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Protocol

Nurse- and midwife-led trials in Australia and New Zealand: Scoping review protocol

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ARTICLE INFO

Article history:

Received 30 March 2021

Accepted 12 May 2022

Keywords:

Clinical trial

Nursing

Midwifery

Randomised controlled trial

Scoping review

ABSTRACT

Background: Research led by nurses or midwives has the potential to successfully address current issues in clinical care. High-quality randomised controlled trials are needed to inform evidence-based practice; however, nursing and midwifery research has commonly been nonexperimental. Two connected scoping reviews of nurse- and midwife-led randomised controlled trials within Australia and New Zealand will be conducted to highlight potential research directions and identify resources for future research.

Aim: The purpose of the two reviews is to map the number and types of randomised controlled trials led by nurses or midwives within Australia and New Zealand.

Methods: The concept of interest is randomised controlled trials with a lead principal investigator holding nursing or midwifery credentials. The lead principal investigator must report an institutional affiliation in Australia or New Zealand, and the trial must recruit at a minimum of one site in Australia or New Zealand. Searches for academic literature will be conducted using Pubmed, Emcare, and Scopus. Sources for grey literature will include the Australian New Zealand Clinical Trials Registry, and grant outcomes published by the National Health and Medical Research Council, Medical Research Future Fund, and Health Research Council of New Zealand. Data analysis and presentation will be conducted separately for each review.

Discussion: These reviews will comprehensively map the experimental research activity of nurses and midwives within Australia and New Zealand and highlight potential research directions. From this, strategies to facilitate high quality nurse- and midwife-led trials can be developed, which are vital for informing evidence-based practice.

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Summary of relevance

Issue

A scoping review is required to map the extent, scale, and types of trials led by nurses and midwives in Australia and New Zealand.

What is already known

Previous reviews have highlighted the dominance of non-experimental nursing and midwifery research. Randomised controlled trials are vital for building upon previous research and informing evidence-based practice.

What this paper adds

This paper highlights the need for higher level evidence to inform nursing and midwifery practice and a comprehensive review of the nursing and midwifery research landscape to inform future research directions and strategies for building nursing and midwifery research capacity.

1. Introduction

Nurses and midwives comprise the largest groups of professionals in the health workforce within Australia and New Zealand (Australian Institute of Health and Welfare, 2016; Ministry of Health, 2016). Nurses and midwives are both highly knowledgeable about health, illness, and current issues in clinical care, and are key to the delivery of healthcare. As a consequence, research initiated and led by nurses and midwives has great potential to improve the health and wellbeing of individuals and communities (Borbasi, Hawes, Wilkes, Stewart, & May, 2002). However, previous reviews of nursing and midwifery research highlight the dominance of non-experimental research and the scarcity of high-quality randomised controlled trials (Borbasi et al., 2002; Mantzoukas, 2009; Wilkes & Jackson, 2011). Although previous research has been valuable, studies have generally been exploratory in nature and findings cannot be reliably generalized to the wider population. The quality of best practice guidelines has also been affected, for example, many nursing-specific guidelines rely on predominantly level 3 evidence (i.e., source of evidence is a synthesis of research evidence predominantly qualitative in nature) or lower to inform evidence-based care (Registered Nurses' Association of Ontario, 2020). There have been calls for more randomised controlled trials to build upon previous research evidence, address questions related to effectiveness, generalisability, and implementability, and inform successful evidence-based nursing and midwifery practice (Australian Clinical Trials Alliance, 2020; Borbasi, Emden, & Jackson, 2005; Hopia & Heikkilä, 2020; Mantzoukas, 2009; Wilkes & Jackson, 2011). Large scale research studies and randomised controlled trials with the potential for high impact are costly to conduct, however, and more resources are needed (Wilkes & Jackson, 2011).

To build nursing and midwifery research capacity in Australia and New Zealand, the Australasian Nursing and Midwifery Clinical Research Network (ANMCRN) was established. The ANMCRN was designed to encourage collaboration among clinical researchers, provide opportunities for sharing of resources and expertise, facilitate nurse- and midwife-led trials aimed at advancing evidence in nursing and midwifery care, and attract competitive research funding in Australia and New Zealand. To support this work, an updated review of randomised controlled trials led by nurses and midwives within Australia and New Zealand is needed to summarise research activity, as well as highlight future research directions and potential resources. Considering the purpose of the review, scoping review methodology was considered the most appropriate form of evidence synthesis (Pollock et al., 2021). Although midwifery is sometimes considered a specialty area within nursing, it is a dis-

tinct profession with unique research priorities and areas of clinical investigation. Consequently, two separate but connected scoping reviews are proposed to enable sufficient investigation of experimental research in each profession.

