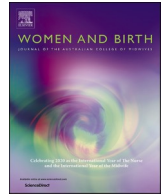




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Midwife led randomised controlled trials in Australia and New Zealand: A scoping review

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ABSTRACT

Background: Midwives are the largest workforce involved in caring for pregnant women and their babies, and are well placed to translate research into practice and ensure midwifery priorities are appropriately targeted in researched. Currently, the number and focus of randomised controlled trials led by midwives in Australia and New Zealand is unknown.

The Australasian Nursing and Midwifery Clinical Trials Network was established in 2020 to build nursing and midwifery research capacity. To aid this, scoping reviews of the quality and quantity of nurse and midwife led trials were undertaken.

Aim: To identify midwife led trials conducted between 2000 and 2021 in Australia and New Zealand.

Methods: This review was informed by the JBI scoping review framework. Medline, Emcare, and Scopus were searched from 2000–August 2021. ANZCTR, NHMRC, MRFF, and HRC (NZ) registries were searched from inception to July 2021.

Findings: Of 26,467 randomised controlled trials registered on the Australian and New Zealand Clinical Trials Registry, 50 midwife led trials, and 35 peer-reviewed publications were identified. Publications were of moderate to high quality with scores limited due to an inability to blind participants or clinicians. Blinding of assessors was included in 19 published trials.

Discussion: Additional support for midwives to design and conduct trials and publish findings is required. Further support is needed to translate registration of trial protocols into peer reviewed publications.

Conclusion: These findings will inform the Australasian Nursing and Midwifery Clinical Trials Network plans to promote quality midwife led trials.

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Statement of significance

Problem or issue

Midwives can play a critical role in leading research and translating their findings into practice. The role of midwives in leading clinical trials in Australia and New Zealand has not been quantified.

What is already known

Research initiated and led by midwives can improve the health and wellbeing of women and their babies. Previous research highlighted a dominance of non-experimental research and a lack of high-quality randomised trials directing midwifery practice and maternity services.

What this paper adds

This paper improves understanding of the scope ($n = 50$) and quality (moderate-high) of midwife-led randomised controlled trials conducted in Australia and New Zealand since 2000.

Introduction

Midwives are a highly skilled professional workforce who are in a unique position to understand the needs of pregnant women, and are therefore well placed to contribute to research [1–3]. Midwife led research brings the lived experience of the practicalities of midwifery into research, providing understanding of the impact of research on women in their care, which helps ensure that midwifery research remains women-centred and focused on midwifery specific priorities [1, 3]. Research initiated and led by midwives has the potential to improve clinical practice and the health and wellbeing of women, as well as lead to careers in research for individual clinicians, [1,4–6] furthermore, research-active health care services report fewer adverse effects [6].

Midwives have historically taken a secondary role in research, working in support roles rather than as project leaders [1,2,7,8]. Almost a decade ago studies in Australia and New Zealand revealed that midwives were under-represented in clinical trials grant funding, [9–11] and several organisational and individual barriers faced by clinical midwives willing to undertake high quality research have been identified. These include: limited access to resources; limited exposure to research activities; a perceived lack of research knowledge and skills; and an inability to access funding for research activities [1–4,12]. Underrepresentation of midwives in clinical research projects can have a flow on effect, limiting clinician influence on evidence based practice guidelines, [13–17] which in turn can impact the implementation of such guidelines in everyday midwifery or maternity care [7,18,19].

Midwife led research projects have predominantly used qualitative or observational, non-experimental research techniques [1,2,5,16,17, 20]. However, as randomised controlled trials (RCTs) are widely acknowledged as the gold standard for health research where appropriate, [21,22] it is important that midwives are involved in leading this type of research.

