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Nurse-led randomised controlled trials in the perioperative setting: A scoping review

Abstract

Purpose: Nurses provide care at each phase of the complex perioperative pathway and are well placed to identify areas of care requiring investigation in randomised controlled trials. Yet, currently, the scope of nurse-led randomised controlled trials conducted within the perioperative setting are unknown. This scoping review aims to identify areas of perioperative care in which nurse-led randomised controlled trials have been conducted, to identify issues impacting upon the quality of these trials and identify gaps for future investigation.

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Methods: This scoping review was conducted in reference to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews. Searches were conducted in PubMed, Embase, Cumulative Index for Nursing and Allied Health Literature and the Cochrane Central Register of Controlled Trials, with a date range of 2014–2019. Sources of unpublished literature included Open Grey, ProQuest Dissertation and Theses, Clinical Trials.gov and the Australian and New Zealand Clinical Trials Registry. After title and abstract checking, full-text retrieval and data extraction, studies were appraised using the Joanna Briggs Institute Critical Appraisal Checklist for Randomised Controlled Trials. Data were synthesised according to the main objectives. Key information was tabulated.

Results: From the 86 included studies, key areas where nurses have led randomised controlled trials include patient or caregiver anxiety, post-operative pain relief, surgical site infection prevention, patient and caregiver knowledge, perioperative hypothermia prevention and post-operative nausea and vomiting in addition to other diverse outcomes. Issues impacting upon quality (including poorly reported randomisation) and gaps for future investigation (including a focus on vulnerable populations) are evident.

Conclusion: Nurse-led randomised controlled trials in the perioperative setting have focused on key areas of perioperative care. Yet, opportunities exist for nurses to lead experimental research in other perioperative priority areas and within different populations that have been neglected, such as in the population of older adults undergoing surgery.

Keywords: perioperative, nursing, randomised controlled trial, scoping review

Introduction

Health care providers are facing pressure to provide effective services to an increasing population with often limited resources. This pressure to provide more with less is evident within the provision of perioperative care. As morbidity increases, so does the complexity of surgery and the pressure upon resources in this highly technical, resource-intensive, fast-paced, acute clinical environment.

For most patients, the experience of undergoing a surgical procedure represents a significant life event. During this critical period, health care practitioners are entrusted to advocate for and maintain the safety of patients when they are removed from family and loved ones and unable to speak up for themselves due to anaesthesia. A safe passage through surgery is the highest priority. However, it has been argued that – despite the amount of effort spent on developing interventions and policy in recent years – progress in optimising patient safety in perioperative care has been much slower than anticipated.

Internationally, perioperative care is described in four distinct phases: pre-admission, the immediate pre-operative (pre-anaesthetic) phase, the intra-operative phase (during induction of anaesthesia and surgery itself) and the immediate post-operative phase of care (prior to patients returning to ward areas). This multi-staged pathway necessarily involves care delivered by a range of health care professions: registered and enrolled nurses, surgeons, anaesthetists, technicians, orderlies and radiographers. However, nurses are a consistent presence at all phases of perioperative care and may work in multiple roles, including pre-operative care, anaesthetic assistance, intra-operative (scrub/scout) and immediate post-operative care roles. In some countries, other professions such as registered operating department practitioners (ODPs) take on perioperative roles.

However, globally, nurses have a ubiquitous presence in health care teams that provide perioperative care and are uniquely placed to understand critical points of care and patient concerns across the whole perioperative pathway. It is imperative that nurses ensure they are both driving health care improvements and identifying research priorities in this specialised field.

Experimental research underpins the assessment of the effectiveness of interventions, yet it is widely acknowledged that randomised controlled trials (the gold standard of experimental research) are expensive, resource-intensive and time-consuming. It is essential that time and finite resources are well spent on interventions that are effective, safe and acceptable to patients. Resources and funding to conduct research are difficult to obtain, and therefore it is imperative that resources are directed to areas where gaps in experimental research exist. Furthermore, there is a need to ensure that resources are directed toward research that will be conducted in a rigorous manner in order to ensure high quality and reliable findings.

Experimental research in the perioperative setting

The conduct of rigorous, randomised controlled trials (RCTs) is often inhibited by well-known factors such as cost, time and resources. There are also other challenges in conducting research within this complex, multidisciplinary field that are not widely acknowledged. For instance,
many recent systematic reviews and meta-analyses of perioperative care lack sufficient detailed reports of individual elements of care which may impact on or confound outcomes. Perioperative outcomes are influenced by a wide range of factors throughout the pre- and post-operative journey and need to account for the truly multidisciplinary nature of perioperative care, by including nursing as well as medical interventions during each phase of care in study designs. Therefore, the complexity of the perioperative pathway needs to be considered in both the design of primary studies and the assessment of these studies via systematic review. Authors have recently questioned the status of RCTsin remaining the ‘gold standard’ design to inform perioperative decision-making. Several authors have suggested that carefully designed before-and-after (observational) studies can be used to inform perioperative decision-making, with the benefit of being less resource-intensive, and more indicative of the feasibility of implementing interventions in actual practice. However, well-conducted, RCTs offer the highest level of scrutiny with the lowest level of bias, and therefore the greatest benefits to our patients, and remain the gold standard of experimental studies.

**Nurse-led research in the perioperative setting**

The multidisciplinary nature of perioperative care can result in challenges for nurses when trying to implement evidence-based practice change, such as negotiating staff buy-in across large multidisciplinary groups. Challenges also exist for perioperative nurses engaging in primary research that is pertinent to the discipline, such as funding. Potential sources of funding for specifically nurse-led research may also be even more scarce given the seemingly limited lack of financial backing for perioperative research both locally and internationally. Yet, the importance of supporting perioperative nurses to undertake research is vital in both facilitating evidence-based change in this domain of care. Nurses must drive research priorities that are relevant to perioperative nursing care. Although perioperative, nurse-led research may be increasing, the extent to which of these are nurse-led perioperative RCTshas not been evaluated.

**Methods**

**Aim**

The purpose of this scoping review is to identify in which domains of perioperative care nurses are leading experimental research.

**Objectives**

The main objectives of the scoping review were the following:

- to identify in which domains of perioperative care nurse-led RCTs have been conducted
- to analyse the issues impacting upon the quality of experimental research undertaken in the perioperative setting
- to identify what, if any, gaps exist in nurse-led experimental research in the perioperative setting, thus identifying priorities for future research.

**Design**

This scoping review was conducted in reference to the methodology set out by the Joanna Briggs Institute (JBI), with the framework developed by Arksey and O’Malley and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR). The scoping review methodology is appropriate for this question as it facilitates a broad exploration of perioperative care domains in which nurses are researching. This approach has been used successfully in similar reviews that have explored the scope of research undertaken in other specialised areas of health care. Scoping reviews are not eligible for registration with PROSPERO.

**Search methods**

A comprehensive search strategy was undertaken to find both published and unpublished (grey) literature in English from 2014 to May 2019, as per the recommendations for scoping reviews established by Peters et al. Only studies published in English were included due to lack of resources for translation. Databases for published literature included PubMed, Embase, Cumulative Index for Nursing and Allied Health Literature (CINAHL) and the Cochrane Central Register of Controlled Trials (CENTRAL). The search for unpublished literature utilised OpenGrey, and ProQuest Dissertation and Theses (PQDT). Searches for trials in progress were conducted using Clinical Trials.gov and the Australian and New Zealand Clinical Trials Registry (ANZCTR). Initial searches of PubMed and CINAHL were conducted to refine index terms and keywords, followed by a second search with keywords and index terms across all databases. Finally, perioperative nursing journals (Journal of PeriAnesthesia Nursing, Journal of Perioperative Practice, AORN Journal, Journal of Perioperative Nursing, Perioperative Care and Operating Room Management) were screened for additional RCTs across the date range.
Initial search terms for CINAHL were as follows:

1. ‘perioperative’
2. MH ‘Perioperative Care’
3. MH ‘Perioperative Nursing’
4. MH ‘Perioperative Period’
5. MH ‘Pre-operative Care’
6. MH ‘Pre-operative Period’
7. MH ‘Intraoperative care’
8. MH ‘Intraoperative Period’
9. MH ‘Postoperative Care’
10. MH ‘Postoperative Period’
11. MH ‘Post Anesthesia Care’
12. MH ‘Post Anesthesia Care Units’
13. MH ‘Anesthetics’
14. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11
15. MH ‘Randomized controlled trials’
16. #12 AND #13.

Inclusion and exclusion criteria

Studies that met the following inclusion criteria were eligible for review:

**Population:** participants receiving care during one or more phases of the perioperative pathway: pre-operatively, intra-operatively or immediately post-operatively.