2. Background

A preliminary search of current (i.e., previous five years) and in progress scoping reviews on nurse- and midwife-led clinical trials in Australia and New Zealand was conducted in Ovid MEDLINE, Ovid Emcare, and JBI Evidence Synthesis. No protocols or reviews were identified on the topics of interest; however, several relevant reviews were noted in nursing.

A couple of evidence syntheses reviewed experimental studies in nursing and midwifery but did not exclusively focus on nurse- or -midwife-led clinical trials. Charalambous et al. (2018) reviewed clinical trials testing interventions led or delivered by nurses in cancer control specifically. Gonella, Di Giulio, Palese, Dimonte, and Campagna (2019) more broadly investigated experimental and quasi-experimental studies published in high-impact nursing journals internationally. These reviews included clinical trial research led by nurses, as well as research with a lead investigator from another discipline and nursing studies that did not include nurses on the research team (i.e., research teams composed of physicians or other professionals in healthcare). Consequently, it is difficult to draw conclusions about research capacity in nursing and midwifery.

The methods used within previous reviews also limited the conclusions that could be drawn about nursing and midwifery research activity within Australia and New Zealand specifically. Gonella et al. (2019) found that Australia and New Zealand had the lowest number of randomised controlled trials ($n = 18/340$) across an eight-year period (2009–2016) compared to Asia, Europe, and America, however, this could be an underestimation of studies in Australia and New Zealand given that the focus of this review was on experimental studies published only in nursing journals (i.e., relevant studies published in non-nursing journals were excluded). Furthermore, 36 of the included studies had a clear midwifery focus, but there was limited separate consideration of these trials within the review and it was unclear how many of the midwifery trials were conducted within Australia and New Zealand. Further investigation and description of midwife-led randomised controlled trials in Australia and New Zealand is required.

One recent scoping review was similar to the proposed reviews in that it focused on supporting nurses to undertake high-impact research by investigating international nurse-led randomised controlled trials, but was limited in scope and focussed on perioperative care only (Munday et al., 2020). The review identified 86 nurse-led randomised controlled trials; five were conducted in Australia. Although the review usefully identified key research areas of perioperative care and gaps for future research, taking a wider focus to include all areas of nursing and midwifery would be beneficial to provide insight into areas for capacity building more broadly among nurses and midwives in Australia and New Zealand.

3. Reviews

The objective is to undertake two separate scoping reviews to map the number and types of randomised controlled trials led by (i) nurses or (ii) midwives within Australia and New Zealand. The two proposed scoping reviews will differ from previous reviews by identifying randomised controlled trials with a lead principal investigator who is a nurse or midwife (i.e., holds relevant credentials, such as RN, NP, RM), as opposed to clinical trials of nurse- or midwife-led interventions and/or clinical trials with a lead principal investigator from other disciplines. Furthermore, the proposed

scoping reviews will focus on randomised controlled trials conducted in Australia and New Zealand, and search results will be analysed and reported separately for nursing and midwifery professions. The two reviews will have a broad methodological approach; the search strategy will not be limited to nursing-specific journals and will include grey literature from a trial registry and grant outcomes databases. This approach has been successfully used in a scoping review of musculoskeletal clinical trials in Australia previously (Bourne, Whittle, Richards, Maher, & Buchbinder, 2014). It is expected that the findings of each review will detail areas of clinical enquiry, identify directions for future research, as well as potential resources for future clinical trials within Australia and New Zealand.

4. Review questions

The primary research question in each review will be: What randomised controlled trials have been led by nurses or midwives in Australia and New Zealand? Secondary research questions will be: Were the identified randomised controlled trials funded, and if so, by which funding source? What was the methodological quality of the identified randomised controlled trials? Where have nurses or midwives published trials (i.e., nursing or midwifery specialist journals compared with health care journals)?

5. Methods

This *a priori* scoping review protocol was guided by the Joanna Briggs Institute (JBI) framework for conducting a scoping review (Peters et al., 2020; Peters et al., 2020), and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses – Scoping Reviews (PRISMA-ScR; Tricco et al., 2018). Final scoping reviews will also be reported in line with the PRISMA-ScR. This project is registered with the Open Science Framework. Institutional ethical approval will not be required before commencing the reviews.

