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REVIEW

A scoping review of nurse-led randomised controlled trials

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Abstract

Background: Nurses comprise the largest portion of the healthcare workforce worldwide. However, nurse representation in the leadership of clinical research and research funding is largely unknown. The Australasian Nursing and Midwifery Clinical Trials Network was established to provide a coordinated network, focussed on building research capacity in nursing and midwifery. To support this work, this scoping review of nurse-led randomised controlled trials was conducted to summarise research activity, as well as highlight future research directions, gaps and resources. Midwife-led trials will be reported elsewhere.

Aim: To quantify number, type and quality of nurse-led randomised controlled trials registered between 2000–2021.

Design: A scoping review of RCTs.

Data Sources: Medline, Emcare and Scopus were searched from 2000 to August 2021. ANZCTR, NHMRC, MRFF and HRC (NZ) registries were searched from inception to July 2021.

Review Methods: This review was informed by the JBI scoping review framework using the PRISMA-ScR.

Results: Our search yielded 186 nurse-led publications and 279 registered randomised controlled trials. Multiple trials had the same nurse leaders. There were more registrations than publications. Publications were predominantly of high methodological quality; however, there was a reliance on active controls and blinding low. Trial registrations indicate that universities and hospital/healthcare organisations were the major sources of funding, while publications indicate that Governments and the National Health and Medical Research Council were the main funding bodies.

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Conclusion: A small number of high-quality, large-scale, nationally funded randomised controlled trials were identified, with a larger number of locally funded small trials. There was a disparity between the number of registered trials and those published. Additional infrastructure, funding and career frameworks are needed to enable nurses to design, conduct and publish clinical trials that inform the health system and improve health outcomes.

Relevance to Clinical Practice: Research initiated and led by nurses has the potential to improve the health and well-being of individuals and communities, and current nurse-led research is of high methodological quality; however, there were very few nurse-led RCTs, conducted by a small pool of nurse researchers. This gap highlights the need for support in the design, conduct and publishing of nurse-led RCTs.

Patient or Public Contribution: This is a scoping review; therefore, patient or public contribution is not applicable.

KEYWORDS

clinical nursing research, clinical research, clinical studies as topic, nurse, nurse's role, nursing research, randomised controlled trials as topic, registries, review

1 | INTRODUCTION

Nurses and midwives comprise nearly 50% of the health workforce worldwide (World Health Organization, 2020a). Nurses are highly knowledgeable about primary, secondary and tertiary care, and current issues across clinical care, and are key to the delivery of quality healthcare, yet relative to the burden of disease on our community the investment in nurse-led clinical trials is not ideal (Australian Institute of Health and Welfare, 2016; Ministry of Health, 2016). Research initiated and led by nurses has the potential to improve the health and well-being of individuals and communities (Borbasi et al., 2002) and to conduct the research needed to inform nursing practice (World Health Organization, 2020b). However, previous reviews of nursing research highlight the dominance of nonexperimental research and the scarcity of high-quality randomised controlled trials (RCTs) (Borbasi et al., 2002; Mantzoukas, 2009; Wilkes & Jackson, 2011). This has a flow-on effect for the clinical practice recommendations made in best practice guidelines, as many nursing-specific guidelines rely on predominantly level 3 evidence (high-quality qualitative research evidence) or lower to inform evidence-based care (Registered Nurses' Association of Ontario, 2020). While clinical trials are prevalent across the health system with other disciplines such as medicine, we may not be addressing critical issues due to the lack of nurse-led clinical trials. The drive to ensure research evidence is used to improve nursing practice feeds into the need for the conduct and publication of high-quality research, focussed on nursing-specific priorities (Borbasi et al., 2002). There is an urgent need for researchers, clinicians, policymakers and consumers to work collaboratively to prioritise the most important questions, secure appropriate research funding and undertake well-designed trials to ensure we deliver best evidence-informed care and optimal outcomes for the community.

Nurse-led RCTs, which build upon previous research evidence, address questions related to effectiveness, generalisability and implementability, and inform successful evidence-based nursing practice, are needed (Australian Clinical Trials Alliance, 2020; Borbasi et al., 2005; Hopia & Heikkilä, 2020; Mantzoukas, 2009; Wilkes & Jackson, 2011).

2 | BACKGROUND

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 (Australasian Nursing and Midwifery Clinical Trial Network, 2022). To support this work, we aimed to gain an understanding of the current nurse- or midwife-led clinical research by mapping the number and types of RCTs led by nurses or midwives within Australia and New Zealand registered between 2000–2021. Two separate but concurrent scoping reviews were conducted to enable sufficient investigation of experimental research in each profession of nursing and midwifery. This information is needed to summarise the current research activity and highlight future research directions and resources. This paper is focussed on the results related to nurse-led RCTs in the current literature; the results of midwifery-led RCTs will be reported elsewhere.

A search for protocols or reviews on nurse-led clinical trials in Australasia in the past 5 years found nothing on the topic; however, several international reviews were noted. Two evidence syntheses reviewed experimental studies in nursing worldwide, but did not exclusively focus on nurse-led trials. Charalambous et al. (2018)

reviewed clinical trials testing interventions led or delivered by nurses in cancer control specifically. Gonella et al. (2019) more broadly investigated experimental and quasi-experimental studies published in high-impact nursing journals. These reviews included nurse-led research, 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 current research capacity in nursing.