**Concept (study designs):** only nurse-led randomised controlled study designs were included. To enable the identification of these particular trials, in-depth investigation of author names and qualifications were performed for those studies in which details were not listed on the abstract or full text. Other trials were included if known to be led by nursing academics but whose qualifications are not explicitly stated in the citation.

**Context:** studies focused on perioperative care including the pre-operative, intra-operative or immediate post-operative setting.

**Screening and eligibility process**

Four reviewers conducted screening of titles and abstracts to identify relevant papers for full-text retrieval (JM, NH, LD, SM). Full texts were then screened for eligibility against the inclusion criteria by the authorship team using a verification form developed for this purpose (see Supplement 1).

**Data charting process**

A flow chart was generated to indicate the papers included in the review at each stage, as per the PRISMA guidelines (Figure 1). A data charting form was developed to record and extract study characteristics and variables relevant to the review question (see Supplement 2). Pairs of reviewers undertook data extraction independently for each article and a third reviewer mediated where there was a lack of agreement.

**Critical appraisal**

Studies identified as relevant to the review were assessed for quality using the JBI Critical Appraisal Checklists for Randomised Controlled Trials. While quality assessment is not considered mandatory in scoping reviews, undertaking this process assisted in identifying common issues that influenced or undermined the quality of RCTs in the perioperative setting. Pairs of reviewers also assessed each included study for quality, with disagreements resolved through discussion and consensus. Where agreement was not resolved through this process, an independent third reviewer was used.

**Synthesis**

Following data extraction and quality assessment, key information from each study was tabulated to assist in determining country of origin, interventions, primary outcomes, surgical population, sample size and funding source (see Supplement 3). Studies were organised according to the primary outcome in order to identify domains of perioperative care. Within each primary outcome, the interventions of interest and the study population assisted in determining gaps in phases of care or where study populations had not been included.

To analyse factors influencing the overall quality of included studies, common quality indicators were synthesised according to the quality assessment checklist where studies had scored poorly. Areas of perioperative care where experimental nurse-led research is appropriate but not yet evident were identified. Data synthesis and analysis were discussed within the authorship team to ensure consensus and that all relevant themes within the review questions were identified. Results are presented in table form, to provide an overview of all included studies as per the data extraction (charting) form.

**Results**

Eighty-six studies were included in the final review (Figure 1). The included studies were geographically widespread (Table 1). The region of origin with the most included RCTs was North America (n = 28) followed by Europe (n=26), Asia (n=15), the Middle East (n=7), Oceania and South America (both n=5).
Identification
Records identified through database searching (n=20,238)

Additional records identified through other sources (grey literature, journal searching) (n=957)

Records after duplicates removed (n=16,593)

Screening
Records screened (n=16,593)

Records excluded (n=16,437)

Eligibility
Full-text articles assessed for eligibility (n=156)

Full-text articles excluded, with reasons (n=72)
1. Not an RCT (n=10)
2. Not nurse led (n=10)
3. Not perioperative setting (n=45)
4. Abstract only in English (n=1)
5. Abstract only (n=1)
6. Confirmation thesis (n=1)
7. Combination of factors (n=4)

Included
Studies included in scoping review (n=86)

Figure 1: PRISMA flow diagram
Table 1: Randomised controlled trials by country and region

| Region          | Country          | Number (n, % of total) |
|-----------------|------------------|------------------------|
| Oceania         | Australia        | 5 (5.8)                |
| South America   | Brazil           | 5 (5.8)                |
| North America   | Canada           | 3                      |
|                 | United States    | 25                     |
| Total           |                  | 28 (33)                |
| Asia            | China            | 3                      |
|                 | Hong Kong        | 1                      |
|                 | India            | 1                      |
|                 | Singapore        | 1                      |
|                 | South Korea      | 3                      |
|                 | Taiwan           | 6*                     |
| Total           |                  | 15* (17)               |
| Europe          | Croatia          | 1                      |
|                 | Denmark          | 2                      |
|                 | France           | 1                      |
|                 | Greece           | 1                      |
|                 | Italy            | 4                      |
|                 | Norway           | 1                      |
|                 | Spain            | 3                      |
|                 | Sweden           | 4                      |
|                 | Turkey           | 9                      |
| Total           |                  | 26 (30)                |
| Middle East     | Iran             | 6                      |
|                 | United Arab Emirates (UEA) | 1                 |
| Total           |                  | 7 (8)                  |
| Overall total   |                  | 86                     |

Note: *Duplication of one study into two publications noted in this group.

Domains of perioperative care addressed by nurse-led RCTs

Six main domains of perioperative care, addressed by nurse-led RCTs were identified, in addition to other diverse clinical outcomes (see Supplement 3):

1. prevention of caregiver and patient anxiety
2. perioperative hypothermia prevention and temperature monitoring
3. post-operative pain relief
4. post-operative nausea and vomiting (PONV) prevention and treatment
5. prevention of surgical site infection (SSI)
6. patient and parental knowledge.

Prevention of caregiver and patient anxiety

Prevention of anxiety, both from the patient and caregivers’ perspective, was the most common primary outcome of interest, accounting for over a fifth of studies (n=20, 23%).

Of the studies including anxiety prevention as the primary outcome, nine studies (47%) were focused on adult patients, nine were focused on paediatric patients (with four of these also including caregivers as a sub-population) and another focused on adolescents and one study concentrated solely on caregiver (parent) anxiety. The interventions of interest included music, education (including videos), visiting pre-operative facilities, play, relaxation and sounds from nature, aromatherapy, photographic displays, distraction versus midazolam, therapeutic listening, different timings of communication and an application with clown doctors.

Perioperative hypothermia prevention and temperature monitoring

Thirteen published studies (15% of included studies) had a primary outcome of preventing perioperative hypothermia or temperature monitoring. However, one study was published twice in two different journals. Active warming (comprising forced air, thermal gown, intravenous (IV) fluid warming or underbody warming) and passive warming strategies (reflective versus cotton blankets or cloths) were tested in various combinations. All perioperative hypothermia studies were conducted in the adult population, but within different surgical specialities: interventional cardiovascular procedures, gastrointestinal or thoracic surgery, obstetrics, laparoscopic cholecystectomy, colorectal surgery, gynaecology, cardiovascular or multiple specialities. One study assessed skin temperatures after blankets warmed to different temperatures in a population of healthy volunteers.

Post-operative pain relief

Post-operative pain relief was the third most common primary outcome of interest (n=13, 15% of included studies) and a secondary outcome in 13 studies (15%). Interventions of interest included hypnosis, anaesthetic technique (for hysteroscopy), play, Reiki, premedication and information, different routes of paracetamol administration, cold application, guided imagery and...
relaxation,25 positioning and early sandbag removal (post-coronary angiography),26 room air versus carbon dioxide insufflation,24,31 and bed positioning.38 Nine studies had adult participants,31,34,36,40,50,51,62,65,92 two were paediatric based,52,72 and one study focused on adolescents.12

Post-operative nausea and vomiting (ONPV) prevention and treatment

Eleven studies (13% of included studies) focused on the prevention or treatment of ONPV. Six studies tested pericardium 6 (P6) acupressure,29,34,64,69,73,89 two studies tested aromatherapy with or without additional therapies,74,84 one study tested early hydration,90 one study tested an individualised pre-operative education intervention90 and one study tested different doses of promethazine.24

Prevention of surgical site infection (SSI)

Five studies (6% of included studies) focused on SSI prevention as the primary outcome, using a variety of interventions: post-operative shampooing,66 pre-operative 2% chlorhexidine gluconate skin preparation cloths,41 silver impregnated versus standard dry sterile dressings (cardiac surgery),26 hair shaving techniques13 and different antiseptic methods.38

Patient and parental knowledge

The primary outcome of interest for five studies (6% of included studies) was patient or parental knowledge.21,62,106 and two in parental knowledge.23,107

Other clinical outcomes

A wide variety of other clinical practices were investigated as primary outcomes in the included RCTs (see Supplement 3).25,27,28,30,33,45,47,51,68,75,76,96,101,102

Perioperative research populations and phases of care addressed by nurse-led RCT designs

Study populations

Predominantly, studies were focused on the adult population (n=71, 83%), with ten studies focusing on paediatrics as the population of interest (12%). Four studies included both caregivers and children as the population of interest.23,47,51,52 while one study focused on caregivers only.107 Two studies focused on adolescents,23,107 and one study included both adults and children.75 Although older adults (>75 years) were included in some studies,22,61,62 they were not specifically identified as the target population in any of the included studies.