5.1. Inclusion criteria

5.1.1. Concept

The overarching concept of interest is nurse- or midwife-led randomised controlled trials. A nurse- or midwife-led trial will be identified according to the relevant credentials (e.g., RN, NP, RM) of the lead principal or chief investigator (herein described as the lead principal investigator) of the trial. The credentials and funding sources (where unclear) of the lead principal investigator of a trial will be verified through correspondence with article authors, checking of trial registrations, and background searches prior to inclusion in the review. A randomised controlled trial will be defined as a trial in which individual participants or clusters of participants are randomly allocated to conditions. All trial phases will be considered and categorised for comparison, as well as all types of healthcare interventions with a clinical outcome (e.g., healthcare treatment, healthcare education, healthcare delivery, preventive intervention).

5.1.2. Context

The context of these reviews will be restricted to randomised controlled trials conducted in Australia and New Zealand. The lead principal investigator must report an affiliation with an institution in Australia or New Zealand (either when the study was undertaken or when published) and the trial must recruit at a minimum of one Australian or New Zealand site. All healthcare settings will be considered.

Table 1

A complete search strategy for Ovid Emcare.

Search	Query
#1	exp Randomised Controlled Trial/
#2	(randomised trial OR randomised controlled trial OR randomised controlled trial OR clinical study OR clinical trial).mp.
#3	#1 OR #2
#4	exp Australia/
#5	(australia* OR new south wales OR sydney OR victoria* OR melbourne OR queensland* OR brisbane OR south australia* OR adelaide OR northern territory* OR darwin OR western australia* OR perth OR tasmania* OR hobart OR australian capital territory OR canberra*).mp.
#6	exp New Zealand/
#7	(new zealand* OR auckland OR wellington OR christchurch).mp.
#8	#4 - #7
#9	(nurs* OR midwife*).in.
#10	#3 AND #8 AND #9
#11	limit #10 to English language

5.1.3. Types of sources

Academic sources will include peer-reviewed journal articles containing randomised controlled trials. Grey literature will include trial registration records and records of sponsorship. Scoping review sources will be restricted to those published in English due to limited resources for translating sources, but there will be no limit placed on publication or registration dates.

5.2. Exclusion criteria

Trials led by a non-nurse or non-midwife that include nurses or midwives as part of their multidisciplinary research team will be excluded. Trials will also be excluded if authors do not explicitly report randomisation, report quasi-randomisation (e.g., allocation by alternation, day, record number), lack a control condition, or include an educational outcome. Qualitative studies, observational studies, conference abstracts, and reviews will be excluded.

5.3. Information sources

A comprehensive methodological approach is proposed to identify randomised controlled trials led by nurses or midwives, including academic (i.e., published journal articles) and grey literature (i.e., trials register and grant funding outcomes). The full search strategy will be conducted once to collect evidence relevant to both reviews.

5.4. Academic literature search

5.4.1. Search strategy

An initial limited search of Ovid Emcare and Pubmed was conducted to identify examples of relevant articles and search terms. The search strategy was further refined through discussion with the working group. See Table 1 for an example full search strategy. Searches will be conducted using Pubmed, Ovid Emcare, and Scopus. The search strategy will be adapted to each database as relevant. A forwards-backwards citation search will be conducted for all included articles to identify additional sources.

5.4.2. Evidence selection

Database search records will be downloaded to EndNote X9.1 (Clarivate Analytics) and uploaded to the online Covidence platform where duplicates will be removed, and records screened. Evidence selection will follow a staged approach as outlined in Table 2. In line with JBI guidelines, at least two independent reviewers will screen the academic literature in each step. However,

Table 2
Approach to screening and evidence selection.

Stage	Description	Number of reviewers
1.	Screening all titles and abstracts to identify randomised controlled trials	Two independent reviewers; conflicts resolved by consensus
2.	First, last, and corresponding author affiliations and credentials examined to determine whether the lead principal investigator is potentially a nurse or midwife	Two independent reviewers; conflicts resolved by consensus
3.	Name and credentials of the lead principal investigator of a trial verified through checking trial registrations and/or correspondence with article authors	One reviewer
4.	For each scoping review, the list of potential randomised controlled trials reviewed by experts in nursing or midwifery to confirm included trials	Two experts in nursing; Two experts in midwifery

one main reviewer will oversee the process for confirming the credentials of the lead principal investigator of a trial (e.g., contacting authors for further information) for simplicity. Members of the ANMCRN are experts in nursing and midwifery clinical trial research and select members will provide guidance during the final selection of sources (e.g., to highlight any trials that may have been missed). Reasons for exclusion will be reported in the final scoping reviews.