The methods used within previous reviews also limited the conclusions that could be drawn about nursing research activity within Australasia specifically. Gonella et al. (2019) found that Australia and New Zealand had the lowest number of RCTs ($n = 18/340$) across an 8-year period (2009–2016) compared with Asia, Europe and America. However, this could be an underestimation given that the focus of this review was on experimental studies published in nursing journals.

Munday et al. (2020) recently conducted a scoping review investigating international nurse-led RCTs, but was limited in scope and focussed solely on perioperative care. The review (Munday et al., 2020) identified 86 nurse-led RCTs conducted worldwide. Although they identified key research areas of perioperative care and gaps for future research, taking a wider focus to include all areas of nursing is needed to provide insight into areas of critical need for capacity building more broadly.

For the ANMCTN to facilitate nurse-led trials and increase the competitiveness of nurses for research funding, an understanding of the current nurse-led research is required. The objective was to undertake a scoping review to map the number and types of nurse-led RCTs conducted within Australia and New Zealand to inform a future action plan to address any gaps in the quality and quantity of nurse-led RCTs.

2.1 | Aim

The aim of this scoping review was to identify nurse-led RCTs conducted in Australia or New Zealand. Specifically: 'What nurse-led RCTs have been conducted in Australia or New Zealand?' and of these RCTs, 'How were the identified RCTs funded?', 'What was the methodological quality of the identified RCTs?' and 'Where have nurses published the results of their RCTs?'

As the two scoping reviews (nurse-led and midwife-led) were run concurrently, combined methods are reported.

2.2 | Design

As our question was very broad, we were mapping the extent of current RCTs led by nurses, and we were investigating multiple evidence types and sources, a scoping review was considered the most appropriate form of evidence synthesis (Peters et al., 2020; Pollock et al., 2021). As this is a scoping review design, the search strategy

is not limited to nursing-specific journals and includes grey literature from trial registry and grant outcomes databases.

An a priori scoping review protocol was developed (Fish et al., 2022) and is registered with the Open Science Framework (<https://osf.io/sg7vd>). The protocol was guided by the JBI framework for conducting a scoping review (Peters et al., 2017, 2020), and the reviews are reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses—Scoping Reviews (PRISMA-ScR) (Tricco et al., 2018; Appendix S1). Institutional ethics approval was not required before commencing the reviews.

2.3 | Search methods

2.3.1 | Eligibility criteria

Trials were included if they were RCTs that recruited at a minimum of one Australian or New Zealand site; the lead investigator reported a relevant nursing or midwifery credential and was affiliated with an Australian or New Zealand institution at the time of trial registration, or date of publication. Where it was unclear, the lead investigator, their credentials and the location of the trial or lead investigator were verified through background searches via Google searches, staff home pages, ORCID registration, Nursing and Midwifery Board registrations, cross-checking of trial registrations, or correspondence with the registered contact person. All healthcare settings and healthcare interventions with a clinical outcome were considered. Sources included peer-reviewed journal articles and grey literature (publicly available trial registration records and funding records). Sources are restricted to those published in English.

Trials were excluded if they were led by a non-nurse or midwife; authors do not explicitly report randomisation, report quasi-randomisation, lacked a control condition or were investigating staff educational or other nonclinical outcomes. Qualitative and observational studies, conference abstracts and reviews were excluded. Secondary reporting of previously acquired RCT data was linked back to the original RCT and reported in the number of publications resulting from that RCT.

2.3.2 | Search for peer-reviewed literature

With assistance from an academic librarian and the ANMCTN, the research team developed and refined a search strategy (Fish et al., 2022). Tools in the SR-Accelerator were used to further refine the search terms and convert search terms from Medline to Scopus (Clark et al., 2020). The search terms proposed in the protocol (Fish et al., 2022) were updated based on this process, removing the specific Australian or New Zealand city queries, and modifying the RCT search query (Table 1). KK ran the search in Medline, Emcare and Scopus using index terms appropriate for each database. KK pooled the search results into an Endnote library and removed duplicates. For the published RCTs, the main paper that presented the

Database searched	Search terms used
Medline search, conducted on 18 August 2021	<p>Search No. Terms used</p> <p>1. Randomized Controlled Trial/</p> <p>2. (randomi#ed adj5 trial).mp</p> <p>3. OR/ 1, 2</p> <p>4. Australia.mp. or exp Australia/</p> <p>5. New Zealand.mp. or exp New Zealand/</p> <p>6. OR/ 4, 5</p> <p>7. (nurs\$ or midwi\$).af.</p> <p>8. AND/ 3, 6, 7</p> <p>9. Limit 8 to (English language and humans)</p> <p>10. Limit 9 to year = "2000 to Current"</p>
ANZCTR	'nurs*', 'midwi*' advanced search options: (a) randomised allocation, and (b) Australia or New Zealand
NHMRC grants registry	'Clinical trial', 'clinical study', 'clinical studies', 'randomised', 'randomized', 'controlled', 'trial', 'nurs', 'midwi'
MRFF grants registry	'Clinical trial', 'clinical study', 'clinical studies', 'randomised', 'randomized', 'controlled', 'trial', 'nurs', 'midwi'
HRC research repository	'Randomised controlled trial', 'RCT', 'clinical study', 'nurse', 'nursing', 'midwife'

TABLE 1 Search terms used by database searched.

results of the trial was selected for extraction and critical appraisal. Publications that presented secondary information (i.e. only quantitative results, subsections of the population involved, data collected or cost analyses) were linked to the main paper covering the trial outcomes.

