectives of delivering research during the pandemic. Of the seven themes identified, team building, collaboration and transformation of process indicate a positive shift in experiences and cross boundary working. In addition, Maxton, Darbyshire and Thompson, (2021) described a changed landscape in relation to CRNursing as a result of the COVID-19 pandemic, with the potential to positively frame experiences for some time to come. Their editorial piece referred to common misconceptions about the CRNurse role yet also asserted the pandemic had enabled a newfound status as valued, recognised clinical team members. While this has not been empirically proven, it is reasonable to assume that the propelling of research into the spotlight during the pandemic will have inevitably led to some change in status for the teams tasked with delivering the research that eventually led the UK through the pandemic. Maxton, Darbyshire and Thompson (2021) signalled, however, the risk of returning to a sub-optimal status, advocating for the new-found flexibility and cohesive teamworking to be preserved, in order to avoid losing the positive shifts gained by CRNurses in terms of their value and status as members of clinical teams.

Through responding to the focus prompt, a number of participants were able to use the opportunity to share potential improvements in working practices that could benefit the research landscape. Cluster number two *How it should be and how we could work together,* incorporated a range of suggestions of how participants perceived things should be, providing practical insight into how relationships between research delivery and clinical service delivery may be improved. Whilst cluster number two largely contained suggestions of how participants felt research *should* be viewed and incorporated, similar views were also sorted into other clusters linked to challenges that were identified. For example, cluster three and four *Behaviours, beliefs and missed opportunities* and *Dissonance and disengagement* incorporated statements which indicated the need for change, and in cluster number one *We value and understand the importance of research* a number of statements also suggested ideas for improvement.

The importance and impact of professional relationships at a range of levels, from understanding the CRNurse role to working cooperatively with the CRNurse, was a key theme apparent across a range of the literature explored in chapters two and three. The data collected in this study appears to support the view that both understanding the work of research delivery teams and being able to work cooperatively with them would enhance the broader research landscape. The results of this study, however, also indicate a number of missed opportunities for such improvement. Participants were nevertheless able to clearly articulate where changes could and should be made to improve communication between CRNurses and those practicing outwith research structures. For example, statement number three. "*There are frequently silos of research going on which would and could influence care delivery and efficiency if there were adequate communication channels"* identifies the perceived separation of research and the desire for improved communication between research delivery and clinical staff. In addition to this, statements one, two and 39 indicated the significance of effective team-working, improved collaboration, and increased opportunities for those outside of research delivery to be involved. This is reflected in the literature concerning the implementation of CRNurse roles. Whilst this study did not intend to seek views on how CRNurse roles should be implemented specifically, there are common themes reflective of the debates in the literature which may be relevant to improving relationships between clinical service delivery and clinical research delivery. For example, there is evidence to suggest that where CRNurse teams are more fully embedded within the clinical specialties in which they operate, relationships are improved, and CRNurses feel more valued, part of the wider team, and their professional identity is improved (Jones, 2017; Tinkler and Robinson, 2020).

Whilst debate and differences of opinion remain apparent regarding the clinical research landscape, evidence collected during this study offers an alternate viewpoint regarding perceptions of research delivery and the CRNurse role. Some of this provides reassurance when compared to the evidence base on how CRNurses believe they are viewed, yet much confirms that significant barriers remain in understanding and engaging with the delivery of research to support its success.

The next aspect to this research is understanding how the views shared and thematically sorted by participants are considered in relation to the generation of resistance or avoidance behaviours. These data are key to then understanding what is important to participants to address. This will be discussed next.

6.3.2 Factors that may generate avoidance and resistance behaviours towards Clinical Research Nurses and their perceived importance to address

This section critically discusses the views of participants collected during the rating stages of the research. This includes the extent to which statements were rated as likely to generate resistance or avoidance behaviours (aim b.), and those statements considered most important to address (aim c.).

As described in the previous chapter, Table 5.2 provides an illustration of the two rating scales used. The rating activity involved participants assigning a score to each of the 99 individual statements, using a scale of between one and four. This produced the corresponding average rating maps discussed in chapter five.

As reported in chapter five, participants on average rated the statements contained within clusters three, four and five *Behaviours, beliefs and missed opportunities*, *Dissonance and disengagement*, and *Time and capacity affects our ability to engage* as most likely to generate resistance or avoidance behaviours.

In chapter three, a notion which has remained present throughout the theoretical reflections in this doctoral work was introduced. This was the proposal made by Pawson and Tilley (1997) that the successful implementation of any '*programme*' is reliant on the very minimal requirements of cooperation and non-disruption. According to Pawson and Tilley, the extent to which individuals might either cooperate or disrupt, relates directly to the perceived relevance of the particular programme, intervention, policy, or strategy to the individual (Pawson, 2006; Pawson, 2013).

Pawson and Tilley's theoretical proposition enables an explicit link to the notion that the views and subsequent behaviours of individuals outwith research teams are mediators in enabling the successful delivery of research, yet this has not previously been tested. In addition, chapter four described the way in which clinical colleagues are generally characterised by CRNurses. They are often perceived to occupy a position of power as gatekeepers in the spaces where CRNurses are required to operate. The extent to which CRNurses feel they are able to build relationships with their perceived gatekeeper colleagues is often considered responsible for the range of behaviours they experience. These behaviours operate on a continuum of acting in support of, to acting in resistance to, the delivery of clinical research (Hill, 2018; Hernon, Dalton and Dowling, 2020; Tinkler, Robertson and Tod, 2022).

McFadyen & Rankin (2017) highlighted the key role of gatekeepers in enabling research delivery teams to access the patients they are seeking to invite, recruit or follow up. McFadyen and colleagues acknowledged the complexity of achieving success, suggesting that access to a particular department to deliver research required active cooperation and support rather than simply approval alone. In support of this, Hernon *et al* (2020) highlighted the importance of building relationships with colleagues outside of research structures, identifying how ward-based nurses could act as an active barrier to recruitment. This is reflected in the likelihood of generating avoidance and resistance behaviours reported in this study. Repeated experiences of this nature generate discomfort for the CRNurse and may provide an explanation for the perception of their colleagues as gatekeepers rather than collaborators.

The extent to which NMAHP colleagues outwith clinical research delivery may consciously see themselves as gatekeepers, however, has not been explicitly explored, despite these characterisations being common in the literature. The data generated by this study goes some way to shed light on this characterisation. It identifies a comparative frustration and a sense of being an outsider on *their* part, as they express a wish to know more about the research going on in their area and are keen for better communication between themselves and CRNurses. Their articulation of such aspirations includes, in some cases, placing responsibility for improved communication with the CRNurse and research delivery team. This conclusion can be drawn from their articulation that research teams should communicate better with them and avoid silo working which they feel creates frustration and reduces opportunities for their involvement. In contrast, some participants acknowledged their own responsibility to be informed about research happening in their area and to seek out CRNurses and actively offer their help or support with identifying patients for studies.

The contrasting views, identified within the GCM phase and discussed above, may be partially explained by the concept of individual locus of control. Locus of control is a psychological, social learning theory, developed by Julian Rotter (1966). The concept describes the extent to which an individual has perceived control over their life and environment. It is a core element in understanding how people live in and interact with their world (April, Dharani and Peters, 2012). Rotter (1966) based his work on Skinner’s law of reinforcement (Skinner, 1965), which in its simplest terms, refers to how one can sub-consciously learn to predict the outcomes of a particular scenario, based on what has happened in the past. Specifically, this relates to responses from others to behaviours and interactions, which can be perceived as positive or negative reinforcement. The ability to discriminate between behaviours and outcomes, and to generalise such anticipations for the future, is what is thought to define locus of control.

Individuals with a strong internal locus of control orientation are more inclined to believe they control their own destiny, and that their own actions, abilities, and decisions will shape their outcomes, generally leading to a positive outcome. This mindset is associated with behaviours and outcomes, taking responsibility for their own actions and for the performance of themselves and their organisations. In addition to this, those with an internal locus of control are inclined to take more initiative when it comes to spotting and solving problems and are considered to be flexible and adaptive in their approach, because they have confidence in their abilities to influence others (April, Dharani and Peters, 2012).

In contrast, those with an external locus of control are more inclined to the opposite mindset. At the extreme, they believe they can do little to improve themselves or their lives, because their own actions, behaviour and efforts will have little or no effect on outcomes, mainly due to events being outside of their control. Individuals with this mindset are more inclined to believe that outcomes are mostly based on luck, chance, fate, or powerful others. It therefore follows that they are less likely to put too much effort into something and may be more inclined to cease trying in a situation where internals would continue. Furthermore, individuals with an external locus of control do not attribute specific outcomes to their own efforts or lack of, meaning that if something goes wrong or they make a mistake, they are more likely to blame someone else or bad luck, because they do not believe their actions had any bearing on the event (April, Dharani and Peters, 2012).

The two extremes noted here may provide some insight into the variety of views that emerged in this study, regarding communication between clinical research delivery structures and clinical service delivery. An understanding of locus of control, and the extent to which individuals feel they are empowered and able to influence a given scenario, or indeed whose responsibility they feel it is, could be a significant mechanism in generating resistance or avoidance behaviours at the interface between clinical research delivery and clinical service delivery.

Considering these opposing viewpoints from an alternative angle, it is possible to also suggest that whilst micro level improvements may go some way to improve relationships in an individual context; neither an increased commitment or effectiveness in communication on the part of the CRNurse, nor indeed the efforts of the NMAHP outwith research, can address such challenges alone. Rather, the meso and macro level reality of time and capacity affecting abilities to engage remains a key generator of the behaviours that inevitably affect the success of studies. In support of this, at a statement level, statement number 16. "*There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched",* was rated as the single statement most likely to generate resistance and avoidance behaviours across the whole study. That is to say, regardless of where the responsibility for improved communication is seen to sit, or how much effort is made on an individual basis, the ratings support the view that where cooperation as a minimum is not actively enabled by those with perceived power within the system, between clinical research delivery and clinical service delivery, the likelihood of success is reduced through resulting resistance and avoidance behaviours.

Reflection point

The themes discussed in this section brought to mind two very different experiences relevant to this research, which occurred at different stages of my career. The first was as a new CRNurse in an acute hospital trust. I was required to attend the outpatients department (OPD) for clinics that were due to run. I would sometimes be required to attend two clinics at the same time, as I covered multiple specialties and if both were going on in the OPD, I would be expected to manage all of the eligible patients between the two to maximise recruitment of relevant patients. I spent a long-time making friends with staff in the OPD, making tea for colleagues when I could, taking bloods for those struggling for time, and helping to clear up at the end of the clinics instead of going back to my desk straightaway to enter data. This was in contrast to some of my CRNurse colleagues who might arrive just five minutes before they were due to see a patient and ask for a room.

I also made a point of trying to proactively inform the OPD team if I knew I would be in clinic the following week, as I knew space was stretched and the way the consultant clinics were set up at the trust (a systemic issue which is now apparent) meant that the CRNurse was never included in the room bookings, and so was often surplus to the space, creating frustration and confusion if arriving unexpectedly, even just to see one patient. After around 3-6 months of being visible and helpful in the department, a particular Healthcare Assistant took an interest in my work and would seek me out when I was in clinic to see how I was getting on. After around 9 months, if this individual was in clinic, they would wave to me as soon as I arrived and point me towards a room they had managed to miraculously reserve, or they would arrange for me to have access to the OPD Lead Nurse's office. Eventually this HCA would even come and find me during clinic and actively alert me to patients they thought might be eligible for the studies I was running. This individual's support and friendship over the time I was in that OPD made my work so much easier and made me feel like part of that team. I was eventually invited to the team Christmas night out and welcomed into the staff room at lunchtimes as one of them. I was never able to influence how the rooms were booked but was able to mitigate the stress the lack of space would cause, both for myself and for the OPD teams.

The second scenario relates to a research focused presentation I was required to deliver later in my career in a role outwith clinical research delivery. The presentation was not about the delivery of research, rather it was about the development of clinical academic careers. When finished and the room was opened for questions, I was challenged by a manager with responsibility for a large OPD, who expressed extreme frustration at the way CRNurses conducted themselves in relation to arriving in OPD and asking for rooms. This individual felt that CRNurses should be informing the OPD when a study is on its way because rooms are booked for consultants, and CRNurses cannot expect a room to be available if it has not been booked as part of the wider clinic. Whilst this may be true, I felt the challenge being laid at the feet of the CRNurse was interesting, given the CRNurse was usually required in clinic to recruit patients who were attending to see a specific consultant, who would have had rooms book for themselves and their "team". The fact that this challenge had been levelled at me during a presentation I was giving about a different topic, and I did not have any responsibility for the CRNurse community at this point, reflects the lack of understanding of the research landscape more generally.

These two contrasting narratives are reflective of the contrasts contained with the statements discussed. They reflect different views in relation to beliefs around whose responsibility it is to communicate for the best possible outcomes.

Behaviours displayed towards the CRNurse by colleagues outwith the research team are reported to impact negatively on the CRNurse, leading to impacts on professional identity, feelings of isolation, poor morale and even a defensive mindset. For example, McNiven *et al* (2021) describe the inclination of research nurses, midwives and AHPs participating in their study, actively planning for the challenging interactions they expected by preparing stock responses. This echoes Skinners law of reinforcement and the expectancy of particular outcomes as described above (Skinner, 1965).

The data in this study appear to confirm the view that suboptimal behaviours are present in the clinical research delivery landscape. The majority of statements offered by participants referring to difficulties engaging with research delivery, however, tended to describe behaviours recognised in, or displayed by, others rather than an admission of the explicit views or behaviours of participants themselves. For example, statement number 59. "*There is a lot of misunderstanding about clinical research in the NHS."* identifies that this participant was aware of misunderstandings about research. The participant generating this statement indicated an awareness of a potential issue yet chose to distance themself from any personal admission of misunderstanding. In addition, statement number 30. *"It is not often considered a priority by managers or heads of services."* provides another example of sub-optimal culture whilst not accepting responsibility. This statement suggests that research is not prioritised by particular groups of individuals, separate to the participant who neither indicated whether they considered research a priority or not.

The tendency of participants to acknowledge, yet distance themselves from, negative behaviours or views may reflect the othering behaviours introduced in chapter three. In relation to this, the framing of statements in this study, may indicate that NMAHPs who practice outside of research recognise that some views and perceptions are unhelpful and potentially damaging, yet may feel powerless to challenge such views. In contrast, it may also be reasonable to suppose that the views described were in reality consistent with their own feelings. However, voicing this as one's own view risks one being personally perceived as misunderstanding clinical research, or not prioritising it, which may not be professionally expected or acceptable. A rhetorical solution is found then in highlighting these perceptions as present, whilst not owning them personally, not using the first person "I", and thereby reducing the risk of being themselves perceived in this way. This is in relative contrast to the approach to owning the more positive statements discussed earlier in this chapter, whereby participants expressed their understanding and awareness of the research landscape.

As referred to in chapter three, the concept of othering involves metaphorically positioning a person or group of persons on the margin of a given social structure where power is generally retained at the centre. Whilst participants in this study could be described as positioning the behaviours and views of others as distinct from their own, the statements here suggest that power is in fact retained by those ‘others’ (often managers) who are described as not prioritising research. Participants were suggesting a lack of managerial prioritisation as a barrier to their ability to engage in and support research delivery.

The evidence generated in this study, therefore suggests that participants were generally aware of the challenges and difficulties associated with the delivery of research in the NHS, yet the way in which they articulated these issues suggested they did not deem themselves responsible for contributing to them. In this case they were merely reporting as an onlooker, observing the issues and behaviours rather than being involved in the perpetuation of them.

This rhetorical technique echoes the concept of discursive distancing, described by (Bridges and Pascoe, 2014). Discursive distancing is described as the activity of dissociation from certain behaviours or views through discussion or dialogue. For Bridges and Pascoe, the concept was linked to the activities of privileged men. In their work, discursive distancing enabled some men to frame themselves as outside of the systems of privilege and inequality that they were part of, whilst also being free to preserve the very inequalities they described. The nature of statements generated in this study, suggesting others present barriers to engagement in research, may indicate that genuine barriers exist for NMAHPs outside of research in engaging with the work of their CRNurse colleagues. It is, however, also possible that such views and perceptions, whilst neither proven nor owned, may provide protection for those who do not wish to engage. This enables them to defend their potential lack of engagement or support in a way that is more comfortable for them to adopt, rather than the risk of voicing or owning a personal lack of interest or sense of value.

As introduced earlier in this chapter, a plethora of research related to national strategies and policy papers applicable to nursing have been published in recent years. The tone and intentions of these strategies are to position research at the forefront of healthcare endeavours and to achieve a research informed and led NHS in all areas and professions. The aims are to transform the NHS into a sector where evidence is consistently generated, shared, and utilised by highly skilled, empowered, and enabled staff, to improve the decisions that are made about services and ultimately improve patient and population outcomes (NHS England, 2021; Health Education England, 2022; Department of Health and Social Care, 2022; National Institute for Health Research, 2021). A further strategy for Midwifery research is currently underway and expected shortly. In addition to these research specific aspirations, the NHS long term plan (NHS England, 2019) and the NHS People Plan (NHS England, 2020) set out ambitions to enable staff to work in compassionate, flexible, and positive cultures, with high quality development opportunities and rewarding careers.

The publication of both the NHS People plan (NHS England, 2020) and the NHS Long Term plan (NHS England, 2019) came at time when the NHS was facing its biggest challenge in responding to the global Covid-19 pandemic. In addition, as part of the wider health system, the NHS has, in recent months, been subjected to perhaps some of the most significant reforms in its history through the Health and Care Act (Department of Health and Social Care, 2022b) and the changes to public health structures in response to the Covid-19 pandemic (Murray, 2022). These reforms have been imposed just nine years following a significant restructure which resulted from the Health and Social Care Act of 2012. Considering these changes through an optimistic lens, the impact of these most recent reforms could lead to increased positive outcomes in the years that follow. In relation to the recent reforms and the impact such restructuring has on the workforce however, the NHS confederation (Pett and Lowe, 2022) has recommended that no further restructures should be imposed for at least a decade.

Whilst this brief overview of recent restructures and challenges appears simplistic, the true impact of practicing in such a complex, underfunded, ever changing and politically squeezed system should not be underestimated in terms of its impact on relationships between staff.

In relation to this, West, Bailey and Williams (2020) identified the unprecedented pressure the pandemic had placed on the NHS. However, they highlighted that many of the pressures were already apparent, and the pandemic had served only to exacerbate what was already significantly impacting on Nurses and Midwives long before COVID-19 arrived. Inequalities, unprecedented and unrelenting pressures at work, and sub-optimal working conditions had already led to an increasing gap between capacity and demand in relation to vacancy rates in the NHS. The Courage of Compassion paper (West, Bailey and Williams, 2020), which sets out eight recommendations in relation to supporting nurses and midwives to practice in psychologically safe and supported workplaces, indicated that the nursing and midwifery workforce requires three core needs to be met to tackle stress and to improve motivation at work. These three needs are neither financially costly, nor unrealistic; they are autonomy, belonging and contribution.

The concept of autonomy links to locus of control and is also related to a concept put forward by Blanchard (2010) termed “assumed constraints”. This concept relates directly to the previously discussed concept of expectancy; the reinforcement experienced in response to a given situation. Blanchard described an assumed constraint as a perceived limitation of experiences both current and in the future based on experiences of the past. Blanchard further stated that at one time or another, most of us will have made the assumption that, because we did not consider ourselves to have direct authority or position power, we could not be leaders or influence outcomes in a given situation. Assumed constraints are some of the most common and powerful constraints in the workplace according to Blanchard (2010). They may develop over time as resilience is reduced and repeated experiences result from negative reinforcement. It is also possible that autonomy can be influenced by the system at a macro level, or indeed by individuals within the system at meso and micro levels, linked to the perceptions that some managers do not support research or see it as important. It may therefore be situational and context specific, as well as influenced by people.

Linking the two concepts of belonging and contribution to the research carried out here, can be translated as the following: CRNurses should be connected to, cared for by, and indeed care for others around them at work. They should expect to feel valued, respected and supported for their contribution, regardless of where in the patient pathway that contribution is made. Finally, and directly in relation to perceptions of how the role may be viewed by others, the CRNurse should be confident of the effectiveness and value of what they contribute to patient outcomes, regardless of the nuances of the role or the perceived clinical or other nature of specific tasks.

Related to the points above, as described in chapter two and earlier in this chapter in relation to how CRNurses feel they are viewed, Hill (2018), Tinkler *et al.*, (2018) and McNiven *et al.*, (2021), provide insight into how CRNurses often express the need to prepare for difficult interactions or conversations with colleagues outside of research structures. To aid this, they report employing emotional labour, including bargaining, and flexing their communication style to adopt an apologetic or inferior stance in order to influence for success. The thinking behind this includes an empathy on the part of the CRNurse for their colleagues who are overstretched and the hope that, in return, those colleagues will be more accepting of their presence and therefore more likely to support with accessing to consult with a patient.

The adoption of this stance by CRNurses, based on past experiences, could inadvertently contribute to generating avoidance or resistance behaviours from NMAHPs outwith research, due to the CRNurse projecting a view that their work is less important that that of their countepart. Indeed, one would not generally expect an apology from an AHP arriving in a department to provide therapy to a patient as part of their care package, though one might expect there to be some discussion about the patient's progress that day. This view is supported by evidence in this study suggesting that clinical care is prioritised over research activity. It is incontrovertible that the provision of high quality and safe care should be paramount, however, research activity and high quality safe care do not need to be mutually exclusive. The perceptions of research being a "*nice extra*" and an *"add on",* however, undoubtedly contribute to such hierarchical attitudes. Hansen *et al.*, (2022) highlighted that the function of the CRNurse, whilst complex, is complimentary to the function of other clinical nursing roles, spanning both clinical and research related care. They presented a four-point model capturing the unique and fundamental aspects of the CRNurse, some of which they identified as intrinsic in every nursing role. The four points were care and trust, the role of the CRNurse, impact, and integration. Care and trust were articulated as spanning the fundamental aspects of any nursing role. Hansen's conceptual paper sought to address misconceptions about clinical research nursing and provided a model with case studies threaded throughout to generate discussion about where the CRNurse role overlaps with other nursing roles. The model may contribute to increased understanding of the role of the CRNurse, and also serve to dispel myths that lead to views about research being separate to clinical care. The challenge for the authors, similar to other literature related to the CRNurse role, however, is to ensure it is visible to those clinical colleagues who are outwith the field of clinical research delivery.

The ratings associated with the likelihood of generating resistance or avoidance behaviours have provided the first insight into the views of NMAHPs outwith research delivery structures; they confirm the likelihood of such behaviours being generated. Indeed, it is reasonable, according to Pawson and Tilley (1997, 2006, 2013), to expect that where a lack of interest, awareness, or sense of value in a particular subject exists, then behaviours that project a sense of reluctance to engage, or a sense of frustration at not feeling more informed or involved, will likely follow. The ratings in relation to views on what was important to address produced a set of pragmatic and considered findings, leading to some interesting discussions and debates during the participant interpretation session. These will be discussed next.

