Abstract
Embarking on a research project can be a daunting task, assisted by a logical process and with expert guidance a pilot study is an excellent method to refine the process and your skills. A pilot study enables the researcher to determine the logistics of the study including time required, participant number and associated resources. This further enables the novice researcher to test data collection tools and ensure the method is robust and workable. This paper discusses the steps in undertaking research via a pilot study. The paper also provides an outline of the research process to ensure a study is feasible and provides nurses with evidence-based answers to clinical questions.

Objectives
• Consider possible questions/research ideas within your unit.
• Determine what would be your objective for the research.
• Understand how research answers clinical questions.
• Understand the steps to consider when planning research.
• Develop a template to review literature on a chosen topic.
• Understand strengths, weaknesses and considerations when reviewing research to ensure validity.

Keywords
Keywords: Nursing research, research plan, pilot study

Introduction
Prior to the focus on evidence-based practice, nursing as a profession was one that always posed questions and, as such, nurses practise in an enquiring manner. Answers to clinical questions are not always evident, hence nurses are in a key position to investigate and develop a body of knowledge related to nursing skills and patient care. Previously identified nursing research priorities tend to be grouped into the following categories: nursing interventions; educational needs of patients; levels of competence and patient outcomes; and validation of nursing interventions (Lewis et al., 1999). More recently, research priorities have focused on technological applications or quality of life issues for patients, whereby nurses are placed in an ideal position to expand the knowledge of patient-related aspects of care due to the close relationships and trust that is developed (Hewitson, 2014). It is, therefore, vitally important that in refining a research question and identifying the correct
methodology all nurses understand the components of the research proposal and the steps required in order to ensure that the question is answered in a systematic and meaningful manner. This article briefly discusses how to develop a research idea, identify a supportive team and undertake a pilot study in order to produce the answer to your question.

The advantages of a pilot study

Pilot studies provide several key advantages when developing research: it serves as a method for the researcher to practise within the research process, to refine the methodology and to assess the effectiveness of data collection and analysis (Doody & Doody, 2015; Musil, 2012). As such, a pilot study can assist the novice researcher to self-assess their readiness, ability and commitment as a researcher (Bebe, 2007). A pilot study is often recommended to review sample size, sampling techniques and time points, recruitment time (Musil, 2012), test validity and reliability of data collection tools (Moule & Hek, 2011), and can ascertain the level of financial and human resources required (Doody & Doody, 2015). Sample size is of key importance to the viability of the research as participant number influences the relationships between variables, and hence statistical power analysis but also provides an in-depth understanding of the data (Musil, 2012). A pilot study can also clarify any misunderstanding or ambiguity the staff may have about the proposal; this is particularly important when a team is involved in data collection. By clarifying steps beforehand, implementation processes will be clearly understood and there will be less staff stress (Schneider et al., 2013). This enhances credibility of future studies (Padgett, 2008) by resolving extraneous variables (Musil, 2012) or any ethical or practical problems prior to a larger study (Kelly, 2007) and ensures the necessary adjustments and revisions are made (Kim, 2011). In a pilot study the researcher should be open about the lessons learnt and how these in itself contribute to nursing knowledge (Doody & Doody, 2015). By sharing this knowledge and receiving peer review of the idea and context (Secomb & Smith, 2011) the protocol and outcomes will be strengthened.

Identification of the idea

No doubt you will have a question or challenge that you’d like to answer, so you’ll need to develop a framework to ‘flesh out’ the idea. The research problem identifies when there is a gap in knowledge and identifies the focus and aim of the project (Grove et al., 2013). The research question goes on to discuss the problem, purpose, study design and plan for data collection and analysis (Grove et al., 2013). Research questions can be generated from your daily practice; however, the problem needs to be researchable or the problem may need to undergo another process such as practice review, an audit or review of available evidence (Polit & Tatano-Beck, 2012). Further refining a research question is an iterative process utilising your own knowledge and expertise in the field, intuition, literature review and reflection (Flynn et al., 2009). Once the research question is identified, it is important to identify research objectives which will outline the anticipated outcomes of the study (Polit & Tatano-Beck, 2012). Quantitative research questions tend to be more precise and portray the relationships between the population studied and the variables, whereas qualitative research questions are more flexible and state the phenomenon of interest and the population to be studied (Doody & Bailey, 2016).