The Australasian Nursing and Midwifery Clinical Trials Network (ANMCTN) was established in 2020 to build nursing and midwifery research capacity, provide opportunities for collaboration and sharing of resources and expertise, facilitate nurse and midwife led trials aimed at advancing evidence in the field, and attract competitive research funding in Australia and New Zealand [23]. To inform and facilitate their goals, two scoping reviews were conducted to determine the scope and quality of 1) nurse led, and 2) midwife led RCTs in Australia and New

Zealand.

this paper aims to answer the question “What midwife led RCTs have been conducted in Australia or New Zealand?” related to this we wanted to know, “How were the identified RCTs funded?”, “What was the methodological quality of the identified RCTs?” and “Where have midwives published the results of their RCTs?”.

The two scoping reviews were run concurrently, with the results separated and reported by profession. As the scoping reviews were run concurrently, combined methodology is reported, however this paper focuses only on midwifery led RCT outcomes. The outcomes of nurse led RCTs is reported elsewhere. The answers to these questions will be used to inform an action plan to increase the quality and quantity of midwife led RCTs conducted in Australia and New Zealand.

Methods

A scoping review methodology was considered the most appropriate form of evidence synthesis to address the aim and questions of this review [24]. A preliminary search found two evidence syntheses that reviewed experimental studies in nursing and midwifery but did not exclusively focus on nurse or midwife led RCTs. Reviews were identified that examined trials conducted by oncology nurses, [25] surgical nurses, [26] and experimental and quasi-experimental nursing studies published internationally [22]. However, no scoping reviews were found that specifically identified midwife led RCTs. Further, this scoping review differs from previous reviews by identifying RCTs with a lead investigator who is a midwife, as opposed to clinical trials of midwife led interventions with a lead investigator from another discipline, and includes grey literature from trial registry and grant outcomes databases to capture unpublished trials data [27].

An a priori scoping review protocol was developed [28] and registered with the Open Science Framework; Registration DOI: 10.17605/OSF.IO/SG7VD. The protocol was guided by the Joanna Briggs Institute framework for conducting a scoping review, [29,30] and the reviews are reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses - Scoping Reviews (PRISMA-ScR) [31].

Eligibility criteria

RCTs were eligible for inclusion if at least one recruitment site was in Australia or New Zealand, and the lead investigator could be identified as holding a relevant nursing or midwifery credential and be affiliated with an Australian or New Zealand institution at the time of trial registration or date of publication. All healthcare settings were considered, as were all types of healthcare interventions with a clinical outcome. Sources were restricted to those published in English. Where nursing or midwifery qualifications were unclear, the lead investigator, their credentials, and the location of the trial or lead investigator were verified through background searches via Google, staff home pages, or the relevant regulatory authority, the checking of trial registrations, or via correspondence with the registered contact person.

Trials led by a non-nurse or midwife that included nurses or midwives as part of their multi-disciplinary research team were excluded. Trials were also excluded if authors did not explicitly report randomisation, reported quasi-randomisation, lacked a control condition, or were investigating only non-clinical outcomes. Qualitative and observational studies, conference abstracts, and reviews were excluded. Secondary reporting of previously acquired RCT data in the peer-reviewed literature was linked and reported in the number of publications resulting from that trial. Therefore, each published data extraction represents a unique individual trial.

Data extraction

For both trial registry and peer-reviewed publications, data were

extracted into unique Excel databases. Criteria extracted included: date of extraction; title and date of publication or registration; authors; lead researcher details including location and credentials; location of research and recruitment country; trial title or acronym; research field and topic; journal title and category (as defined by Scopus); trial phase; trial design methodology including blinding techniques and methods of measurement or statistical analysis; intervention type; priori sample size calculation and actual number of participants; number of sites; funding details; number of citations and related publication links. Registry data extraction also included registration type and recruitment status.