As highlighted earlier, participants rated the statements contained within three clusters as most likely on average to generate resistance or avoidance behaviours. These were clusters three, four and five *Behaviours, beliefs and missed opportunities*, *Dissonance and disengagement*, and *Time and capacity affects our ability to engage*. Of these three clusters, number five *Time and capacity affects our ability to engage* was rated by participants, on average, as the most important to address. Cluster number four *Dissonance and disengagement*, rated on average as the second most likely to generate resistance or avoidance by participants, was in contrast rated much lower in terms of importance to address. This was also reflected in the importance ratings of cluster number three *Behaviours, beliefs and missed* *opportunities.* In further contrast to the ratings above, whilst cluster number six, which is a stand-alone statement *I keep thinking of ways to facilitate research as everyone's' business but it's hard,* was rated as the least likely to generate resistance or avoidance behaviours, it was rated as the second most important to address after cluster number five.

As outlined in chapter five, the significance of these ratings generated an interesting discussion, and the intentions of participants rating in this manner became apparent at the participant interpretation session. Whilst it may have been reasonable to expect a desire to address negative behaviours head on, participants expressed a wish instead to focus on the rather more positive aspects. This included an aspiration to adopt what may already work well, implement the practical suggestions offered by other participants, and explore what they as individual NMAHPs might feasibly be able to do more of themselves. In this study, participants appeared to rate pragmatic, positive and more achievable statements as equally important.

A desire to generate some quick wins that felt more achievable and within their ability to influence or act, whilst also focusing on longer term changes to the system-wide culture and challenges, was expressed. This may again link to the concept of locus of control, whereby participants felt able to suggest improvements, and to select those within their own ability to influence. Because the contents of cluster number two *How it should be and how we could work together* provided useful recommendations in relation to this, it is perhaps the reason it was the second highest rated cluster in relation to importance to address.

As described in chapter five, at a statement level, statement number 34. "*I lack the support to get as involved in research as I'd like*." was felt to be a potential key facilitator to naturally addressing other issues. In relation to this, participants suggested support to explore, feel comfortable with, and learn about the positive aspects of research, should begin at an undergraduate level, and should continue to be facilitated across the healthcare system, involving leaders at every level.

The Council of Deans for Health published a report in 2019 (McCormack, Baltruks and Cooke, 2019) calling for interventions to improve research confidence and ensure research literacy for undergraduates when qualifying. The report acknowledged, however, that the majority of undergraduate exposure to clinical research was academic in nature and focused on the development of ones' own research. Evidence of the positive impact of exposure to clinical research delivery during undergraduate training suggests that pockets of excellent practice exist, yet research delivery placements are yet to be commonplace within the undergraduate curriculum and are instead ad-hoc, bespoke placements which are not widely available (Harrison, 2014; Whitehouse, 2017; Whitehouse and Smith, 2018). Consequently, it is possible to predict that such opportunities will generally be accessed by those individuals naturally interested in the field, meaning those harder to engage individuals who may not be aware of, understand or value research activity, will remain uninfluenced.

In a study to test an educational intervention aimed at raising awareness of cancer clinical research nursing, Hood, Wilson and Croudass, (2022) identified that of the 733 participants, 84% stated they would not consider a CRNurse role in a pre-intervention survey. Furthermore only 19% felt they could articulate what the role of the CRNurse was. Following the intervention, delivered to over 2000 undergraduates, across four universities in the UK, 99% of participants felt they knew what the role of the CRNurse was and 65% would now consider the role as a career option. Whilst the data contained within the statements and clusters did not relate to undergraduate experiences and knowledge, it is reasonable to postulate that the suggestion at the interpretation session regarding early education about the importance of clinical research within clinical service delivery should be improved. In support of this view, Harrison (2014) identified almost a decade ago that undergraduates require an appreciation of "*not just of where, but how the evidence for practice is derived" (pg.455).*

The concepts discussed above can be linked to the choice of statement which was seen as the most important to address across the whole data set. This was statement number 39. *"There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects."* This statement reflects a positive appetite towards involvement and engagement in research. This does, however, appear to contrast somewhat with the expression of limited motivation to take an active interest in clinical research delivery because everyone is already overstretched. These two extremes provide insight into variations in culture and staff experience evident across the NHS. Furthermore, they serve to confirm the relevance of a critical realist perspective in acknowledging the importance of context and in considering the potential utility of interventions.

Clinical research delivery is a core feature of clinical service delivery. In addition to the vast amount of messaging related to its strategic prioritisation, an increasing number of individual organisational strategies reflect the core nature of research in improving their ability to provide high quality services to the populations they serve. In contrast to these meso and macro level commitments however, the reality of enabling this within services remains challenging, and reflects the workforce, funding and cultural challenges (behaviours and experiences of nurses and midwives) described by West, Bailey and Williams (2020). Evidence generated as part of this study continues to indicate that opportunities to engage with research delivery are few for those clinical staff practicing at the interface with patients and service users, regardless of their interest in or understanding of it. As discussed in the early scene setting of chapter one, there is evidence of a dichotomy between clinical service delivery and clinical research delivery (van't Hoff and Selvaratam, 2018). The nature of the statements contained within clusters three, four and five within this study provide contemporary evidence of the existence of such a dichotomy, and the statement seen as most important to address across the dataset confirms there is an appetite to change this.

Finally, statement and cluster number six *“I keep thinking of ways to facilitate research as 'everyone’s business' but it is hard”* generated an insightful discussion during the participant interpretation session. Chapter five discussed the positioning of this statement as central on the point map, largely due to the manner in which this statement had been sorted with many others on the map. This suggests that the statement linked to many other themes depending on how it had been interpreted by participants during the sorting activity. As a result, this statement could be described as a bridging statement between other issues ongoing. It became apparent during the participant interpretation session, that this statement had been interpreted in at least two different ways.

The first was that the activity of facilitating and promoting research as everyone’s business is hard. This links with multiple concepts, such as locus of control, assumed constraints, and how enabled, supported, prepared, and empowered

NMAHPs feel in relation to engaging with research, and in promoting it to others as a worthwhile venture. The second was that research itself, and the activity of doing, supporting, or engaging with research, is hard. This perspective links with the perceptions of the work of research, what is involved and the level of knowledge and understanding required to carry out the tasks and responsibilities associated with research. Both of these perspectives, discussed during participant interpretation, could reasonably be drawn from that single statement.

Whilst the meaning intended by the participant who provided that particular statement will remain unknown, the dialogue generated by that statement provided a powerful reminder, from a critical realist perspective, that knowledge is transitive and there are multiple ways of knowing about a particular subject (Buch-Hansen and Nielsen, 2020). It also confirmed the notion that, as humans, we take in and interpret information in very personal and context specific ways, thereby demonstrating how one person's view of a scenario could be different to another's' interpretation with neither being considered to be absolute, or as right or wrong. This notion, alongside the other concepts discussed, is key in considering the evidence generated by this study.

6.3.3 Implications and recommendations for future practice and research

As discussed in chapter three, critical realist philosophy postulates that it is impossible to be certain about some aspects of the world. Knowledge is transitive and therefore subject to constant change because we can never know all there is to know about some aspects of the world (Maxwell, 2012). The results of this study go some way to providing alternative, growing, and changing knowledge of both the perceptions that CRNurses hold about how they are viewed, and the views of those healthcare professionals outwith research delivery, about the research delivery landscape. This knowledge, however, remains incomplete, and further research is required in relation to the findings of this work, both to build on the original realist synthesis and the data generated during the empirical phase.

In making recommendations intended to address what does not work so well, and also to build on the more positive aspects of what does appear to work, it is important to be aware of the implications of context, as discussed previously. The common risks of implementing larger scale interventions across systems, include generating more problems by simply blocking a particular mechanism, rather than understanding the whole picture, including how and where such a mechanism is triggered or not. Whilst interventions are usually introduced with the aspiration of addressing problems (such as the introduction of the CRNurse role to improve recruitment and retention to clinical research), the complex interaction between context, mechanism and outcome is why such different perceptions are noted from one context to another.

The implications of this study suggest that there is still a need to integrate the delivery of research in the NHS into the hearts, minds, and daily routine of professionally registered clinical staff, practicing alongside or in parallel with CRNurses and research delivery teams. This challenge has prevailed for many decades and has been the content of much debate. Contemporary strategies, however, continue to seek culture change and articulate the need to improve attitudes towards research. This appears to have progressed little in recent decades, despite this rhetoric forming part of the earliest strategies related to the current structure and landscape of research (Department of Health, 2006).

The consideration of broader NHS structures, hierarchy, and cultures, and how they interact with individual experiences and tendencies, should therefore not be underestimated. Additionally, in considering individual, micro level, tendencies, it is important to understand the various experiences, preferences and views that might lead to particular behaviours, such as locus of control, and the concept of individual autonomy and assumed constraints. The following recommendations are offered based on the data generated within this study through the different phases from ideas generation to participant interpretation. Recommendations have been organised according to policy, practice, and research implications.

Policy

1. Senior figures with responsibility for Nursing, Midwifery and Allied Health Professionals in NHS England, Health Education England and the NIHR will be contacted and encouraged to review and discuss the results of this research to enable maximum influence in current ongoing strategic work. In addition to the stakeholders mentioned here, this research will seek to influence policy and practice going forward by ensuring the results are widely shared, discussed and disseminated to senior figures within the Royal College of Nursing Research Committee and other relevant professional associations.

2. Work should be undertaken, in line with the NHS People Plan, to address where negative behaviours are displayed at the interface between clinical research delivery and clinical service delivery. This should include work to facilitate NHS staff in understanding the impact of their perceptions and resulting behaviours on others they work alongside, recognising and valuing the different roles and responsibilities.

3. In line with the Courage of Compassion (West *et al*, 2020) document, consideration should be given to how current NHS hierarchies and structures act as mechanisms in generating resistance and avoidance behaviours in the context of this study. Work should be undertaken to map the recommendations in that document directly to the interface between clinical research delivery and clinical service delivery. This includes the extent to which NMAHPs practicing outside of clinical research structures, and CRNurses themselves, are able to influence decision making, effective multidisciplinary team working and compassionate, nurturing cultures to enable psychological safety and effective communication

4. Undergraduate placements are a key element of learning about the operational work of the research delivery landscape. These should be introduced widely. This should be considered a priority as part of the main undergraduate curriculum for all NMAHP professions. Whilst this may present

challenges to placement capacity and require further bold thinking, it will be critical to future success and should be incorporated into future policy work.

5. The delivery of research should become the responsibility of every qualified healthcare professional. This includes ensuring every individual is aware of and enabled to support and engage with CRNurse teams, thereby removing barriers within clinical settings

Practice

1. Future approaches to the implementation of the CRNurse role should learn from and take greater account of previous research undertaken. This should be considered in relation to the spatial and political boundaries they cross, and the resulting interface between research delivery and clinical service delivery. This may require some bold thinking and courageous decisions to implement large scale change. However, closer working between or more embedded working within clinical research delivery teams and clinical service delivery is critical to the success of clinical research, and critical to the experiences and perceptions of all involved

2. Targeted training, development and support with enabling autonomy to support and get involved with the delivery of research should be designed and implemented at ward/department, ward/department manager and middle manager levels in the NHS. This should be set up as an intensive programme of work until research becomes fully embedded as part of the fabric of clinical service provision. This will help ensure that aspirations espoused at executive and senior manager levels, are facilitated, lived and experienced through the behaviours and values of those responsible for setting the tone and leading teams in clinical departments. This should not be limited to GCP training, rather it should support and enable stretched middle managers to see the potential and value of research going on in their area and for them to be empowered to support and enable it at all levels

3. Work should be undertaken to improve communication and team working between those delivering clinical research and those working where clinical research is delivered. Consideration should be given to the individual context, the type of research being delivered, and to what is needed to facilitate positive working relationships

4. NMAHPs working outwith clinical research structures should be actively trained, supported and enabled to learn more about clinical research and how it is delivered in the NHS. Organisations should ensure this is achieved through a mixture of high-quality induction programmes, preceptorship programmes, dedicated placements or rotational posts, protected time and links between departments and clinical research delivery structures.

Research

1. An ethnographic study (as originally planned) should be undertaken to enable the observation of real time interactions between healthcare professionals at the interface between clinical research delivery and clinical service delivery. This will triangulate the findings from this study and provide further, richer, context specific evidence derived from direct observation, upon which to develop interventions to address the challenges confirmed as part of this study

2. Whilst this study focused on only one of the 13 programme theories generated by the early realist synthesis, the remaining 12 have implications for practice and hold the potential to provide additional key insights at different levels of context into the interface between clinical research delivery and clinical service delivery. Data collected from this study has been found to reflect the themes within some of those theories, however, their testing was outside of the scope of this thesis. Further research should incorporate the empirical testing of the remaining theories, published within the realist

synthesis, to provide further insight and momentum towards maximising what works well and to better understand what is required to improve experiences and practice in this space

3. The potential positive impact of the recent global pandemic should be empirically explored, to understand what mechanisms led to improved visibility and experiences anecdotally reported, and to retain those facilitators to maximise any potential longitudinal impacts of COVID-19

4. Evidence collected and generated about the clinical research landscape and its interface with clinical service delivery must, in the future, seek to disseminate more widely. This is with the aim of influencing beyond the current separate pockets of literature, which are generally accessed and debated only by those practicing within that field

5. In relation to the recommendation above, when considering issues related to the clinical research delivery landscape and its interface with clinical service delivery, other collections of literature should be drawn on to enlighten the issues. For example, considering the issues of resistance and avoidance behaviours at the interface between clinical service delivery and clinical research delivery, has been assisted by considering wider literature related to political geography, psychological theory, leadership literature, and NHS culture

6.4 Reflections on strengths and limitations

The original aspirations of this doctoral work were to explore beneath the surface of the interface between clinical service delivery and clinical research delivery. The intentions were to illuminate how these structures interact in the real world, to provide a voice to those individuals regularly cited in the literature as gatekeepers, who had been previously unheard, and to enable a greater understanding of how the delivery of research is enabled or obstructed within different clinical contexts. The focus of this being on the generation of resistance or avoidance behaviours, and their impact in this space.

The original ambition of achieving this through an ethnographic study was prevented by the COVID-19 pandemic. Instead, the adoption of a group concept mapping (GCM) approach, carried out through a critical realist lens, has provided rich, powerful, and unique data, which has enabled a novel contribution to the evidence base. As signposted earlier, a discussion related to these novel contributions will be presented in more detail in chapter seven. Prior to this, the following section will reflect on the strengths and limitations of this study providing insight into areas considered to be of benefit to this work and those where improvements would be beneficial.

6.4.1 Strengths

Adopting a critical realist philosophy was a particularly useful theoretical platform from which to explore how the role of the CRNurse is viewed by those practicing alongside yet outside of research delivery structures. The utility of exploring issues through this lens enabled views to be collected that took account of the inherent complexity and social nature of research delivery structures within the NHS, and how they interfaced with other clinical service structures. The critical realist perspective enabled this research to confirm that, in such an open system, there are multiple internal and external stakeholders, actors, participants, policies, and strategies with the ability to influence the landscape in a range of ways. In doing so, the research was able to confirm the existence of resistance or avoidance behaviours, and gain insight into where and how these might be likely to be triggered at different levels. As a result, the critical realist lens also enabled the collection of a range of context specific views in relation to what is thought as important to address and indeed what practical steps might be taken towards this end. The combination of such a philosophical stance with a web-based, group orientated research methodology has actively facilitated and maximised the development of a unique and previously unheard perspective of the topic, whilst also providing novel contributions in relation to the use of GCM from a critical realist perspective.

The benefits of a web-based GCM platform enabled the continuation of the research during a period of time when face-to-face data collection was not feasible. This meant that the research was not paused, despite the change in methodological approach. Participants were able to access the study remotely, and at their convenience, within the time constraints of each of the phases. They were able to see their progress through the study, and those joining at ideas generation were able to see the statements offered by other participants to inform their contributions.

A GCM approach in comparison to the originally intended ethnographic study, enabled a wider sample of participants to join the study, reflecting a range of contexts which would not have been possible in an ethnography. Indeed, an ethnography would have, by nature of the design, been limited to a single setting due to the scope of this doctoral study and would therefore have been subject to limitations in transferability and relevance to other settings.

From a practical utility perspective, the online platform provided a secure setting within which to develop and undertake the research. The platform maximised the ability to work through the different phases of the study, and the capabilities within the platform enabled judgemental rationality in selecting which elements (maps for example) were deemed adequate in terms of illustrating the data and testing the selected theory. In addition, the ability to contact participants, and alert them to the next activity, through the platform provided a secure way of storing and accessing participant data and mapping their progress through the different steps within the study.

The GCM approach, as a methodological choice, also provided a high level of rigour to the final dataset, in that the generation of statements, the subsequent thematic analysis, ratings and group interpretation were completed almost entirely by participants, with facilitation and guidance from the researcher. Whilst there were elements of the research that required researcher input, such as checking the quality of data at each stage to inform the next, finalising cluster solutions and working with the software to generate maps for interpretation, the true partnership nature of this approach provides reassurance in relation to the application of the methods and the evidence generated by this study. Themes were generated by participants with noticeable relevance to the issues and the GCM approach enabled participants to sort individually, without being influenced in a particular direction, based on their own context and views on the landscape. The use of a web-based platform to enable this is considered to be of benefit because, had the sorting and rating taken place in a different, perhaps face-to-face, group setting, the outcomes may have been different. This includes the risk of stronger voices overpowering others, similar to the challenges of facilitating a focus group (Krueger and Casey, 2015). Kane and Trochim (2007) reflect this view, stating that sorting and rating activities are particularly suited to remote approaches, because they are rather more solitary activities, led by participants own views and experiences. The intentions of GCM are not to reach consensus, rather to reflect the range of views of all participants, and this was achieved in this study, providing a unique dataset.

Whilst there were a number of strengths noted throughout the study, limitations were also apparent. A number of these were known or predicted from the outset, whilst some emerged later, as the different stages of the study progressed. These will be discussed next.

6.4.2 Limitations

In contrast to the relative benefits of adopting a web-based data collection process, a number of limitations became apparent, which might have been avoided with either a face-to-face GCM approach, or indeed the adoption of the original plan to undertake an ethnographic study. As described in chapter five, the generation of titles for clusters appeared to be a challenge for some participants, meaning that some clusters were left without titles and some titles did not accurately reflect the content of a given cluster on checking. Also, as discussed in chapter five, some participants did sort statements in a binary manner rather than thematically, presenting a challenge when checking the sorted data for validity. This did not adversely impact on the useable data for the study, however, and in reality the eventual clusters generated, and the content of those clusters, identified that participants were mainly able to put statements together effectively.

In addition to the challenges presented by developing cluster titles, it was noted that participants often required reminders to complete activities. For example, participants would commence ideas generation, input two or three statements and then not finish their session. In addition, they may commence sorting or indeed rating, reach halfway with the statement set, but then stop and not complete or close off the activity. This required close monitoring and emails to participants, thanking them for their participation, but inviting or encouraging them to complete their entries, finish sorting/rating, or add cluster titles etc. The reasons for lack of completion may be multiple. Virtual data collection does have some disadvantages as opposed to face-to-face data collection. It requires more careful planning and participant follow-up. The time set aside for each activity is usually extended over a number of weeks rather than completed at a single meeting, and this can lead to challenges motivating participants to continue, which may account for the reducing numbers of participants engaging with each stage of the research in this study. In support of this, Kane and Trochim (2007) suggest that one has to be realistic and recognise that not all participants will engage at the same level and pace that would be achieved in a face-to-face setting.

It is possible that the number of statements participants were eventually asked to sort (99), whilst within the recommended limits, may have presented a burden in relation to thinking about where each might be best positioned with another, what each meant to the participant, and then proceeding to rate each statement on two separate scales. On reflection, it may have been wiser to reduce the statement set to around half of what was finally selected; however, this may have then presented a risk of missing key themes. There could also be a risk in terms of rigour, if the research was not in keeping with both the critical realist perspective of seeking out views through a range of levels and contexts, and the GCM intentions of enabling and maximising participant voice.

It was noted that in comparison to the numbers joining at the outset, relatively low numbers of participants followed through from their chosen initial stage to the next stage of the study and beyond. This was particularly noted in relation to the low number of participants who eventually attended the interpretation session (five expressed intent to attend, however three attended on the day). Whilst there is a risk of criticism in relation to the low attendance at the interpretation session, as discussed in chapter five, Rosas and Kane (2012) did not assess the validity or impact of interpretation activities in their pooled analysis. Furthermore, they stated the intentions of interpretation are to share data with participants and to help participants to understand the data and subsequent interrelationships between. It is not possible to predict the potential impact of a smaller group attending the interpretation session on the overall results of this research, however, the aim of interpretation is to add richness to the recommendations, which was achieved in this study. The challenges with recruitment and retention throughout the sequential stages of the GCM phase may be explained in a number of ways. In the midst of a global pandemic, at a time when the NHS was at its most stretched in terms of demands and pressures, it is possible that the people this study was seeking to engage, were simply exhausted and did not feel they had the energy to participate or indeed continue to participate in research outside of their busy working lives. The relative benefits and convenience of a web-based platform may have been less attractive than a facilitated face-to-face session because the nature of being asked to participate at such a time and over many months, meant that most participants would have engaged in their own time, rather than attending a single session within work time.

It is possible that participants were motivated to share their views at ideas generation. This is because the ease with which statements could be generated and entered anonymously, may have provided emancipation for individuals, in being able to express their views with low risk. When being asked to then sort a large number of statements into themes and continue on to rate these statements, this may have been a less attractive option than simply expressing their views on a subject and leaving the data to be analysed by the researcher.

This study was seeking to reach an inherently difficult to engage population. This will inevitably have impacted on the data and the likelihood of success, yet it was important to attempt. The intentions were to seek out those individuals cited as gatekeepers who were labelled as not interested in, or aware of, research. Accessing these individuals and asking for their views on research, the topic they were considered to avoid or resist, was therefore going to be in itself a significant challenge.

Reflecting on the approach to recruitment, which was inevitably impacted by the COVID-19 pandemic, the study was shared via professional forums and social media only, rather than by direct recruitment through NHS organisations. This was due to the pandemic related pause on the Health Research Authority assessing and processing studies other than urgent public health and COVID-19 related research. The use of Twitter in particular as a platform to share the study invitation generated findings which may have implications for future research of this nature. The study was retweeted 586 times and liked 493 times during the different stages of the GCM phase. The likes and retweets, however, did not translate into the same number of individuals accessing the platform and participating in the study. It is possible that individuals liking, and retweeting had intended to participate, but for reasons unknown, they did not subsequently go on to join. It is also possible, however, that due to the preferences, views, and beliefs of the community within which the study was shared, the social media activity related to the study was limited to individuals who would not have been eligible to participate, such as CRNurses, and clinical academics.

According to Cinelli *et al.*, (2021), social media may not effectively enable the collection of diverse perspectives due to the nature of what are termed echo chambers. Echo chambers are thought to result from the tendency of like-minded individuals to frame and reinforce narratives shared by that group. This is notably played out when considering an individual’s followers or online community, as individuals tend to follow those whose beliefs and preferences are congruent with their own. The sharing and promotional activity associated with this study was generally carried out by research active or informed individuals whose values were already congruent with those of the research. Some were in CRNurse roles or were already leading and developing their own research. Although generic nursing, midwifery and AHP accounts did retweet the study and advocate for participation, it is possible that the overall influence of these accounts was limited, and simply liking and retweeting indicated the levels to which individuals felt able to or were eligible to participate.