Determining research feasibility

The terms pilot study and feasibility study are often interchanged; however, for clarity a feasibility study tries out ‘pieces’ of the study (such as data collection tools), whereas a pilot study determines the operation of the process, and all components of the study (NETSCC, 2016). Feasibility studies are pieces of research undertaken before a main study, in order to ascertain if the study is possible in regards to sample size, randomisation, recruitment, eligibility, outcome measures, follow-up rates, availability of data, time and data analysis (NETSCC, 2016). Despite the semantics regarding terminology, a preliminary study (whether it is called a pilot or feasibility study) is the ideal way to test out concepts for a larger study. A robust feasibility assessment will help identify possible problems with recruitment and may highlight logistical challenges that may be faced during the study. Feasibility assessments also identify aspects of research that need detailed contingency planning, including the identification of ‘worst case scenarios’.

This part of the process determines the requirements of the project in comparison to the likely outcomes, that is, whether the outcome is likely to influence practices to the extent that it is a viable option to invest the necessary time and resources. Feasibility also looks at the team construction and experience of researchers, availability of participants, equipment and resources, ethical considerations, time required and financial costs, both tangible and in kind (Grove et al., 2013). Time is a significant consideration and must be clearly estimated, hence guidance from an experienced researcher or clinician with research experience is often needed at this point. From idea development to proposal creation, ready for commencement, may take approximately 6–12 months, so it is essential to be fully prepared for this time investment (Grove et al., 2013).
Identifying support systems

Suitable primary team identification is critical to ensure success of the project. A team needs to contain people that are motivated, committed both ‘in kind’ and paid time, with a variety of mixed experience (from inexperienced to expert researchers), which will ultimately develop nursing culture, but also adds to the quality of research conducted (Grove et al., 2013). The role of the primary investigator (PI) is similar to a project manager. The PI ensures that the team is unified, approvals are acquired, consensus is sought, the research timeline is followed and documentation is completed.

Additionally, academic advisors and experienced researchers provide valuable advice in developing structure and foreseeing and managing any problems that may be encountered along the research journey. Each facility should investigate local and external support services such as nursing research or hospital-based research departments, links with associated academia and universities as well as assuring institutional support for the project. All authors must actively contribute and participate in the study and provide input into the development of knowledge (Schneider et al., 2013). All team members should be provided with guidelines about their role and expectations, and teams should meet regularly to discuss study progress, identified challenges, plan analysis and the collation and facilitation of reporting requirements dictated by funding/organisational bodies (Schneider et al., 2013). Author order should be discussed early in the study process. Authors should jointly decide the order presented and have a rationale for this order (International Committee of Medical Journal Editors, 2015).

Putting research into practice Question 2

Determine who may assist you locally Engage all relevant stakeholders, consider a consumer

Who would you want on your team and what skills would they bring?

Undertaking a literature review

Research commences with the identification of a problem or question, followed by a literature search for current information, which is critically reviewed, then a trial is proposed and results are interpreted (Moule & Hek, 2011). Effectively researching and presenting information is a skill and it is advisable to have some training in effective database searching prior to embarking on this task. Large research collections such as the Johanna Briggs Institute (JBI) Renal Node, Systematic Reviews and Clinicians Knowledge Network (CKN) provide access to a variety of nursing and medical literature including CKN databases such as CINAHL (Cumulative Index Nursing and Allied Health Literature), Pubmed and Medline, and are a good starting point for understanding current ideas and previous research related to the topic you have chosen. Select several key search terms including alternative terms and determine if limiting the search to select years is appropriate. It is beneficial to review the keywords used by other authors as alternatives may be evident (Coughlan et al., 2013). Additionally, by also limiting the search to English-language, human-research studies and full-text papers, a more manageable and comprehensive review of the literature can be obtained (Schneider et al., 2013). Also, if you search several databases for completeness of data, this ensures your time is used effectively and your search provides appropriate breadth and depth of content (Coughlan et al., 2013). Hence professional guidance from a librarian in accurate database searching is recommended, including the use of data collation tools and referencing programs such as Endnote, Reference Manager or Procite (Moule & Hek, 2011).