Clinical Trial registry searches

Four clinical trial registries were searched from 2000 to June–July 2021. The Australian New Zealand Clinical Trials Registry (ANZCTR), [32] a voluntary database funded by the Australian government and recognised internationally by the Primary Registry in the World Health Organization Registry Network, was selected for inclusion. Registered trials are given an ANZCTR number to be included in any publications resulting from the trial [33]. The National Health and Medical Research Council grant registry and the Medical Research Future Fund, the largest funders of health and medical research in Australia, and the Health Research Council of New Zealand database, a database supported by the New Zealand Government, were also included. Reported nursing or midwifery qualifications were investigated for review inclusion. Listed study contact details were utilised for relevant studies that did not indicate the lead investigator to screen for study eligibility. ANZCTR numbers were also extracted from peer-reviewed published data results and cross-referenced.

Peer-reviewed database search

Searches were conducted in Medline, Emcare, and Scopus in consultation with an academic librarian and the ANMCTN working group. Search terms were further tested in SR-Accelerator using SearchRefiner to establish most relevant search terms [34,35]. The Polyglot Search Translator was used to convert search terms from Medline to Scopus [36]. Search terms proposed in the scoping review protocol [28] were updated based on the iterative process of searching the databases and assessing the results. Results of database searches were deduplicated in EndNote, transferred to systematic review software [37] and deduplicated again. The results were then run through RobotSearch RCT finder (a program designed to find RCTs in a large dataset of mixed publications using artificial intelligence) [38] using a balanced filter to identify RCTs. As a check for accuracy, the original search results were manually compared to the Robotsearch screened result. Any references with RCT in the title that were not included in the Robotsearch results were assessed against the ANZCTR and grant databases that had already been screened and included for assessment if they were not previously excluded. The Johanna Briggs Institute RCT Critical Appraisal Tool (CAT) [32,39] was then used to assess the selected peer-reviewed journal articles. The CAT criteria assess participant selection, blinding, and statistical analysis techniques to determine the methodological rigour of the study and how the study has addressed the possibility of bias, awarding a score out of 13 [39]. All peer-reviewed publications that had been identified at this stage were awarded a CAT score and included for analysis. As trial registrations included proposed, ended and incomplete trials, and did not include peer-reviewed published results, the CAT was not applicable. However, methodological quality was examined through the trials' proposed methodological techniques of randomisation, blinding and control.

Results

Trial registry searches for nurse or midwife led RCTs found 4425 potentially relevant records, from which we identified 50 unique

midwife led ANZCTR registered trials located in Australia or New Zealand that utilised true randomisation from 2000 to present.

Peer-reviewed journal article database searches found 6154 potentially relevant results for both nurse and midwife led RCTs. An additional 297 publications associated with ANZCTR registered trials were found, resulting in a total of 6451 potentially relevant results. From these, 1237 duplicates were removed, leaving 5214 potentially relevant results that were entered into the RobotSearch RCT finder, [16] with 5 papers returned to the study following an accuracy check by the research team. In total, 3069 publications for 3017 RCTs were imported to Covidence [40] for screening by the research team.

The lead investigator was unclear in 83 studies, 37 in total were confirmed as nurse or midwife led studies following communication with the contact authors. The research team read 1045 publications covering 1038 RCTs in full to assess their inclusion. Publications reporting on the same RCT were linked and the main paper covering RCT outcomes was included for extraction and critical appraisal. Following screening, a further 817 articles were excluded. Altogether, 222 peer reviewed publications were extracted and appraised for both nursing and midwifery, with 35 midwifery led RCTs identified after screening [41–75]. The PRISMA flow diagram [76] (Fig. 1) outlines the search process and reasons for exclusion. [Supplementary Table 1](#) provides all screening details for the included midwife led publications.

Midwife led RCTs in Australia and New Zealand

In total, 50 midwife led RCTs in the ANZCTR database met our inclusion criteria; 47 conducted in Australia, and 3 in New Zealand. Most selected trials were conducted by midwives that held university-based positions ($n = 27$), followed by midwives that held hospital or health service-based research positions ($n = 11$). Some research was carried out by midwives in solely clinical hospital or health service roles ($n = 9$), and three lead investigators reported both clinical and university-based positions on their trial registration. Studies identified included trials that were active ($n = 12$ recruiting, 3 not recruiting), had not yet begun recruiting participants ($n = 5$), or had stopped early ($n = 3$), and therefore not all trials had publications that met selection criteria to be included in our scoping review. However, it should be noted that many of these trial registrations had not been updated since they were first entered or soon after, and therefore their current recruitment status could not be verified.