A discussion regarding the selection of the eventual focus prompt for the empirical phase has been presented both in chapter five and earlier in this chapter. It is reasonable to identify, however, that a different focus prompt would have arguably generated different data. The challenge for this research was, in part, deciding how specific and how provocative to be in terms of the prompt. A prompt considered to be too controversial, or direct may have risked non-participation, or the generation of antibodies from participants. Too benign a prompt would have risked diluted and non-specific data, leading to limited insight.

The challenges related to participant numbers and continuation across the different steps in the empirical data collection, meant that effective subgroup analysis was not possible. It also became apparent, after the completion of ideas generation, sorting and rating activities, that one of the participant demographics questions had failed in the web-based platform. The area of practice was not populated by any participant, despite it being compulsory, therefore it was impossible to extrapolate any inferences from this data. Furthermore, due to low numbers participating beyond the original ideas generation step, it was impossible to draw any inferences regarding subgroup views on the likelihood of generating resistance or avoidance, and on those issues seen as important to address.

The decision not to proceed with the originally planned ethnographic study inevitably impacted the conduct, participation, and results of this research. In an ethnographic study, the burden of the research and associated work lies with the researcher, who observes, assimilates, analyses and interprets what is seen in relation to the social groups and behaviours/interactions observed. As a participant, the only real work of being involved in an ethnography is in being oneself, therefore the burden is significantly less than other more participative approaches. Participating in the GCM study was an active decision on the part of each individual who joined and took part at any stage. Participation required labour on the part of such individuals beyond an initial consent. It is also possible that the longer-term burden of the COVID-19 pandemic affected initial decisions to participate and then any decision to continue through the various stages of the research to interpretation.

6.5 Chapter summary

This chapter has presented a critical discussion of the research findings and made comparisons with the existing evidence base. The main discussion covered three elements aligned with the aims of the research. The first section discussed how the clinical research nurse role and research delivery is perceived by healthcare professionals operating outside of, yet alongside, clinical research teams within NHS organisations. This involved a critical analysis of the original statement generation and sorting activities completed during the group concept mapping (GCM) phase. This section revealed a range of participant views which could be considered to range from positive to negative in tone. Some reflected a sense of awareness and understanding of the value of clinical research in the NHS, and an aspiration to be more involved in supporting the delivery of research for the benefit of their patients. In addition, some reflected frustration at a lack of support, time or education to be involved, whilst a proportion expressed views that indicated they were not interested in nor aware of the delivery of research in their clinical context. The eventual six clusters the data were sorted into, reflected key themes describing behaviours, experiences and perceptions positioned on a continuum from support and awareness to disengagement and lack of interest or time.

The second section examined the factors considered by participants to generate avoidance or resistance behaviours towards CRNurses, combined with an analysis of the factors participants indicated were important to address. This involved critiquing the data generated during both of the GCM rating activities (sorting and rating). This revealed a range of statements considered by participants as likely to generate resistance and avoidance behaviours. Whilst some statements identified as likely to generate such behaviours were rated as important to address, the findings also indicated a range of statements sorted as less likely to be generative of resistance and avoidance were identified as more important to address. The interpretation session revealed that this was in part due to an aspiration from participants to seek out what they considered to be quick wins, less complex solutions and more practical interventions, they felt better able to influence. The hope was that by addressing those issues seen to be simple yet fundamental to the bigger issues, the bigger issues may then naturally resolve as a result.

The third section of the main discussion presented the main implications and key recommendations arising from this study. The key recommendations incorporated 13 suggestions relevant to clinical practice and future research at a range of levels, layers of complexity and points of interface between clinical service delivery and clinical research delivery in the NHS. This was followed by critical reflections on the perceived strengths and limitations noted across the thesis.

Throughout the main discussion, a number of original contributions to knowledge were indicated. These will be discussed in more detail in the conclusion chapter, which will now follow.

CHAPTER 7. CONCLUSION

This final chapter draws together the key constructs of the thesis, summarising what has been revealed by the different stages of this research in relation to the aims, objectives and theories set out in the earlier chapters. This chapter will highlight how the research undertaken provides fresh insight and illuminates debate and discussion at the interface between clinical service delivery and clinical research delivery. This will be drawn out sequentially, through explicitly setting out the original contributions of this research to the knowledge and evidence base, both methodologically and theoretically.

Original contribution one - Identification of a research gap addressing the views of NMAHPs practicing outwith clinical research structures about clinical research delivery and the CRNurse role.

This doctoral work builds on my own previous research carried out to explore the perceptions of CRNurses regarding the extent to which they are enabled to successfully deliver clinical research. Originally intended to improve the recruitment and retention of patients in clinical research studies, such previous published research had highlighted and reported on a number of potential influencing factors, positioned at micro, meso and macro levels within the healthcare system. One such factor, evident across the CRNurse related literature, related to CRNurse interactions with other Nurses, Midwives and AHPs who practice outside of clinical research structures. The extent to which these NMAHPs would support the CRNurse emerged as key in enabling CRNurses to go about their business to successfully deliver a study.

The early chapters of the thesis summarised the evolution of clinical research delivery, as an activity in the NHS. This included the history, development, and implementation of the CRNurse role and associated research delivery structures. Throughout this historical mapping, a range of factors emerging from the literature and reported to mediate the success of clinical research delivered by the CRNurse, were highlighted.

Early in the thesis, the necessity to explore the views of professionals who practice outwith the delivery of research was established. This was due, in part, to the previous research conducted in this area, and the identification that literature to date in this field was generated almost entirely by CRNurses and research delivery teams in isolation. Furthermore, this literature rarely accounted for or linked to broader concepts related to social, political and system factors impacting the NHS. The small amount of literature that did report on the views of those outwith research structures tended to focus on the subject of opportunities to generate research evidence alongside clinical practice, rather than the delivery of research. Within this literature, difficulties were noted in relation to broader understanding of the research landscape, including understanding the differences between CRNurse roles and those of nurse researchers and clinical academics. Such difficulties were reflected in the evidence base related to the CRNurse role and were considered as having potential to explain some of the behaviours described by CRNurses at the interface between their role and that of clinical service delivery.

Original contribution two – The adoption of a critical realist stance to explore the interface between clinical research delivery and clinical service delivery has not been adopted previously. Combined with GCM methods, critical realism has enabled a potential methodological contribution to knowledge

The relevance of adopting a critical realist stance for the purposes of this research was established early in the thesis. The critical realist philosophy, as a theoretical platform from which to explore how the role of the CRNurse is viewed by those practicing outwith research delivery structures, had not been previously reported in the literature. The adoption of this stance in this work, therefore served as an original contribution to the evidence base. The utility of this approach enabled flexibility in completing the realist synthesis in this subject, and was valuable in the practical application of the GCM phase. The application of critical realism resulted in the collection and consideration of evidence that had not previously been achieved, and would not have been feasible through alternative philosophical lenses. This evidence proved critical in providing insight, resulting from the inherent complexity and social nature of the NHS.

The critical realist synthesis, reported in chapter four, enabled the consideration of evidence, which would be typically excluded in traditional systematic review approaches. The iterative, retroductive approach, incorporating a range of evidence types, supported the generation of 13 distinct, yet linked theories related to how CRNurses and research delivery structures may interface with other clinical services. Such theories highlighted the potential of multiple internal and external stakeholders, to influence the landscape in a range of ways. In doing so, the synthesis was able to identify that resistance or avoidance behaviours exhibited at the interface between clinical research delivery and clinical service delivery, may serve as mechanisms in mediating the success or failure of clinical research in a range of contexts. This linked back to Pawson and Tilley's (1997) concept of cooperation and non-disruption or, as identified in the synthesis, a lack thereof.

The realist synthesis further established the necessity to gain insight from those Nurses, Midwives and AHPs, practicing outwith clinical research structures, yet reported by CRNurses to display such behaviours. The empirical data collection would therefore seek to provide evidence of where and how these behaviours might likely be triggered at different levels, whilst also identifying those issues viewed as important to address by participants.

Whilst a critical realist ethnography had originally been considered appropriate to complete the empirical phase of this work, the COVID-19 Pandemic rendered this face-to-face, observational approach impossible to conduct. This led to a change in methodological approach whilst seeking to remain true to the critical realist philosophical stance taken. Combining the philosophy of critical realism with the mixed methods approach of group concept mapping reported in chapter five, enabled an original and detailed, stepwise exploration of views about the delivery of clinical research and the CRNurse role. The combination of such a philosophical stance with a web-based, group orientated research methodology facilitated and maximised the generation of previously unheard perspectives on the topic. This approach also provided potentially novel contributions in relation to how GCM approaches can be considered to support data collection and evidence generation from a critical realist perspective.

Linking the structured ontology of critical realism to GCM methodology, enabled consideration of the range of domains within which the data generated, sorted, and rated might have the potential to trigger mechanisms at the interface between clinical research delivery and clinical service delivery. In addition to this original approach, the research uncovered three potential key principles which may generate methodological debate as to whether they might serve as enablers in undertaking critical realist research using GCM methodology in the future. These were described briefly in chapter five and include: ensuring programme theory forms the foundation of the focus-prompt used in ideas generation; ensuring minimal sanitisation of participant voice in ideas synthesis; and ensuring the design of rating scales test the extent to which a mechanism may be triggered.

The combination of consistently reflecting on GCM methodology whilst incorporating a critical realist philosophy is what guided the eventual exploration of the likelihood of each statement in generating a resistance or avoidance behaviours at the rating stage. A methodological paper is underway, exploring these key potential principles in more detail and will form one of the planned dissemination activities associated with the doctoral work.

Original contribution three – Confirmation of the existence of perceptions likely to generate resistance or avoidance behaviours at the interface between clinical research delivery and clinical service delivery, by those practicing outwith research structures.

The testing of the selected theory through the GCM phase confirmed, through the views of participants, that perceptions exist which are likely to generate resistance and avoidance behaviours. That such confirmation was generated by NMAHPs practicing outwith clinical research delivery structures, provides a further original contribution to knowledge, adding additional insight into the perceptions of CRNurses and research delivery teams.

A total of 99 unique statements were generated by participants, in response to an open-ended sentence seeking views on their perceived role in relation to the delivery of clinical research in the NHS. Six clusters were eventually selected as the most practically adequate cluster solution in reflecting the thematic sorting of statements by participants. The six clusters reflected topics which indicated awareness, support, and value associated with the delivery of clinical research in the NHS varied, from active support for, to avoidance of and resistance to. The subsequent rating of the data confirmed those statements most likely to generate resistance and avoidance behaviours at the interface between clinical research delivery and clinical practice.

The rating data also identified that whilst avoidance and resistance behaviours were considered by participants as likely to be generated, the mechanisms leading to such behaviours appeared most likely to be mediated by contextual, systemic factors and limitations outside of their control. This is to say that mostly contextual factors, and the powerful influence of other actors in the system, rather than personal views related to a lack of awareness, value, or support for research, were mediators in generating resistance and avoidance behaviours. These findings are considered significant, worthy of further exploration and are potentially transferable across other evidence bases, such as those exploring the challenges related to clinical academic careers.

Original contribution four – Evidence of NMAHPs practicing outwith clinical research structures expressing a desire to be involved in supporting research delivery, yet feeling frustrated at the structures in which they work.

The data generated, analysed, and interpreted within the GCM phase of the research appear to indicate a sense of frustration within the healthcare system. This seemed to be due to a lack of ability to influence, a lack of autonomy, and variation in how supported professionals consider themselves to be, in relation to engaging with and supporting research delivery. These concepts reflect those highlighted by West, Bailey and Williams (2020), linked to the workforce crisis within nursing and midwifery. In addition to individual tendencies such as locus of control, these concepts may offer partial enlightenment as to the difficulties expressed in prioritising and supporting research activity within the healthcare system, yet provide evidence of some desire to do so.

7.1 Final thoughts

This research has contributed unique insights into the perceptions and experiences, of NMAHPs practicing outwith research delivery structures. These perspectives confirm the existence of sub-optimal attitudes and perceptions with the potential to generate resistance or avoidance behaviours in some contexts at the time the research was carried out. This work has also successfully illuminated previously unheard perspectives, indicating that research delivery is valued, understood, and supported in some contexts. Such views may challenge aspects of the current evidence base related to sense of value and provide further encouragement in relation to what is needed to address the remaining issues.

Eliciting the views of participants practicing outwith research delivery structures on what could and should be done differently to improve the success of clinical research delivery, has provided an opportunity for their perspectives to be heard and considered. The main aspects highlighted related to a desire for time to engage with research to be enabled within clinical practice. It was identified that support and encouragement to engage with research should commence at undergraduate levels. Increased opportunities for those outside of clinical research delivery to be involved with supporting studies was another aspect which was highlighted as important in this study. Finally, improved communication between clinical research delivery teams and clinical service delivery was felt to be pivotal to the success of research if a reduction of resistance and avoidance behaviours were to be achieved. The extent to which addressing these three aspects might improve the success of research delivery, is not yet known and has been recommended as worthy of further exploration.

The results of this study provide new and distinct perspectives, which may shift awareness of both the perceptions that CRNurses hold about how they are viewed, and the views of those healthcare professionals outwith research delivery, about the research delivery landscape. Because such knowledge exists within the transitive domain, it remains incomplete and open to change. Further research is required in relation to the findings of this work, both to build on and test the original theories generated in the realist synthesis, to further test and reflect on the data generated during the empirical phase, and to take account of the recommendations set out in chapter six. There is, however, much to be optimistic about as a result of amplifying such previously unheard voices and linking this research to broader evidence bases and to the current research strategy rich landscape which the NHS aspires to lead.

The epigraph presented at the outset of this thesis was selected to highlight that what is to come in the years ahead cannot be predicted nor foreseen by an individual, instead, the task can only be to seek to collectively enable the future, which requires better understanding of the many layers involved. The intentions of this research were to seek out and contribute additional and alternative insight into the relationships and subsequent interactions, which are arguably key to the success of many interventions within a clinical setting, not limited to the delivery of clinical research.

The political, social, and hierarchical structures within and impacting on the NHS, inevitably influence interactions and interventions across a range of professions, multidisciplinary teams, and settings. This ultimately affects the approach to and quality of patient care. To add original and previously unheard insight to enable even the smallest of improvements in the delivery of clinical research, could improve access for many more patients who would previously have been prevented from being offered the opportunity to engage in such research.

Those leading and setting the priorities for the NHS espouse a commitment to research, as identified in a range of strategies and plans discussed throughout this thesis. The extent to which such strategies and plans are supported and enabled in subsequent years depends on the cooperation and non-disruption of the NHS workforce at a range of levels. This research has highlighted a number of key issues related specifically to relationships at the interface between clinical research delivery and clinical service delivery. The extent to which these issues will continue to generate mechanisms such as avoidance and resistance behaviours depends on the successful enabling of less tangible constructs, well debated across NHS leadership literature, such as autonomy, psychological safety, and culture.

The closing statement offered by Stobbart (2013) in her thesis exploring the conduct of randomised controlled trials in an acute stroke unit remains pivotal almost a decade later:

> *“it can be argued that patients, the public, and healthcare practitioners will not become familiar with research activities until they become normalised within our everyday lives, and more specifically, our healthcare.”*

Whilst it is reasonable to suggest that positive steps forward have been made in the research landscape, the pace and scale of change is arguably much less than satisfactory, and change is required at a range of levels to normalise research. To start with the optimisation of relationships and behaviours at the interface between research delivery and clinical service delivery may enable the eventual removal of the terms ‘interface’ and ‘between’. That is to say, such an interface should not exist, rather research should be embedded within the hearts, minds, and everyday practice of all healthcare professionals. Research should be ubiquitous, regardless of an individual’s role in being aware of, incorporating, supporting, delivering, or leading such a pivotal endeavour in improving the health of our population.

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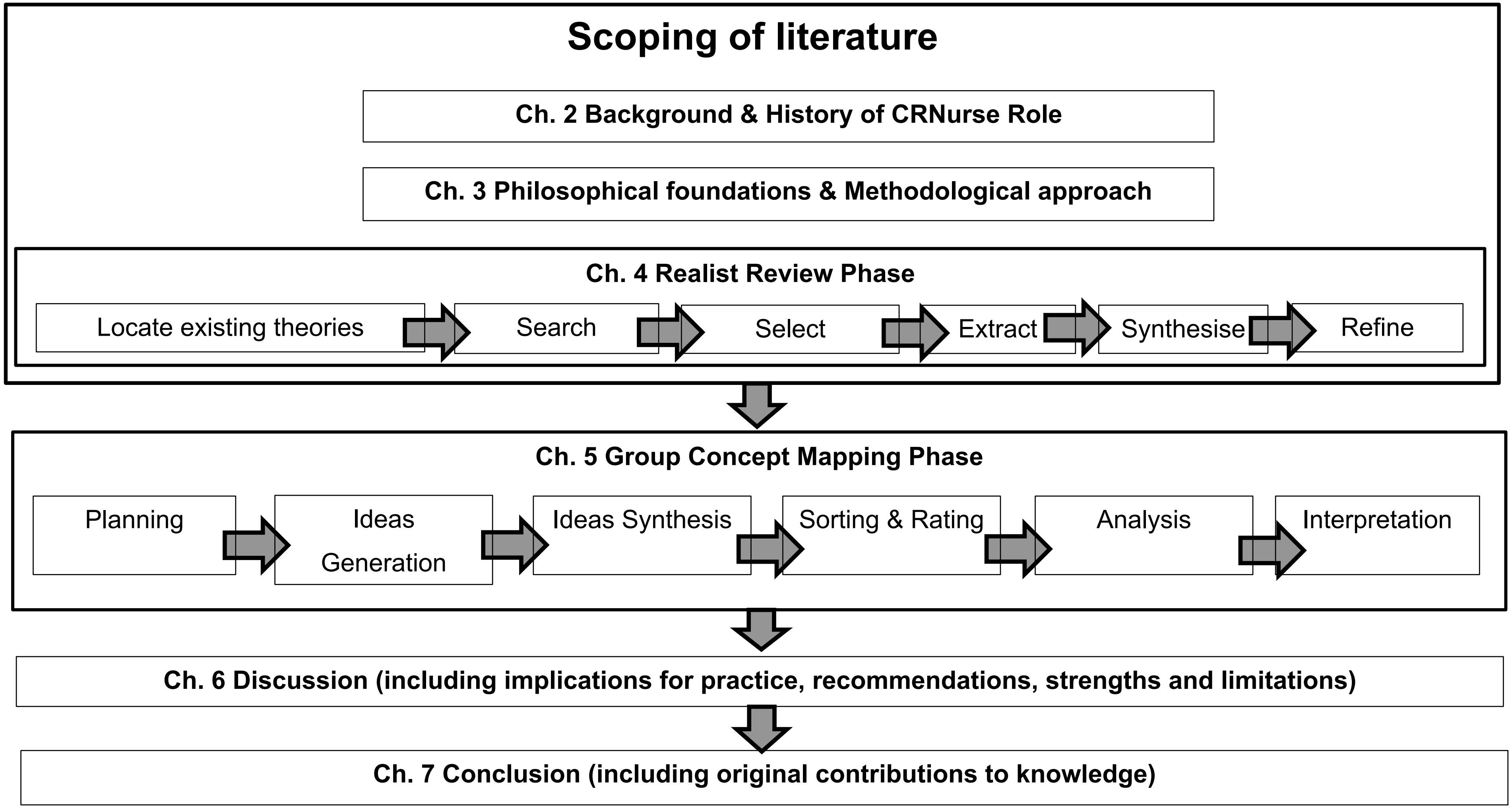
APPENDICES

Appendix 1. Thesis diagram



Appendix 2. Reflection and discussion re typologies of review methods

What am I trying to achieve?

I'm trying to find out "what" is written about: 1. The attitudes towards, 2. The understanding of and 3. Healthcare colleagues' perceptions of Clinical Research Nurses in the NHS and how this area has developed over time to help us to refine a research question for the main study.

My main overarching worry is that if I choose a question that is too specific, I will not find enough data in that area. I know that healthcare colleagues' perceptions of CRNurses is a fairly untapped area, but it feels like the next natural step, though I've been told others are starting to look at it.