Critical appraisal of the literature determines the strength and weakness of articles, and whether the current proposal will be extensive enough to answer the aim. The critiquing process reviews the merits and ‘lessons learned’ during the study, including any limitations of the work, such as relevance and applicability, determining if any facets of the research have undermined the conclusions of the study (Cutcliffe & Wood, 2007). This includes ensuring that the research has not already been done, and if similar studies have been undertaken that their recommendations are utilised. This may include replicating methodology, data collection tools or questionnaires (with permission) (Moule & Hek, 2011). Moule and Hek note that this needs to be undertaken in a systematic manner, and is time-consuming, requiring determination and perseverance, and hence needs to be clearly considered within the research time frame (2011).

A system for organising articles and references is essential and a bibliographic reference with all key information is recommended (Coughlan et al., 2013). Tables to display and compare the literature such as the following example are helpful to provide a layout/overview of the literature:

<table>
<thead>
<tr>
<th>Author/s</th>
<th>Year</th>
<th>Intervention</th>
<th>Variables</th>
<th>Outcomes</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Article 2</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Once this literature has been collated and analysed, a formal literature review summary needs to be written.

Understanding types of research

Whilst not all nurses will undertake research themselves, they may be part of a team involved in research, or they may be required to review research for academic studies and to understand the current evidence base involved in changing nursing-related health care. Regardless of the role, nurses are involved in conducting, critically appraising and utilising research in their daily practice (Grove et al., 2013). Nurses
use a variety of research methods to generate knowledge and review practices (Grove et al., 2013), primarily quantitative, qualitative, outcome and intervention research.

The method or type of research is as important as the question, and this needs to be appropriately selected. Understanding complex research methods, data collection tools and protocols is not part of the day-to-day experience of nurses, many of whom are unlikely to be prepared and educated in their use (Cutcliffe & Wood, 2007). An experienced researcher will guide the team in selecting the appropriate methods and can suggest possible data collection tools. The method chosen will aim to eliminate bias or influence on the data and may include concepts such as randomisation, prospective data collection or blinded-studies; hence once chosen the method should be extensively investigated to ensure all key concepts are covered in the research design and protocol. An overview of research approaches is covered in the Campbell and Roden article in the Renal Society of Australasia Journal (2010). Research rigour is the strength of a study’s design and methods, to answer its research questions with certainty (Kearney, 2015).

Determining the research aim

Based on the literature review, the purpose of the proposed study will be narrowed down from an aim into a concise statement (Moule & Hek, 2011). This includes deciding what comparisons are required, identifying realistic strategies and investigating what outcomes are feasible. Grove et al. (2015) note key points for formulating a research problem and purpose (adapted here) which will assist the clinician to determine a plan:

Identify opportunity for research based on observation of nursing practice or challenges/questions posed by patients/nurses

Identify possible research topic

Generate possible questions and key concepts

Research problem (literature review and external input)

Define research purpose: clear objectives, questions or hypothesis

Undertake research as per developed protocol; provide discussion and analysis of concepts

Outcome focuses on posing answers to questions or clarification of ideas resulting from research

Disseminate findings

Determining required resources

Seeking financial approval for research is a highly competitive and challenging component of research, hence it is vital to get guidance from experienced researchers if financial requests are likely. Pilot studies are often viewed as a “trial of concept” and provide key evidence of the viability of future endeavours; however, many pilot studies are undertaken through the generosity of organisational finances. Therefore, as a preliminary step, nursing executive and cost centre approval is required for in-kind time and resources. Finances may be required for equipment, testing procedures such as pathology, wages, associated skills such as statistical review or research assistant time/resources.

The following may be considered and investigated for financial assistance: all accessible nursing avenues; governmental support; professional support/scholarships; and organisational support. Also, seek advice from academia/local researchers and take advantage of the advice and supportive skills of experts it helps you write a successful funding proposal.