Phases of care

Almost half of studies involved interventions that were delivered during the pre-operative phase of care (n=41, 48%), 13 studies delivered interventions during the intra-operative phase (n=13, 15%),24,26,31,43,46,53,75,86,92,99,101,107 and 13 studies (15%) delivered interventions solely in the post-operative phase.24,36,39,44,47,48,64,66,68,73,75,77,92,96,107 Eight studies (9%) were based on interventions that were delivered during multiple phases of the perioperative pathway.24,36,39,42,56,61,76,81,96 Almost half of the included studies assessed outcomes at multiple phases of the perioperative pathway (n=34, 40%), while 24 studies (28%) assessed post-operative outcomes extending beyond the immediate Post Anaesthesia Care Unit (PACU) phase.24,27,34,35,39,44,47,51,61,62,64,66,68,73,75,89,90,91,92,101

Issues impacting upon the quality of experimental research undertaken in the perioperative setting

Issues impacting upon the quality of RCTs included in this review were related predominantly to the reporting of blinding techniques. Blinding of participants was unclear or not implemented in 79 per cent of included studies (n=68), binding of those delivering the intervention was not used or was unclear in 80 per cent (n=69) of studies, and binding of outcome assessors was not used or was unclear in 73 per cent (n=63) of included studies. Many studies did acknowledge the reasons for lack of blinding and most often this was related to the nature of the intervention under study; yet, most often, lack of blinding of one or more key groups was not discussed or acknowledged as a limitation.

In addition, a lack of, or unclear, randomisation was found in just over a quarter of included studies (35%, n=31). Similarly, a high number of included studies were assessed as having incomplete follow-up or there was inadequate analysis or description of differences between groups (32%, n=28). Duplication of study results was also found in one instance, where the same study was published in different journals with a different author order.85,87
Discussion

To our knowledge, this is the first scoping review to investigate the range of nurse-led randomised controlled trials conducted in the perioperative setting. Geographically, this review has revealed that North America contributed the highest number of studies to this review, with the United States of America (USA) the most prolific individual country in terms of conducting nurse-led perioperative RCTs in the last five years. This contrasts with a recent scoping review of RCTs and quasi-experimental studies published in nursing journals, whereby Taiwanese nursing researchers were found to have published the most frequently in nursing journals. However, our review also included studies that, although nurse-led, were published in journals that were not specifically nursing-focused, and only focused on RCTs which was appropriate to address the review question. Similarly, though, our review also found no African studies for inclusion. This may be unsurprising given that a 2015 scoping review of clinical nursing and midwifery research in African countries found that, at the time of the review, most included research was qualitative, and focused on primary or secondary prevention of cancer. Additional obstacles to conduct and publication of nursing research in this region include a lack of resources (including funding, library access, equipment and collaborators) and political and civil unrest.

This review of 86 studies revealed that there are six clearly identifiable areas in which nurses are leading experimental research (specifically RCTs) relevant to perioperative care. The most common primary outcome across included studies was the prevention of anxiety and this was investigated using a range of supportive interventions. Given how commonly pre-operative anxiety is experienced, and the detrimental patient outcomes associated with anxiety, this may be justified despite anxiety prevention not being a stated priority by professional associations. The investigation of supportive or complementary therapies may be reflective of the growing interest in complementary therapies in health care more broadly. The quality issues noted in this review, in which a large proportion of studies assessed the effectiveness of supportive therapies, indicate that nursing researchers are utilising facets of the randomised controlled study design adaptively (and creatively). Given the expense and resources required to conduct RCTs, it is imperative for nurses to ensure that these resources are well spent on trials that are well conducted and provide useful findings. At this stage, it may be pertinent for the focus on anxiety prevention to shift from primary research to translation into practice.

Almost half of the included studies (47%) assessed interventions that were delivered during the pre-operative phase. A moderate number (n=13, 15%) delivered interventions during the intra-operative phase but due to the nature of the interventions and outcomes under study – for example, the focus on anxiety reduction which would be difficult to assess intra-operatively due to anaesthesia – few studies assessed outcomes during the intra-operative phase of care (n=4, 5%). This gap in the literature is an opportunity for nurses to design experimental studies that measure the outcomes of interventions and outcomes related to intra-operative or procedural nursing care. Despite anxiety prevention being the most common outcome in the included studies, one did highlight that further investigation with teens or adolescents is worthy of future study.

While some regions and countries have established perioperative research priorities, an international consensus is not evident. The lack of consensus may be influenced by the diverse and differing needs between developed and under-developed regions, but also reflects the variation in the processes used to determine the published perioperative priorities (including the variation in stakeholder involvement). The perioperative pathway is complex, multi-staged and involves numerous health professions in the delivery of care. Therefore, it is logical that any work to establish areas of perioperative care that requires a stronger evidence base needs to ensure multidisciplinary input – as well as ensuring that health care consumers also have input.

In the United Kingdom (UK), the National Institute of Academic Anaesthesia and James Lind Alliance (JLA) Research Priority Setting Partnership’s agreed on ten anaesthetic and perioperative care priorities include a range of issues. These range from the study of the term effects of anaesthesia, to establishing ‘success’ measures for perioperative care. The authors determined that specific care and physiological questions were ranked more highly by clinicians, whereas lay stakeholders ranked communication and long-term outcomes of anaesthesia more highly. Similarly, Biccard et al’s Delphi study of perioperative investigators in South Africa, while recognising the need for a co-ordinated perioperative research agenda, established national priorities that focused on a
wide range of quite specific clinical care aspects although lay input into this process was not evident. The failure to investigate outcomes that matter to patients within pragmatic trials is not unique to perioperative care. Nonetheless, the primary outcomes of anxiety prevention and knowledge generation identified in this review align more closely with lay stakeholder-identified priorities related to communication, which may be unsurprising given that patient advocacy is a key nursing role.

This review also found that safety outcomes received minimal attention in the nurse-led trial research included in this review. It has also been argued that safety outcomes, having also been neglected, should also be reported in pragmatic trials in the perioperative setting. Within the perioperative nursing field, Steelman’s top ten patient safety priority areas, established by perioperative nurses in the USA, identify only one of the primary outcomes of interest found in the included studies in this review as a safety concern (perioperative hypothermia prevention). However, many of these safety concerns may not lend themselves as a focus of experimental research due to being rare events (for example, wrong-site surgery, prevention of retained surgical items, surgical fires) while others are less so (medication errors, pressure injuries). A number of aspects of perioperative hypothermia prevention are also identified in the Association of periOperative Registered Nurses (AORN) 2019 Research Gaps. The AORN Research Priorities for Perioperative Nursing 2018–2023 focuses on patient education practices as well as the need to improve outcomes for vulnerable populations.

The outcomes from this review of nurse-led RCTs do align, to some degree, with care priorities established by the Australian Government that are published in clinical indicators and guidelines. In the Australian setting, perioperative hypothermia (measured as the number of patients arriving into PACU with a temperature of less than 36°C), pain, PONV, surgical site infection and post-dural puncture headache – all outcomes of interest in the included studies – are key clinical indicators assessed by the Australian Council on Healthcare Standards in the most recent Australasian Clinical Indicator Report: 2010–2017. This report highlights that, for some areas, meeting the key performance indicators has been problematic. For example, in 2017 there was an increased incidence of perioperative hypothermia reported. Therefore, it can be argued that the continued focus on developing strategies to manage this condition is warranted.

All health care professionals leading experimental perioperative research need to ensure that the populations upon which research is focused are reflective of the needs of the surgical populations. As mentioned, no studies specifically focused on the needs of older adults were found in this review. Studies of younger, fitter populations may not be truly reflective of surgical populations outside of trial settings; thus, the practical application of research findings is reduced, and the interests of the older adults receiving surgical care may not be met. This need has been evident over the last ten years. In 2010, a large multicentre, prospective observational study of older adults undergoing surgery in Australia and New Zealand highlighted that complications and mortality among this cohort were prevalent, and strategies were urgently needed to address these issues. However, nurse-led RCTs in the perioperative setting do not reflect the trend of focusing on older adults, and patients with cancer, which were reported more broadly in nurse-led experimental research across clinical settings.