Potential questions	Method	Advantages	Disadvantages	Other comments
What is written about the Clinical Research Nurse role? (I feel like I've looked at this broadly in the past and others have done) What is known about how Clinical Research Nurses are perceived by their healthcare colleagues? What is written about attitudes towards Clinical Research Nurses? What is written about how perceptions can impact on behaviours and performance? (too broad	**<u>Scoping Review</u>** Lends itself to a broad question or topic to understand what has been done in a field so far. Is generally an overview, describing the size and scope of what is written about a specific subject, doesn't generate a hypothesis or answer a question Maps key concepts and enables some synthesis, but not necessarily critical, it is about describing what is out there, not the quality of it	Enables the inclusion of ongoing research Boundaries of the literature are determined by the process itself rather than systematically pre-define Useful where the literature in a particular area has not been fully reviewed or where the literature is so diverse that it can't be systematically reviewed	Papers suggest it requires at least 2 reviewers for all screening, charting etc. Potential issues with publishing due to the perceived weaknesses with this method in terms of rigour?	Papers state that a scoping review could lead to one, more or no subsequent systematic reviews. Would it inform the development of a clear research question or would it add more uncertainty into the mix? Protocol should be developed prior which

and not specific to the CRNurse) Include terms such as “understanding” and “self-perceptions” PCC (Population, Concept, Context)		Useful to establish if research evidence exists on a topic and to identify where there are gaps (this may be helpful if there is nothing on our subject)		makes me wonder about the boundaries of the process as per advantages, but literature suggests changes are common.
As above	**<u>Mapping Review</u>** (I’m becoming more confused between this and scoping review ☺) Similar to Scoping Review - some of the literature uses the term interchangeably The purpose is generally to map existing literature with the aim of planning a more detailed review Appropriate when there is a large and diverse body of literature to get to grips with what is out there	Enables a full and exhaustive search The aim is to provide a thorough and repeatable analysis of all relevant literature. The outcome is a high-level map visualizing the status of the field, which is slightly different to a scoping review.		I am not sure this is appropriate, and I don’t quite understand how it differs much from scoping review on further reading?
In the NHS System (C) How do perceptions of and behaviours towards CRNurses(M) impact on CRNurse Experiences(O)	**<u>Mixed studies/mixed methods review</u>** Could be a **Realist Synthesis** (Context Mechanism Outcome paradigm)	Provide a more complete picture of the landscape than Qual or Quant alone	Lack of clarity about best way/time to integrate Qual and Quant components	I thought a mixed methods review would enable me to undertake an actual

What factors(M) contribute to CRNurses descriptions of feeling mis-understood or undervalued(O) in their role?(C) (We can't assume that colleagues undervalue or misunderstand CRNurses. The evidence so far is from CRNurse perceptions not the opinions of those staff the CRNurses are referring to, and this is complex, so this question is biased, but we need to understand why CRNurses feel undervalued by their colleagues as they do provide evidence and describe experiences clearly) How are Clinical Research Nurses perceived by their healthcare colleagues?	What works, how does it work and why does it work like that? Could be **segregated method** **Integrated method** **Contingent method**	"The focus is not on whether a particular program works, but on the resources available to facilitate program success." Freedom to include a range of data Allows Qual & Quant to be assessed separately and then brought together in a final analysis Combining and assessing Qual & Quant together where both sets of data are similar enough Repeated sequential synthesis through developing new questions based on last synthesis	We don't have an intervention as such. Iterative to the extent that it can change focus and direction lots. In the case of Realist Review: the process can lack transparency regarding the choice of evidence selected + lack of explicit guidance regarding how to process contradictory evidence May involve complex methods to aggregate the data but this isn't done often due to challenges maintaining rigour with this method.	stakeholder exercise alongside a lit review, but I think I may have read the paper wrong! I think it was referring to the ability to review perhaps a quantitative study alongside a study that had involved a stakeholder review...! It feels like I am coming back to the realist review method, but I don't know if the Clinical Research Nurse workforce could be classed as a complex policy intervention?! I suppose the way that Research was introduced into the NHS

What literature exists to evidence how Clinical Research Nurses feel they are perceived by their healthcare colleagues? What factors determine how CRNurses are viewed by their healthcare colleagues?				through the NIHR 12 years ago could be classed as that, but that's not what the research question is about? I like the idea of doing something a bit different to learn some new skills too.... ☺
What is written about the Clinical Research Nurse role? (Again, I feel like I've looked at this broadly in the past and others have done) What is known about how Clinical Research Nurses are perceived by their healthcare colleagues? What is written about attitudes towards Clinical Research Nurses? What is written about how perceptions can impact	**Critical Review** Reminds me of a narrative review but with more rigour A comprehensive and analytical review of the literature, commenting on the strength of the papers reviewed. This is more than describing the scope and size of the body of a literature as there is some comment on the strength of papers This method can lead to a hypothesis based on the synthesis and critical analysis of the literature.	Inclusion of "Diverse sources" suggests that we can include a range of literature, Jesson & Lacey paper appears to demonstrate this. Generates a hypothesis not an answer, may be helpful to identify a research question for the main study. Grant and Booth describe being able to "take stock" which	Seen as weaker than Systematic review due to less structured approach. Approach to interpretation may be seen as subjective and open to bias depending on rigour and approach?	If I were to be assessing the quality of papers for the PhD, I would feel more comfortable with using the CASP framework rather than an ad hoc opinion on the quality? Again thinking about the strength and rigour of this approach with a

on behaviours and performance? What is the next step in understanding the factors influencing the experiences of Clinical Research Nurses?	Grant and Booth paper states there is no formal quality assessment and that the assessment is made based on contribution from a conceptual standpoint.	might be a nice way to draw a line under what is out there to identify what next...		view to publishing? Seems an approach that could work, as long as we are clear about what is to be included in terms of paradigms and literature.

Appendix 3. Document characteristics of papers included in the realist review

No	Author, Year (Reference)	Country	Evidence Type	Approach or Methodology	Main Theme of Paper	Setting
1	Boulton MG, Beer S. (2018) Factors affecting recruitment and retention of nurses who deliver clinical research: A qualitative study. *Nursing Open* 5 555–566.	UK	Empirical Study	Focus Groups	Factors influencing intention to remain in post	Multiple Settings
2	Brady O (2017) Clinical research offers a rewarding career option for nurses. *Nursing Times* [online]; 113: 10, 34-36.	UK	Discussion/Opinion Piece	Not Applicable	Influencing perceptions of others/highlighting benefits of the CRN role	Not Applicable
3	Brinkman-Denney, S. (2013) An international comparison of the clinical trials nurse role. *Nursing Management (UK)*, 20(8), 32-40.	International	Literature Review	Systematic Review	Role of the CRN	Multiple settings
4	Brown, J., Barr, O., Lindsay, M., Ennis, E. & O'Neill, S. (2018) Facilitation of child health research in hospital settings: The views of nurses. *Journal of Clinical Nursing*, 27(5-6), 1004.	UK	Empirical Study	Questionnaire or Survey Design	Value, Visibility, Understanding and Awareness of CRN Role	Secondary Care
5	Campbell, T. (1998) Patient-focused care: primary responsibilities of research nurses *British Journal of Nursing* 7 (22)	UK	Narrative Review	Not Applicable	Role of the CRN	Primary Care

6	Coulson C, Grange A (2012) Developing clinical research nurses. *Nursing Times;* 108 (22/23) 23-25.	UK	Empirical Study	Mixed Methods	Education, Training & Development in relation to CRN role	Secondary Care
7	Dunleavy, L., Griggs, A., Wiley, G. and Hughes, M. (2011) Overcoming the hurdles: setting up clinical trials in three UK hospices**.** *International Journal of Palliative Nursing* 17 (3)	UK	Discussion/Opinion Piece	Not Applicable	CRN Perceptions and Experiences	Third Sector
8	Fuchs, B. (2017) Can we talk about power? The King's Fund	UK	Discussion/Opinion Piece	Not Applicable	Leadership and Culture in the NHS	Not Applicable
9	Gelling, L. (2010) Clinical Research Nursing has a bright Future *Nurse Researcher* 17 (2) 3	UK	Editorial	Not Applicable	Influencing perceptions of others/highlighting benefits of the CRN role	Not Applicable
10	Gibbs, C. L. & Lowton, K. (2012) The role of the clinical research nurse. *Nursing Standard*, 26(27), 37-40.	UK	Discussion/Opinion Piece	Not Applicable	Role of the CRN	Secondary Care
11	Goosen, S. (2015) The importance of teamwork in nursing *Professional Nursing Today* 2015;19(3):4-6	UK	Discussion/Opinion Piece	Not Applicable	Importance of teamwork within. Nursing	Not Applicable
12	Gordon, C. (2008) Exploring the new specialty of clinical research nursing. *Nursing Times*, 104(29), 34-35.	UK	Narrative Review	Not Applicable	Role of the CRN	Secondary Care

13	Green L. (2011) Explaining the role of the nurse in clinical trials. *Nursing Standard,* 25 (22) 35-9.	UK	Discussion/Opinion Piece	Not Applicable	Role of the CRN	Secondary Care
14	Hamer S (2015) The nurse's changing role in clinical research. *Nursing Times;* 111: 39, 12-14.	UK	Discussion/Opinion Piece	Not Applicable	Research in Nursing	Not Applicable
15	Hardicre, J. (2013) An exploration of the role of the research nurse and its impact. *British Journal of Nursing*, 22(3), 168-169.	UK	Discussion/Opinion Piece	Not Applicable	Role of the CRN	Not Applicable
16	Hardicre, J. (2013) Developing research nurses: a structured taxonomic model. *British Journal of Nursing*, 22(7), 416-418.	UK	Empirical Study	Scoping Exercise	Education, Training & Development in relation to CRN role	Secondary Care
17	Hemingway B, Storey C (2013) Role of the clinical research nurse in tissue viability. *Nursing Standard.* 27, 24, 62-68	UK	Discussion/Opinion Piece	Not Applicable	CRN Perceptions and Experiences	Secondary Care
18	Hill, G. (2018) *Exploring Clinical Research Nurse's Experiences of working with Clinical Nurses*. Professional Doctorate Queen Margaret University.	UK	Empirical Study	Semi-structured Interviews	CRN Perceptions and Experiences	Secondary Care
19	Houlston, C. (2012) The role of a research nurse in translating evidence into practice. *Nursing Management (through 2013)*, 19(1), 25-8	UK	Discussion/Opinion Piece	Not Applicable	CRN Perceptions and Experiences	Secondary Care

20	Hyland, D. & Moloney, M. C. (2016) Spotlight on clinical research nursing. *World of Irish Nursing & Midwifery*, 24(3), 52-53.	UK	Discussion/Opinion Piece	Not Applicable	Role of the CRN	Not Applicable
21	Jones, H. (2017) *Exploring the experience of Clinical Research Nurses working within acute NHS trusts and determining the most effective way to structure the workforce: A mixed methods study* Doctorate in Nursing (Healthcare) Kings College London	UK	Empirical Study	Mixed Methods	CRN Team Structures	Secondary Care
22	Kunhunny, S. & Salmon, D. (2017) The evolving professional identity of the clinical research nurse: A qualitative exploration. *Journal of Clinical Nursing*, 26(23-24), 5121.	UK	Empirical Study	Focus Groups	CRN Perceptions and Experiences	Secondary Care
23	Larkin, M. E., Beardslee, B., Cagliero, E., Griffith, C. A., Milaszewski, K., Mugford, M. T., Myerson, J. M. Ni, W. Perry, D. J., Winkler, S. and Witte, E.R. (2019) Ethical challenges experienced by clinical research nurses: A qualitative study *Nursing Ethics* 26(1) 172–184	US	Empirical Study	Semi-structured Interviews	CRN Perceptions and Experiences	Secondary Care
24	Lawan, M. (2017) Trials and beyond: role of the cardiovascular research nurse British Journal of Cardiac Nursing 12 (4)	UK	Discussion/Opinion Piece	Not Applicable	Role of the CRN	Secondary Care

25	Ledger, T. (2008) Developing Clinical Research Nurses. *Nursing Management* 15 (2) 28-33	UK	Case Study	Scoping Exercise	Role of the CRN	Secondary Care
26	MacArthur, J., Hill, G. & Callister, D. (2014) Professional issues associated with the clinical research nurse role. *Nursing Standard*, 29(14), 37-43.	UK	Empirical Study	Questionnaire or Survey Design	Education, Training & Development in relation to CRN role	Multiple Settings
27	McCormack, B. (2004) Clinical Research Nurses should be involved in Nursing Research strategies of the future. *Nursing Times* 9 (1) 28-29	UK	Discussion/Opinion Piece	Not Applicable	Influencing perceptions of others/highlighting benefits of the CRN role	Secondary Care
28	McDermott S, Hathaway, K., Saunders, C. (2014) Developing good practice for clinical research nurses. *Nursing Standard.* 28, 26, 40-44.	UK	Narrative Review	Not Applicable	Role of the CRN	Secondary Care
29	McFadyen, J. & Rankin, J. (2017) The Role of Gatekeepers in Research: Learning from Reflexivity and Reflection. *GSTF Journal of Nursing and Health Care.* 4 (1)	UK	Discussion/Opinion Piece	Retrospective reflection	Gatekeeping	Not Applicable
30	National Institute for Health Research. (2016) The Role of the Clinical Research Nurse: In their own words. https://www.nihr.ac.uk/documents/the-role-of-the-clinical-research-nurse/11505	UK	Web page or Blog	Not Applicable	Role of the CRN	Multiple Settings

31	National Institute of Health Research (2019) Keep Making a Difference: Nurses and Midwives https://www.nihr.ac.uk/documents/keep-making-a-difference-nurses-and-midwives/22555#Keep_Making_a_Difference	UK	Web page or Blog	Not Applicable	Role of the CRN	Multiple Settings
32	Norton, C. (2015) Research nurses have a crucial role in delivering patient care. *Nursing Times* Vol 111(19)	UK	Discussion/Opinion Piece	Not Applicable	Role of the CRN	Secondary Care
33	Routlegde, J., Burns, M., Davidson, S. E., Johnson, K., Swindell, R., Khoo, V. (2003) The emerging role of the Cancer Research Nurse in promoting Evidence Based Care in Radiotherapy *European Journal of Cancer 1* (5) supplement 1139	UK	Conference Abstract (Oral)	Prospective and retrospective data review	Importance of Role of the CRN	Secondary Care
34	Smith S, Gullick J, Ballard J, Perry L. A proposed clinical research support career pathway for non-investigators. International Journal of Nursing Practice. 24 (e12641).	Australia	Discussion/Opinion Piece	Not Applicable	CRN Perceptions and Experiences	Tertiary
35	Spilsbury, K., Petherick, E. & Cullum, N. (2008) The role and potential contribution of clinical research nurses	UK	Empirical Study	Focus Groups	CRN Perceptions and Experiences	Secondary Care

	to clinical trials. *Journal of Clinical Nursing*, 17(4), 549-557.					
36	Stephens-Lloyd, A. (2004) The extended role of the clinical research nurse: Building an evidence base for practice. *Nursing Times* 9 (1) 18-27	UK	Discussion/Opinion Piece	Not Applicable	Role of the CRN	Secondary Care
37	Stephenson, J. (2017) Exclusive: New strategy will emphasise role played by research nurses *Nursing Times.* *https://www-nursingtimes-net.sheffield.idm.oclc.org/news/research-and-innovation/new-strategy-will-emphasise-role-played-by-research-nurses-07-09-2017/*	UK	Good News Story/Article	Not Applicable	Value, Visibility, Understanding and Awareness of CRN Role	Not Applicable
38	Thompson Hones, H., Palmer, G. and Whelan, S. (unable to identify year) Day in the life of a research nurse. located via http://www.wales.nhs.uk/sitesplus/documents/863/day%20in%20the%20life%20of%20a%20research%20nurse.pdf	UK	Discussion/Opinion Piece	Not Applicable	CRN Perceptions and Experiences	Secondary Care
39	Tinkler, L., Smith, V., Yiannakou, Y. & Robinson, L. (2018) Professional identity and the Clinical Research Nurse: A qualitative study exploring issues having an impact on participant recruitment in research. *Journal of Advanced Nursing*, 74(2), 318.	UK	Empirical Study	Focus Groups	CRN Perceptions and Experiences	Secondary Care

40	University of Oxford Health Experiences Research Group (2019) *Nurses, midwives & allied health professionals in research-research nurses and midwives experiences of working with clinical colleagues.* https://www.healthtalk.org/experiences-nurses-midwives-allied-health-professionals-research/research-nurses-midwives-and-ahps-experiences-of-working-with-clinical-colleagues	UK	Empirical Study	Semi-structured Interviews	CRN/Research active NMAHPs Perceptions and Experiences of working with clinical colleagues	Secondary Care
41	Whitehouse, C., Smith, H. A. (2018) The Whitehouse Report: Review of research nursing and midwifery structures, strategies and sharing of learning across the UK and Ireland in 2017. The Florence Nightingale Foundation	UK	Service Evaluation	Semi-structured Interviews	Review of Research Nursing and Midwifery CRN Team Structures, the role of the CRN, perceptions, experiences of CRNs and views of those outwith research roles	Multiple settings
42	Wytrykowski S (2019) Evaluation of a primary care clinical research nursing service. *Nursing Times* [online]; 115: 1, 30-32.	UK	Service Evaluation	Questionnaire or Survey Design	Role of the CRN	Primary Care

Appendix 4. RCN ViPER guidelines for session facilitators

What is a ViPER?

A ViPER is a novel approach to delivering research presentations for networking. It is an evaluation of Visual Presentation with Expert Review (ViPER).

It promotes interaction and discussion rather than the routine didactic approach used in the majority of conference presentations. The aim of a ViPER is to allow attendees to have an input to the work being presented: to provide constructive feedback, new ideas, a different viewpoint and hints and tips for future development. For presenters it allows them to raise the profile of their work and promote the research to potential future collaborators.

How a ViPER is delivered

1. A poster is developed and should be available to be viewed by attendees prior to the conference. We will be asking ViPER presenters to provide copies of their poster in advance of the conference as PDFs documents which will go on the website for delegates to view. A copy will also be sent to the session facilitator.

2. A4 copies of the poster will also be circulated to attendees at the start of the ViPER presentation.

3. The presenter displays their poster in the presentation room (poster boards will be set up in the room for this purpose). Presenters should then spend 5 minutes summarising the poster and use no more than 3 PowerPoint slides to do so. The summary may focus on the background, rationale, methodology, key findings and/or discursive key issues but not all issues/facts as presented in the poster.

4. The session facilitator will then verbally highlight 3 – 5 key themes/issues for consideration and for group discussion. The 'facilitators role is to encourage debate and discussion amongst the attendees and presenter for the remaining 20 minutes. You may also wish to spend a few minutes at the end to sum up the session's key points.

Preparation for the ViPER

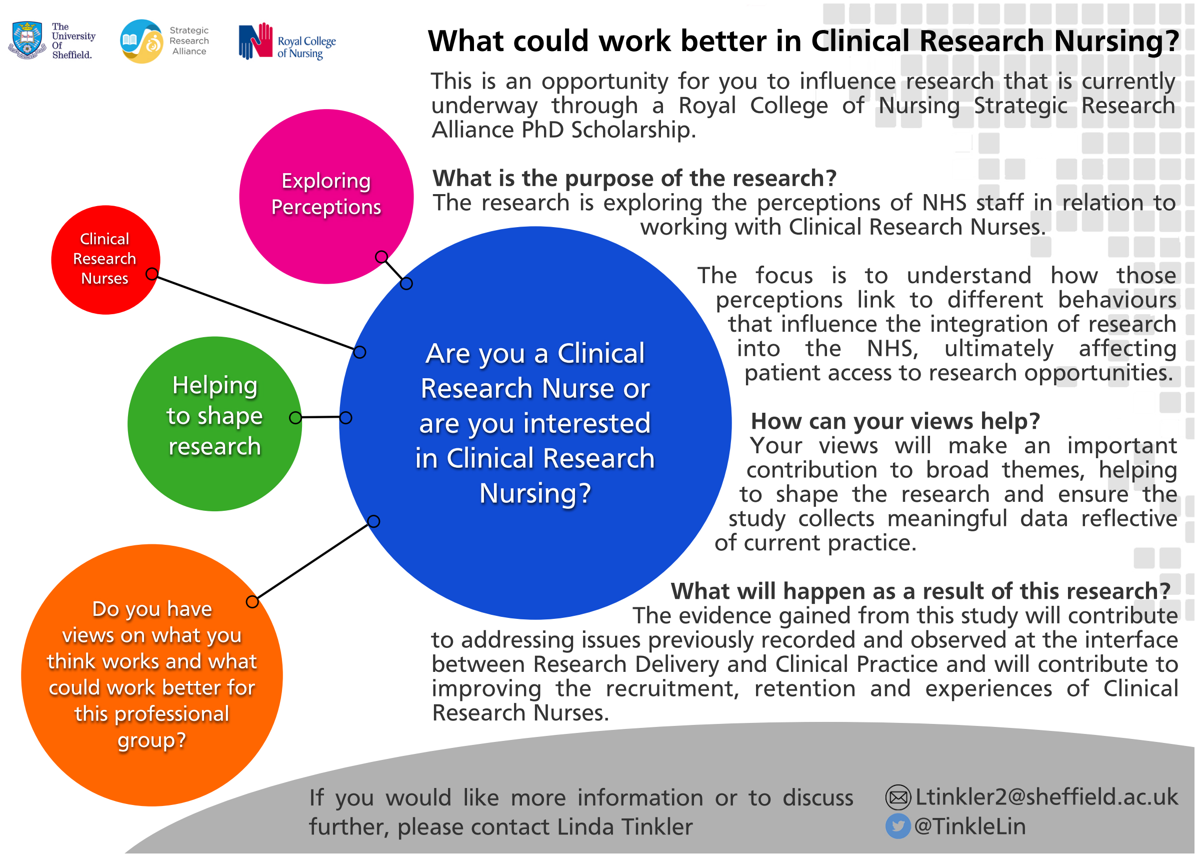
- The facilitator and the presenter(s) should meet either in person or by phone, to review the poster and agree the discussion points prior to the session commencing. This needs to take place ahead of the session and no less than 24 hours prior to the delivery of the ViPER.

- The facilitator should have a list of key themes/questions ready to stimulate debate and discussion, in case attendees ask no questions. The presenter should be able to assist with providing these.

- It is useful to consider 'lateral,' and/or topical issues as well as those presented in the poster and PowerPoint slides.

- Consider the use of open questions i.e. how, what, where are more likely to stimulate debate and/or discussion.

Appendix 5. ViPER session information leaflet



The University Of Sheffield

Strategic Research Alliance

Royal College of Nursing

What could work better in Clinical Research Nursing?

This is an opportunity for you to influence research that is currently underway through a Royal College of Nursing Strategic Research Alliance PhD Scholarship.

What is the purpose of the research?
The research is exploring the perceptions of NHS staff in relation to working with Clinical Research Nurses.

The focus is to understand how those perceptions link to different behaviours that influence the integration of research into the NHS, ultimately affecting patient access to research opportunities.

How can your views help?
Your views will make an important contribution to broad themes, helping to shape the research and ensure the study collects meaningful data reflective of current practice.

What will happen as a result of this research?
The evidence gained from this study will contribute to addressing issues previously recorded and observed at the interface between Research Delivery and Clinical Practice and will contribute to improving the recruitment, retention and experiences of Clinical Research Nurses.

Are you a Clinical Research Nurse or are you interested in Clinical Research Nursing?

Exploring Perceptions

Clinical Research Nurses

Helping to shape research

Do you have views on what you think works and what could work better for this professional group?

If you would like more information or to discuss further, please contact Linda Tinkler

✉ Ltinkler2@sheffield.ac.uk

@TinkleLin

Appendix 6. ViPER session poster

The University Of Sheffield.

Royal College of Nursing

Strategic Research Alliance

What could work better and in what context in Clinical Research Nursing?

A Realist Review to explore the factors influencing Multiprofessional perceptions of the CRN role

Linda Tinkler, Steve Robertson, Angela Tod, The University of Sheffield, RCN Strategic Research Alliance

Introduction & Background

The importance of clinical research in improving health outcomes is widely acknowledged.
The Clinical Research Nurse (CRN) role is a fundamental aspect of this agenda, yet the role remains broadly misunderstood outside of clinical research. Increasingly, evidence highlights the challenges faced by CRNs in practicing within their roles. The Realist Synthesis described here is the first part in a Royal College of Nursing (RCN) Strategic Research Alliance PhD Scholarship.

Methods

A realist synthesis was undertaken to explore what insights there are into causal mechanisms that influence how Clinical Research Delivery is perceived by healthcare professionals. The synthesis also explored how the resulting outcomes impacted on the experiences of Clinical Research Nurses, their practice and broader capacity to ensure successful patient recruitment to research in the NHS.

Evidence was searched for surrounding an initial middle range programme theory:

If there are social barriers present in the wider clinical environment, then this may impact on the ability of key colleagues to enable, support and promote research in their clinical area. This may negatively impact on working relationships at the interface between the CRN and key colleagues out with the research team, damaging the morale and job satisfaction of CRNs and reducing capacity to deliver research and provide opportunities to patients as part of their clinical pathway.

Initial scoping searches included the Cochrane Library of Systematic Reviews(n=1), BNI/CINAHL/HMIC(n=21) grey literature including The King's Fund(n=3) The Health Foundation(n=2) and theses (n=4), with iterative snowball searching continuing as appropriate to the realist methodology.