Developing a proposal protocol

A proposal summary or protocol is required to provide direction during the study, to apply for financial support, and for ethical and governance authorisation within the workplace to permit the study itself. Please refer to Table 1 for a guide on information required for a study protocol.

Table 1: A research plan should include the following information:

<table>
<thead>
<tr>
<th>1. Summary</th>
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<tbody>
<tr>
<td>2. Objectives</td>
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<tr>
<td>3. Background including:</td>
</tr>
<tr>
<td>a. Aim</td>
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<tr>
<td>b. Significance</td>
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<tr>
<td>c. Literature review</td>
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<tr>
<td>4. Trial design including:</td>
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<tr>
<td>a. Intervention</td>
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<tr>
<td>b. Patient population (inclusion and exclusion criteria)</td>
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<tr>
<td>c. Sample size</td>
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<tr>
<td>d. Outcome measures</td>
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<tr>
<td>5. Description regarding intervention or procedures including:</td>
</tr>
<tr>
<td>a. Recruitment</td>
</tr>
<tr>
<td>b. Intervention or treatment plan</td>
</tr>
<tr>
<td>c. Monitoring processes</td>
</tr>
<tr>
<td>6. Data sources including any laboratory samples, questionnaires and assessments</td>
</tr>
<tr>
<td>7. Data management</td>
</tr>
<tr>
<td>8. Data analysis</td>
</tr>
<tr>
<td>9. Ethical considerations including:</td>
</tr>
<tr>
<td>a. Ethics committee and governance approvals</td>
</tr>
<tr>
<td>b. Benefits versus risks</td>
</tr>
<tr>
<td>c. Confidentiality</td>
</tr>
<tr>
<td>10. Publication, including how this information will be disseminated</td>
</tr>
<tr>
<td>11. References</td>
</tr>
<tr>
<td>12. All appendices should be attached (refer to Table 2)</td>
</tr>
</tbody>
</table>
Considered “low-risk”. Ensuring external review has occurred not all studies require a complete ethics review (such as a
Although all studies will need some form of external review, is the key document to be submitted for ethics approval.
Application Form (NEAF https://www.neaf.gov.au/), which
Clear guidelines are available for each organisation, and
transparency in clinical practice.
Organisations are governed by local, national and international
mandates to protect the public and ensure safety and
members to undertake some form of training in order to be
(Schneider et al., 2013). It is advisable for the PI and/or team
et al., 2013). It is advisable for the PI and/or team
et al., 2013). As a rule, inclusion and exclusion criteria are used
to reduce bias, which will strengthen the study whilst at the
same time providing generalisability (Schneider et al., 2013). As a result, one of the primary reasons for undertaking a pilot
study is to determine the outcome of these determinants and if adjustments are required for larger studies.

**Determining sample size**
Research will often focus on a representative sample otherwise trials would be too costly and time-consuming; however, the
sample must reflect the target population in numerous ways such as diagnosis, treatment considerations and gender (Moule
& Hek, 2011). Likewise, expert advice aids in determining the most appropriate sample size, and review of previous related
studies will assist the researcher in determining clear inclusion/ exclusion criteria, randomisation processes and sampling
techniques (Moule & Hek, 2011). Eligibility criteria focus on those characteristics that limit or unify a population, for example gender, and provide the ability to identify differences between the sample and an alternative population (Schneider et al., 2013). As a rule, inclusion and exclusion criteria are used
to reduce bias, which will strengthen the study whilst at the
same time providing generalisability (Schneider et al., 2013). As a result, one of the primary reasons for undertaking a pilot
study is to determine the outcome of these determinants and if adjustments are required for larger studies.

**Requesting ethics approval**
In considering the ethical impact of studies on human participants, numerous factors must be considered such as respect, beneficence, informed consent, freedom from financial or competitive interests and protection of the vulnerable (Schneider et al., 2013). It is advisable for the PI and/or team members to undertake some form of training in order to be familiar with these principles and the safeguard requirements. Organisations are governed by local, national and international mandates to protect the public and ensure safety and transparency in clinical practice.

