Title: Interventions to prevent in-hospital falls in older people with cognitive impairment for further research: a mixed studies review

Short title: Cognitively impaired older patients and falls

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Abstract

Background. While advances in falls prevention in the adult population have occurred, the care requirements for older patients with cognitive impairment at risk of falling are less established.

Objectives. The aim of this review was to identify interventions to prevent in-hospital falls in older patients with cognitive impairment for further research and describe the strategies used to implement those interventions.

Design. A seven-stage mixed studies review was used.

Methods. Seven electronic databases were searched. The SPIDER framework guided the review question and selection of search terms. The Mixed Methods Assessment Tool was used to appraise the quality of research studies and the Quality Improvement Minimum Quality Data Set was used to appraise the quality of quality improvement projects. A convergent qualitative synthesis was used to analyse the extracted data. The adapted PRISMA guideline informed the procedures.

Results. Ten projects (five quality improvement and five research) were included. Five themes emerged from the synthesis: engaging with families in falls prevention, assessing falls risk to identify interventions, extending nursing observation through technology, conducting a medication review, and initiating non-pharmacological delirium prevention interventions. Implementation was not well described and commonly focused on capital investment to initiate a falls prevention program and education to introduce staff to the new techniques for practice.

Conclusions. Emerging research and quality improvement studies demonstrate that effective falls prevention with this vulnerable population is possible but requires further investigation before widespread practice recommendations can be made. Further research and quality improvement in this area should consider adoption of an implementation framework to

address sustainability.

Relevance to clinical practice: Reducing falls in older people with cognitive impairment requires nurses to work more closely with pharmacists, occupational therapists and social workers to develop strategies that work and are sustainable.

Keywords:

In-hospital fall, prevention, cognitive impairment, delirium, dementia

Contribution of the Paper

What does this paper contribute to the wider global clinical community?

- Multicomponent programs are needed to prevent falls in older patients with cognitive impairment
- Preventing delirium, a form of cognitive impairment, and engaging families through communication technologies, such as ‘TOP5’, are areas for further research in relation to reducing in-hospital falls
- Implementing, and in particular sustaining, in-hospital falls prevention interventions once the upfront capital investment is removed, is an important area for further research

Introduction

In-hospital falls are a major cause of harm for patients aged 65 years and older (Morris & O’Riordan, 2017). Falls are generally categorised as with or without injury (Cameron et al., 2018). While a fall may not result in injury, fear of falling among patients, families and health professionals can negatively impact physical activity and increase deconditioning, further increasing the risk of falling (Resnick & Boltz, 2019).

Health outcomes for older people who fall in hospital are significant. A large study in Australia (n=2,945) found that older people admitted from home were less likely to return home after an in-hospital fall with injury, often discharged to permanent long-term residential care at significant emotional and financial cost (Basic & Hartwell, 2015). The outcomes are worse for older people with cognitive impairment, with one study finding that older hospital patients with cognitive impairment fell at a ratio of 2 to 1 compared to older patients without cognitive impairment (Harlein, Halfens, Dassen & Lahmann, 2011).

The direct care costs attributed to falls are substantial in many countries, such as the United States (Florence et al., 2018), Australia (Morello et al., 2015), and the United Kingdom (NHS Improvement, 2017). Falls in older patients have been associated with an average increased length of stay of 8 days, incurring mean additional hospital costs of Aus\$6699 (95% CI, \$3888-\$9450) per stay (Morello et al., 2015). In the USA, the medical costs attributable to fatal and nonfatal falls in hospitalised older adult patients were estimated at US\$50 billion in 2015 (Florence et al., 2018).

The proportion of acute hospital beds occupied by older people with cognitive impairment is high. A prospective study of 493 patients aged 70 years and older in four acute hospitals in Australia found that almost 30 per cent had cognitive impairment, increasing to 47 per cent in the oldest patients, aged over 90 years (Travers, Byrne, Pachana, Klein & Gray, 2013). However, these estimates may be an under representation as recent studies in

England (Crowther, Bennett & Holmes, 2017) and Ireland (Timmons et al., 2015) found as many as a quarter to a third of patients with dementia did not have their diagnosis recorded in their medical records. Briggs and colleagues (2017) conducted cognitive assessment of patients aged over 70 years presenting to a large teaching hospital in Dublin and found that more than a third had dementia, of which two thirds were undiagnosed prior to presentation.