CMO #1

In the context where key colleagues are not aware of the importance, value and utility of research to their role, the patients in their care, or the wider NHS, then they may be unaware of the impact of their behaviours on the CRN and the wider research agenda (M), leading CRNs to feel undervalued, unwelcome and invisible, thereby hindering positive working relationships and reducing access to research opportunities for patients (O)

CMO #2

In the context where key colleagues do not understand the importance, value and utility of research to either their role or the patients in their care, then they may display active resistance to research being delivered (M) in their clinical area, this may lead CRNs to feel undervalued, unwelcome and invisible, thereby hindering positive working relationships and reducing access to research opportunities for patients (O)

CMO #3

In the context where key colleagues do not understand the importance, value and utility of research to either their role or the patients in their care, then they may display avoidance in relation to research being delivered in their clinical area (M), this may lead CRNs to feel undervalued, unwelcome and invisible, thereby hindering positive working relationships and reducing access to research opportunities for patients (O)

Programme Theory

If key colleagues do not understand the importance, value and utility of research to their role, their patients, or the wider NHS agenda then they may inadvertently display avoidance of or resistance to research being delivered in their clinical area, thereby hindering positive working relationships with CRNs and reducing access to research opportunities for patients.

Results

Through a process of retroduction, published and un-published evidence on the range of causal mechanisms impacting on Multiprofessional individual, team and organisational perceptions of research, were used to refine the intial middle range programme theory. The example programme theory presented provides insight into what could work better (and what doesn't work), in what context in relation to the CRN role. Evidence related to perceived social barriers and the perceptions of Multiprofessional colleagues including the resulting behaviours at the interface between CRNs and their colleagues, demonstrates how a lack of visibility, awareness, interest and understanding of research at individual, team and organisational level can affect organisational culture in relation to research. Each element, has the potential to impact on CRN experiences, affecting morale and job satisfaction, affecting their ability to successfully deliver research.

Conclusion

Realist synthesis is a useful method to explore the challenges perceived in this professional group. Insight is provided into the various complexities and resulting behaviours associated with levels of Multiprofessional visibility, awareness, understanding and interest in clinical research in the NHS. The synthesis facilitates additional understanding of important contextual factors and causal mechanisms to be further considered and tested in the resulting realist evaluation.

References

1. Emmel, N., Greenhalgh, J., Manzano, A., Monaghan, M. And Dalkin, S. (2018) Doing Realist Research. London: Sage
2. Hill, G. (2019) 'Exploring Clinical Research Nurses' Experiences of Working With Clinical Nurses' Professional Doctorate Thesis, Queen Margaret University, Edinburgh
3. Tinkler, L., Smith, V., Yiannakou, Y., Robinson, L. (2018) Professional identity and the Clinical Research Nurse: A qualitative study exploring issues impacting on participant recruitment in research. Journal of Advanced Nursing 74(2):318-328 DOI: https://doi.org/10.1111/jan.13409
4. NIHR 2016 The Role of the Clinical Research Nurse- In their own words. Available at: https://www.nihr.ac.uk/documents/the-role-of-the-clinical-research-nurse/11505#THE_ROLE_OF_THE_CLINICAL_RESEARCH_NURSE-_In_their_own_words
5. Hemingway B, Storey C (2013) Role of the clinical research nurse in tissue viability. Nursing Standard. 27 (24) 62-68.

Appendix 7. ViPER session content and discussion plan

Brief Intro and background, 1-2 mins inc. previous research in this area

PhD - Realist Methods, time does not enable us to go into full detail but useful methodology in healthcare as it acknowledges the reality and inherent complexity of implementing programmes (and roles in this case) in the NHS.

Theory driven approach, a unique paradigm (different from empirical orthodox positivist) instinct, hunches, lived experience, expertise in the area all acceptable in developing theories

Evidence informed rather than evidence based (Shift in my thinking!)

Enables researcher to use retroduction which is the activity of searching for or unearthing the underlying causal mechanisms that lead to different outcomes

This all depends on the context of implementation

Overarching question for Realist Review was:

> *What insights are there regarding causal mechanisms that can influence how Clinical Research Delivery is perceived by healthcare professionals and what are the resulting impacts on Clinical Research Nurse experiences and practice and capacity to ensure successful patient recruitment to research in the NHS?*

Evidence was searched for and collected surrounding what we call middle range programme theories, these are general theory statements that do not necessarily provide specific causal mechanisms but enable us to cast our net wide to understand more about the programme (or role in this case). In the interests of time, today will focus on one tiny aspect of the work which looked at social barriers in delivering research as my previous research has led me to be interested in the interface between CRNurses and other professional colleagues:

You can find the MRT on the left-hand side in bold with green shading behind it

> *If there are social barriers present in the wider clinical environment, then this may impact on the ability of key colleagues to enable, support and promote research in their clinical area. This may negatively impact on the morale and job satisfaction of CRNurses and working relationships at the interface between the CRNurse and key colleagues out with the research team, reducing capacity to deliver research and provide opportunities to patients as part of their clinical pathway.*

I would like us to use today’s time to unpack the possible social barriers using the more refined Programme Theory and the associated Context Mechanism Outcome configurations that have resulted from the lit review, again we have just one to look at and discuss today in the interests of time.

Programme Theory is in the left blue circle and the associated specific Context, Mechanism, Outcome configurations are in the green, orange and red circles. These are not exhaustive but merely a snapshot for today's session. The CMOs help to unpack and understand the broader programme theory, enabling a deeper understanding of the underlying mechanisms at work in the implementation of this role.

Three CMOs due to differences between unconscious behaviours impacting on the CRNurseurse, avoidance behaviours and active resistance behaviours. It appears all three are evident in the literature depending on the context (at this stage I feel the context is mediated or actually is culture, leadership, personal preferences, behaviour styles, Micro, Meso, Macro level mechanisms going on etc. to be unpacked further in the PhD).

1. Is there a CMO that you felt you can relate to or identify with?
2. Or one that gave you antibodies?
3. Social barriers may include lots of different things can we use these to unpack and enhance the discussion?

- CRNurse related in terms of their characteristics, background, experience, confidence and communicative approach to their healthcare colleagues
- Healthcare colleagues outside of research related:
- Fear of increased workload
- Awareness of research
- Understanding of research
- Visibility of research at micro, meso, macro levels
- Views about specific studies and their value to patients
- Gatekeeping behaviours (paternal or advocacy?)
- Personal values, preferences and beliefs about research
- Previous experiences or opinions about research
- Ability to demonstrate or remain in equipoise
- Own workload/own agenda (including prioritisation of "care"),
- Incentives culture
- Views and assumptions about the CRNurse role
- Target based culture

Summarise themes from session

Thank you for discussion and input. Based on this small aspect of the work and the many opportunities to take this to the next step, where do you feel we should look next?

NHS Culture as a whole?

Leadership (lots to be found in leadership lit related to these concepts)?

Characteristics of individuals both CRNurse and others (Leadership, behaviours etc.)?

Look at the interface between CRNurse/HCPs and observe the different mechanisms?

Appendix 8. Participant information leaflet

Participant Information Sheet

1. Research Project Title.

Exploring the interface between **Re**search delivery and clinical practice. Grou**p** concept mapping the factors influencing multip**r**ofessional p**e**rception**s** of r**e**search delivery a**n**d the impac**t** on **C**linical **R**esearch **N**ursing in the nhs. (Represent-CRN Study)

2. Invitation paragraph.

You are invited to participate in this study using a process called group concept mapping, to generate, sort and rate your views on the delivery of clinical research in the nhs.

Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This study is aimed at generating, sorting and rating themes on how **Clinical Research Nursing and research delivery** is perceived by healthcare professionals operating outside of clinical research teams within NHS organisations. **This study is not exploring views regarding nurse led research or research generated by nurses as part of their clinical roles.**

Clinical Research is an important part of the care pathway for our patients. By exploring how research delivery is currently viewed by those practicing separate from, y*et al*ongside research delivery roles, we hope to shed light on the mechanisms that lead to different perceptions of research and identify potential solutions to address ongoing challenges.

The aim is to identify how research delivery is best implemented in the NHS and to enable more patients to have the opportunity to participate in research that is relevant to their health. The information being collected as part of this study will be kept confidential and as such individual participants will not be identified in any publication arising from it.

Please take enough time to read this information carefully.

If you have any questions about this piece of research, please contact

Linda Tinkler (Researcher) ltinkler2@sheffield.ac.uk

3. What is the project’s purpose?

This study is part of a doctoral training programme funded by the Royal College of Nursing (Strategic Research alliance https://www.rcn.org.uk/professional-development/research-and-innovation/research-alliance-with-university-of-sheffield) and sponsored by the University of Sheffield Department of Nursing and Midwifery. The overall study is expected to last for approximately 9 months.

The purpose of this research is to explore the views of NHS staff operating outside of Clinical Research teams, in relation to the Clinical Research Nurse role and research delivery. By exploring your views, we hope to shed light on the mechanisms leading to the different perceptions of research

4. Why have I been chosen?

You have been chosen because your clinical role means that you are likely to interact with Clinical Research Nurses (CRNs) delivering research studies. These interactions may influence how the research projects are delivered in your organisation and how successful they are. Other staff in similar roles, are also being invited to participate. Your participation will help to improve how healthcare professionals understand of the role of the CRN, and how different perceptions can impact upon the practice of CRNs and clinical teams. The results of this study will be used to contribute to existing evidence, but also to specifically identify areas for support, change and or development to help CRN teams in the future. The results will also be developed to inform further research.

5. Do I have to take part in the study?

You are under no obligation to participate in the study. It is entirely your decision whether you choose to take part or not. If you do decide to take part, you are free to change your mind and discontinue your participation at any time, without giving a reason. If you decide not to take part or to withdraw at any time during the study your legal rights will not be affected by this decision.

6. What will happen to me if I take part? What do I have to do?

This study will involve three stages of participation via a web-based interface. To do this, you will be asked to register with an email address of your choice. You should be aware that if you choose to use a work email address there is a chance that you and potentially your organisation will be identifiable, due to the first name or initial and surname and set up of nhs email addresses. This information is used only for the purposes of contacting you about participation in the study and is not included in any data analysis or publication. The following demographic data will be collected at the beginning: your profession, specific role, highest level of qualification, band, clinical specialty or area of practice, and your level of awareness of research being delivered in your clinical area.

Stage 1 Ideas generation

You will be invited to respond to a single statement called a focus prompt. This is in the form of an open-ended sentence. You will be encouraged to complete the sentence repeatedly until all of your views on the topic have been expressed.

Following completion of this activity, the statements submitted by all participants will be analysed by the researcher, supported by discussion with the PhD supervisory team. A structured process will be followed to remove duplicate statements and to ensure that all views collected are accurately reflected. The aim of this is to consolidate the range of statements into a manageable set, ensuring all views collected are represented, but without duplication. The resulting full set of statements is then prepared by the researcher and shared with you again to enable you to participate in the next stage.

Stage 2. Organising (sorting and rating)

You will be invited to undertake two activities during this stage. The first will involve examining the set of statements and sorting them into groups (themes) of your choosing, based on where you feel particular statements are similar or different to each other. There is no set (right or wrong) approach to this, you will be free to sort in any way you see fit.

You will then be asked to rate each statement according to your perceptions of how important each is in direct relation to the success of clinical research delivery in your organisation and the subsequent potential impact of each on successful delivery of clinical research, i.e. *How important is each of these views, and what is the potential impact of each view on the success of research delivery in my organisation?*

Each rating activity will be completed using a simple 4-point rating scale.

The data resulting from the stages described above will then be used by the researcher to construct a range of visual representations, illustrating the sorted statements, similarities and disparities, and participant views on importance and impact. The analysis and representation will be undertaken using the Group Wisdom, Concept Systems Global© software package.

Stage 3. Interpretation and planning

In this stage, visual representations of the analysis will be shared with you. You will be asked to provide further feedback. This stage of the research is important both to enable a deeper understanding of the collective views and to inform the resulting recommendations.

7. What are the possible disadvantages and risks of taking part?

Because of the nature of the study, we do not expect there to be any risk of harm, or injury whilst participating.

8. What are the possible benefits of taking part?

Whilst there are no immediate benefits for people participating in the project, it is hoped that you may find that sharing experiences in relation to your perceptions and understanding of research and seeing the views of other professionals in your field is beneficial. This may inform your practice and understanding of the role of the Clinical Research Nurse, however, this cannot be guaranteed. Your participation in this study will contribute to addressing important issues in relation to the implementation of the CRN role and will contribute to an increasing body of literature related to the delivery of research in the NHS. Your contribution may also positively impact on the future development of the role.

9. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential and will only be accessible to members of the research team. You will not be able to be identified in any reports or publications. If you agree to us sharing the information you provide with other researchers (e.g. by making it available in a data archive) then your personal details will not be included unless you explicitly request this.

10. What is the legal basis for processing my personal data?

We will need to use information from you for this research project. Personal information about you will be collected only for the purposes of conducting the research. This information will be limited to the email address you choose to use and will only be used to contact you about your participation during the study. We will also ask you to tell us your profession, role and specific area of practice/specialty. This information will aid the researcher in the data analysis; however, it will remain anonymous.

We will keep all information about you safe and secure. Your personal information (email address) will be deleted at the point of data analysis. According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice https://www.sheffield.ac.uk/govern/data-protection/privacy/general

11. What will happen to the data collected and the results of the research project?

Your participation in the study will remain confidential. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

At the point where the study is completed, written up and submitted for publication, anonymised study related data will be stored securely as described above for a 10-year period as set out in the University's Standard Operating Procedure for archiving of research data. This is to permit any subsequent inspection of study findings due to questions or queries. After this period, all information will be destroyed.

In certain circumstances your study data may be looked at by authorised members of the University of Sheffield, or regulatory bodies, for the purpose of checking that the research study is being carried out properly.

Due to the nature of this research, it is very likely that other researchers may find the data collected to be useful in answering future research questions. We will ask for your explicit consent for your data to be shared in this way.

12. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

The results of this study will be written up forming part of a Doctoral Thesis. The study will also be written up and submitted to peer reviewed journals and presented at relevant conferences.

13. Who is organising and funding this research?

This study is being organised and undertaken by the researcher Linda Tinkler. Linda has a background in researching the role of the CRN and Research delivery in the NHS and is a Trust Lead for Nursing, Midwifery and AHP Research in a large NHS Foundation Trust in the North East of England. Linda has been awarded funding from the Royal College of Nursing Strategic Research Alliance with The University of

Sheffield to carry out the project. The University of Sheffield is sponsoring this study.

Linda has more than 10 years' experience of developing, leading and delivering clinical research, and also has experience in undertaking qualitative research. She is being supported through this project by Professor Angela Tod, a Professor of Older People and Care at the University of Sheffield. Linda is also being supported by Dr Steven Robertson from the University of Sheffield.

14. Who is the Data Controller?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

15. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by asking the researcher, Linda Tinkler
- by sending an email to dataprotection@sheffield.ac.uk

16. Who has ethically reviewed the project?

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the Department of Nursing and Midwifery.

17. What if something goes wrong and I wish to complain about the research?

If you have any questions, concerns or complaints about any aspect of the research study, you should speak to the researcher.

Linda Tinkler BSc (Hons), MClinRes (Leadership), RN
Post Graduate Researcher
The Department of Nursing and Midwifery
The University of Sheffield
Barber House Annexe
3a Clarkehouse Road
Sheffield
S10 2LA
Ltinkler2@sheffield.ac.uk

You may also wish to contact Linda’s Supervision Team:

Professor Angela Tod
The Department of Nursing and Midwifery
The University of Sheffield
Barber House Annexe
3a Clarkehouse Road
Sheffield
S10 2LA
a.tod@sheffield.ac.uk

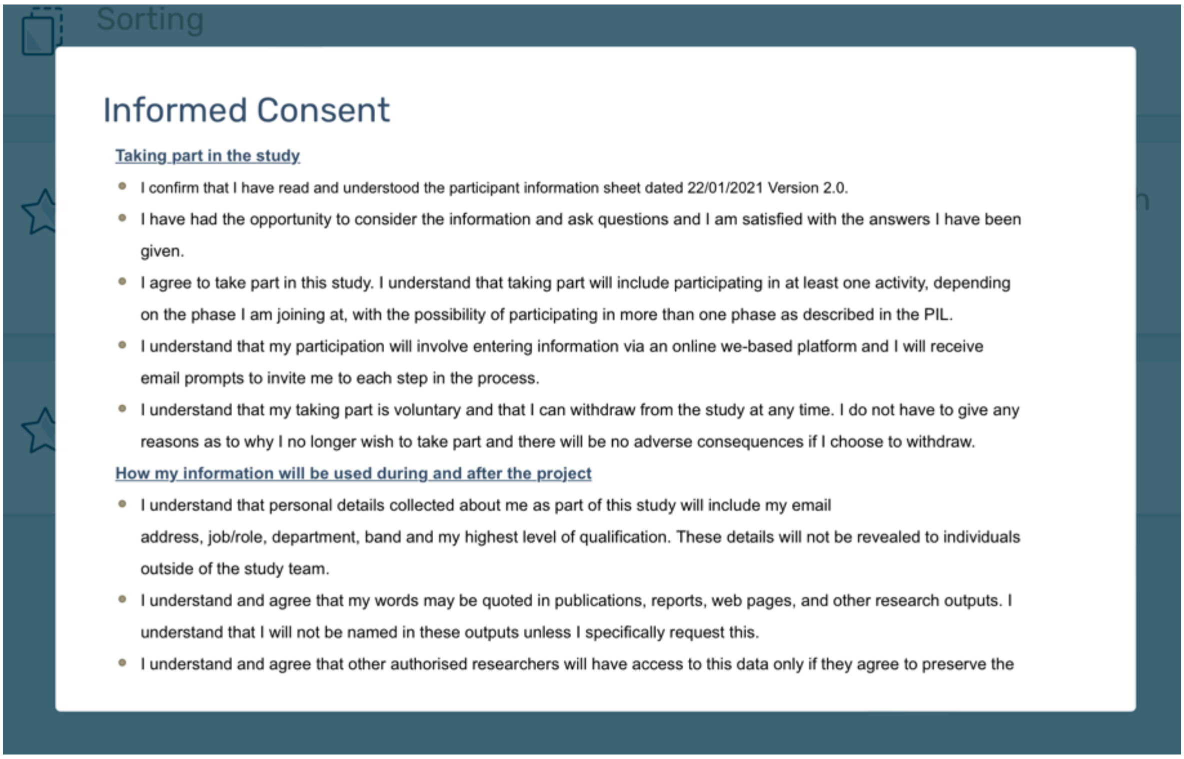
Dr Steve Robertson
The Department of Nursing and Midwifery
The University of Sheffield
Barber House Annexe
3a Clarkehouse Road
Sheffield
S10 2LA
s.robertson@sheffield.ac.uk

However, if you feel that your questions or complaint have not been addressed satisfactorily you can contact the Head of Department Professor Tony Ryan on: t.ryan@sheffield.ac.uk who will then escalate the complaint through the appropriate channels. If your complaint relates to how your personal data has been handled, you can contact Anne Cutler, The University of Sheffield Data Protection Officer dataprotection@sheffield.ac.uk Further information about how to raise a complaint can also be found in the University's Privacy Notice: https://www.sheffield.ac.uk/govern/data-protection/privacy/general If you feel your complaint has not been handled to your satisfaction, you can contact the Information Commissioner's Office.

I have read the information, what do I do next?

If you would be happy to participate in this part of the study, **we will ask you to log on to the data collection software here where you will be asked to create an account and indicate your consent to participate.** We would like to thank you for taking the time to read this information. Please download and keep this information sheet for your records

Appendix 9. Consent statements and downloadable form



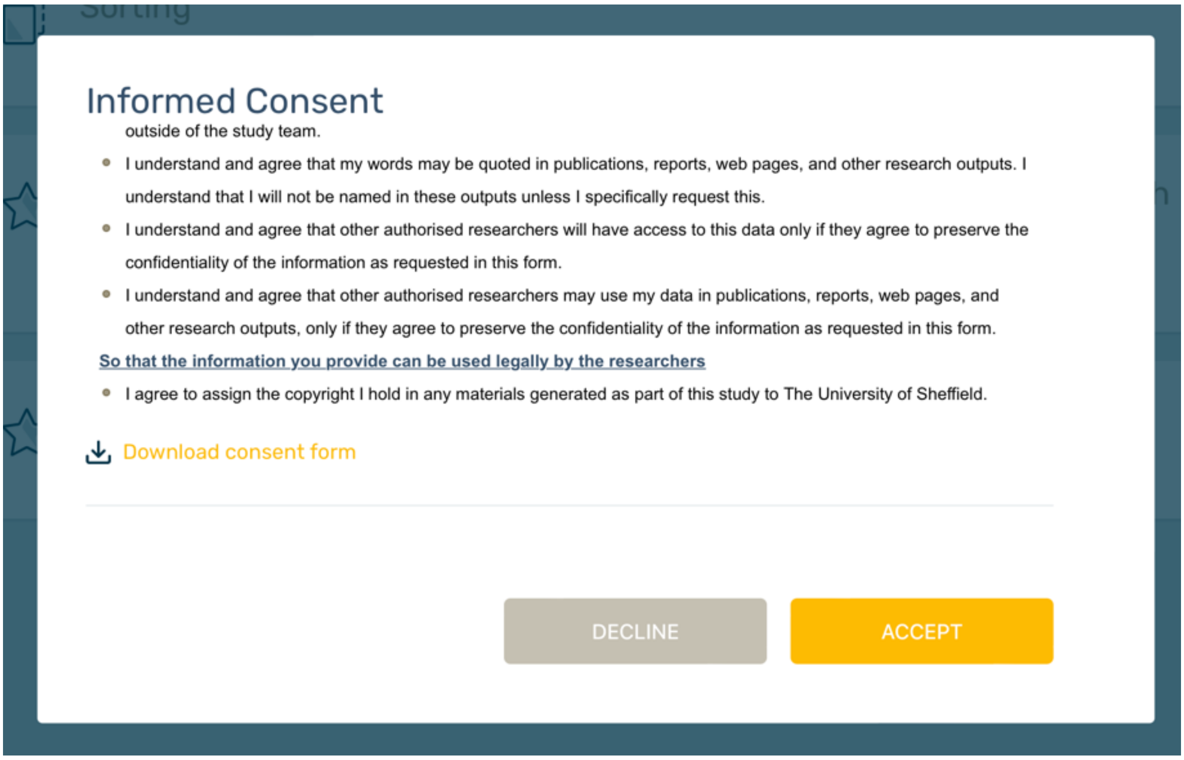
Informed Consent

Taking part in the study

- I confirm that I have read and understood the participant information sheet dated 22/01/2021 Version 2.0.
- I have had the opportunity to consider the information and ask questions and I am satisfied with the answers I have been given.
- I agree to take part in this study. I understand that taking part will include participating in at least one activity, depending on the phase I am joining at, with the possibility of participating in more than one phase as described in the PIL.
- I understand that my participation will involve entering information via an online we-based platform and I will receive email prompts to invite me to each step in the process.
- I understand that my taking part is voluntary and that I can withdraw from the study at any time. I do not have to give any reasons as to why I no longer wish to take part and there will be no adverse consequences if I choose to withdraw.

How my information will be used during and after the project

- I understand that personal details collected about me as part of this study will include my email address, job/role, department, band and my highest level of qualification. These details will not be revealed to individuals outside of the study team.
- I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs. I understand that I will not be named in these outputs unless I specifically request this.
- I understand and agree that other authorised researchers will have access to this data only if they agree to preserve the



Informed Consent

outside of the study team.