Clear guidelines are available for each organisation, and
more commonly are nationally based with the National Ethics Application Form (NEAF https://www.neaf.gov.au/), which is the key document to be submitted for ethics approval. Although all studies will need some form of external review, not all studies require a complete ethics review (such as a clinical audit) and those with minimal interventions may be considered “low-risk”. Ensuring external review has occurred enables research to be published, regardless of the low-risk or complete ethical approval. Additionally, clinical trials are also required to be registered with a national authority such as the Australian New Zealand Clinical Trials Registry (ANZCTR) to provide public disclosure of the trial objectives and design, to protect the public and facilitate effective management and reporting (Schneider et al., 2013).

**Data collection, entry and analysis**
This part of the process includes selecting subjects, collecting data in a consistent manner, maintaining control for integrity and validity of the study, ensuring that there are no influences or changes during the data collection period and solving problems along the way (Grove et al., 2013). The challenges for the nurse who is part of the workforce where the research is being undertaken, whilst also undertaking the research is “the duality of roles” (Borbasi et al., 2005). “Inconsequential information” may be provided to the nurse under the guise of their research role that may have an impact on clinical care. How this information is dealt with confidentially and without influence is a challenge for the novice researcher and may need to be discussed with more experienced members of the team. These challenges require rigorous reflection on the research experience to expose underlying assumptions and judgements (Coghlan & Casey, 2001). As nurse researchers engage in their project they have to balance the tacit political processes at play within the organisation with the credibility required of the research (Coghlan & Casey, 2001; Beale & Wilkes, 2001).

**Data collection** techniques and analysis will depend on the research method chosen. The raw data will need to be collated from current data collection tools into computer programs (often spreadsheets) so that this can be easily transferred to computer analysis software. It is important to avoid any judgement statements and not to draw any conclusions from the data until this is properly collated and themes validated (in qualitative techniques) or statistical significance is confirmed (quantitative techniques). All data presented in the spreadsheet needs to be de-identified and password-protected. As per the national ethics guidelines, all patient data need to be stored for five years from the date of publication, in a double-locked area such as a locked filing cabinet in a locked office, so storage of hard copies and data files needs to be considered in terms of confidentiality, where this is kept and who is responsible for destroying the information at the end of this period (Australian Government, 2007). However, it is important to note that records may need to be retained for longer durations for some categories of trials, such as clinical trials, patient disease or condition-specific trials or trials which have community or heritage value.

<table>
<thead>
<tr>
<th>Table 2: Additional resources (appendices) required for planning and data collection will be needed and should include (if applicable):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient information and consent forms (PICF)</td>
</tr>
<tr>
<td>• Timelines</td>
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<tr>
<td>• Date collection sheets</td>
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<tr>
<td>• Surveys</td>
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<tr>
<td>• Budget planner including in-kind time</td>
</tr>
<tr>
<td>• Spreadsheet to transfer clinical data into format that can be transferred to statistical program (statistical advice is extremely beneficial at this point)</td>
</tr>
<tr>
<td>• Any advertising material to recruit participants</td>
</tr>
<tr>
<td>• Sample questions for focus groups/interviews</td>
</tr>
</tbody>
</table>

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Data entry is a time-consuming process which may warrant financial input to ensure the project meets time deadlines. In the planning stages of the research, discuss with experienced researchers how this stage may be managed. Suggestions for successful data entry include ensuring all data entry is reviewed regularly during the project to develop processes for missing data (rather than discovering this at the end of the project); developing a systematic process during data entry, minimising the data-entry period to two hours to avoid fatigue and errors, and ensuring entry backups are attended (Grove et al., 2013).

Data analysis identifies what was significant/not significant, that is, determining whether the outcome was real or happened by chance, and if there were variations in predicted results, as well as describing limitations and clarifying meanings (Grove et al., 2013). This requires significant skills in interpretation and relies on an experienced researcher, and hence analysis strategies need to be discussed with team members early in the study, and the identification of experts is essential. Dependent on the type of research, the following methods may be utilised (Tables 3 and 4). Novice researchers will need to be aware of the potential of bias during the research process, and where able seek appropriate advice from skilled experts in how to anticipate and minimise such risk.