The nurse- or midwife-led randomised controlled trial is the unit of interest. All peer-reviewed journal articles associated with the same randomised controlled trial will be linked together within Covidence and assigned a Study ID. Moreover, grey literature will be linked with academic literature to determine the number of trials included in the synthesis. In the line with the recommendations of the Cochrane Collaboration (Li, Higgins, & Deeks, 2020), the following aspects will be examined to link sources: trial registration numbers, investigator and author names, funding identifiers, as well as intervention and study details. A flow diagram of the selection of evidence will be presented in accordance with the PRISMA-ScR (Tricco et al., 2018).

5.4.3. Data charting process

Data charting will be conducted on the Covidence platform. For each review, data will be extracted from studies by one reviewer, and an independent reviewer will verify the data extracted. A data charting form was developed for journal articles included in these scoping reviews (see Appendix A for supplementary information); adapted from the JBI extraction instrument template (Peters et al., 2020). The data charting form will include details to assess study eligibility (i.e., lead principal investigator details and credentials, country of intervention, type of study, and source type). In addition to this, details about the trial, methods, intervention, funding, results, the number and quality of publications, as well as key trial conclusions will be extracted. Extracted data will be exported, linked with data extracted from the grey literature, and combined onto a single data charting form (Li et al., 2020). If there is contradictory data across sources, the main data source will be identified through contacting the authors.

5.4.4. Critical appraisal

The methodological quality of included randomised controlled trials will be assessed using the JBI Checklist for Randomised Controlled Trials (Tufanaru, Munn, Aromataris, Campbell, & Hopp,

2020). Critical appraisal will be conducted by one reviewer and verified by a second reviewer, with conflicts resolved by consensus. Although critical appraisal is not mandatory in scoping reviews (Peters et al., 2020; Peters et al., 2020), it was included to address the overarching objective of the reviews to provide information about the types of randomised controlled trials led by nurses or midwives in Australia and New Zealand. Randomised controlled trials will not be excluded based on methodological quality.

5.4.5. Data analysis and presentation

To address the primary research question, evidence will be analysed using qualitative content analysis and frequency counts of key data fields: occurrence of nursing or midwifery randomised controlled trials according to country, author affiliation type, trial phases, number of sites, topic areas, intervention types, and study methods. To address the secondary research questions, methodological quality of published randomised controlled trials will be reported for each randomised controlled trial and overall in a summary table, and journals will be categorised as discipline specific (i.e., nursing or midwifery) or healthcare journals (remainder) according to existing categorisation in the SCImago Institution Rankings portal (i.e., subject area and category). Frequency tables will be supported by a descriptive summary of results. No comparisons are planned across nursing and midwifery results; however, any noteworthy differences may be included in the discussion sections of each review if they arise. Select ANMCRN members who are experts in nursing or midwifery clinical trial research will contribute to writing the scoping review publications.

5.5. Grey literature search

Incorporating grey literature in these reviews was deemed important because of the substantial delay that can occur between planning, undertaking, and publishing clinical trial research. The Australian New Zealand Clinical Trials Registry (ANZCTR) and competitive funding outcomes in Australia and New Zealand will be searched to identify nurse- and midwife-led randomised controlled trials in the grey literature. All grey literature evidence will be screened by one reviewer. A second independent reviewer will support the screening process by providing expert advice when uncertainties arise.

5.5.1. Australian New Zealand Clinical Trials Registry

5.5.1.1. Search strategy. The ANZCTR publishes a catalogue of clinical trials recruiting in Australia, New Zealand, and other countries. An initial search was conducted to identify examples of relevant trials and the contents of registration records. The search revealed that most registration records included principal investigator name and affiliation(s), with the remainder including names and affiliations of study contacts.

The catalogue will be searched to identify nurse- and midwife-led randomised controlled trials that have been planned, commenced, and those that have completed recruitment. Registration records will be searched using key search terms 'nurs*' or 'midwife*', with advanced search options: (a) randomised trials, and (b) Australia or New Zealand.

5.5.1.2. Evidence selection. Records retrieved from ANZCTR will be downloaded to Microsoft Excel. For trials with a principal investigator, names and affiliations will be screened for relevance, followed by a background search to verify the credentials of the lead investigator. For the remainder, the names and affiliations of study contacts will be screened to identify potentially relevant trials, and the associate(s) contacted to identify the lead investigator and their credentials.

5.5.1.3. Data charting, analysis, and presentation. A data charting form was developed for trial registrations (see supplementary information). Unique fields for data extraction include the type of registration (e.g., prospective, retrospective) and recruitment status. The method for analysis and presentation will be as previously outlined for academic literature.