- I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs. I understand that I will not be named in these outputs unless I specifically request this.
- I understand and agree that other authorised researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.
- I understand and agree that other authorised researchers may use my data in publications, reports, web pages, and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.

So that the information you provide can be used legally by the researchers

- I agree to assign the copyright I hold in any materials generated as part of this study to The University of Sheffield.

CONSENT FORM:

Exploring the interface between **Re**search delivery and clinical practice. Grou**p** concept mapping the factors influencing multip**r**ofessional p**e**rception**s** of r**e**search delivery a**n**d the impac**t** on **C**linical **R**esearch **N**ursing in the nhs. (Represent-CRN Study)

Check boxes to be completed via the web-based platform

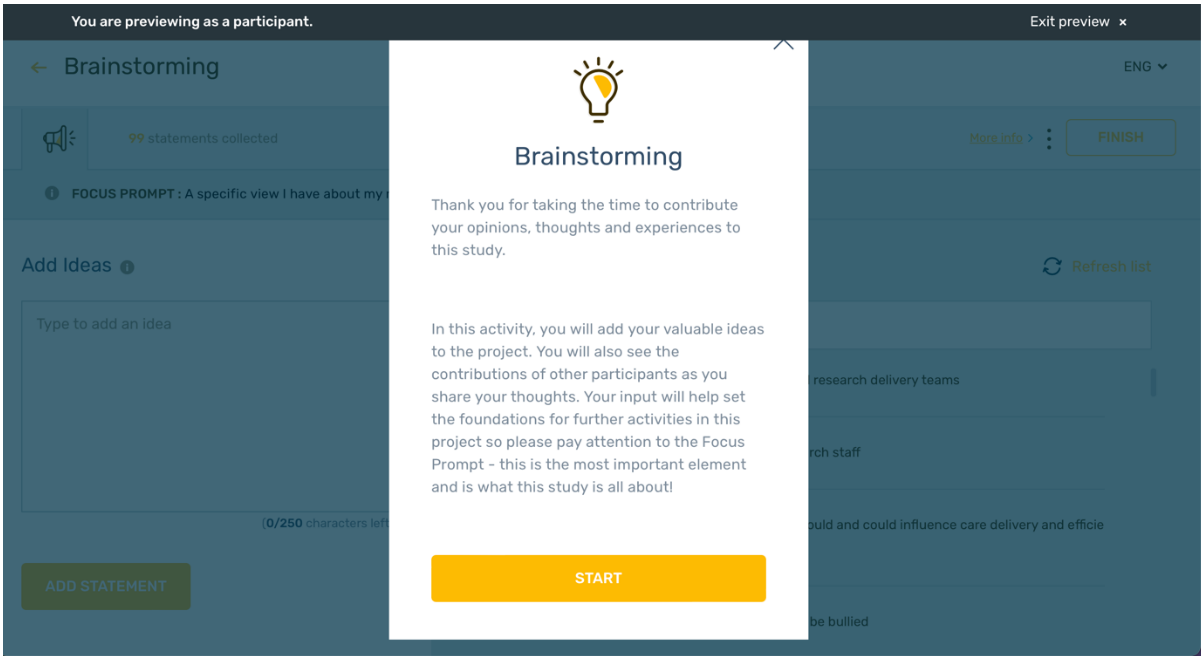
Taking part in the study	
I confirm that I have read and understood the participant information sheet dated 22/01/2021 Version 2.0.	☐
I have had the opportunity to consider the information and ask questions and I am satisfied with the answers I have been given.	☐
I agree to take part in this study. I understand that taking part will include participating in at least one activity, depending on the phase I am joining at, with the possibility of participating in more than one phase as described in the PIL.	☐
I understand that my participation will involve entering information via an online we-based platform and I will receive email prompts to invite me to each step in the process.	☐
I understand that my taking part is voluntary and that I can withdraw from the study at any time. I do not have to give any reasons as to why I no longer wish to take part and there will be no adverse consequences if I choose to withdraw.	☐
How my information will be used during and after the project	
I understand that personal details collected about me as part of this study will include my email address, job/role, department, band and my highest level of qualification. These details will not be revealed to individuals outside of the study team.	☐
I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs. I understand that I will not be named in these outputs unless I specifically request this.	☐
I understand and agree that other authorised researchers will have access to this data only if they agree to preserve the confidentiality of the information as requested in this form.	☐
I understand and agree that other authorised researchers may use my data in publications, reports, web pages, and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.	☐
So that the information you provide can be used legally by the researchers	
I agree to assign the copyright I hold in any materials generated as part of this study to The University of Sheffield.	☐

Consent indicator then completed online by typing name into web-based platform.

Name of Participant **Date** **Signature**

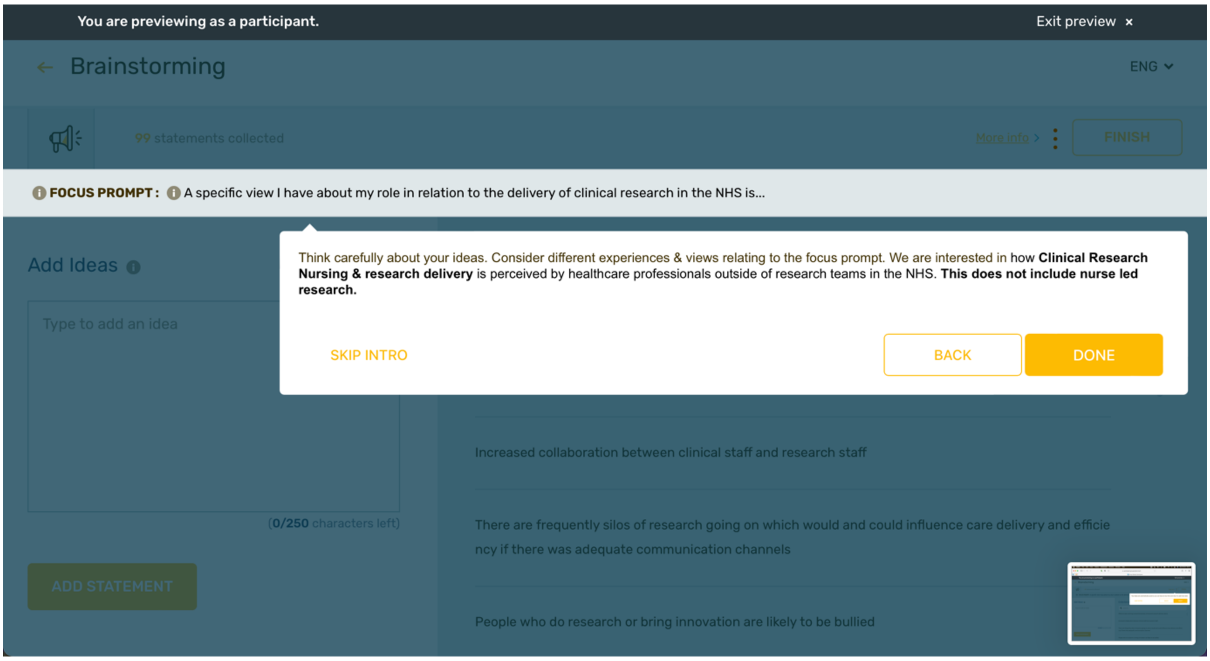
Appendix 10. Screenshots of GCM web-based platform (participant interface)

Ideas generation stage



Thank you for taking the time to contribute your opinions, thoughts and experiences to this study.

In this activity, you will add your valuable ideas to the project. You will also see the contributions of other participants as you share your thoughts. Your input will help set the foundations for further activities in this project so please pay attention to the Focus Prompt - this is the most important element and is what this study is all about!



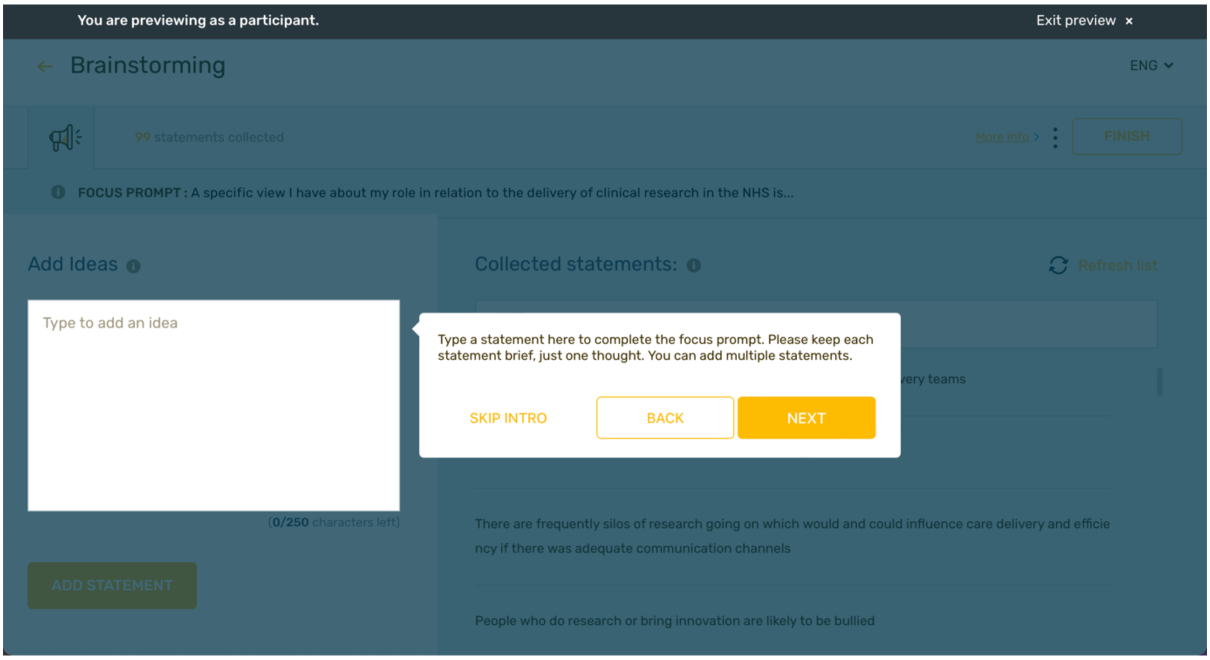
FOCUS PROMPT : A specific view I have about my role in relation to the delivery of clinical research in the NHS is...

Think carefully about your ideas. Consider different experiences & views relating to the focus prompt. We are interested in how **Clinical Research Nursing & research delivery** is perceived by healthcare professionals outside of research teams in the NHS. **This does not include nurse led research.**

Increased collaboration between clinical staff and research staff

There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels

People who do research or bring innovation are likely to be bullied



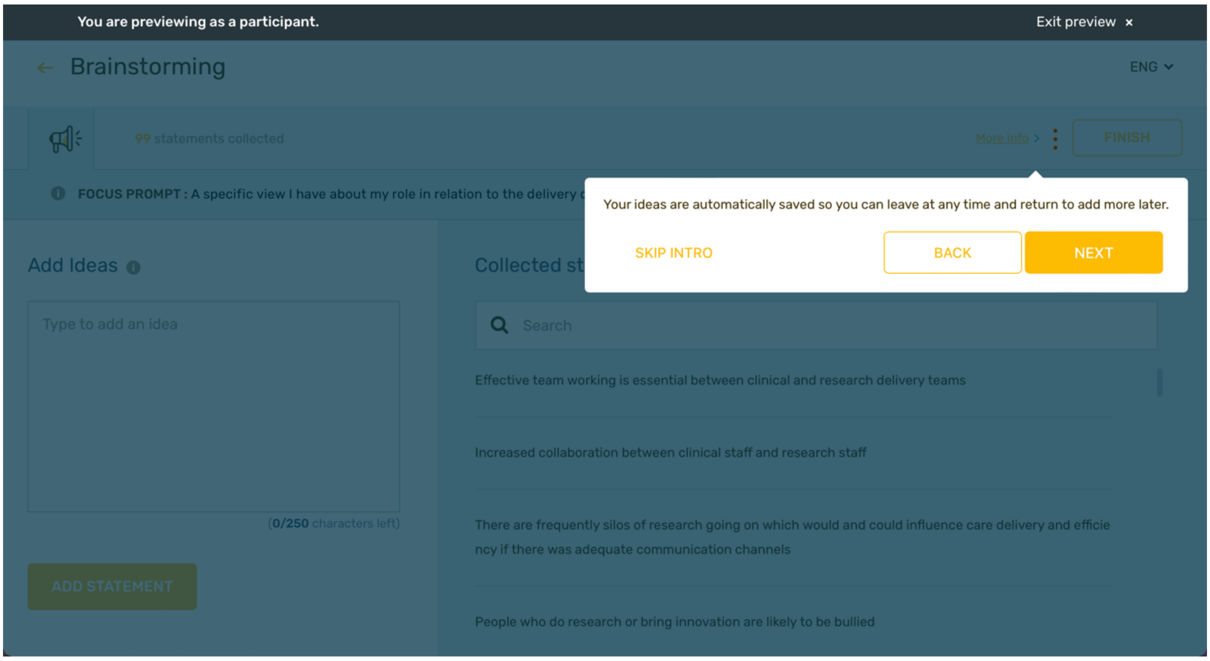
You are previewing as a participant.

FOCUS PROMPT : A specific view I have about my role in relation to the delivery of clinical research in the NHS is...

Type a statement here to complete the focus prompt. Please keep each statement brief, just one thought. You can add multiple statements.

There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels

People who do research or bring innovation are likely to be bullied



You are previewing as a participant.

FOCUS PROMPT : A specific view I have about my role in relation to the delivery

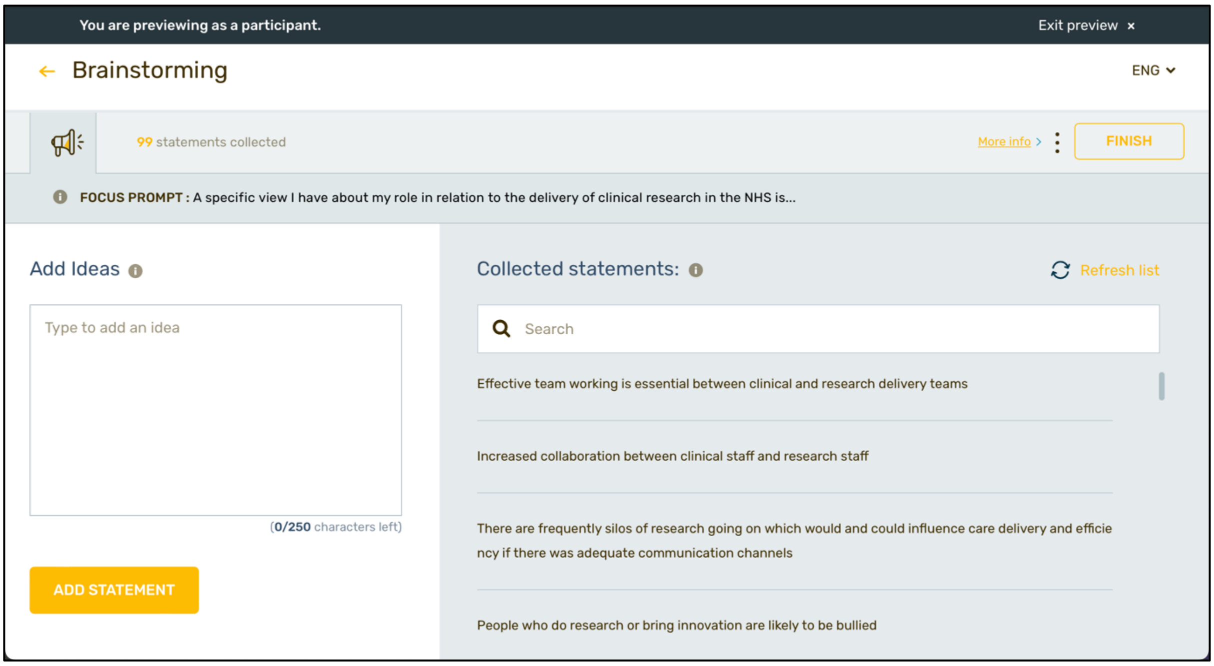
Your ideas are automatically saved so you can leave at any time and return to add more later.

Effective team working is essential between clinical and research delivery teams

Increased collaboration between clinical staff and research staff

There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels

People who do research or bring innovation are likely to be bullied



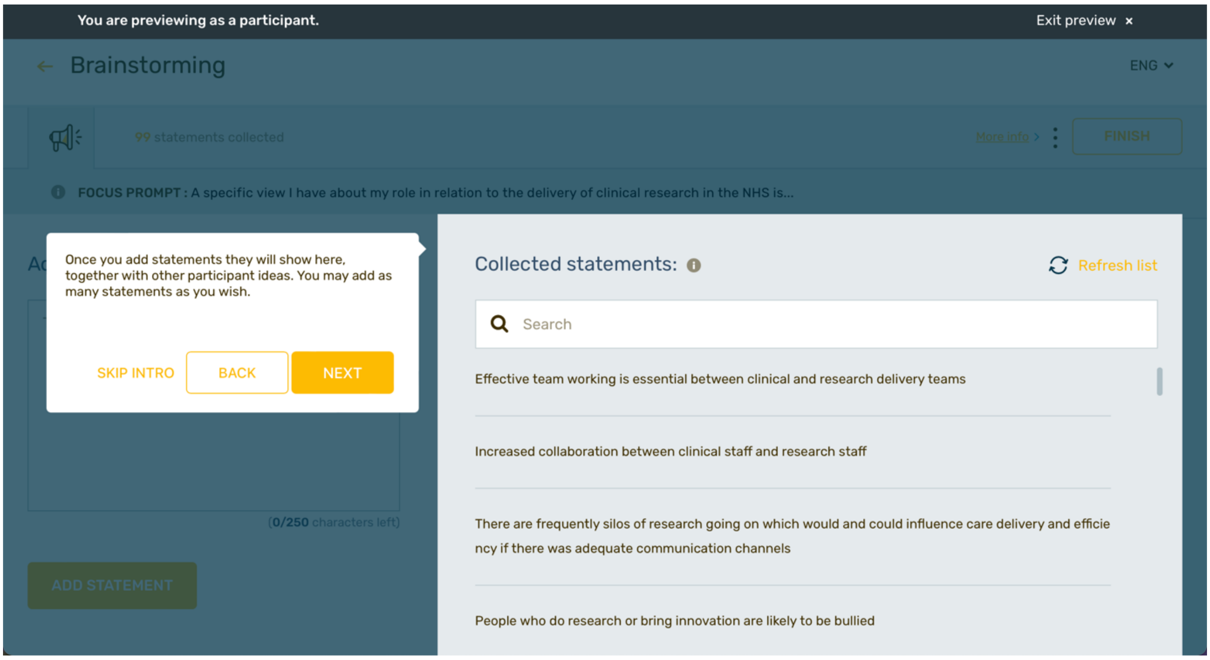
FOCUS PROMPT : A specific view I have about my role in relation to the delivery of clinical research in the NHS is...

Effective team working is essential between clinical and research delivery teams

Increased collaboration between clinical staff and research staff

There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels

People who do research or bring innovation are likely to be bullied



FOCUS PROMPT : A specific view I have about my role in relation to the delivery of clinical research in the NHS is...

Once you add statements they will show here, together with other participant ideas. You may add as many statements as you wish.

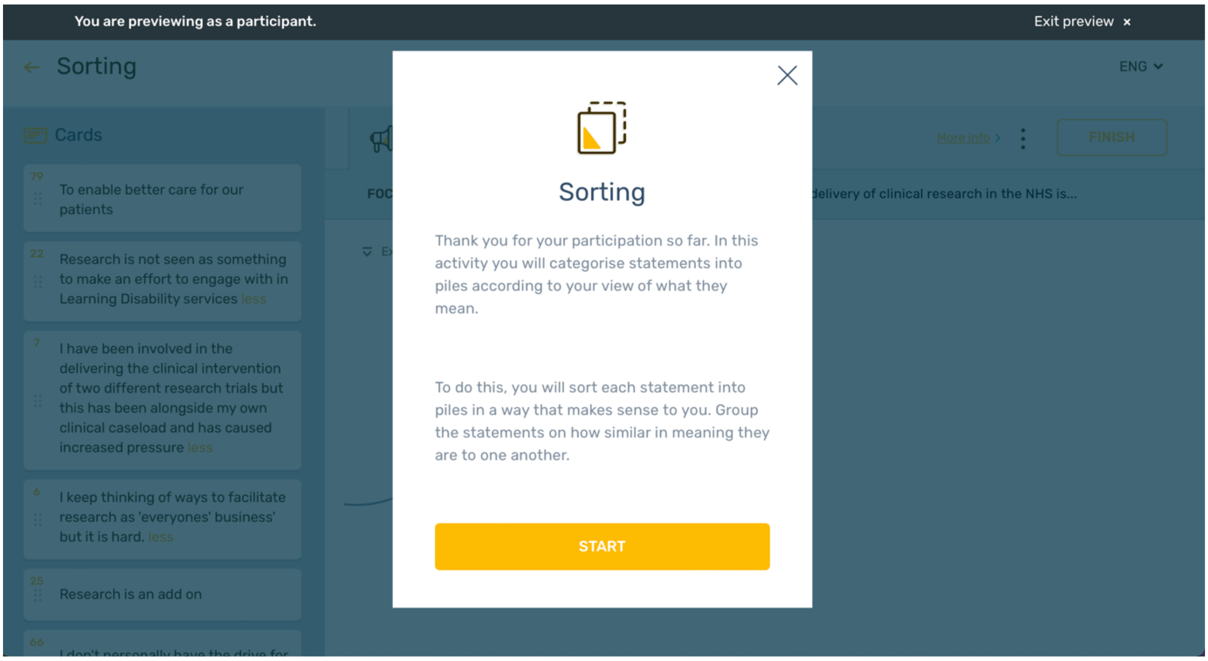
Effective team working is essential between clinical and research delivery teams

Increased collaboration between clinical staff and research staff

There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels

People who do research or bring innovation are likely to be bullied

Sorting activities



79 To enable better care for our patients

22 Research is not seen as something to make an effort to engage with in Learning Disability services less

7 I have been involved in the delivering the clinical intervention of two different research trials but this has been alongside my own clinical caseload and has caused increased pressure less

6 I keep thinking of ways to facilitate research as 'everyones' business' but it is hard. less

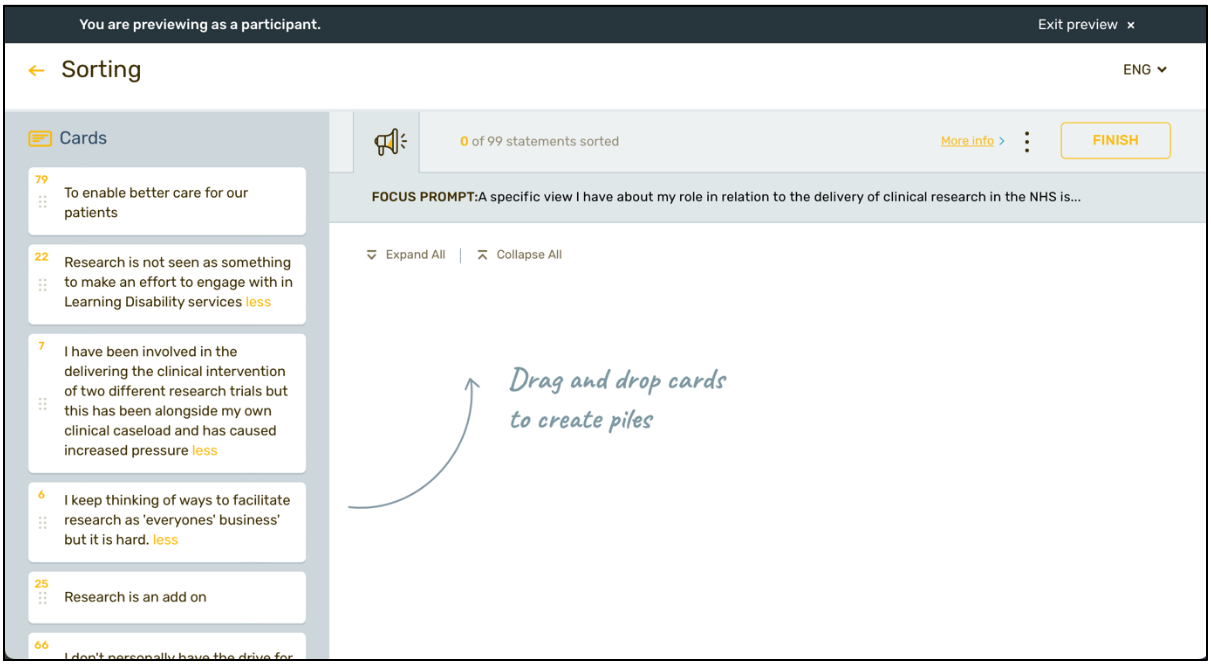
25 Research is an add on

66 I don't personally have the drive for

Sorting

Thank you for your participation so far. In this activity you will categorise statements into piles according to your view of what they mean.