2.3.3 | Search for grey literature

Four registries were searched from 2000 to June–July 2021: Australian New Zealand Clinical Trials Registry (ANZCTR); The National Health and Medical Research Council (NHMRC) grant registry; The Medical Research Future Fund (MRFF); and the Health Research Council of New Zealand (HRC). These are the primary trial registries for Australian and New Zealand clinical trials conducted by either nurses or midwives. The ANZCTR is part of a worldwide initiative to make all clinical trials public. It is funded by the Australian government and recognised internationally by the Primary Registry in the World Health Organization Registry Network (Australian and New Zealand Clinical Trials Registry, 2022). The NHMRC and MRFF are the largest funders of health and medical research in Australia, and the HRC research repository contains records of all HRC-funded studies and is supported by the New Zealand Government. We expected to see an overlap of RCTs in these databases.

Key word searches and preliminary screening for eligibility (RCT, and a nurse or midwife research lead) were conducted across the four registries by JF, KK and DF; results were downloaded to Excel spreadsheets.

2.4 | Study selection

Screening was conducted independently on the databases by KK, KN, DF and JF. Test sets of data screening and extraction were conducted on all databases by all reviewers and compared for consistency (80% or higher agreement was deemed appropriate); any discrepancies were discussed to confirm consistency (Tricco et al., 2018). Any trials that were unclear were flagged for further review and discussion with at least one other reviewer; disagreements were resolved by group consensus.

RobotSearch RCT finder is a programme designed to find RCTs in a large dataset of mixed publications using artificial intelligence (Marshall et al., 2018). This programme was used by KK to screen the de-duplicated literature search results for RCTs using a balanced filter. As a check for accuracy, the original search results were manually compared with the Robotsearch RCT finder screened result. Any references with RCT in the title that were not included in the Robotsearch RCT finder results were assessed against the ANZCTR and grant databases that had already been screened; if they were not previously excluded the articles were then included for further assessment. These results were then screened by title and abstract and then full text in Covidence by KK, DF and KN to assess their fit to the eligibility criteria.

Where ANZCTR entries listed the lead investigator, names and affiliations were used to conduct a background search to verify their credentials. Trials with a lead investigator with a nursing or midwifery credential were included for further review according to the eligibility criteria listed above. For trials without a lead investigator listed, a background search was conducted on study

contacts to identify potentially relevant trials. Trials that did not list a nurse or midwife for scientific enquires nor public enquiries were excluded. Trials that listed a nurse or midwife for scientific enquires and public enquiries or trials for which a nurse or midwife was listed for public queries or scientific enquires, but another healthcare professional was also listed were included for further screening.

Due to the limited information provided in the MRFF grant database (funded institution, project name and lead investigator name), we were unable to determine which grants were RCTs. As such, the lead investigator was searched for in Google to confirm they were a nurse or midwife. Further searching was conducted in the ANZCTR to see whether the project name was registered. Finally, targeted internet searching was conducted to find any information available on the projects that could confirm they were RCTs. The HRC Research Repository registry did not allow us to download registration summaries, so all screening was conducted within the registry and relevant results copied into a word document. Search records were saved according to year, and the lay summary was read to confirm the study was an RCT. If there was any indication, it could be an RCT the study was entered into an Excel spreadsheet, listing the year, budget, researcher, host institution and proposal type. When all grants had been screened, the ANZCTR excel spreadsheet was searched to see whether the related trials had already been included or excluded in this study, and a Google search was conducted to ascertain whether the lead investigator was a nurse or midwife. Any potentially relevant trials were included for further screening. Data from NHMRC grants registry were sorted by grant number and reviewed for duplication. Potentially relevant grants were screened by title, key words and media notes to confirm they were RCTs.

Final screening of the potentially relevant results involved reading the entries in detail to determine their fit to the eligibility criteria. The trials for which the lead investigator could not be confirmed, or the credentials could not be discerned through background searching; the contact person was emailed for confirmation.

2.4.1 | Critical appraisal

The JBI RCT critical appraisal tool (Tufanaru et al., 2020) was used to assess the methodological quality of the peer-reviewed journal articles. The main paper that presented the results of the trial was appraised. There is no tool to critically appraise the methodological quality of the database entries; however, the proposed methodological approaches (randomisation, blinding and control groups) were extracted. Critical appraisal is not considered standard for scoping reviews (Peters et al., 2022); however, this review wanted to establish the methodological quality of nurse-led RCTs. As such, the scores are reported but had no impact on inclusion to the review.

TABLE 2 Information extracted from data sources.