Interpretation of results
This will become evident after the data is analysed but also includes acknowledgements of the limitations of the study and development of conclusions and generalisability (if the study can be applied to other groups, relevance, significance and further research is usually discussed) (Moule & Hek, 2011).

Maintaining motivation during the study
Little is often written about the problems or challenges encountered during the study period (Grove et al., 2013), and this is often of the greatest interest to future researchers or clinicians, and influences the ability to undertake future robust research. Commonly noted problems include people problems such as changes in the research team, external influences or participant withdrawal, and passive resistance from professional and non-professional team members (Grove et al., 2013). Researcher problems can vary from role conflict, lack of skills in data collection, institutional and event problems (including resource and staff implications) (Grove et al., 2013). Often intercurrent issues may cause a delay in study goals due to patient withdrawal from the program; samples being missed; lack of clinical time; and hindered communication. Therefore, it is vitally important to keep the study team updated regularly — aim for monthly meetings — and the wider nursing team involved in the study updated periodically — second-monthly ward/unit meetings are useful to explain progress and challenges. This helps the team to concentrate on the positives and ensures all local staff are participating and planning so the next steps can commence. It is important to ensure a support team is in place before the ethics process is embarked upon as each member needs to be noted on the applications and roles accounted for accordingly.

Dissemination of findings
Ultimately, all research findings should be published in order to develop clinical knowledge, an evidence base and assist future researchers. Hewitson (2014) advocates that sharing results improves our knowledge and improves practice both at an academic level, and through learning and communication. Schneider et al. (2013) suggest that the outcome of the research needs to be discussed at the planning phase, considering the goal of the research, who the target audience will be and hence the most appropriate means of disseminating the findings. They go on to say that once the information is published this does not mean it is easily translated into practice; therefore, the findings need to be easy to interpret and implement. Therefore, provide sufficient detail about current ideas and theories, the process and ‘action plans’, costings and clear, concise discussion and recommendations (Schneider et al., 2013).

Summary and clinical practice relevance
Whilst this is a brief guide, undertaking training, reviewing plans with colleagues, and/or developing mentoring, collaborative relationships with researchers (Schneider et al., 2013) are all pivotal to ensuring the success of a research project. As with every nursing specialty, the process and language is unfamiliar to a novice and hence guidance and discussion in the planning stage will pave the way to a less problematic journey.

All nurses need to be involved in the development, understanding and implementation of nursing knowledge to expand our practice and benefit patients and the profession (Cutcliffe & Wood, 2007). Managing a research project is complex and requires dedication to details in regard to the implementation, monitoring and evaluation stages (Schneider et al., 2013), guided by team expertise and clear communication.

Commencing your research journey or quality project with a pilot study is a highly recommended method of trialling both process and people, ensuring the questions and outcomes provide sufficient answers to the chosen question. This, in turn, may open the door for future research within the area and thereby increase the evidence base in nursing knowledge.
Table 3: Quantitative studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Findings/Implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schneider et al., 2013</td>
<td>Correlation coefficient</td>
<td>Calculated to demonstrate size and direction of relationship between two variables</td>
</tr>
<tr>
<td>Moule &amp; Hek, 2011</td>
<td>Content analysis</td>
<td>Can be assisted by specific software for qualitative data analysis</td>
</tr>
<tr>
<td>Generalisability is not required</td>
<td></td>
<td>Constant comparisons may be sought</td>
</tr>
</tbody>
</table>

Table 4: Qualitative studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schneider, Z., Whitehead, D., LoBiondo-Wood, G., &amp; Haber, J., 2013</td>
<td>Questionnaires/focus groups/interviews/text</td>
</tr>
<tr>
<td>Moule, P., &amp; Hek, G., 2011</td>
<td>Content analysis</td>
</tr>
</tbody>
</table>

Recommended reading


For a comprehensive review of all aspects related to nursing research based within the Australian context, refer to:


References