5.5.2. Competitive funding outcomes in Australia and New Zealand

5.5.2.1. Search strategy. Within Australia, grant outcomes are published by the National Health and Medical Research Council (NHMRC; [National Health and Medical Research Council, 2020](#)) and the Medical Research Future Fund (MRFF; [Department of Health, 2019](#)). Publicly available NHMRC grant outcomes databases will be downloaded and project grant outcomes will be searched using the following key terms: 'clinical trial,' 'clinical study,' 'clinical studies,' 'randomised,' 'controlled,' 'nurse,' 'nursing,' and 'midwife.' The MRFF grant recipients dataset will also be downloaded and all funding agreements searched using the same key terms.

Within New Zealand, grant applications are published by the Health Research Council of New Zealand (HRC; [Health Research Council of New Zealand, 2020](#)). A search engine function will facilitate searching the library using key terms: 'randomised,' 'controlled,' 'trial,' 'randomised controlled trial,' 'clinical study,' 'nurse,' 'nursing,' and 'midwife.'

5.5.2.2. Evidence selection. Potentially relevant grants will be retrieved from databases, compiled in a separate Excel file, and screened once more. Lead principal investigator names and affiliations will be screened for relevance, followed by a background search to verify credentials.

5.5.2.3. Data charting, analysis, and presentation. A data charting form was developed for grant outcomes (see supplementary information), including fields for the funded institution, grant type, field of research, and total amount. Analyses to address the secondary research questions will include a frequency count of nursing or midwifery clinical trial grants and totalling funding amounts. Results will be presented in tabular form and broken down according to year. A descriptive summary of funding outcomes will accompany the frequency table.

6. Discussion

Nurses and midwives comprise the largest component of the health workforce in Australia and New Zealand. They play a key role in developing best nursing and midwifery practice, preserving the core values of health systems globally, and advocating for health equity. A thorough understanding of the nursing and midwifery research landscape in Australia and New Zealand is vital for identifying strengths and weaknesses in the system, as well as for identifying barriers to and enablers of nurse- and midwife-led experimental research.

These connected reviews will map nursing and midwifery experimental research in Australia and New Zealand. Strengths of the reviews will be the comprehensive search strategy (i.e., academic and grey literature searches) and thorough background searching to identify the credentials of lead principal investigators. Such a thorough overall search strategy will enable a comprehensive summary of previous and current research activity, potential resources for future clinical trials, as well as knowledge and research gaps. From this stance, it will be possible to develop strategies designed to support the quality and quantity of nurse- and midwife-led research in the Australian and New Zealand region.

One limitation of the proposed reviews is that the academic literature search will be restricted by the inclusion of author institutional affiliations in nursing or midwifery. This approach was considered appropriate because of the high number of search records returned when searching for randomized controlled trials in Australia and New Zealand broadly and limited project resources for title screening and evidence selection. However, restricting the search by author affiliation may lead to some clinical trials being missed because the affiliation information included in databases has changed over time (e.g., Pubmed titles only included the affiliation of the first author prior to 2014, but now includes multiple affiliations for each author), and in some cases, author affiliations may not include a reference to nursing or midwifery. To mitigate this limitation, a comprehensive search strategy is proposed, including searching a clinical trials registry and published competitive grant outcomes. In addition to this, the list of potential randomized controlled trials to include in the reviews will be assessed by members of the ANMCRN who are experts in nursing or midwifery research to confirm included trials and highlight any trials that may potentially be missed.

Funding

The two scoping reviews will be funded by the Australasian Nursing and Midwifery Clinical Research Network (ANMCRN). Members of the ANMCRN are experts in nursing and midwifery clinical trial research and their role in the review process will be as follows: (a) select members will provide guidance during the final selection of sources (i.e., to highlight any trials that may have been missed), and (b) select members will contribute to writing scoping review publications. The role of the ANMCRN in evidence selection and data presentation has been described within the main text of the manuscript.

Ethical statement

Although the manuscript did not require ethical approval, it was developed in accordance with ethical standards in systematic reviews.

CRedit authorship contribution statement

Author contribution statement JAF contributed to conceptualisation, drafting and finalisation of the review protocol. Authors CMR, RG, SM, CH, SK, GL, FN, SN, GS, LW, PY, ME contributed to conceptualisation, provided methodological and expert guidance, and reviewed draft revisions of the protocol. All authors approved the final manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

Acknowledgments

The two scoping reviews will be funded by the Australasian Nursing and Midwifery Clinical Research Network (ANMCRN). The role of the ANMCRN in evidence selection and data presentation has been described within the main text. The authors also wish to acknowledge Dr Micah Peters who provided guidance on scoping review methodology.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:[10.1016/j.colegn.2022.05.005](https://doi.org/10.1016/j.colegn.2022.05.005).

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