Information extracted
Reference (literature) ^a
ANZCTR number (trials)
Title of trial and acronym
Principal Investigator
Credentials ^b
Affiliations and country
Field of nursing or midwifery
Topic area
Journal (literature)
Journal category (literature - used Scopus categorisation)
Number of citations (literature - used Scopus citation tracker)
Recruitment country
Trial design
Trial phase
Reported use of CONSORT
Intervention type
Number of intervention sites
A priori sample size calculation
Reported sample size (literature)
Funding
Grant funder
Number of publications linked to the trial

^aData unique to a source are indicated in brackets.

^bBased on self-reporting of a nursing or midwifery qualification in the article, trial registration or publicly available sources, such as staff or professional webpages, or registration boards, or via email correspondence.

2.4.2 | Data extraction

Data deemed relevant to the research questions were extracted into custom-built excel spreadsheets for each source type, based on expert opinion and consensus of the development group, and test extraction by the reviewer team; key data were extracted to answer the review questions (Table 2). The information was synthesised narratively.

3 | RESULTS

There were 6154 potentially relevant publications from the journal database searches (Figure 1). A further 297 publications were found in the registries, resulting in 6451 potentially relevant results. After the removal of duplicates and screening for RCTs using RobotSearch RCT finder (Marshall et al., 2018), 2906 publications (covering 3017 RCTs) were imported to Covidence (Veritas Health Innovation, 2022) for screening. Title and abstract screening excluded a further 1861

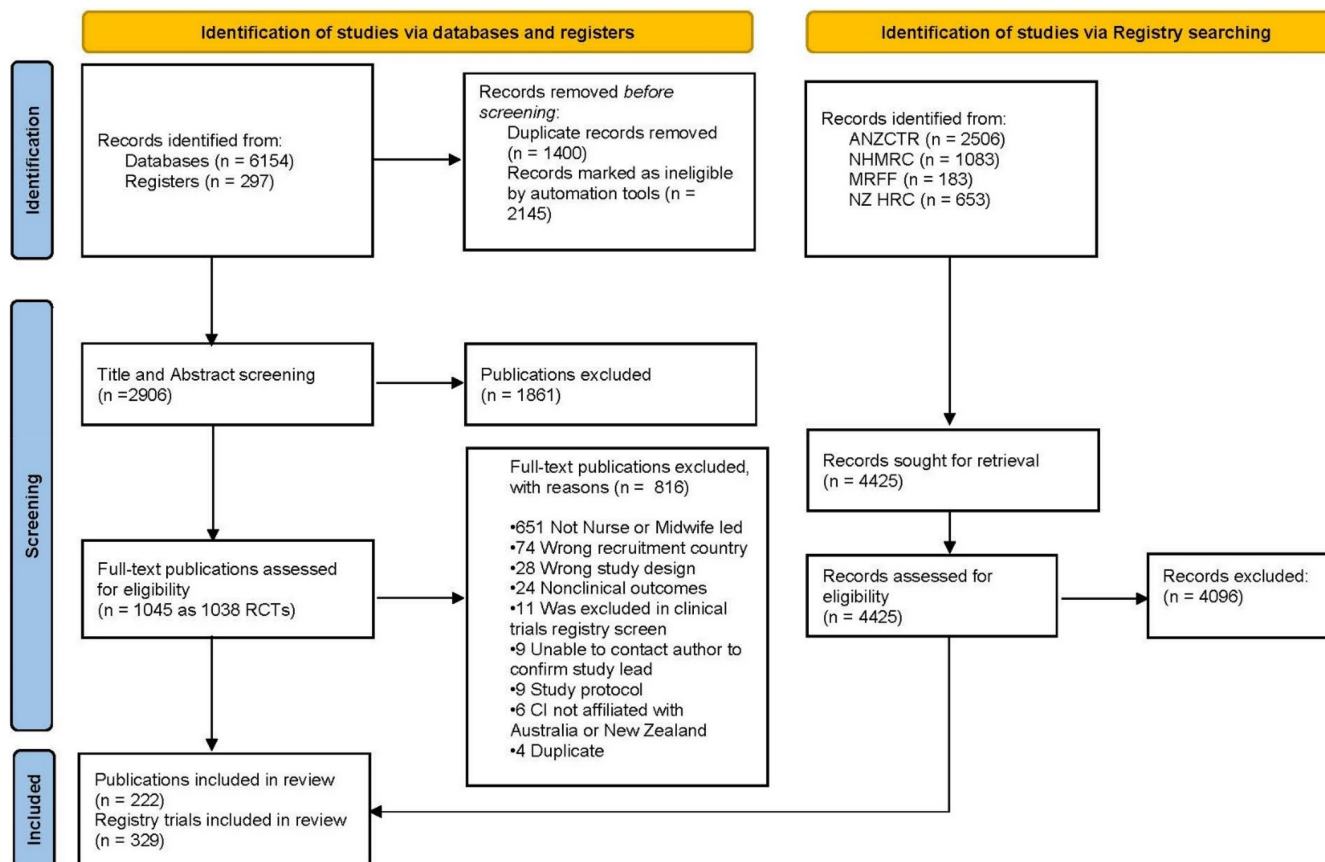


FIGURE 1 PRISMA flow diagram of journal article search process (Page et al., 2021).

papers; 1045 publications covering 1038 RCTs were read in full to assess their inclusion. At this stage, the publications were linked together in Covidence if they reported on the same trial. In 83 studies, it was not clear who the lead investigator was, or if the lead investigator was a nurse or midwife. The contact author of these publications was emailed for confirmation of the lead investigator and 37 further trials that met the inclusion criteria were included. A further 817 articles were excluded (see Figure 1 for exclusion reasons), resulting in publications relating to 222 RCTs extracted and appraised. Of these, 186 were nurse-led and will be reported on here (Table S1 has details of the included nurse-led publications).