To do this, you will sort each statement into piles in a way that makes sense to you. Group the statements on how similar in meaning they are to one another.



79 To enable better care for our patients

22 Research is not seen as something to make an effort to engage with in Learning Disability services less

7 I have been involved in the delivering the clinical intervention of two different research trials but this has been alongside my own clinical caseload and has caused increased pressure less

6 I keep thinking of ways to facilitate research as 'everyones' business' but it is hard. less

25 Research is an add on

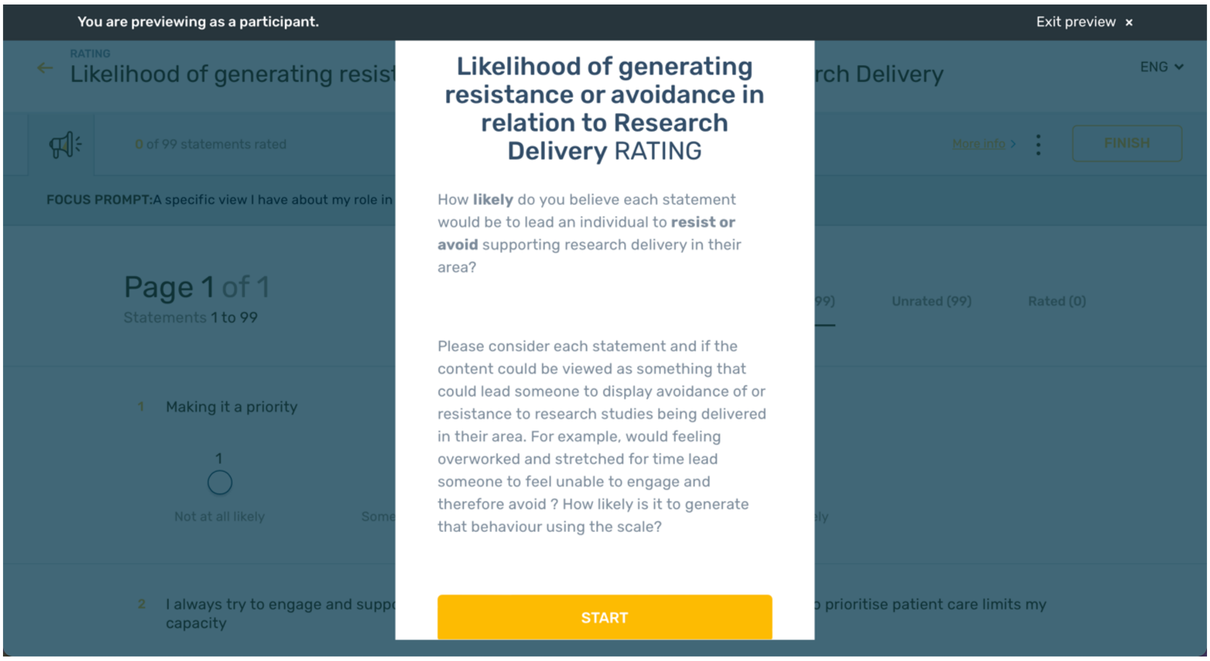
66 I don't personally have the drive for

0 of 99 statements sorted

FOCUS PROMPT: A specific view I have about my role in relation to the delivery of clinical research in the NHS is...

Rating activities

Likelihood of generating avoidance or resistance behaviours



FOCUS PROMPT:A specific view I have about my role in

1 Making it a priority

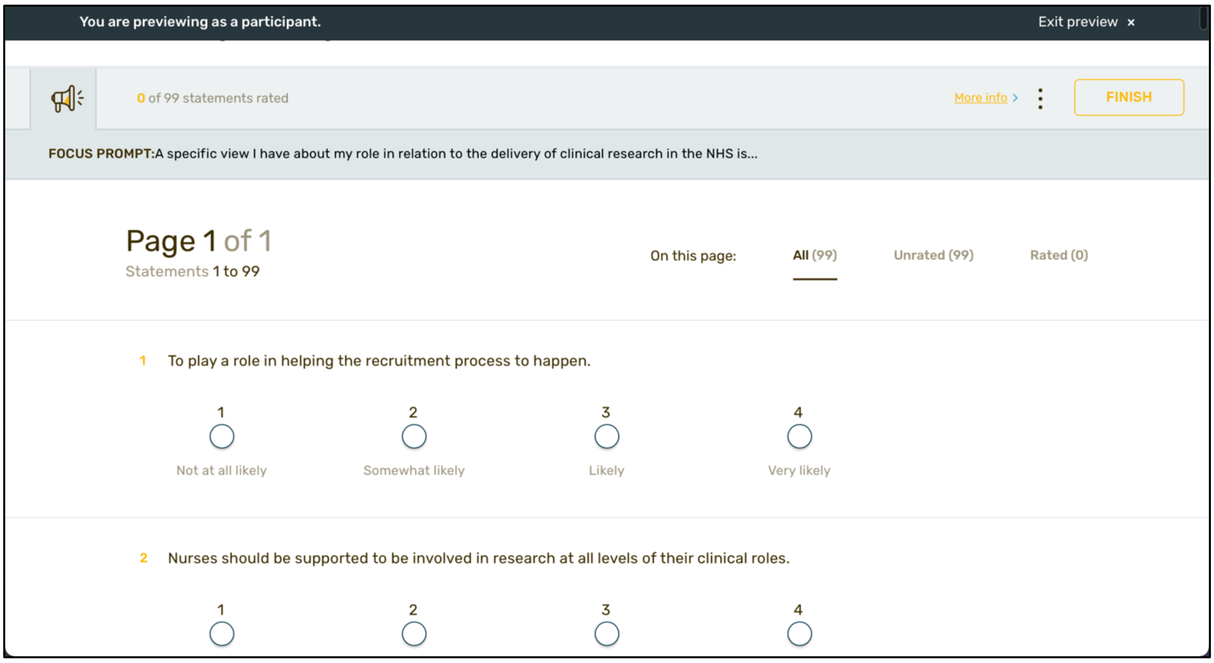
2 I always try to engage and supp

prioritise patient care limits my capacity

Likelihood of generating resistance or avoidance in relation to Research Delivery RATING

How **likely** do you believe each statement would be to lead an individual to **resist or avoid** supporting research delivery in their area?

Please consider each statement and if the content could be viewed as something that could lead someone to display avoidance of or resistance to research studies being delivered in their area. For example, would feeling overworked and stretched for time lead someone to feel unable to engage and therefore avoid ? How likely is it to generate that behaviour using the scale?



FOCUS PROMPT:A specific view I have about my role in relation to the delivery of clinical research in the NHS is...

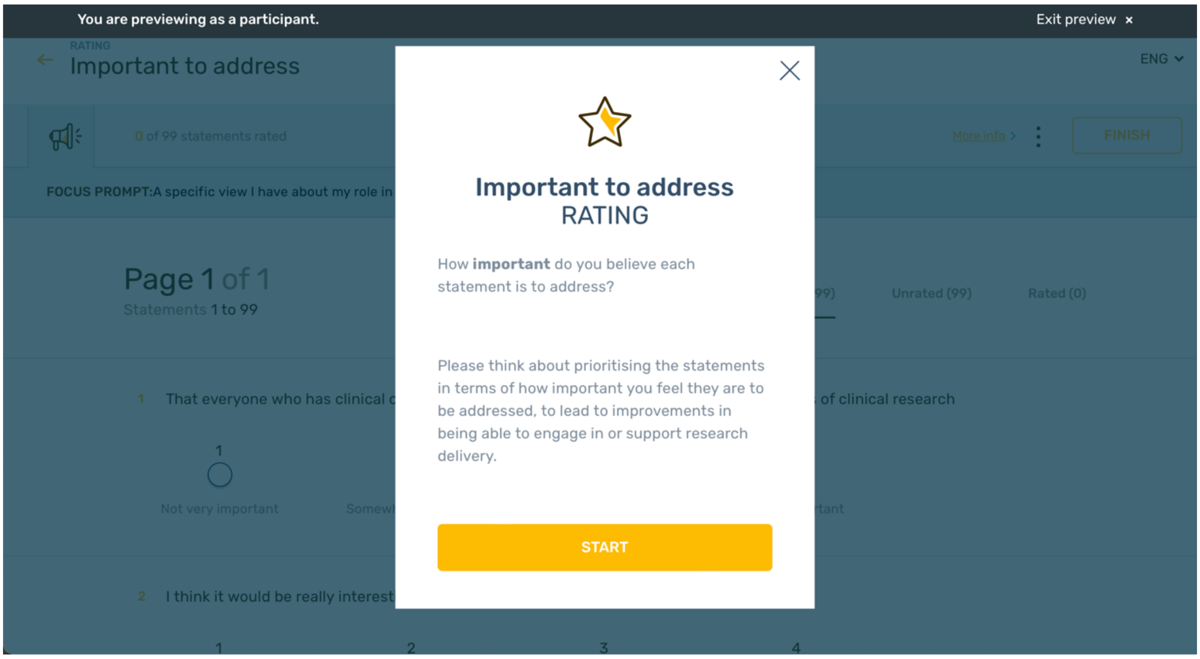
1 To play a role in helping the recruitment process to happen.

○ 1 Not at all likely ○ 2 Somewhat likely ○ 3 Likely ○ 4 Very likely

2 Nurses should be supported to be involved in research at all levels of their clinical roles.

○ 1 ○ 2 ○ 3 ○ 4

Importance to address


You are previewing as a participant.

Exit preview ×

RATING

Important to address

ENG

0 of 99 statements rated

More info

FINISH

FOCUS PROMPT:A specific view I have about my role in

Page 1 of 1

Statements 1 to 99

Unrated (99)

Rated (0)

1 That everyone who has clinical c… of clinical research

Not very important

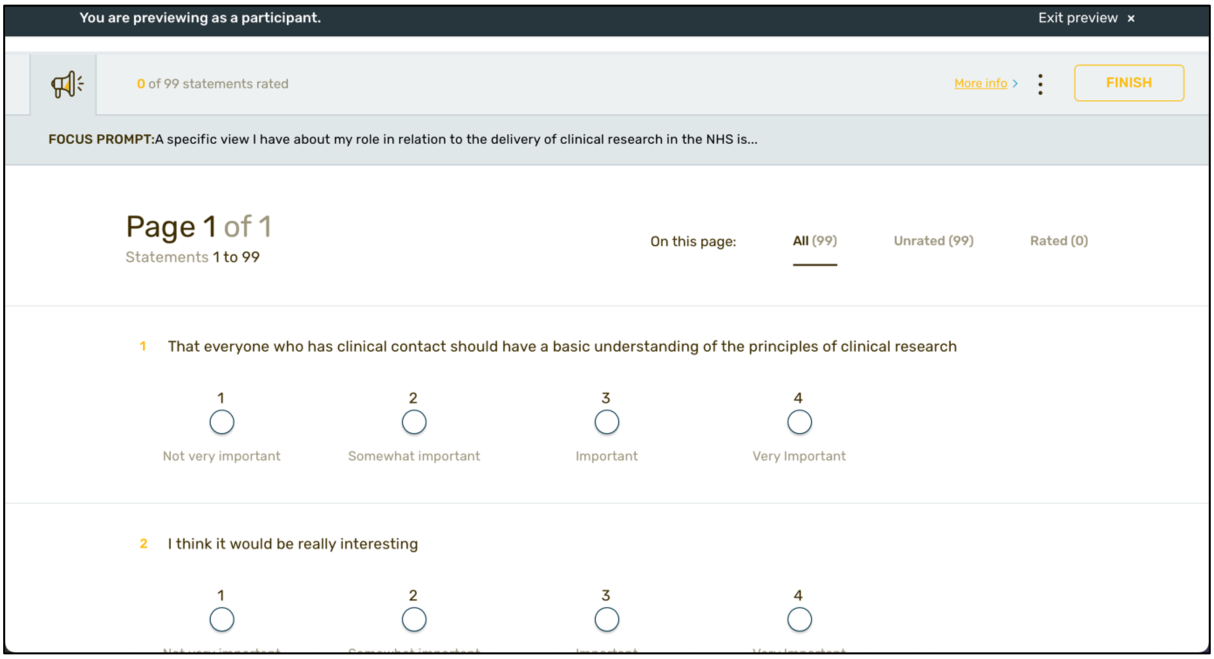
2 I think it would be really interest

Important to address
RATING

How **important** do you believe each statement is to address?

Please think about prioritising the statements in terms of how important you feel they are to be addressed, to lead to improvements in being able to engage in or support research delivery.

START


You are previewing as a participant.

Exit preview ×

0 of 99 statements rated

More info

FINISH

FOCUS PROMPT:A specific view I have about my role in relation to the delivery of clinical research in the NHS is...

Page 1 of 1

Statements 1 to 99

On this page: All (99) Unrated (99) Rated (0)

1 That everyone who has clinical contact should have a basic understanding of the principles of clinical research

1 ○ Not very important
2 ○ Somewhat important
3 ○ Important
4 ○ Very Important

2 I think it would be really interesting

1 ○
2 ○
3 ○
4 ○

Appendix 11. Final statement set submitted for sorting and rating

No	A specific view I have about my role in relation to the delivery of clinical research in the NHS is:
1	Effective team-working is essential between clinical and research delivery teams
2	Increased collaboration between clinical staff and research staff
3	There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels
4	People who do research or bring innovation are likely to be bullied
5	People who do research or bring innovation lack peer support
6	I keep thinking of ways to facilitate research as 'everyones' business' but it is hard.
7	I have been involved in the delivering the clinical intervention of two different research trials but this has been alongside my own clinical caseload and has caused increased pressure
8	Usually laborious and requires heavy admin work
9	It sometimes can be time consuming
10	I always try to engage and support research activities in the unit but sometimes time limits my capacity
11	It is hard to be involved within our working hours.
12	I lack the time to get as involved in research as I'd like
13	Time isn't prioritised within clinical working to allow engagement in research
14	Education isn't prioritised within clinical working to allow engagement in research
15	We just don't have the time
16	There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched
17	The delivery of research requires further learning away from patient care
18	The delivery of research requires further time away from patient care
19	Research it is often hard to integrate it into my clinical practice as it is extra to my workload.
20	Research is not taken into consideration on a day to day basis in a clinical setting
21	Research is not seen as necessary in Learning Disability services
22	Research is not seen as something to make an effort to engage with in Learning Disability services

23	Because research is seen as 'an add on' instead of part of clinical care, clinicians don't have time to engage in research.
24	Clinical care and research are seen as separate entities
25	Research is an add on
26	Research is a nice extra
27	Research is seen as a bother rather than core business
28	Research is something that someone else does
29	Often clinical research is not seen as a priority within the department
30	It is not often considered a priority by managers or heads of services.
31	Clinical research is expected to take a back seat in order for clinical practice to be delivered
32	Patient contact is seen to be of more importance than research in a clinical setting
33	I always try to engage and support research activities in the unit but sometimes the need to prioritise patient care limits my capacity
34	I lack the support to get as involved in research as I'd like.
35	As a clinician, I am perfectly placed to work alongside the delivery team. I screen, recruit, take consent and deliver interventions etc with the support of my delivery team
36	That everyone has a responsibility to enable clinical research to take place in the NHS
37	The importance of promoting research engagement to other nurses and AHP's
38	I believe I have a duty of care to at least participate in research as a clinician.
39	There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects.
40	My role supports research in practice
41	To help researchers with their projects
42	to know who my local research teams are
43	to ensure my local research teams know me
44	to ensure my local research teams know how I can help
45	To facilitate data collection for research if approached by members of the research team and asked to help with this.
46	To be aware of ongoing research projects
47	To help with identifying appropriate patients if they fit study criteria.
48	It could be part of the routine nurses work to seek out appropriate trials and or patients

49	there are frequently missed opportunities for district nursing staff to identify and signpost potential research participants toward appropriate studies.
50	It is important to be involved or advise our patients about clinical research as it improves patient care.
51	to play a role in helping the recruitment process to happen.
52	We were asked to treat research as a 'business'.
53	The more 'customers' we recruit, the higher the chances of retaining funding
54	Research has become more about money and less about patients
55	The challenges of embedding clinical research in the NHS during various pressures (money, workforce, pandemic etc.) is costing patients opportunities of accessing clinical trials.
56	Research studies need to explain their purpose in a way that junior and unregistered nurses can engage with.
57	Junior nurses do not have enough knowledge of ongoing research and the importance of it.
58	Research should be made more visible and exciting.
59	There is lot of misunderstanding about clinical research in NHS
60	I find research dull and difficult to understand
61	I am not very well informed about research
62	Research is invisible to nurses
63	Research is invisible to patients
64	I have no idea what research studies are currently being recruited for
65	Nurses should know about research in their area, but we don't
66	I don't personally have the drive for research
67	I do not really have anything to do with it
68	Research is seen as elitist
69	I don't find out the outcome of the research I support
70	There is limited motivation amongst staff to take an active interest in clinical research delivery because they don't feel the results will have a direct impact on their work.
71	Unaware of any relation of my role to clinical research in the nhs in my current trust
72	There is inconsistency of approach
73	The clinical trials associated with the department I work for and the university we are affiliated to are very medically focused
74	It is up to Doctors to recruit patients

75	Do what you are told to do, and support the doctors with their research involvement.
76	The clinical trials associated with the department I work for and the university we are affiliated to have limited focus on non-pharmacological clinical research
77	The training I have received in order to undertake the clinical interventions for research trials has been beneficial to my clinical role
78	There is a historical belief that clinical research nurse roles can't be undertaken by non nurses (ie AHPs). I think this should be encouraged to change
79	To enable better care for our patients
80	Research is the key part of how we improve the lives of people with an LD
81	Research is the key part of how we improve LD services and keep moving forward
82	It's good for my patients to be able to take part in clinical research when they attend for their care
83	Clinical research is important to the NHS
84	I understand the importance of research
85	That everyone who has clinical contact should have a basic understanding of the principles of clinical research
86	It should be integral to my clinical work.
87	Research should be at the core of what we do as nurses
88	My role is pivotal to improve research on the front line
89	Nurses should be supported to be involved in research at all levels of their clinical roles.
90	It is encouraged
91	It provides an opportunity to work collaboratively with people you wouldn't usually work closely with
92	I think it would be really interesting
93	Being proactive
94	Making it a priority
95	Research in large teaching hospitals is given a lot of credibility
96	Lots of community staff believe that research is a highly technical, advanced activity
97	Lots of community staff believe that research happens in hospital
98	Lots of community staff believe that research doesn't apply to them.
99	The majority of people I know leave clinical roles to work in research.

Appendix 12. Email correspondence regarding amending rating scales in response to data collected

On Wed, 16 Jun 2021 at 12:12, Linda Tinkler <ltinkler2@sheffield.ac.uk> wrote:
Hi All

Just a very quick courtesy email to let you know that I have updated the link in our participant information leaflet to enable participant access to the sorting and rating activities as the brainstorming link is now obsolete due to phase one being closed.

There are no material or wording changes to the leaflet, I have simply replaced the link referred to in the last paragraph with the link below.

https://participant.groupwisdom.tech/project/1432/sorting-rating

Link to PIL attached for you in case this is required for records and audit trail.

https://sites.google.com/sheffield.ac.uk/sra/home/represent-crn

I trust this is ok.

Many thanks
Linda

Linda Tinkler BSc (Hons), MClinRes (Leadership), RN
PhD Student, Royal College of Nursing Strategic Research Alliance
Division of Nursing & Midwifery
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Email: ltinkler2@sheffield.ac.uk

Strategic
Research
Alliance

From: Jane McKeown <j.mckeown@sheffield.ac.uk>
Date: Wednesday, 2 June 2021 at 15:07
To: Linda Tinkler <ltinkler2@sheffield.ac.uk>, Rachel L King <rachel.king@sheffield.ac.uk>
Cc: Angela M Tod <a.tod@sheffield.ac.uk>, Steven Robertson <s.robertson@sheffield.ac.uk>, Dentistry And Health Sciences Research Support Hub Team <hesdenreshub@sheffield.ac.uk>
Subject: Re: 037476 Represent CRN

Dear Linda
Thank you for the update on your research. I have looked at the changes you are proposing and discussed with Rachel. We are both of the opinion that the changes you propose are a natural part of the research process - responding to your earlier data. We do not feel that the changes you propose add any new ethical concerns and as you say may in fact reduce burden for participants. As

such we do not feel an amendment is necessary for University ethics but we will ask Kate to upload this email trail into your ethics application on the system to form a record and audit trail.

If you have also been through NHS ethics it may be advisable to drop them an email detailing the minor changes you plan to your protocol and ask them how to proceed - I can't imagine it would be a substantial amendment - but worth checking with them (disregard this if you did not go through NHS ethics - I lost track).

I hope that helps
Regards
Jane
Dr.Jane McKeown
Lecturer / Senior Nurse Research Lead
(Principal Research Ethics Contact)
Health Sciences School
Division of Nursing and Midwifery
The University of Sheffield
Barber House Annexe
3a Clarkehouse Road
Sheffield S10 2LA

On Wed, 2 Jun 2021 at 09:59, Linda Tinkler <ltinkler2@sheffield.ac.uk> wrote:

Hi Jane

I hope you are keeping well and getting to enjoy some of the lovely weather we have finally been seeing? I have just completed supervision with Angela and Steve this morning and we wanted to ask an ethics related question if you didn't mind please.