We found 35 peer reviewed publications of RCTs led by midwives in Australia and New Zealand since 2000, on a range of midwifery-related topics (Table 1). Four publications included research on midwifery topics, where nursing qualifications were found for the lead investigator, but midwifery qualifications could not be verified. The research team agreed to include these articles in the midwifery-led review, due to their focus on midwifery research (see [supplementary table](#) for more details). Only one publication involved research in New Zealand. In total, 18 publications were linked to ANZCTR registered trials. We were unable to find eligible publications for 30 midwife led ANZCTR registered trials. The RCTs in 13 publications were not found on any trial registration database. Midwifery focused articles were published in Midwifery journals ($n = 19$), Healthcare journals ($n = 14$), and nursing specific journals ($n = 2$), as defined by Scopus.

Funding sources were varied for both ANZCTR registered and peer-reviewed publications (Table 2). Universities ($n = 18$, 7), NHMRC ($n = 13$, 9) and other government funding bodies ($n = 7$, 10) were dominant funding sources, although trials were also funded by industry ($n = 2$, 4), hospital or health care organisations ($n = 9$, 4), and charitable organisations ($n = 11$, 5). Four publications did not report their funding source, and 2 ANZCTR and 2 publications explicitly stated that they were self-funded or received no external funding.

The methodological quality of identified RCTs

Peer-reviewed published RCTs were assessed utilising the Joanna

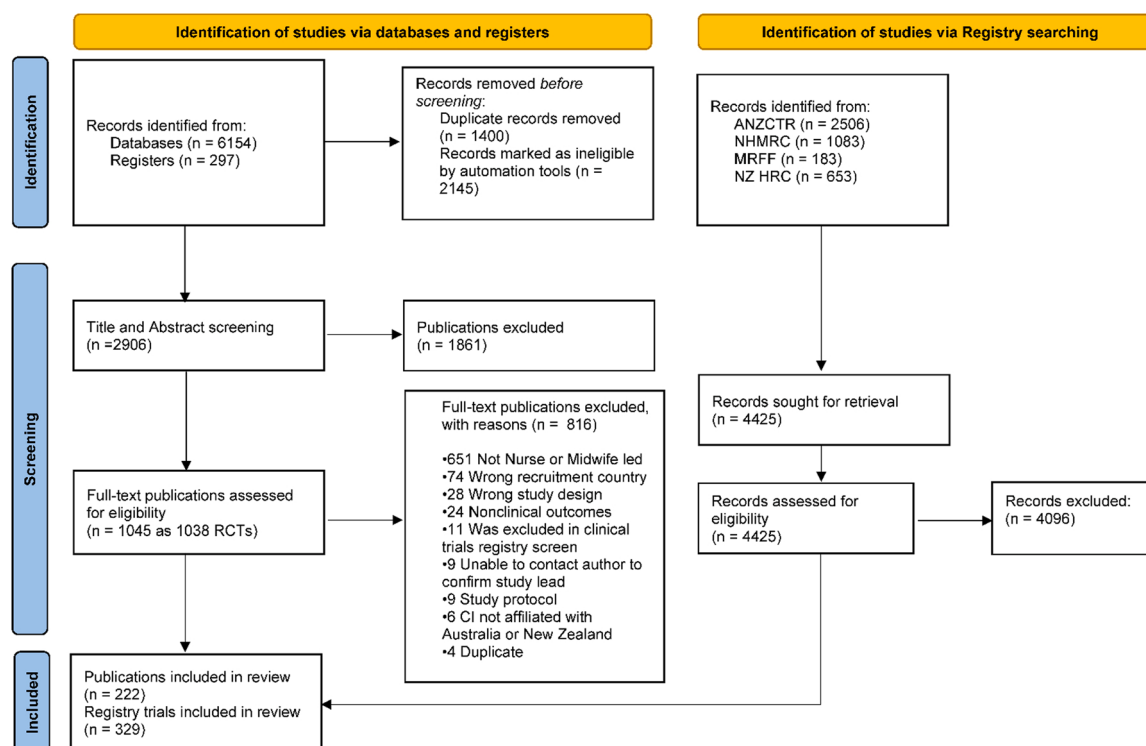


Fig. 1. PRISMA flow diagram of search process for peer-reviewed literature and registry trial data for both nurse and midwife led RCTs.