This review has also revealed that common quality indicators are problematic in the conduct of RCTs in this setting. Unclear randomisation was evident across the majority of studies, despite the inclusion criteria only specifying randomised controlled designs. There was a lack of blinding in the included studies. In the studies where blinding was implemented, the method of blinding varied considerably. Successful blinding may have occurred for the participant, those delivering interventions and/or the outcome assessors. While a number of studies acknowledged and provided an explanation for a lack of blinding, many other studies either reported but did not explain, or did not acknowledge the lack of blinding at all. Where acknowledged, most often blinding was not achieved due to the nature of the intervention. This is perhaps unsurprising, given that most of the interventions were delivered and/or outcomes assessed at time points of care where patients were awake. It is acknowledged that interventions such as the use of forced air warming, or some complementary therapies, are extremely problematic when trying to include effective blinding techniques for participants. Nonetheless, bias related to lack of participant blinding may be offset by the assessment of objective outcome measures and the use of outcome assessor blinding, where possible.

**Limitations**

There is potential that some nurse-led RCTs meeting the inclusion criteria have been inadvertently missed, despite our extensive and thorough search process. The process
of identifying nurse-led studies was complex during the search phase of this review. Not all studies clearly identified the professional background of authors. This meant that additional searches of the primary author’s name were, in some instances, needed to identify whether or not studies were nurse-led.

This review also only provides a picture of randomised controlled studies conducted by nurses in the last five years. Quasi-experimental, observational and qualitative studies were not included, nor were secondary analyses such as systematic reviews and meta-analyses. Therefore, this review cannot provide an indication of the non-experimental or synthesised body of evidence generated by nurses in this clinical setting. We also only included studies published in English. Future studies may seek to investigate the body of nurse-led research conducted using these study designs to gain a more inclusive snapshot of research in this clinical setting.

Conclusions
This scoping review has identified clear areas of perioperative care that have been the focus of nurse-led randomised controlled trials. The emphasis has been on supportive care of both patients, and caregivers. Most conducted research has involved multiple phases of care, across the perioperative pathway. Significant issues affecting the quality of experimental nurse-led research conducted in the perioperative setting have also been identified, mainly relating to blinding and randomisation. Acknowledging these issues provides opportunities for maximising research quality in nurse-led experimental research. Gaps in perioperative nursing research exist in focused assessment of intra-operative or procedural aspects of care, patient safety outcomes and care of vulnerable groups. Opportunities also exist for nurses to contribute to multidisciplinary research priority setting in the perioperative field and focus on the translation of evidence to practice in areas such as anxiety prevention where further extensive experimental research may not be warranted. Priority settings must also include patients and caregivers as stakeholders to ensure that we are meeting their needs.

Ethical considerations
This review did not involve primary research and therefore ethical approval was not required. However, a potential conflict of interest relating to one of the primary review authors also being the author of one of the included randomised controlled trials was noted. In this instance, the review author was not involved with the critical appraisal of this study.

Acknowledgments
This review is one of a series of scoping reviews currently being conducted by researchers within the acute and critical care research group at Queensland University of Technology (QUT). They aim to identify current nurse-led research activities in acute and critical care settings (including perioperative care) and nursing research priorities. This collaborative group includes a number of university-based researchers and clinician researchers working in acute and critical care settings to ensure that the review outcomes are clearly linked to clinical practice. Within this group, we wish to acknowledge the input of Dr Petra Lawrence for assistance in critical appraisal and data extraction.

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A potential conflict of interest related to one of the primary review authors also being the author of one of the included randomised controlled trials was noted. However, in this instance, the review author was not involved with the critical appraisal of this study. SK reports that her employer (QUT) has received monies on her behalf from BD Medical for educational consultancies, outside the submitted work. The authors report no other possible conflicts of interest in this work.

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Nurse-led randomised controlled trials in the perioperative setting: A scoping review

Supplement 1: Verification form

| Question                                                                 | Response |
|-------------------------------------------------------------------------|----------|
| Is the paper a randomised controlled trial?                             | Yes      |
| Is the paper nurse-led (is the first or last author a nurse as per listed qualifications)? | Yes      |
| Is the article published between January 2014 and May 2019?              | Yes      |
| Is the topic of the paper related to perioperative care at one or more phases (pre-admission; pre-operatively; intra-operatively; immediately post-operatively)? | Yes      |
| Eligible for inclusion?                                                 | Yes      |

Supplement 2: Data extraction form

| Author/s | Year of publication | Country of origin | Primary aim | Secondary aim/s | Study population | Sample size | Study design | Intervention | Comparator/s | Timing of intervention | Timing of comparator | Outcome measurements | Outcome assessor | Outcome points | Outcome measurements methods | Findings |
|----------|---------------------|-------------------|-------------|-----------------|------------------|-------------|--------------|--------------|---------------|-----------------------|---------------------|----------------------|-------------------|-----------------|-----------------------------|-----------|

| Findings |
|----------|
| Primary outcome |
| Secondary outcome/s |
| Reviewer comments |
| Funding source |
### Supplement 3: Table of included studies