Australian New Zealand Clinical Trials Registry returned 2506 potentially relevant records. Of these, 329 were flagged for further screening, resulting in 274 nurse-led trials included, a further three ANZCTR-registered trials were found in the HRC registry search and two through the peer-reviewed literature search resulting in 279 nurse-led trials included. The NHMRC database returned 1083 potentially relevant records; of these, 47 were included for further screening and 16 studies we were unsure of the lead investigator's credentials. Emails were sent to the listed contact to confirm the lead investigator and their credentials. This resulted in the inclusion of seven NHMRC-funded studies. The MRFF database returned 183 potentially relevant records of which one met the inclusion criteria.

The HRC Research Repository returned 653 potentially relevant records. Of these, 208 were identified as potentially relevant. Emails were sent to the listed contact on three records to confirm the lead investigator and their credentials; only one was nurse-led. Detailed screening found eight grants that met the inclusion criteria. Of the ANZCTR results, 112 were cross-referenced to the peer-reviewed journal articles, 10 were cross-referenced to the NHMRC registry, one was cross-referenced to the MRFF registry, and eight were cross-referenced to the HRC grant registry. As all results found in the four registries were included in the ANZCTR database, and this had the most detailed information, we have referred to this registry from here on.

4 | WHAT RCTS HAVE BEEN LED BY NURSES IN AUSTRALIA AND NEW ZEALAND?

4.1 | ANZCTR

Of the 279 RCTs led by 88 different nurses in the ANZCTR which met our inclusion criteria, 254 were conducted in Australia, 23 in New Zealand, and two were multisite trials conducted in Australia

and overseas (Canada and China). Most trials were conducted by nurses with university-based positions (Table 3). However, trials were also carried out by nurses with hospital or health service-based research positions or who worked in both university and clinical roles. Studies included trials that were still active, but had not yet begun recruiting participants, or had stopped early, and therefore, not all trials had publications that met the selection criteria to be included in our scoping review (Table 3). It should be noted that many of these trials had not been updated in the registries since registration, or for several years after they were underway. This meant we found publications of results for trials that stated they were still recruiting or had not yet started recruiting in the registries we searched.

4.2 | Publications

We found primary publications related to 186 RCTs covering a wide range of intervention types and topics (Table 4). Further investigation found 356 publications (primary results and secondary analysis) connected to these trials (Figure 2). Of the 186 RCTs, 172 were conducted in Australia, 12 were conducted in New Zealand, and two were multisite trials conducted in Australia and overseas (Taiwan, America). There were 112 publications reporting nurse-led RCTs that could be linked to trials identified in the ANZCTR database, leaving 167 registrations in the ANZCTR that we could not find publications for and 74 publications without identified registration.

TABLE 3 Details of included nurse-led trials found in the ANZCTR database.

Lead investigator professions ^a	Number of trials
University position, academic (research or teaching)	206
University and clinical positions (when provided)	64
Hospital or health service-based researcher ^b	50
Hospital clinical position ^c	18
Location of researcher	
Australia	261
New Zealand	16
Recruitment status	
Completed	149
Not yet recruiting	72
Active (recruiting)	44
Stopped early	8
Active (not recruiting)	6

^aAt time of research publication. Note that some researchers have been recorded multiple times for different pieces of research or different roles.

^bMay also work in a clinical role, research position listed in trial registry.

^cWhere listed as the only position.

TABLE 4 Topics and type of intervention (as listed in ANZCTR) investigated in nurse-led RCTs.

Type of intervention	Publications (n = 186)	ANZCTR (n = 279)
Treatment	111	127
Education	41	52
Prevention	31	98
Intervention ^a	2	-
Rehabilitation	1	1
Diagnosis	1	1
Topic investigated ^b		
Surgical/postsurgical or critical care	39	30
Cardiovascular/stroke	34	50
Aged care	20	23
Intravenous device	18	2
Skin care and wound prevention	11	24
Paediatrics	11	-
Respiratory	10	24
Cancer	9	26
Mental health	8	25
Injury/accidents	8	18
Infection control	6	32
Diabetes	5	32
Arthritis/joints/orthopaedics	5	5
Incontinence	4	2
Viral disease (HIV/Hepatitis C)	3	-
Medication management	2	1
Palliative care	2	1
Health service/public health	-	41

^aThese were interventional in nature but covered multiple categories.

^bPublications can cover more than one topic.

5 | WHAT WAS THE METHODOLOGICAL QUALITY OF THE IDENTIFIED RCTs?

Although we are not able to 'score' the ANZCTR trials database entries in the same way we can the journal articles, we found varied methodological approaches proposed in the 279 RCTs included, as seen in Table 5. All trials used true randomisation to meet selection criteria and reported various randomisation techniques. Treatment interventions were the most common, followed by prevention and education. Blinding was not always possible in the trials, with 126 out of 279 trials reporting open (unmasked) interventions. However, in 60 trials where participants and/or treating clinicians could not be blinded, analysis was carried out by blinded assessors. Few trials noted triple blinding, or double blinding of either participants and assessors, or participants and treating clinicians. Most interventions included an active control, while a much smaller number proposed to use placebo controls.