Table 1

Topics investigated in midwife led RCTs.

Type of Intervention	ANZCTR Trials	Peer Reviewed Publications
Prevention	22	3
Treatment	22	19
Education	3	11
Diagnosis	3	2
Topic ^a investigated		
Alternative and Complementary Medicine	2	–
Antenatal	37	4
Mental Health	4	1
Pain Management	2	–
Postnatal / Breastfeeding	15	8
Public Health / Health Promotion	1	–
Reproductive Health / Childbirth	48	25
Respiratory	3	–
Surgery / Surgical	1	–

^a Publications can cover more than one topic.

Table 2

Funding sources reported in publications and trial registries.

Journal Funding Source ^a	ANZCTR Trials	Peer Reviewed Publications
University	18	7
National Health and Medical Research Council	13	9
Charitable organisation	11	5
Hospital or health care organisation	9	4
Government (other)	7	10
Industry	2	4
Funding source unclear	–	4
No external funding (self-funded)	2	2
Other collaborative groups (unnamed)	1	–

^a RCTs were often funded through multiple sources.

Briggs Institute RCT Critical Appraisal Tool (CAT) [39]. Out of 13 criteria described previously, midwife led RCTs scored between 7 and 13, with an average score of 9.95, indicating moderate to high methodological quality for the majority of publications. The publication date of the papers, as illustrated in Fig. 2, had no impact on methodological quality of the studies.

Because ANZCTR trial registrations included proposed, ended, and incomplete trials, and did not include peer-reviewed published results, the CAT was not applicable, and so methodological techniques were collated for these trials (Table 3).

As required by our selection criteria, all registered trials utilised true randomisation, through computer-generated, manual or block randomisation techniques. All publications analysed participants in the groups to which they were randomised, and all were found to use appropriate statistical analysis. Significantly, blinding of participants or treating clinicians was identified as unsuitable in the majority of both ANZCTR and published RCT authors, with either open (unmasked) (n = 31, 12) or single blinding of the assessor only (n = 9, 14) techniques reported. Nevertheless, assessors were blinded in most publications (n = 20), even when blinding of the participant and treating clinician was not possible (n = 14). Only 2 ANZCTR and 2 publications included placebo controls, while the majority of ANZCTR (n = 45) and almost half of all publications (n = 17) cited the use of active control groups. This reliance on active controls may have contributed to issues with blinding in many midwife led RCTs, however, this would not necessarily impede the use of a blinded assessor for some or all outcomes.

Discussion

This scoping review found only 50 midwife led ANZCTR registered trials from January 2000 to July 2021. Over the same time period, 26,467 clinical trials from Australia and New Zealand were registered on ANZCTR. Even fewer (n = 36), peer-reviewed publications relating to midwife led Australian and New Zealand based RCTs were found. Such low numbers, and a higher number of trials registered than published,