| First author (year), country | Primary aim                                                                                                                                                                                                 | Primary outcome | Secondary outcome/s                                                                 | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding                                                                                          |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------------------------------------------------------------------------|-----------------|---------------------|-----------------------|---------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Al-Azawy (2015) Norway      | To compare and evaluate the effect of premedication, standardised pre-operative information and anxiety on pain intensity, drug consumption and satisfaction.                                                   | Pain intensity  | Pre-operative anxiety on pain intensity and drug consumption                          | Adults >18      | Patients undergoing ablation for AF under conscious sedation | 60                    | I: pre-operative information, medication one hour prior to surgery | Supported by Department of Heart Disease Haukeland University Hospital, Bergen. No specific funding mentioned. |
| Al-Yateem (2016) UAE        | To assess play distraction versus premedication.                                                                                                                                                    | Anxiety        | Anxiety (STAI)                                                                       | Children 3–8    | ASA I–II undergoing elective day surgery under GA     | 168                   | I: one hour prior to surgery; 0: during anaesthesia, pre-operatively, induction, anaesthetically, upon discharge | Funded by a grant from University of Sharjah.                                                                                                     |
| Ayik (2018) Turkey          | To measure effects of lavender oil aromatherapy massage versus usual care.                                                                                                                                 | Anxiety (STAI)  | Sleep quality                                                                        | Adults >18      | Colorectal surgery                                      | 80                    | I: pre-operatively – night before and morning of surgery; 0: pre-operatively – night before and morning of surgery (after massage / usual care) | No specific grant funding received.                                                                                                                        |
| Baker (clinical trial protocol) USA | To compare IV versus oral acetaminophen (paracetamol).                                                                                                                                   | Pain           | 1. Opioid consumption 2. PONV 3. Post-operative respiratory depression 4. Administration of reversal agents 5. LOS in PACU 6. Satisfaction | Adults >18      | Multiple surgical specialties                          | 120                   | I: pre-operatively 0: within 24 hours (except patient satisfaction – two days post-operatively) | Not stated.                                                                                       |
| Bakhshi (2014) Iran         | To assess effects of positioning and early sandbag removal.                                                                                                                                              | Back pain      | 1. Foot pain 2. Haematoma 3. dorsalis pedis pulse 4. Bleeding                       | Adults          | Post-coronary angiography patients                     | 80                    | I: after catheterisation; 0: one, two, three and six hours post-operatively and the following morning | No statement of funding evident.                                                                                                                        |
| Baradanfar (2018) Iran      | To evaluate impact of warming (forced air versus warmed IV fluids versus control) on physiological indices.                                                                                  | Core body      | 1. Blood pressure 2. Heart rate 3. Shivering                                        | Adults 18–65    | Laparoscopic cholecystectomy                           | 96                    | I: from induction of anaesthesia until PACU discharge; 0: before induction of anaesthesia until discharge from PACU | Funding by Isfahan University of Medical Sciences.                                                                                                   |
| Brix (2016) Denmark         | To compare two anaesthetic techniques.                                                                                                                                                    | Post-operative pain (NRS) | 1. Intraoperative fentanyl use 2. Analgesic and antiemetic use in PACU 3. PONV occurrence 4. Time to PACU discharge 5. Recalled worst pain after discharge 6. Recalled PONV after discharge | Adult females   | Ambulatory operative hysteroscopy                     | 153                   | I: Initial surgery; 0: immediately post-operatively and two weeks post-discharge | Author has received funding from Hede Nielsen Family Foundation, the Gurli and Hans Engell Friis Foundation, the Aase and Ejnar Danielsens Foundation and the Health Research Fund of Denmark. |
| Çakar (2017) Turkey         | To assess pre-operative oral carbohydrate vs standard fasting.                                                                                                                                          | Pre-operative  | 1. Post-operative complications 2. Physiological parameters 3. PONV 4. Pain         | Adults 16–80    | Thyroidectomy                                           | 95                    | I: from 00.00 hours night before surgery; 0: 10 pm and 6 am prior to surgery, every two hours post-surgery | No statement of funding.                                                                                                                              |
| Carlson (2018) Sweden       | To assess the effectiveness of pre-operative visits to the operating theatre on anxiety.                                                                                                               | Anxiety (mYPAS) | Parental anxiety (STAI)                                                               | Children 3–12   | ENT day surgery                                         | 57                    | I: prior to the day of surgery; 0: in the waiting room, after arrival to OR, at anaesthesia induction; 0: (parents) in waiting room and once child anaesthetised | Centre of clinical research in Värmland supported the project.                                                                                         |
| First author (year, country) | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-------------------------------|-------------|-----------------|---------------------|------------------|----------------------|----------------------|---------------------------------------------------|---------|
| Carr (2015) USA              | To compare P6 stimulation versus control on PONV | PONV (Likert nausea scale score) | Nil | adult females 18–67 years | laparoscopic cholecystectomy | 56 | I: intraoperatively 0: on admission to PACU; at 30 and 60 mins, PACU discharge, at home up to 24 hours | No statement of funding. |
| Charette (2015) Canada       | To assess guided imagery and relaxation combined with education versus usual care. | pain intensity 1. anxiety (STAI-Y) 2. coping strategies 3. regular activities | adolescents and young adults | spinal fusion for scoliosis | 40 | I: commenced pre-operatively 0: day of surgery to two weeks post-discharge | Funded by the Canadian Nurses Foundation; the Quebec Inter-university Nursing Intervention Research Group (GRIISIQ); the Quebec Ministry of Education, Recreation and Sports; the Fonds de Recherche du Québec-Santé (FRQS); The Sante Justine Hospital Foundation; the Foundation of Stars and the Gustav Levinschi Foundation. |
| Chartrand (2017) Canada      | To examine the effect of a pre-operative DVD on parental knowledge versus standard care. | parental knowledge 1. participation 2. anxiety 3. children’s distress 4. analgesia 5. length of recovery | parent–child dyads (children 3–10 years) | elective ENT outpatient or dental surgery | 105 | I: after pre-assessment clinic appointment 0: in the recovery room until discharge from day surgery. | Study funded by Children’s Hospital of Eastern Ontario Research Institute Surgery Associates Research and Development Fund. First author also received scholarships. |
| Chen (2014) USA              | To compare carbon dioxide versus room air insufflation. | discomfort abdominal girth | adults >18 years | screening colonoscopy | 98 | I: during colonoscopy 0: upon arrival to recovery room, at time of post-anesthesia recovery (PAR) score of 10 or pre-procedure baseline, when eligible for discharge | No funding received. |
| Chen (2015) Taiwan           | To assess effects of music versus no music on psychophysiological responses | Psycho-physiological parameters (HR, RR, SBP, DBP) 1. pain (VAS) 2. opioid dosage | adults | elective total knee replacement | 30 | I: pre-operatively; in OR and in PACU 0: pre-operatively, in surgical waiting area, in PACU and in post-operative ward | No funding statement. |
| Chevillon (2015) USA         | To evaluate impact of multifaceted pre-operative education versus standard care | post-operative delirium 1. anxiety (STAI) 2. knowledge 3. predictors of delirium 4. days of mechanical ventilation 5. ICU stay (days) | adults | pulmonary thromboendarterectomy | 129 | I: one day prior to surgery 0: intra-operatively (cardiopulmonary indicators), daily for up to seven days after surgery or until ICU discharge | No funding statement. |
| Choi (2018) South Korea      | To compare durations of bed rest and immobilisation (three groups). | incidence of post-dural puncture headache (PDH) | adults >18 years | elective orthopaedic knee or hip, or bladder surgery, or haemorrhoidectomy under spinal anaesthesia | 138 | I: post-surgery 0: immediate post-ward transfer then daily for five days | No funding statement. |
| First author (year), country | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-----------------------------|-------------|----------------|---------------------|-----------------|---------------------|----------------------|--------------------------------------------|---------|
| Conway (2017) Australia     | To assess effectiveness of forced air warming versus usual care (passive warming) for hypothermia prevention. | post-procedure temperature | 1. shivering 2. thermal comfort 3. major post-operative complications 4. cardiovascular complications, cardioversion or myocardial infarction | adults >18 years | interventional cardiovascular procedures <30 minutes duration with sedation | 140 | I: during procedure O: during procedure, post-operatively, at 30 days (complications) | First author awarded an NHMRC Early Career Fellowship. Study funded by St Vincent's Clinic Foundation Multidisciplinary Patient Focussed Research Grant. Equipment provided by Covidien Investigator sponsored Research Program. |
| Dehghan (2017) Iran         | To compare dramatic puppet versus therapeutic play versus usual care. | anxiety | nil | children 6–12 years | appendectomy | 75 | I: pre-operatively, morning of surgery O: night before surgery, pre-operatively before anaesthesia | Supported by Mashhad University of Medical Sciences. |
| Deitrick (2015) USA         | To compare two doses of IV promethazine (6.25mg versus 12.5mg). | PONV (verbal descriptive scale) | post-operative sedation (institution’s internal sedation scale) | adults 18–75 years | ambulatory surgery | 120 | I: throughout Phase I and Phase II recovery O: throughout Phase I and Phase II recovery | Combined AORN/STTI International Small Grant. |
| Dickinson (2015) USA        | To assess silver impregnated dressings versus dry sterile dressings. | wound healing | infection | Adults | cardiac surgery with sternotomy wound | 315 | I: incision closure O: five days post-operatively and throughout recovery | No funding statement but dressings donated by manufacturers. |
| Duparc-Alegria (2018) France| To assess impact of short hypnotic session versus usual care. | post-operative pain (VAS) | 1. anxiety level 2. total morphine consumption | children 10–18 years | routine major orthopaedic surgery | 119 | I: just prior to surgery O: 24 hours post-operatively | Funded by Ministry of Health grant and sponsored by Assistance-Publique-Hôpitaux de Paris-Direction Recherce Clinique et du Développement. |
| Erdling (2015) Sweden       | To compare oesophageal and nasopharyngeal temperature in patients receiving prewarming versus no prewarming. | difference in temperature change between devices and warming groups | effect of prewarming, age and Body Mass Index (BMI) upon measured temperatures (two devices) | adults | elective open colorectal surgery under combined anaesthesia | 53 | I: pre-operatively (prewarming) or intra-operatively O: before epidural, after test dose, anaesthesia start and then at 30 minute intervals | No funding statement. |
| Ertug (2017) Turkey         | To compare nature sounds versus relaxation exercises versus no intervention. | anxiety | nil | adults >18 years | elective surgery (under GA) | 159 | I: day of surgery O: day of surgery recruitment, after intervention, 30 minutes post-intervention | No funding statement. |