In the last twelve years, several reviews have explored aspects of falls intervention with older people in institutional and community settings (Cameron et al., 2018; Hempel et al., 2013; Lach, Harrison & Phongphanngam, 2017; Oliver et al., 2007; Rubenstein & Josephson, 2006; Tricco et al., 2017). However, three of these is not specific to older people with cognitive impairment (Cameron et al., 2018; Hempel et al., 2013; Tricco et al., 2017) and one was not systematic (Rubenstein & Josephson, 2006). Of the remaining two reviews, both focused on older people with cognitive impairment, one was limited to published research studies and included predominantly community-based studies (Lach et al., 2017) and the other was also limited to research studies and included institutional care homes (Oliver et al., 2007). There are no reviews to date specifically focused on interventions to reduce falls for older people with cognitive impairment in hospital.

Evidence-based interventions that reduce falls in hospital include assessment for modifiable risk factors using a validated tool (Cameron et al., 2018; Hempel et al., 2013; Rubenstein & Josephson, 2006), falls risk reminders such as coloured armbands or door signs (Hempel et al., 2013; Oliver et al., 2007), and exercise (Cameron et al., 2018; Lach et al., 2017; Rubenstein & Josephson, 2006). For people with cognitive impairment, routine medication review is also recommended (Oliver et al., 2007). In these reviews, there was a strong focus on high quality evidence and, as such, quality improvement studies were often excluded. Whilst high quality evidence in a highly researched area like in-hospital falls is critical, understanding what works for the unique vulnerabilities of older patients with

cognitive impairment remains obfuscated. Extending the literature search to quality improvement studies may reveal other in-hospital falls prevention interventions that work for older people with cognitive impairment. Using this approach, key interventions that have met with some success can be identified for further investigation, to encourage high quality research into the care of this vulnerable population.

In the published systematic reviews, how falls prevention programs were implemented was often not addressed in the reviews (Lach et al., 2017; Oliver et al., 2007; Rubenstein & Josephson, 2006) or there was limited evidence of implementation strategies provided in the original studies (Hempel et al., 2013; Tricco et al., 2017). Staff education was commonly used to implement falls prevention programs (Cameron et al., 2018; Hempel et al., 2013) but systematic approaches to implementation were not described in these reviews. Considering the characteristics of the population, intervention complexities, and the considerable impact of falls, how to implement in-hospital falls prevention activities specifically for older patients with cognitive impairment is worthy of further investigation.

The aim of this review was to identify interventions that may be effective in reducing in-hospital falls in older patients with cognitive impairment and describe the strategies used to implement those interventions.

Methods

A seven-stage mixed studies review (Pluye, Hong & Vedel, 2016) was conducted. A meta-narrative synthesis approach was adopted. Meta-narrative synthesis is informed by a constructivist approach to knowledge production and is used to explore complex phenomena and establish key concepts (Pluye & Hong, 2014). In this case, the aim was to explore the complexity associated with falls prevention in older people with cognitive impairment, seeking to identify potential interventions and implementation strategies that may be

investigated through high quality research. The review included primary research studies and quality improvement projects reporting on multi-component interventions or programs found to reduce falls in hospitalised older people with cognitive impairment. This strategy was expected to solicit a wide range of falls prevention interventions. The guidelines for the preferred reporting items for systematic reviews and meta-analysis (PRISMA) (Moher, Liberati & Tetzlaff, 2009) - adapted version guided this study (see Supplementary File 1).

1. Review Questions

This review aimed to examine falls prevention interventions that may be effective in reducing the incidence of falls in older people with cognitive impairment in inpatient hospital settings. The Sample, Phenomenon of Interest, Design, Evaluation and Research Type (SPIDER) framework (Cooke, Smith & Booth, 2012) was used to assist in question development and in breaking the questions down into search terms (Table 1).