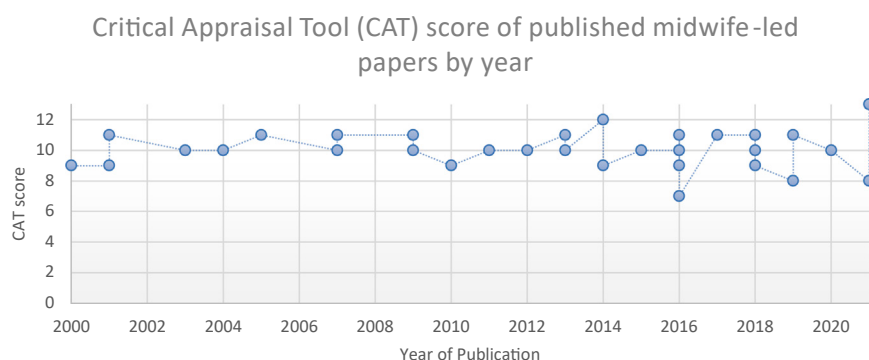


Fig. 2. JBI RCT Critical Appraisal Tool (CAT) score of published midwife-led papers by year.

Table 3

Methodological techniques utilised in midwife led ANZCTR registered and published RCTs.

Methodological techniques	ANZCTR Trials (planned)	Peer Reviewed Publications (reported)
Block randomisation	26	3
Simple randomisation (manual)	3	21
Simple randomisation (computer-generated)	18	6
Unclear	3	2
Blinding techniques		
Open (not masked)	31	12
Single blinded – participant	0	1
Single blinded – treatment	0	0
Single Blinded – assessor	9	14
Double Blinded – participant and treatment	0	1
Double blinded – participant and assessor	1	4
Triple blinded – participant, treatment, assessor	3	2
Unclear	6	2
Control groups		
Active control	45	17
Placebo	2	2
Not stated	3	17

over 20 years indicates that additional support for midwives to design, conduct research and publish findings is required.

Publications were predominantly of moderate to high methodological quality according to the CAT, with scores between 7 and 13 for all publications. CAT scores were limited by author-reported unsuitability of blinding participants and/or clinicians for many midwife led interventions, as authors reported practical and ethical considerations that prevented blinding of participants or treating clinicians. However, blinding of assessors was included in the majority of RCTs. This result is consistent with the literature, which identified sample selection as a key methodological consideration for midwifery research [77]. Ethical considerations required the use of active control groups, rather than a placebo control, as has been identified in midwifery research and discussed elsewhere [4,78]. Nevertheless, an inability to blind participants and/or clinicians would not impede the use of blinding in the analysis of data through a blinded assessor. Blinded assessors were utilised in a slim majority (19 out of 35) of published papers, strengthening the reliability of the outcomes.

Funding differences were noted between ANZCTR registered trials and peer-reviewed publications, with more university, NHMRC and charity funded trials listed in the ANZCTR registry. More industry funded trials were found in publications, as were non-NHMRC government funded trials, while health care organisation funding was comparable in both groups. These results suggest increased publications are resulting from external funding sources, however not enough externally funded

RCTs were identified in this search to confirm this is the case.

Despite a spike in publications in 2016–2017, there was no upward trend to suggest an increase in midwife led RCTs in recent years. The recent COVID-19 pandemic may have reduced the number of RCTs carried out in midwifery since 2020; however, there is no data currently available to assess this impact [4,79].

Previous studies have identified an overall reduction (since 2009) in the proportion of successful government-sponsored grants in Australia's highly competitive grants funding environment as an inhibitor for upcoming midwives starting research careers [2]. As each research team member is required to demonstrate their research experience, clinician midwife researchers may be disadvantaged during selection processes [2]. Other workplace factors may also limit clinician research opportunities. For example, McNeill and Nolan found that perceptions of research as taking both time and space away from clinical care limited some midwife engagement in research [77]. Research carried out by clinician midwives or midwives who hold both clinical and research positions were minimal, with only six midwives that held both clinical and research positions identified in both registry trial data and peer reviewed publications over the last 20 years. This indicates that resources and support are required to strengthen clinician-researcher skills and capabilities for midwives in Australia and New Zealand.