| First author (year), country | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|----------------------------|-------------|----------------|---------------------|-----------------|---------------------|---------------------|-------------------------------------------------|---------|
| Fetzer (2018) USA          | To assess effectiveness of pre-emptive pre-operative belladonna and opium suppository versus routine care. | post-operative bladder comfort (bladder urgency via five-point Likert scale and pain via 0–10 VAS) | 1. narcotic requirements 2. LOS | adults | uroscopy | 50 | I: after anaesthesia induction and before insertion of surgical scope O: during PACU at every 15 minutes until discharge, outpatient discharge | One author funded by Vermont/New Hampshire Association of Perianaesthesia Nurses for cost of study medication. |
| Franzoi (2016) Brazil      | To compare listening to music versus usual care (toys and television). | anxiety | 1. HR 2. SBP 3. DBP 4. RR 5. oxygen saturation | children 3–12 years | elective surgery under GA | 52 | I: day of surgery O: 15 minutes post-intervention | No funding statement. |
| Fuganti (2018) Brazil      | To evaluate effect of prewarming versus usual care (cotton blankets) on body temperature. | tympanic temperature | 1. air temperature in OR 2. humidity OR | adults >18 years | elective gynaecological surgery | 86 | I: pre-operatively O: after prewarming and at 30 minute intervals until end of surgery | No funding statement. |
| Garcia (2018) Brazil       | To compare therapeutic listening versus standard care. | anxiety | 1. surgical fears 2. salivary cortisol 3. HR 4. RR 5. SBP 6. DBP | adults >18 years | surgery for colorectal cancer | 50 | I: day of surgery O: pre-intervention at 2.5 hours, then 1 hour post-procedure | Supported by Conselho Nacional de Desenvolvimento Cientifico e Tecnologico (CNPq), Brazil, grant. |
| Gomez-Urquiza (2016) Spain | To compare projection of photos versus photos and music versus usual care | anxiety | 1. HR 2. RR 3. DBP 4. SBP | adults 25–50 years | ENT surgery | 180 | I: day of surgery O: pre-operatively from 45 to 120 minutes prior to surgery | No funding received. |
| Gross (2016) USA           | To assess outcomes after three different dressing practices. | air leak | 1. patient comfort 2. skin integrity at incision site | adults >18 years | patients with chest drains | 64 | I: following insertion of chest tube in OR O: upon post-operative arrival to trauma centre and then daily up until a maximum of five days | No funding statement. |
| Groton (2015) USA          | To evaluate effectiveness, tolerability and cost of three bowel preparations (three groups). | effectiveness of bowel preparation | 1. tolerability 2. cost | adults >18 years | outpatient colonoscopy | 276 | I: prior to colonoscopy O: during colonoscopy, post-procedure and at follow-up clinic | No funding received. |
| Ham (2017) South Korea     | To assess saline solution replacement versus not changing saline solution. | colony-forming units (CFU) | nil | adults >18 years | colectomy for colon cancer | 52 | I: intra-operatively after colon removal (intervention) O: 48 hours post collection | Funded by Konkuk University GLOCAL Campus, Republic of Korea. |
| First author (year), country | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-----------------------------|------------|----------------|---------------------|-----------------|---------------------|----------------------|------------------------------------------------|---------|
| Handan (2018) Turkey        | To assess impact of music during caesarean delivery versus usual care. | Anxiety (VAS) | 1. body temperature 2. oxygen saturation 3. RR 4. HR 5. SBP 6. DBP | females | caesarean delivery for multiple births | 60 | I: during surgery 0: at the end of surgery | Supported by the Scientific Research Project Fund of Karamanoglu Mehmetbey University. |
| He (2015) Singapore         | To assess therapeutic care versus standard care (plus information pamphlet). | Inpatient elective surgery | 1. post-operative pain | children 6–14 years | 95 | I: three to seven days prior to surgery 0: baseline, day of surgery, 24 hours post-surgery | Funded by the National Medical Research Council New Investigator Grant, Ministry of Health, Singapore. |
| Hoffman (2017) USA          | To assess efficacy of P6 acupressure versus placebo | PONV incidence N/A | 1. negative emotional manifestation 2. post-operative pain | adults | Planned ambulatory surgery; high risk for PONV | 110 | I: pre-operatively: 30-60 minutes pre-induction 0: three recovery phases – Phase 1 (PACU), Phase 2 (pre-discharge), Phase 3 (24 hours post-discharge) | No funding statement. |
| Kapritsou (2018) Greece     | To compare fast-track conventional recovery protocols. | LOS | 1. readmission rates 2. complications 3. pain (VAS) | adults 30–82 years | Hepatectomy | 62 | I: immediately after surgery 0: point of discharge | No funding received. |
| Karunagaran (2016) India    | To assess video-assisted learning versus usual care. | Knowledge | 1. anxiety (STAI) 2. physiological and behavioral responses 3. relationship between knowledge, anxiety and physiological responses | Adults | Gastroscopy | 72 | I: pre-procedure 0: 30 minutes prior to procedure | College of Nursing, Christian Medical College, Vellore, Tamil Nadu. |
| Kelly (2017) USA            | To assess effectiveness of folded and rolled dry cotton blankets warmed in 130°F or 200°F cabinets. | Skin temperature | 1. thermal comfort 2. safety | Adults >18 years | Hospital volunteers or employees (healthy volunteers) | 20 | I: in-vitro (in perioperative setting) 0: at regular intervals up to 40 minutes after blanket application | No funding statement. |
| Klintworth (clinical trial protocol) USA | To examine the use of 2% chlorhexidine gluconate cloths pre-operatively and daily post-operatively versus standard care. | Surgical site infection | 1. serious adverse events 2. mortality | Adults >18 years | Colorectal surgery | 163 | I: pre- and post-operatively up to four days 0: up to 30 days post-operatively | No funding statement. |
| Koenen (2017) Australia     | To compare reflective blankets versus cotton blankets for reduction of core-periphery heat gradient. | Pre-operative change in foot temperature | 1. normothermia on arrival to PACU 2. proportion of patients requesting additional warmed blankets | Adults | Elective surgery more than one hour duration | 328 | I: pre-operative holding bay 0: on admission and then at regular intervals until before discharge from PACU | Supported by the NSW Health Education and Training Institute (Rural Research Capacity Building Program). |
| First author (year, country) | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-----------------------------|-------------|----------------|---------------------|-----------------|---------------------|---------------------|-----------------------------------------------|---------|
| Kose (2016) Turkey | To examine different hair shaving practices. | Surgical site infection | Body image | Adults | Elective cranial surgery | 200 | I: pre-operatively in OR O: Post-operatively – first, third, fourth, seventh and tenth days | Funded by Gulhane Military Medical Academy Scientific Research Council. |
| Kurtovic (2017) Croatia | To compare post-operative analgesic efficacy of intermittent versus PCA paracetamol. | Post-operative analgesic efficacy | Nil | Adults 27–80 years | Elective lumbar discectomy of intervertebral disc extrusion at L4-L5 | 56 | I: in OR on completion of surgery to 48 hours post-operatively every six hours O: In OR on completion of surgery to 48 hours post-operatively | No funding statement. |
| Lee (2015) Taiwan | To examine Clickamico app with clown doctors versus dolls versus standard care (brochure). | Hypothermia duration | 1. cost effectiveness 2. thermal comfort | Adults | Post-spinal surgery (in PACU) | 100 | I: PACU O: post-operatively: on admission to PACU until normothermia achieved | No funding statement. |
| Lee (2016) Taiwan | To assess nurse-delivered education with video versus standard care. | Anxiety (STAI and cortisol levels) | Pain | Adults ≤ 20 years | Lumbar spinal surgery | 86 | I: day before surgery O: day before surgery; 30 minutes pre-surgery, day after surgery | No funding statement. |
| Li (2014) Hong Kong | To assess therapeutic play with dolls versus standard care (pre-operative preparation). | Anxiety (STAIIC) | 1. parental anxiety 2. satisfaction (child and parental) | Children 7–12 years | Elective surgery | 108 | I: day of surgery O: before and after intervention, post procedure | Supported by the Health and Health Services Research Fund, Food and Health Bureau, Hong Kong SAR Government. |
| Liguori (2016) Italy | To examine Clickamico app with clown doctors versus standard care (brochure). | Pre-operative anxiety | Nil | Children 7–12 years | Elective surgery | 40 | I: night prior to procedure O: afternoon before surgery, day of surgery (on transfer) | Funded by the Department of Health Sciences at the University of Florence, the Meyer Children’s Hospital, and the Meyer Foundation. |
| LoRusso (2018) USA | To evaluate perioperative blood glucose levels of Type II diabetic patients with use of etomidate versus propofol for induction of anaesthesia. | Perioperative blood glucose | Nil | Adults | Patients with Type II diabetes undergoing surgery | 18 | I: at induction O: at induction and following emergence from anaesthesia | No funding statement. |
| Lynch (2015) USA | To compare room air versus carbon dioxide insufflation. | Pain intra-procedure and anaesthetic-ly (non-verbal and verbal pain scale) | 1. length of recovery 2. nursing tasks and time | Adults | Routine screening or surveillance colonoscopy under moderate sedation | 191 | I: during procedure O: during and post-procedure | No funding received. |
| Ma (2015) China | To assess three perineal disinfection solutions. | Pre-operative bacterial count | Nil | Adults or children | Urethral opening surgery | I: five times a day O: one and two days post-procedure | No funding statement. |
| Martin (2014) USA | To examine the impact of therapeutic suggestion under anaesthesia. | LOS | 1. anxiety (VAS and CRA scale) 2. pain (FLACC and Wong-Baker FACES pain rating scale) 3. intravenous morphine dosage 4. PONV 5. emergence delirium 6. implicit memory | Children 4–8 years and self-identified primary caregiver | Non-coblation transsclerotomy or adenotonsillectomy | 94 | I: completion of surgery until readiness to wake up in PACU O: post-operatively (PACU) | Funded by ASPAN grant, and an XTO Energy Clinical Scholars Grant. |
| First author (year, country) | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-------------------------------|-------------|----------------|---------------------|-----------------|---------------------|-----------------------|-----------------------------------------------------|---------|
| McClurkin (2016) USA          | To assess impact of self-selected music versus music versus no music (usual care). | anxiety (STAI) | 1. patient satisfaction 2. relationship between STAI and NVAAS | adults 18–75 years | day surgery (multiple specialities) | 133 | I: pre-operatively O: after surgery, day of surgery (on transfer) | Funded by Baylor St. Luke’s Nursing Research Council and the Friends of Nursing. |
| Mirbagheri (2015) Iran        | To assess effects of monitoring versus usual learning activities. | clinical perioperative competence | nil | adults | OR students | 60 | I: over 15 months O: before and after intervention | No funding statement. |
| Molloy (2018) USA            | To compare preventative use of dorzolamide-timolol ophthalmic solution with balanced salt solution. | intraocular pressure | time effects | adults | patients scheduled for prolonged steep Trendelenburg procedures | 90 | I: following induction of anaesthesia O: baseline, then every 30 minutes during surgery | No funding statement. |
| Mousavi (2018) Iran          | To assess supportive educational nurse-led interventions versus standard care | anxiety (STAI) | sleep (SSQoS) | adults | Elective coronary artery bypass graft (CABG) surgery | 160 | I: one and two days prior to surgery O: day of admission, right before surgery | Funded by Tehran University of Medical Sciences. |
| Munday (2018) Australia      | To compare pre-operative warming plus IV fluid warming versus usual care including IV fluid warming. | perioperative heat loss | 1. hypothermia 2. maternal thermal comfort 3. MAP 4. shivering 5. agreement between temperature devices 6. neonatal temperature 7. Apgar score | women >18 years | women undergoing elective Caesarean delivery with intrathecal morphine | 50 | I: pre-operatively O: post-operatively up to discharge | Funded by Perioperative Nurses Association of Queensland (PNAQ). |
| Nieh (2018) Taiwan           | To assess efficacy of forced air warming versus passive insulation on rewarming. | rewarming | thermal comfort | adults >20 years | laparoscopic thoracic or abdominal surgery over one hour anaesthesia | 127 | I: during anaesthesia until PACU discharge O: every 30 minutes intra-operatively and in PACU until normothermia achieved | Taichung Veterans General Hospital, Republic of China. |
| Nilsson (2014) Sweden        | To assess effectiveness of P6 acupressure (with Sea-Band) versus placebo on post-operative nausea. | post-operative nausea | frequency of vomiting | adults >18 years | elective infratentorial or supratentorial craniotomy | 120 | I: applied at the end of surgery O: on arrival to PACU, then at specified intervals until 48 hours post-operatively | Devices partly provided by SeaBand Ltd, remainder provided by Department of Neurosurgery of Umeå University Hospital. Study supported by hospital’s research foundation. |