Nurse-led RCT publications by year

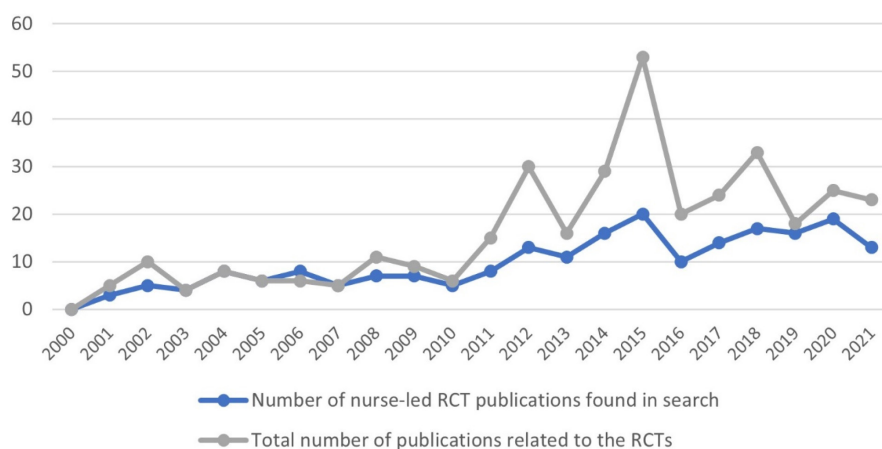


FIGURE 2 Number of RCT publications reporting on the main results per year, and the number of overall publications related to these RCTs found in the peer-reviewed literature.

TABLE 5 Methodological techniques utilised in nurse-led ANZCTR registered RCTs.

Methodological techniques planned	ANZCTR (n = 279)
Block randomisation	121 (43%)
Simple randomisation (computer-generated)	137 (49%)
Simple randomisation (manual)	16 (6%)
Simple randomisation, not described	5 (2%)
Blinding techniques planned	
Triple blinded—participant, treatment, assessor	27 (10%)
Double blinded—participant and treatment	3 (1%)
Double blinded—participant and assessor	7 (3%)
Single blinded—participant	6 (2%)
Single blinded—treatment	1 (0.4%)
Single blinded—assessor	60 (21%)
Blinded, no details given	49 (17%)
Open (not masked)	126 (45%)
Control groups planned	
Active control	256 (91%)
Placebo	20 (7%)
Dose comparison control	2 (0.7%)
Historical control	1 (0.4%)

Publications that were linked to the same RCT but presented secondary information (i.e. only subsections of the population involved or the data collected) were not appraised (reflected in Figure 2). This resulted in 186 unique publications being critically appraised. Publication dates ranged from 2001–2021; date of publication had no impact on methodological quality of the studies according to the JBI RCT critical appraisal tool (Tufanaru et al., 2020). Most publications were of moderate to high methodological quality; 81% scored between 9–13 on the JBI RCT tool (Figure 3), indicating good methodological quality in the research found. The average critical appraisal score was 9.6, with a spread of 3–13 out of a possible top score of 13. Only 77 (41%) of the publications referenced the

Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz et al., 2010) in reporting their findings.

In 156 primary RCT publications (84%), the participants were not blinded to the intervention. Of these, four trials had those delivering the intervention blinded (3%), and 70 trials used a blinded outcomes assessor for some, or all outcomes (45%). In 170 RCTs, the person delivering the treatment was not blinded (91%). Of these, 18 blinded the participants to the treatment type (10%), and 74 used a blinded outcome assessor for some, or all outcomes analysed (43%).

The 174 publications that reported participant characteristics for their randomised groups found them to be similar (no significant differences); the remaining 31 publications either did not report participant characteristics or did not provide enough detail to assess for clinically important differences that may impact trial findings.

6 | WHERE HAVE NURSES PUBLISHED TRIALS?

Most articles were published in healthcare journals (as defined by Scopus) (n = 124) and then nursing journals (n = 65) (Table S1). Most RCTs (n = 113) had one publication reporting on the trial; however, 66 RCTs had 2–4 linked publications, and one had 24 linked publications.

7 | WERE THE IDENTIFIED RCTS FUNDED, AND IF SO, BY WHICH FUNDING SOURCE?

Of the 186 journal articles found, 34 did not provide funding information and seven were self-funded (Table 5). Of the publications that reported funding, 132 sited multiple sources of funding. Funding sources were listed in the ANZCTR as primary and secondary sources of funding (Table 5). Although the ANZCTR data suggest that universities and hospital or healthcare organisations provided most of the research funding, the published results of the trials indicate Government and the NHMRC to be the major sources

FIGURE 3 Frequency and percentage of scores using the JBI RCT Critical appraisal tool (CAT).