A lack of midwife led research can impact upon the implementation of evidence-based care. Historically, [1,8,18–20,80] and as recently as 2021, [7] studies have identified continued use of outdated traditions or a reluctance to use newer evidence-based guidelines from some midwives. A 2019 international systematic review found that updated evidenced based best practice was not always employed in midwifery clinical settings [18]. In their qualitative research project, Dagne and Tebeje reported that midwives were reluctant to use research findings in clinical care, as they felt unsupported, with some fearing accountability for potential client harm [81]. They recommended that more support was needed for midwives to utilise research in clinical decision-making practice. Additional support for more clinician led research in midwifery, as “holders of authoritative knowledge” with lived clinical experience, [19] could contribute towards the translation of research into everyday clinical care [19].

Overall, these findings demonstrate that published midwife led RCTs conducted over the last 20 years in Australia and New Zealand, although sporadic, are of moderate to high quality. However, as out of the 4425 registered trials and 1045 publications that were identified on the topic of nursing or midwifery, only 35 papers and 50 Registered RCTs were midwife led, it is clear that midwife-led RCT research represents a very small proportion of midwifery RCT research in Australia and New Zealand. Translating registration of RCT protocols in a national database such as the ANZCTR into peer reviewed publications was identified as an area that required improvement, for the future of midwife led RCT research, translation into clinical care, and transparency of research in general.

Limitations

Due to the questions asked, it is likely that relevant RCTs and publications linked to them may have been missed. This scoping review, along with the companion scoping review regarding nurse-led RCTs, aimed to map the extent of RCTs led by nurses and midwives; however, this is not something that can be easily searched for in peer-reviewed publication databases. The research team tried to address this through a comprehensive and extensive search strategy covering multiple research repositories. However, we discovered that many nurses and midwives do not list their registration status or full qualifications (for example, research qualifications including Ph.D. or Masters were listed but preceding nursing or midwifery qualifications were omitted) on publications, or even on staff home pages or other career focused websites (i.e.: Research Gate, LinkedIn, ORCID). This made it difficult to confirm qualifications and indicated that clinical qualifications and skills were not prioritised. Researchers not providing their clinical qualifications on trial registries and academic sites could suggest a potential omission of clinical experience in research, which requires further exploration [7,19,77]. Nevertheless, this scoping review used a multi-faceted approach to attempt to address this issue and find unlisted clinical qualifications. Overall, we are confident that this review provides a good overarching indicator of the RCTs conducted by midwives in Australia and New Zealand over the last 20 years.

Conclusion

This scoping review utilised registry trial data and peer-reviewed database searches to determine the scope and quality of midwife led clinical trial research in Australia and New Zealand since 2000. While limited in scope, publications found were assessed to be of moderate to high quality. Improvements are needed to increase publications from ANZCTR registered trials, and support midwife-led research to inform evidence-based care. Barriers to data collection included lead researchers not listing their clinical qualifications on academic research trial entries. These findings, and the findings of the companion scoping review on nurse led RCTs, will inform the newly created ANMCTN in their role of promoting opportunities for quality nurse and midwife led RCT research, potentially informing best practice and improving patient care for both disciplines.

Ethical approval

None declared.

Author contribution

All authors conceptualisation; all authors methodology; all authors formal analysis; KN KK ME GS data curation; CH KN KK writing original draft; CH AG KB ME writing review & editing.

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Declaration of Competing Interest

The authors declare their involvement in various clinical trials that have been referenced in this scoping review. Caroline Homer also declares she is the current Editor-in-Chief of Women & Birth. The Deputy Editor, Prof Linda Sweet, managed this submission and made the final decision. All other authors have no further conflicts to declare.

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Author contributions

All co-authors have reviewed the final version submitted for review and agree to submission.

Clinical trial registry and registration number

Not applicable.

Scoping review protocol: Fish, J., Rickard, C., Gray, R., Middleton, S., Homer, C., Keogh, S., Leslie, G., Nemeh, F., Neville, S., Sharplin, G., Yates, P., Whitehead, L., Eckert, M. A scoping review of nurse- and midwife-led randomised controlled trials in Australia and New Zealand: a protocol. 2020 December 14.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.wombi.2023.03.003](https://doi.org/10.1016/j.wombi.2023.03.003).

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