| Notte (2016) USA             | To measure effect of Reiki versus usual care on perceived pain. | perceived pain | 1. post-operative analgesic consumption 2. satisfaction with Reiki 3. satisfaction with hospital experience | adults 18–30 years | total knee arthroplasty (TKA) | 43 | I: after admission, after admission to PACU, daily for three post-operative days O: before and after each treatment or at each participant–nurse encounter | Funded by Sharpe/Strumia Research Foundation of Bryn Mawr Hospital. |
| Oh (2017) Korea              | To compare effects of truncatunaeus electrical nerve stimulation reflex band with wrist band, with acupressure on Nei-Guan acupuncture point. | PONV ( Rhodes Index of Nausea, Vomiting and Retching) | frequency of patient-requested anti-emetics | adult females 16–65 years | gynaecology surgery under general anaesthesia with POA | 54 | I: prior to anaesthesia O: at 0–24 hours after PACU discharge | No funding received. |
| Oliveira (2016) Brazil       | To assess pre-operative orientation video versus usual care. | patient knowledge | nil | adults >18 years | cardiac surgery | 90 | I: approximately 72 hours prior to surgery O: Post-intervention | Funded by Fundo de Apoio à Pesquisa do Instituto de Cardiologia (FAPIC). |
| Oulu (2018) Turkey           | To assess the effect of cold application versus no cold application on pain and bleeding. | pain bleeding | sepsplast to correct deviated septum | adults >18 years | | 60 | I: in ENT clinic for 15 minutes prior to surgery O: post-operatively at regular intervals up to 24 hours | No funding received. |
| Palese (2015) Italy          | To assess post-operative shampooing versus no shampooing. | comfort | 1. surgical site contamination (CFU) 2. surgical site infection | adults >18 years | elective craniotomy | 53 | I: post-procedure O: 30 days post-surgery | No funding statement. |
| First author (year, country) | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-----------------------------|-------------|----------------|--------------------|-----------------|---------------------|----------------------|-----------------------------------------------|---------|
| Paris (2014) USA            | To examine effect of various warming methods on maternal body temperature during Caesarean delivery. | maternal core body temperature | 1. maternal hypothermia  
2. estimated blood loss  
3. post-operative pain  
4. rescue blanket use  
5. maternal shivering  
6. maternal–newborn bonding  
7. first axillary newborn temperature  
8. cord pH  
9. Apgar scores (one and five minutes) | women | elective, singleton Caesarean delivery | 226 | I: pre-operatively until two hours post-delivery  
O: pre-operatively through to fourth postpartum hour | Medline Industries donated the warming pad and temperature sensing Foley catheters. |
| Sáenz-Jalón (2015) Spain    | To evaluate effectiveness of information booklet alone or with clarification questions versus standard care (three groups). | short- and long-term knowledge regarding totally implantable access ports (TIAPs) | physiological indicators of anxiety | adults >18 years | patients diagnosed with cancer, admitted to day surgery for insertion of TIAP | 105 | I: In day surgery waiting room  
O: before TIAP implantation, in waiting room, at three months | No funding statement. |
| Razera (2015) Brazil        | To assess feasibility and efficacy of intra-operative underbody warming vs passive warming. | intra-operative hypothermia | 1. temperature decline (via nasopharyngeal temperature)  
2. prothrombin time  
3. activated partial thromboplastin time  
4. thrombin time  
5. complications: in OR and post-operatively  
6. shivering  
7. pain (VAS) | adults >18 years | open and laparoscopic surgery for gastrointestinal tumours | 110 | I: intra-operatively  
O (primary): from anaesthesia induction, every 20 minutes until end of procedure  
O (secondary): in OR, end of anaesthesia, post-operative day 1 | Funded by the Science and Technology Commission of Shanghai Jiao Tong University. |
| Pool (2015) USA             | To assess raising head of bed to 15 degrees versus keeping flat. | patient comfort: pain (VAS) |  | nil | adults | cardiac angiography | 71 | I: post-procedure  
O: before procedure, every 15 minutes post-procedure | No funding statement. |
| Pu (2014) China             | To assess feasibility and efficacy of intra-operative underbody warming vs passive warming. | intra-operative hypothermia | 1. temperature decline (via nasopharyngeal temperature)  
2. prothrombin time  
3. activated partial thromboplastin time  
4. thrombin time  
5. complications: in OR and post-operatively  
6. shivering  
7. pain (VAS) | adults >18 years | open and laparoscopic surgery for gastrointestinal tumours | 110 | I: intra-operatively  
O (primary): from anaesthesia induction, every 20 minutes until end of procedure  
O (secondary): in OR, end of anaesthesia, post-operative day 1 | Funded by the Science and Technology Commission of Shanghai Jiao Tong University. |
| Ovarforth (2014) Denmark     | To assess mobilisation shortly after lumbar disc surgery versus walking from PACU to ward. | feasibility | 1. safety  
2. wellbeing (Bournemouth questionnaire) | adults >18 years | elective lumbar discectomy | 22 | I: one hour post-operatively  
O: one hour post-operatively | Funded by Glostrup Hospital, the Capital Region of Denmark. |
| Reynolds (2015) Australia   | To assess BPU, SSD and TA versus usual care. | feasibility | 1. peripheral arterial catheter failure  
2. dislodgement  
3. occlusion  
4. phlebitis  
5. infection: local or CRBSI | adults >18 years | surgical patients booked for post-operative ICU | 123 | I: operating theatre  
O: on insertion of arterial catheter in OR, daily in ICU, on ICU discharge | Funding provided for products by the Alliance for Vascular Access Teaching and Research Group (AVATAR) at Griffith University. |
| Razera (2015) Brazil        | To assess use of educational video versus usual care. | knowledge of informal caregivers | nil | Unclear: caregivers of children | informal caregivers of children undergoing primary choleiplasty and/or palatoplasty | 80 | I: post-operatively, on day of discharge (24 hours post-surgery)  
O: peri- and post-operatively on discharge | PhD scholarship funding by Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP). |
| Rhodes (2015) USA           | To assess effect of pre-operative education and orientation versus no education and orientation. | anxiety | 1. caregiver anxiety  
2. LOS  
3. morphine equivalent use  
4. patient/caregiver satisfaction | children 11–21 years | posterior spinal fusion (PSF) surgery | 65 | I: pre-operative  
O: two weeks pre-operatively, immediately prior to surgery, during surgery, post-operative day 2, on discharge | No funding statement. |
| Sáenz-Jalón (2017) Spain    | To assess the limb occlusion pressure technique versus standard pneumatic ischemia technique. | arterial blood pressure | 1. ischemia time  
2. anaesthetic incidents: pain, administration of opiates  
3. surgical incidents: interruptions to procedure, bleeding  
4. LOS | adults | upper limb surgery requiring surgical ischemia and locoregional anaesthesia | 160 | I: intra-operative  
O: intra-operatively and post-operatively (LOS) | Funded by Premio Nacional de Investigación de Enfermería Valdecilla a del año 2012. |
| First author (year, country) | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-----------------------------|-------------|----------------|---------------------|------------------|---------------------|----------------------|--------------------------------------------------------|---------|
| Sahin (2018) Turkey         | To evaluate acupressure versus placebo application on P6 acupoint. | PONV           | 1. post-operative pain severity | adults (females) | laparoscopic cholecystectomy | 1: one hour prior to surgery | O: at two, six and 24 hours post-operatively | No funding statement. |
| Salomon (2018) USA          | To assess pre-operative telephone communication by nurse anaesthetist versus standard care (face-to-face on morning of surgery). | anxiety (APANS, STAI Y-1) | nil | adults | office-based anaesthesia for urological procedures | 41 | I: pre-operative – night before surgery (intervention), day of surgery (control) | O: pre- and post-operatively | No funding statement. |
| Simone (2017) Italy         | To evaluate the efficacy of a nursing educational intervention. | parental anxiety (STAI) | nil | adults | parents of children undergoing cardiac surgery for interventricular defect for the first time | 96 | I: pre-operatively | O: unclear (stated pre- and post-operatively | No funding statement. |
| Sites (2014) USA            | To evaluate controlled breathing with peppermint aromatherapy versus controlled breathing alone for PONV relief. | PONV           | administration of post-operative anti-emetics | adults >18 years | elective laparoscopic, ENT, orthopaedic or urological day surgery under GA with intubation | 330 | I: upon initial report of PONV in PACU or day surgery | O: post-operatively in PACU or day surgery | No funding statement. |
| Stallings-Welden (2018) USA | To examine the effectiveness of aromatherapy with standard care for PONV. | PONV           | 1. post discharge nausea and vomiting (PONV) 2. risk factors for PONV | adults >18 years | ambulatory surgical patients | 221 | I: post-operatively and through discharge | O: post-operatively and after discharge | No funding statement. |
| Stewart (2018) USA          | To compare tablet-based interactive distraction with oral midazolam. | perioperative hypothermia | 1. emergence delirium 2. PACU LOS 3. caregiver anxiety (seven-point Likert) 4. caregiver satisfaction (seven-point Likert) | children 4–12 years and caregivers | outpatient surgery | 102 patients (and 102 care-givers) | I: pre-induction | O: on admission, parental separation, mask induction and then on emergence | Funded by West Coast University. |
| Su (2018) Taiwan            | To assess efficacy of forced air warming versus passive insulation. | perioperative hypothermia | 1. shivering 2. pain 3. blood loss 4. adverse cardiac events | adults >20 years | laparoscopic thoracic or abdominal surgery | 124 | I: during anaesthesia, intra-operatively until end of PACU | O: every 30 minutes intra-operatively and in PACU until normothermia achieved | Taichung Veterans General Hospital, Republic of China. |
| Tsai (2017) Taiwan          | To assess effectiveness of three antiseptic handwashing methods amongst surgical staff. | CFU counts      | time for hand cleansing | adults | practicing surgeons and scrub nurses with experience of conventional surgical and waterless hand rub OR protocols | 180 | I: immediately pre-operatively | O: before and after surgical hand disinsection, immediately after operation | Funded by Taipei Medical University, Shuang Ho Hospital. |
| Ullan (2014) Spain          | To assess effect of play versus usual care | pre-operative anxiety (STAI) | 1. SBP 2. DBP 3. HR 4. cortisol levels | adults | surgical otorhinolaryngology patients | 95 | I: during hospital stay | O: each hour post-operatively, commencing when consciousness regained | Funded by The Council of Education of the Junta of Castilla and Leon Spain, and the Spanish Ministry of Education. |
| Unulu (2018) Turkey         | To assess effectiveness of P6 acupuncture. | nausea intensity | 1. patient information 2. anxiety 3. perianesthesia comfort 4. general comfort | adults | gynaecologic (not obstetric) surgery | 1: within 12 hours after procedure | O: post-operatively (0–2, 2–6, 6–12, 12–24 and 24–48 hours | No funding statement. |
| First author (year, country) | Primary aim | Primary outcome | Secondary outcome/s | Participant age | Surgical population | Total sample size (n) | Timing of intervention (I) and timing of outcome (O) | Funding |
|-------------------------------|-------------|----------------|---------------------|-----------------|---------------------|----------------------|-----------------------------------------------|---------|
| Webster (2014) Australia     | To assess consumption of carbohydrate fluids versus usual care | Time to readiness to discharge | 1. time to first flatus 2. time to first bowel movement 3. mortality (from any cause during trial) 4. adverse outcomes | adults >18 years | elective bowel surgery | 46 | I: from 19.00 the night prior to surgery 0: post-operatively | No funding statement. |
| Wilson (2016) Canada         | To assess individualised education prevention. | nausea | 1. pain 2. analgesic and anti-emetic administration | adults | total knee replacement surgery | 1 | I: pre-operatively 0: post-operatively day 3 | Partially funded by the Kingston General Hospital Women’s Auxiliary Millennium Fund. |
| Wistrand (2016) Sweden       | To compare preheated and room temperature skin disinfectant solution. | patients’ experience | 1. skin temperature 2. patients’ experience | adults >18 years | patients undergoing pacemaker, implantable cardioverter-defibrillator or cardiac resynchronisation therapy under local anaesthesia | 220 | I: OR (immediately prior to procedure) 0: Before and after skin disinfection (in OR) | Funded by research council of Örebro County Council. |
| Wu (2019) China              | To assess safety and feasibility of early oral hydration in the PACU. | PONV | 1. thirst 2. incidence of oropharyngeal discomfort 3. patient satisfaction | adults | elective laparoscopic cholecystectomy | 1735 | I: post-operatively (PACU) 0: post-operatively up to day 1 | Funded by the Sichuan Provincial Health Department. |
| Zaman (2018) Iran            | To assess effect of warm versus room temperature IV fluids. | shivering | 1. core temperature 2. oxygen saturation 3. vital signs | adults | elective abdominal surgery | 70 | I: intra-operatively 0: post-operatively – on admission to PACU and at 30 minutes in PACU | No funding statement. |