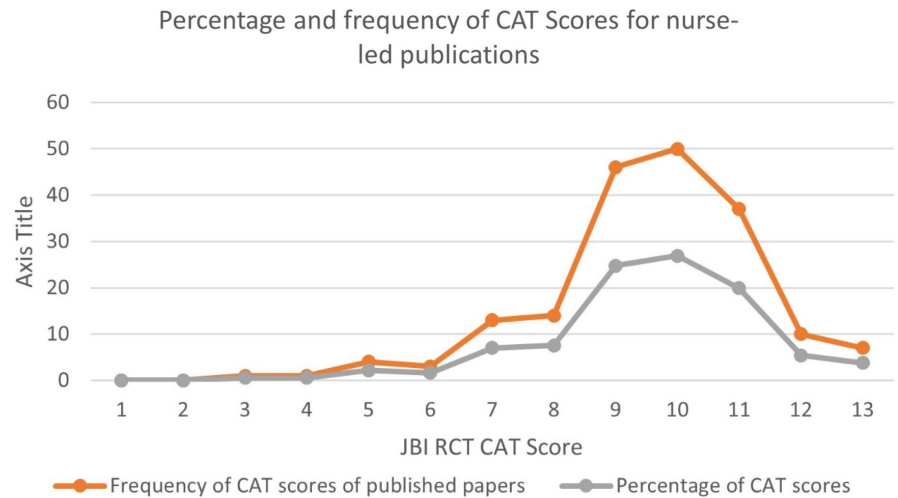


TABLE 6 Funding sources reported in publications and trial registries.

Journal funding source ^a	Publications (n = 186)	ANZCTR primary (n = 279)
Government (non-NHMRC)	52	54
NHMRC	34	37
Industry	33	27
Hospital or healthcare organisation	29	48
Charitable organisation	29	59
University	25	78
No external funding (self-funded)	7	8

^aNB: RCTs were often funded through multiple sources.

of funding. Eleven entries in the ANZCTR were withdrawn or suspended, five due to a stated lack of funding, and the other six reported either recruitment problems or no reason for suspending the research (Table 6).

8 | DISCUSSION

This scoping review found 186 nurse-led RCTs in the literature, and 279 registered RCTs in the ANZCTR during the preceding 20-year period (2000–2021). These figures are higher than those identified in previous research (Gonella et al., 2019; Munday et al., 2020). However, most nurse-led publications found in our review were in healthcare-centric journals, rather than nursing-specific journals, and covered a broad range of topics, suggesting previous research would have missed many of these trials (Charalambous et al., 2018; Gonella et al., 2019; Munday et al., 2020).

The publications were predominantly of high methodological quality according to the JBI RCT critical appraisal tool scores with 150 publications scoring 9–13 on the tool (80%) and only two

publications scoring four or less on the tool. The reported use of the CONSORT statement did not seem to affect the methodological quality of the publications; the scores for publications referencing the CONSORT statement were 4–13, and this is in line with the overall methodological quality of the publications. The CONSORT statement was first published in 1996, meaning it was in circulation and use during the period covered in this review. Blinding of assessors was a weakness in the RCTs found, and attention to this area would strengthen nurse-led research. In many trials, participants or those delivering treatments were not blinded to their assignment with the reason stated that they had active controls; this is due in large part to the nature of the interventions investigated (education, therapy etc.). While the reliance on active controls may contribute to the limited use of blinding in many nurse-led RCTs, this does not preclude blinding; furthermore, this would not impede the use of a blinded assessor. This option was rarely reported in the published research we found, nor in the research planned in the clinical trials registries we searched, yet this would strengthen the reliability of the outcomes.

The topics covered a broad range of health conditions; however, as can be seen in Table 3, there were far more trial registrations than publications in all topic areas. For example, of 26 cancer-focused trial registrations over the 20-year period, only eight publications were found. This relationship was seen across nearly all topics (aged care and surgical or critical care were the exceptions) and reflects earlier research, suggesting this is an international issue in nursing research (Borbasi et al., 2002). However, this is not unique to nurse-led trials; Al-shbool et al. (2019) found 66.5% of clinical trials registered on ClinicalTrials.gov that were completed were published in lung cancer research. Our search found only 40% of nurse-led registered RCTs had published, suggesting publication of results is an area that needs support in nurse-led research. As the ANZCTR is often not updated after registration, it is not known if this is due to null or negative results, lack of funding for publication, no publications written, or trial not completed. Also of note, of the 279 RCTs found in the registry searches, there were 88 different nurses acting as the lead investigator; in the 186 published trials, there were 78 different nurses

acting as lead. This indicates quite a small group of highly active nurse researchers in Australia and New Zealand.

Regarding the funding of nurse-led RCTs, 269 registered trials and 145 publications reported a funding source, a small increase on previously reported international funding data (Borbasi et al., 2002). Although the ANZCTR data suggest that universities and hospital or healthcare organisations provide most of the research funding, suggesting small-scale local resources, the peer-reviewed literature indicates Governments and NHMRC to be the major sources of funding, indicating these trials are more likely to have the resources to ensure trial completion and time required for publications. The publications without reported funding had fewer connected publications (i.e. other publications linked to the same trial). All but one of the publications that reported self-funding had only one resultant paper. Overall, these results suggest there are increased publications from external funding sources.