The paragraph below (in the current protocol) relates to the second (rating) phase of the study, and we want to make sure we have this right to reduce workload and burden on participants and to ensure we are asking a relevant question that they feel they can answer.

Participants will be asked to rate each statement according to their perceptions of how important each is in direct relation to the success clinical research delivery in their organisation and the subsequent potential impact of each on successful delivery of clinical research, i.e. How important is each of these views, and what is the potential impact of each view on the success of research delivery in my organisation?

We have been reviewing the data generated in the first phase of the study and would like to ask please, how feasible it would be to tweak our original rating plans to rate slightly differently - based on the perceived likelihood to generate avoidance or resistance behaviours (i.e. *how likely is this to generate avoidance or resistance behaviours*) and how important each might be to address, rather than *impact on success* per se of research delivery. This is because the statements generated by participants so far lead us to think that non-research staff participants may not necessarily know or understand what factors have the potential to impact on the *success* of research delivery (and perhaps this will be a bit of a jump for them), but they should be able to make the link between the statements generated and avoidance or resistance behaviours either in themselves or that they may have seen in others.

Going back to the original theoretical proposition we chose to go with, generated by the Realist Review:

> *If key colleagues are **not interested in, aware of, or do not understand** the importance, value and utility of research to their role, their patients, or the wider NHS agenda, then they may **unintentionally or intentionally** display avoidance of or resistance to research being delivered in their clinical area. This presents a risk to positive working relationships with CRNs and access to research opportunities for patients. Consequently, this could impact on organisational performance in relation to research activity and culture.*

I/we feel it would be reasonable to suggest (and not too big a jump) that many of the statements generated so far have the potential to influence how people might behave in relation to research delivery going on in their area (whether positive or negative).

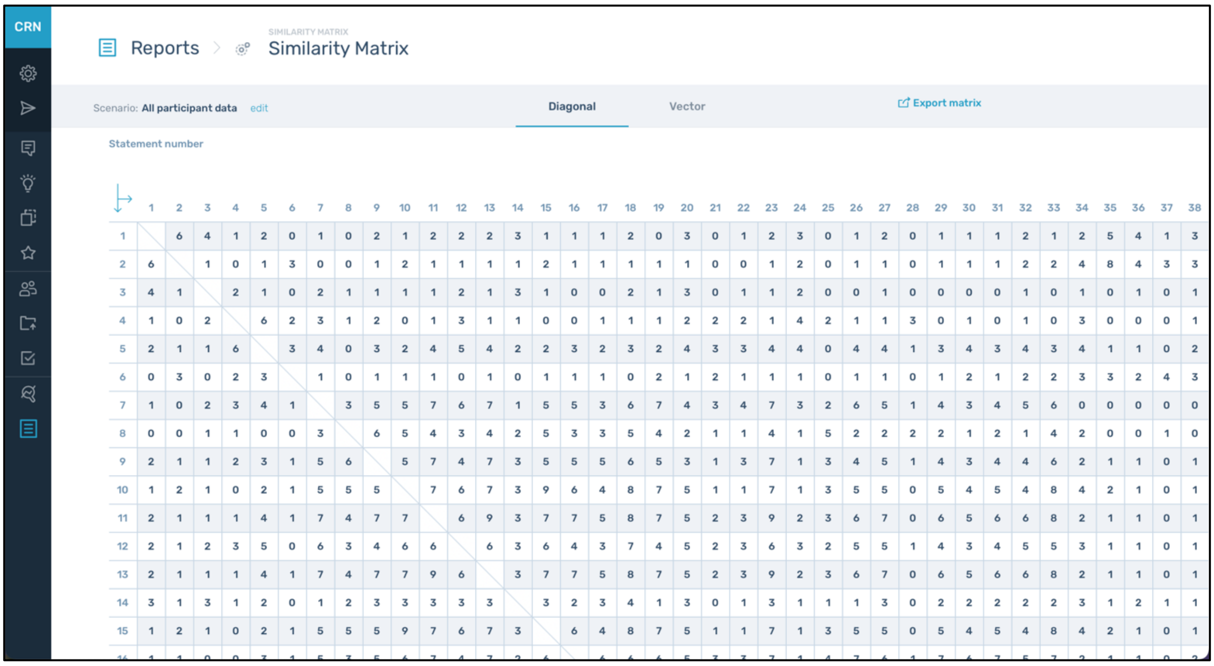
We think this is a very minor change to what we are asking participants to do and this is being driven by the data generated so far. This should generate less burden than the original rating plans, however, we felt it important to check whether an amendment would be required before taking the next steps.
Your thoughts and advice on this would be very much appreciated Jane.

Many thanks and apologies for the long email.
Linda

Linda Tinkler BSc (Hons), MClinRes (Leadership), RN
PhD Student, Royal College of Nursing Strategic Research Alliance
Division of Nursing & Midwifery
Sheffield University
Email: ltinkler2@sheffield.ac.uk

Strategic
Research
Alliance

Appendix 13. Similarity matrix extracts



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
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2	6		1	0	1	3	0	0	1	2	1	1	1	1	2	1	1	1	1	1	0	0	1	2	0	1	1	0	1	1	1	2	2	4	8	4	3	3
3	4	1		2	1	0	2	1	1	1	1	2	1	3	1	0	0	2	1	3	0	1	1	2	0	0	1	0	0	0	0	1	0	1	0	1	0	1
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5	2	1	1	6		3	4	0	3	2	4	5	4	2	2	3	2	3	2	4	3	3	4	4	0	4	4	1	3	4	3	4	3	4	1	1	0	2
6	0	3	0	2	3		1	0	1	1	1	0	1	0	1	1	1	0	2	1	2	1	1	1	0	1	1	0	1	2	1	2	2	3	3	2	4	3
7	1	0	2	3	4	1		3	5	5	7	6	7	1	5	5	3	6	7	4	3	4	7	3	2	6	5	1	4	3	4	5	6	0	0	0	0	0
8	0	0	1	1	0	0	3		6	5	4	3	4	2	5	3	3	5	4	2	1	1	4	1	5	2	2	2	2	1	2	1	4	2	0	0	1	0
9	2	1	1	2	3	1	5	6		5	7	4	7	3	5	5	5	6	5	3	1	3	7	1	3	4	5	1	4	3	4	4	6	2	1	1	0	1
10	1	2	1	0	2	1	5	5	5		7	6	7	3	9	6	4	8	7	5	1	1	7	1	3	5	5	0	5	4	5	4	8	4	2	1	0	1
11	2	1	1	1	4	1	7	4	7	7		6	9	3	7	7	5	8	7	5	2	3	9	2	3	6	7	0	6	5	6	6	8	2	1	1	0	1
12	2	1	2	3	5	0	6	3	4	6	6		6	3	6	4	3	7	4	5	2	3	6	3	2	5	5	1	4	3	4	5	5	3	1	1	0	1
13	2	1	1	1	4	1	7	4	7	7	9	6		3	7	7	5	8	7	5	2	3	9	2	3	6	7	0	6	5	6	6	8	2	1	1	0	1
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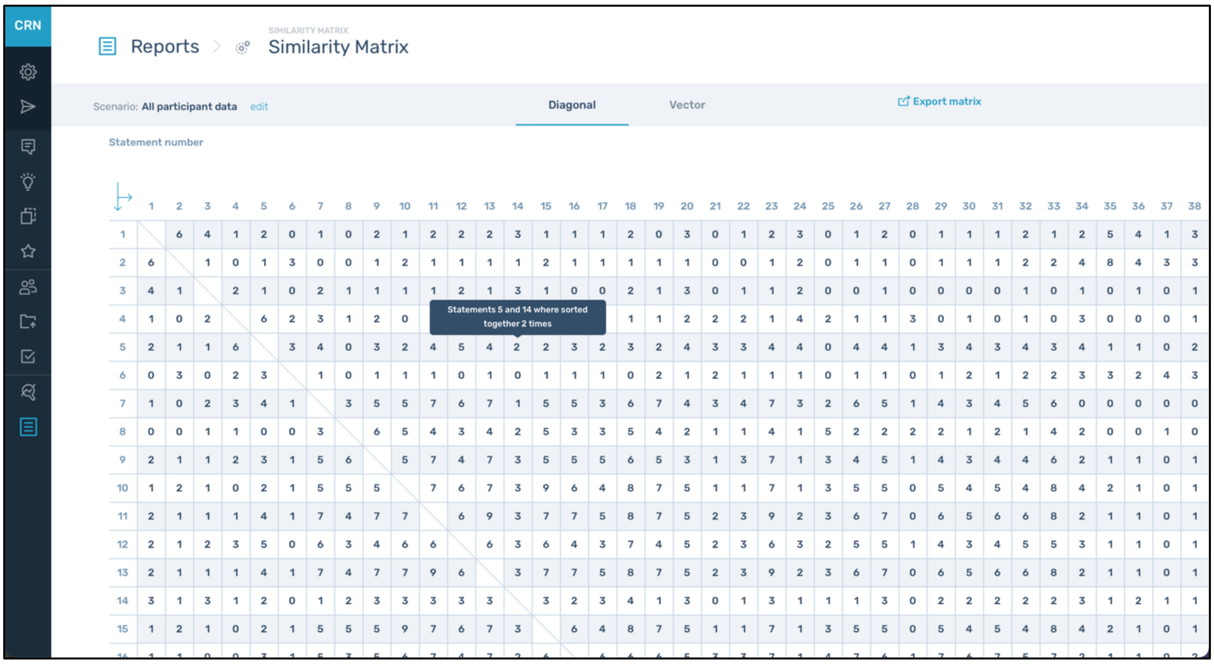

Statements 5 and 14 where sorted together 2 times

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
1		6	4	1	2	0	1	0	2	1	2	2	2	3	1	1	1	2	0	3	0	1	2	3	0	1	2	0	1	1	1	2	1	2	5	4	1	3
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3	4	1		2	1	0	2	1	1	1	1	2	1	3	1	0	0	2	1	3	0	1	1	2	0	0	1	0	0	0	0	1	0	1	0	1	0	1
4	1	0	2		6	2	3	1	2	0								1	1	2	2	2	1	4	2	1	1	3	0	1	0	1	0	3	0	0	0	1
5	2	1	1	6		3	4	0	3	2	4	5	4	2	2	3	2	3	2	4	3	3	4	4	0	4	4	1	3	4	3	4	3	4	1	1	0	2
6	0	3	0	2	3		1	0	1	1	1	0	1	0	1	1	1	0	2	1	2	1	1	1	0	1	1	0	1	2	1	2	2	3	3	2	4	3
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8	0	0	1	1	0	0	3		6	5	4	3	4	2	5	3	3	5	4	2	1	1	4	1	5	2	2	2	2	1	2	1	4	2	0	0	1	0
9	2	1	1	2	3	1	5	6		5	7	4	7	3	5	5	5	6	5	3	1	3	7	1	3	4	5	1	4	3	4	4	6	2	1	1	0	1
10	1	2	1	0	2	1	5	5	5		7	6	7	3	9	6	4	8	7	5	1	1	7	1	3	5	5	0	5	4	5	4	8	4	2	1	0	1
11	2	1	1	1	4	1	7	4	7	7		6	9	3	7	7	5	8	7	5	2	3	9	2	3	6	7	0	6	5	6	6	8	2	1	1	0	1
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15	1	2	1	0	2	1	5	5	5	9	7	6	7	3		6	4	8	7	5	1	1	7	1	3	5	5	0	5	4	5	4	8	4	2	1	0	1

Appendix 14. Cluster merge information extract

Merged	Cluster	Statement number	Statements
14 cluster merged 1-2	Cluster 1		
		1	Effective team working is essential between clinical and research delivery teams
		41	To help researchers with their projects
		45	To facilitate data collection for research if approached by members of the research team and asked to help with this.
		47	To help with identifying appropriate patients if they fit study criteria.
		48	It could be part of the routine nurses work to seek out appropriate trials and or patients
		90	It is encouraged
	Cluster 2		
		2	Increased collaboration between clinical staff and research staff
		35	As a clinician, I am perfectly placed to work alongside the delivery team. I screen, recruit, take consent and deliver interventions etc with the support of my delivery team
		39	There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects.
		79	To enable better care for our patients
		82	It's good for my patients to be able to take part in clinical research when they attend for their care
		83	Clinical research is important to the NHS
		89	Nurses should be supported to be involved in research at all levels of their clinical roles.
		91	It provides an opportunity to work collaboratively with people you wouldn't usually work closely with
13 cluster merged 8-9	Cluster 8		
		4	People who do research or bring innovation are likely to be bullied
		28	Research is something that someone else does
		56	Research studies need to explain their purpose in a way that junior and unregistered nurses can engage with.
		63	Research is invisible to patients
		74	It is up to Doctors to recruit patients
		75	Do what you are told to do, and support the doctors with their research involvement.
	Cluster 9		
		60	I find research dull and difficult to understand
		62	Research is invisible to nurses
		67	I do not really have anything to do with it

		99	The majority of people I know leave clinical roles to work in research
12 cluster merged 13-14	Cluster 13		
		5	People who do research or bring innovation lack peer support
		12	I lack the time to get as involved in research as I'd like
		14	Education isn't prioritised within clinical working to allow engagement in research
		20	Research is not taken into consideration on a day to day basis in a clinical setting
		73	The clinical trials associated with the department I work for and the university we are affiliated to are very medically focused
	Cluster 14		
		7	I have been involved in the delivering the clinical intervention of two different research trials but this has been alongside my own clinical caseload and has caused increased pressure
		9	It sometimes can be time consuming
		11	It is hard to be involved within our working hours.
		13	Time isn't prioritised within clinical working to allow engagement in research
		16	There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched
		18	The delivery of research requires further time away from patient care
		19	Research it is often hard to integrate it into my clinical practice as it is extra to my workload.
		23	Because research is seen as 'an add on' instead of part of clinical care, clinicians don't have time to engage in research.
		27	Research is seen as a bother rather than core business
11 cluster merged 1-2-3	Cluster 1		
		1	Effective team working is essential between clinical and research delivery teams
		41	To help researchers with their projects
		45	To facilitate data collection for research if approached by members of the research team and asked to help with this.
		47	To help with identifying appropriate patients if they fit study criteria.
		48	It could be part of the routine nurses work to seek out appropriate trials and or patients
		90	It is encouraged
	Cluster 2		
		2	Increased collaboration between clinical staff and research staff
		35	As a clinician, I am perfectly placed to work alongside the delivery team. I screen, recruit, take consent and deliver interventions etc with the support of my delivery team
		39	There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects.
		79	To enable better care for our patients

		82	It's good for my patients to be able to take part in clinical research when they attend for their care
		83	Clinical research is important to the NHS
		89	Nurses should be supported to be involved in research at all levels of their clinical roles.
		91	It provides an opportunity to work collaboratively with people you wouldn't usually work closely with
	Cluster 3		
		36	That everyone has a responsibility to enable clinical research to take place in the NHS
		38	I believe I have a duty of care to at least participate in research as a clinician.
		50	It is important to be involved or advise our patients about clinical research as it improves patient care.
		86	It should be integral to my clinical work.
		93	Being proactive
10 cluster merged 7-8-9	Cluster 7		
		3	There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels
		42	To know who my local research teams are
		64	I have no idea what research studies are currently being recruited for
		71	Unaware of any relation of my role to clinical research in the nhs in my current trust
		78	There is a historical belief that clinical research nurse roles can't be undertaken by non nurses (ie AHPs). I think this should be encouraged to change
	Cluster 8		
		4	People who do research or bring innovation are likely to be bullied
		28	Research is something that someone else does
		56	Research studies need to explain their purpose in a way that junior and unregistered nurses can engage with.
		63	Research is invisible to patients
		74	It is up to Doctors to recruit patients
		75	Do what you are told to do, and support the doctors with their research involvement.
	Cluster 9		
		60	I find research dull and difficult to understand
		62	Research is invisible to nurses
		67	I do not really have anything to do with it
		99	The majority of people I know leave clinical roles to work in research
9 cluster merged 13-14-15	Cluster 13		
		5	People who do research or bring innovation lack peer support
		12	I lack the time to get as involved in research as I'd like
		14	Education isn't prioritised within clinical working to allow engagement in research

		20	Research is not taken into consideration on a day to day basis in a clinical setting
		73	The clinical trials associated with the department I work for and the university we are affiliated to are very medically focused
	Cluster 14		
		7	I have been involved in the delivering the clinical intervention of two different research trials but this has been alongside my own clinical caseload and has caused increased pressure
		9	It sometimes can be time consuming
		11	It is hard to be involved within our working hours.
		13	Time isn't prioritised within clinical working to allow engagement in research
		16	There is limited motivation amongst staff to take an active interest in clinical research delivery because everyone is already overstretched
		18	The delivery of research requires further time away from patient care
		19	Research it is often hard to integrate it into my clinical practice as it is extra to my workload.
		23	Because research is seen as 'an add on' instead of part of clinical care, clinicians don't have time to engage in research.
		27	Research is seen as a bother rather than core business
	Cluster 15		
		10	I always try to engage and support research activities in the unit but sometimes time limits my capacity
		15	We just don't have the time
		17	The delivery of research requires further learning away from patient care
		26	Research is a nice extra
		29	Often clinical research is not seen as a priority within the department
		30	It is not often considered a priority by managers or heads of services.
		31	Clinical research is expected to take a back seat in order for clinical practice to be delivered
		32	Patient contact is seen to be of more importance than research in a clinical setting
		33	I always try to engage and support research activities in the unit but sometimes the need to prioritise patient care limits my capacity
		55	The challenges of embedding clinical research in the NHS during various pressures (money, workforce, pandemic etc.) is costing patients opportunities of accessing clinical trials.
8 cluster merged 1-2-3-4	Cluster 1		
		1	Effective team working is essential between clinical and research delivery teams
		41	To help researchers with their projects
		45	To facilitate data collection for research if approached by members of the research team and asked to help with this.
		47	To help with identifying appropriate patients if they fit study criteria.
		48	It could be part of the routine nurses work to seek out appropriate trials and or patients
		90	It is encouraged

	Cluster 2		
		2	Increased collaboration between clinical staff and research staff
		35	As a clinician, I am perfectly placed to work alongside the delivery team. I screen, recruit, take consent and deliver interventions etc with the support of my delivery team
		39	There should be more opportunities for those not involved in research delivery teams to express an interest in being involved in research projects.
		79	To enable better care for our patients
		82	It's good for my patients to be able to take part in clinical research when they attend for their care
		83	Clinical research is important to the NHS
		89	Nurses should be supported to be involved in research at all levels of their clinical roles.
		91	It provides an opportunity to work collaboratively with people you wouldn't usually work closely with
	Cluster 3		
		36	That everyone has a responsibility to enable clinical research to take place in the NHS
		38	I believe I have a duty of care to at least participate in research as a clinician.
		50	It is important to be involved or advise our patients about clinical research as it improves patient care.
		86	It should be integral to my clinical work.
		93	Being proactive
	Cluster 4		
		34	I lack the support to get as involved in research as I'd like.
		53	The more 'customers' we recruit, the higher the chances of retaining funding
		94	Making it a priority
7 cluster merged 5-6	Cluster 5		
		37	The importance of promoting research engagement to other nurses and AHP's
		40	My role supports research in practice
		43	To ensure my local research teams know me
		51	To play a role in helping the recruitment process to happen.
		58	Research should be made more visible and exciting.
		81	Research is the key part of how we improve LD services and keep moving forward
		85	That everyone who has clinical contact should have a basic understanding of the principles of clinical research
		95	Research in large teaching hospitals is given a lot of credibility
	Cluster 6		
		44	To ensure my local research teams know how I can help
		46	To be aware of ongoing research projects
		77	The training I have received in order to undertake the clinical interventions for research trials has been beneficial to my clinical role
		80	Research is the key part of how we improve the lives of people with an LD
		84	I understand the importance of research

		87	Research should be at the core of what we do as nurses
		88	My role is pivotal to improve research on the front line
		92	I think it would be really interesting
6 cluster merged 11-12	Cluster 11		
		8	Usually laborious and requires heavy admin work
		25	Research is an add on
		54	Research has become more about money and less about patients
		66	I don't personally have the drive for research
		68	Research is seen as elitist
		69	I don't find out the outcome of the research I support
		70	There is limited motivation amongst staff to take an active interest in clinical research delivery because they don't feel the results will have a direct impact on their work.
		96	Lots of community staff believe that research is a highly technical, advanced activity
		97	Lots of community staff believe that research happens in hospital
	Cluster 12		
		21	Research is not seen as necessary in Learning Disability services
		22	Research is not seen as something to make an effort to engage with in Learning Disability services
		24	Clinical care and research are seen as separate entities
		57	Junior nurses do not have enough knowledge of ongoing research and the importance of it.
		59	There is lot of misunderstanding about clinical research in NHS
		61	I am not very well informed about research
		72	There is inconsistency of approach
		76	The clinical trials associated with the department I work for and the university we are affiliated to have limited focus on non-pharmacological clinical research
		98	Lots of community staff believe that research doesn't apply to them
5 cluster merged 10-11-12	Cluster 10		
		6	I keep thinking of ways to facilitate research as 'everyones' business' but it is hard.
		49	There are frequently missed opportunities for district nursing staff to identify and signpost potential research participants toward appropriate studies.
		52	We were asked to treat research as a 'business'.
		65	Nurses should know about research in their area, but we don't
	Cluster 11		
		8	Usually laborious and requires heavy admin work
		25	Research is an add on
		54	Research has become more about money and less about patients
		66	I don't personally have the drive for research
		68	Research is seen as elitist

		69	I don't find out the outcome of the research I support
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		98	Lots of community staff believe that research doesn't apply to them
4 cluster merged 7-8-9-10-11-12	Cluster 7		
		3	There are frequently silos of research going on which would and could influence care delivery and efficiency if there was adequate communication channels
		42	To know who my local research teams are
		64	I have no idea what research studies are currently being recruited for
		71	Unaware of any relation of my role to clinical research in the nhs in my current trust
		78	There is a historical belief that clinical research nurse roles can't be undertaken by non nurses (ie AHPs). I think this should be encouraged to change
	Cluster 8		
		4	People who do research or bring innovation are likely to be bullied
		28	Research is something that someone else does
		56	Research studies need to explain their purpose in a way that junior and unregistered nurses can engage with.
		63	Research is invisible to patients
		74	It is up to Doctors to recruit patients
		75	Do what you are told to do, and support the doctors with their research involvement.
	Cluster 9		
		60	I find research dull and difficult to understand
		62	Research is invisible to nurses
		67	I do not really have anything to do with it

		99	The majority of people I know leave clinical roles to work in research
	Cluster 10		
		6	I keep thinking of ways to facilitate research as 'everyones' business' but it is hard.
		49	There are frequently missed opportunities for district nursing staff to identify and signpost potential research participants toward appropriate studies.
		52	We were asked to treat research as a 'business'.
		65	Nurses should know about research in their area, but we don't
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