Abbreviations: AF = atrial fibrillation; APAIS = Amsterdam Preoperative Anxiety and Information Scale; AORN = Association of periOperative Registered Nurses; ASA I–II = American Society of Anesthesiologists classification normal healthy patients to patients with mild systemic disease; ASPAN = American Society of PeriAnesthesia Nurses; BPU = Bordered Polyurethrane; CFU = colony forming unit; CRA scale = Child Rating of Anxiety scale; CRBSI = Catheter-related bloodstream infection; DBP = diastolic blood pressure; ENT = ear, nose and throat; FLACC = Faces, Legs, Activity, Cry, Consolability scale; GA = general anaesthetic; GSQS = Groningen’s Sleep Quality Scale; HR = heart rate; ICU = intensive care unit; IV = intravenous; LOs = length of stay; MAP = mean arterial pressure; mYPAS = modified Yale Preoperative Anxiety Scale; mYPAS-SF = modified Yale Preoperative Anxiety Scale Short Form; NHMRC = National Health and Medical Research Council; NRS = numeric rating scale; NVAAS = Numerical Visual Analog Anxiety Scale; OR = operating room; P6 = pericardium acupuncture point; PACU = Post Anaesthesia Care Unit; PCA = patient-controlled analgesia; PONV = post-operative nausea and vomiting; RR = respiratory rate; SBP = systolic blood pressure; SSD = sutureless securement device; STAIC = State–Trait Anxiety Inventory for Children; STAI-Y = State–Trait Anxiety Inventory (Form Y); STTI = Sigma Theta Tau International; TA = tissue adhesive; UAE = United Arab Emirates; USA = United States of America; VAS = Visual Analog Scale.