This review covered 20 years of registered trials, grant funding and peer-reviewed research publications. Although we found more nurse-led RCTs than previous international research (Charalambous et al., 2018; Gonella et al., 2019; Munday et al., 2020), this is a very small number of the health research pool published and funded over this time, and the results are in line with these international reviews. This scoping review found 1045 publications relevant to the field of nursing and midwifery in the literature, but only 186 publications were reporting nurse-led RCTs. There were 651 trials (63%) that focussed on nursing or midwifery practice but were led by medical practitioners, psychologists or other healthcare practitioners. Of the 26,467 clinical trials registered on ANZCTR, 279 were nurse-led RCTs. In the year 2020 (the last full year included in our search), 147 registered RCTs were found on ANZCTR using nurse* or midwi*. Of these, 16% were led by nurses or midwives, while 56% were led by medical practitioners. This goes up to 65% if you include non-nurse doctorates (PhDs). Nurses are a key part of the health workforce worldwide (World Health Organization, 2020a) and are highly knowledgeable in providing clinical care and in the issues and gaps that currently exist in healthcare. Research initiated and led by nurses has the potential to improve the health and well-being of individuals and communities (Borbasi et al., 2002, 2005) and improve the recommendations contained in best practice guidelines developed and used in nursing (Registered Nurses' Association of Ontario, 2020). Support for nurses to develop and lead RCTs that build upon previous research evidence, addressing questions related to effectiveness, generalisability and implementability and can inform successful evidence-based nursing practice are needed (Australian Clinical Trials Alliance, 2020; Borbasi et al., 2005; Hopia & Heikkilä, 2020; Mantzoukas, 2009; Wilkes & Jackson, 2011; World Health Organization, 2020a, 2020b). While this review focussed on Australian and New Zealand nursing research, the international literature indicates this is an issue worldwide and these supports could be considered for other countries (Charalambous et al., 2018; Gonella et al., 2019; Hopia & Heikkilä, 2020; Mantzoukas, 2009; Munday et al., 2020).

Based on our findings, we recommend the ANMCTN develop a targeted plan to promote nurse-led research capacity through support and education in the development, execution and publication of high-quality RCTs, promotion of the importance of trial registries and nurse-led research and the impact up-to-date online profiles have on applications to research groups and funding bodies. According to Borbasi et al. (2002), 'As nurses comprise the largest sector of the health care workforce and their work has the potential to impact significantly on the health and well-being of the general public, nursing researchers should be lobbying funding bodies for increased resources to study the effects of their care'. Our search has suggested this is still the case today and should be an area of focus for the ANMCTN.

9 | LIMITATIONS

While we used accepted methods to search for nurse-led RCTs, it is likely that some have been missed. The scoping review aimed to map the extent of RCTs led by nurses using a comprehensive and extensive search strategy covering multiple research repositories and through emailing listed contacts; however, we discovered over the course of this research that many nurses do not list their registration status or full qualifications on publications, or even on staff home pages or other career focussed websites (Research Gate, LinkedIn, ORCID). This made it difficult to confirm qualifications in some instances. Due to the 20-year timeframe, contact details supplied were not always current, and we were unable to trace some authors. However, this scoping review used a multifaceted approach to address this issue and provides a good overarching indicator of the number and characteristics of RCTs conducted by nurses in Australia and New Zealand over the last 20 years.

10 | CONCLUSION

As with previous research in this area, this review found limited nurse-led research in the field of nursing, highlighting the opportunities for expansion of the contribution that nurse-led RCTs can make to healthcare and the health of the population. Areas for support and improvement in nursing-specific research include increasing nurse-led RCTs, including those receiving nationally competitive funding. Targeted career frameworks and supports for nurses to design and conduct high-quality research, attain funding and write publications that lead to system impact are urgently required. Registration of trial protocols in a national database and reporting of the registration in subsequent publications is important to the transparency of research in general. This review highlighted the high quality of nurse-led RCTs and the paucity of published research. This information will be used to develop a targeted plan to build nurse-led research capabilities, and support effective, impactful nursing research careers.

11 | RELEVANCE TO CLINICAL PRACTICE

11.1 | What problem did the study address?

Previous reviews of nursing research highlight the dominance of nonexperimental research and the scarcity of high-quality RCTs, meaning many nursing-specific guidelines rely on observational evidence to inform evidence-based care.

Given the scope and prevalence of nurses across every aspect of health care, research initiated and led by nurses has the potential to improve the health and well-being of individuals and communities, but the current scope of nurse-led RCTs across Australasia is not known.

11.2 | What were the main findings?

The nurse-led RCTs found were of high methodological quality; however, there were very few nurse-led RCTs ($n = 279$) conducted by a small pool of nurse researchers ($n = 78$) over the last 20 years, and only 40% of nurse-led registered RCTs had published results.

11.3 | Where and on whom will the research have impact?

This information will create knowledge on which to base support for nurses in the design, conduct and publishing of high-quality RCTs relevant to the extensive field of health care they traverse with the aim of improving the evidence base for nursing clinical practice.

AUTHOR CONTRIBUTIONS

Conception and design of methodology, interpretation of data and revisions of manuscript: ME; design of methodology, searching, screening, analysis, and interpretation of sources, drafting and revisions of manuscript: KK; screening, analysis, and interpretation of sources, drafting and revisions of manuscript: KN; conception and design of methodology and revisions of manuscript: CR, SK, RG, SM, CH, LW, and GS.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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