The research questions that directed the review were:

1. What interventions may be effective in reducing fall rates in older people with cognitive impairment in acute care settings?
2. What strategies underpin implementation of the identified falls prevention interventions for older people with cognitive impairment in acute care settings?

2. Eligibility Criteria

The search strategy included primary research studies using quantitative, qualitative and mixed methods designs and quality improvement reports. Studies or quality improvement projects were included if they met the following criteria:

- Reduction in falls reported with raw data or statistics relating to rate or number of falls (end point criteria);
- Reported a single or multicomponent intervention;
- Conducted in acute and subacute in-patient hospital settings; and

- Sample included older patients with cognitive impairment either exclusively or as part of a larger sample.

Using raw data or statistics related to the rate or number of falls as an endpoint is consistent with the approach adopted by Cameron and colleagues (2018). In this case, to achieve our aim of generating a wide range of potential interventions for research investigation, we purposefully focused on those studies where the outcomes indicated an improvement in number or rate of falls. Single or multicomponent interventions included techniques and tools that focused on preventing falls in medical and surgical wards. Older patients were defined as those aged 65 years and older (55 years and older for indigenous populations). Cognitive impairment was defined as delirium and/or dementia.

Studies or quality improvement projects were excluded if they were conducted outside of acute and subacute inpatient hospital settings and if the study/project excluded people with cognitive impairment (generally classified as a Mini Mental State Examination (MMSE) score of ≤ 22). Studies that evaluated a model of care, such as an acute care of the elderly unit, were excluded. Studies that validated an existing or new falls risk assessment instrument were excluded.

A review timeframe, 2007-2018 inclusive, was set as it incorporates a period of rapid falls management/prevention policy and guideline development in Australasia (Australian Commission on Safety and Quality in Health Care, 2009), the United Kingdom (Lamb et al., 2008; National Institute for Health and Care Excellence, 2013), and North America (Ganz et al., 2013). An early systematic review on falls reduction interventions focused on the effect of cognitive impairment or dementia on intervention effectiveness (Oliver et al., 2007) provided the cut-off date. During the selected period, there has been a sustained effort worldwide to improve the quality and safety of healthcare through addressing the significant burden and impact of falls on healthcare systems and on the individual, with a particular

focus on addressing the greater fall risks associated with older people with cognitive impairment (Australian Commission on Safety and Quality in Health Care, 2013; Ganz et al., 2013).

3. Sources of information

A healthcare librarian was consulted to help refine the search strategy, recommend databases and conduct the electronic database search.

4. Search Strategy

Three search strategies were employed. Initially seven electronic databases were searched on the grounds that they are comprehensive and appropriate for the topic: Cumulative Index to Nursing and Allied Health (CINAHL), Cochrane Central Register of Controlled Trials (CENTRAL), Embase (Excerpta Medica Database), Medline, Pubmed, Proquest and Scopus. Secondly reference lists of eligible studies were hand searched to identify additional references, and finally Scopus was used to forward search for citations of retrieved articles to identify subsequent publications and key authors in the field. Subject headings and keywords were adapted according to the nuances of each database; words were truncated as appropriate and the searches conducted on the title, abstract and key words.

Duplicate records were identified and removed prior to screening. Two members of the research team (GSS & AA) assessed the eligibility of the selected titles and abstracts, reviewing the titles and abstracts against inclusion and exclusion criteria. The full text was retrieved for titles and abstracts with insufficient information to make a judgement to confirm their relevance. Consensus determined the selection of relevant articles for inclusion in the mixed studies review, with the project lead (LG) making the final decision when required. A record was kept of this stage of the process using a reference management system (EndNote X9) (Clarivate Analytics, 2016). A PRISMA flow chart of study selection was created.

5. Quality Appraisal

The heterogeneity of study designs included in a mixed studies review can create challenges in appraising study quality (Pluye et al., 2016), therefore research and quality improvement data were appraised separately. Primary research study publications were assessed using the Mixed Methods Appraisal Tool (MMAT), version 2018 (Appendix 1 in Hong et al., 2019). There are two main approaches to appraising the methodological quality of research studies. A longstanding approach has been to create a design hierarchy, on the assumption that the inferences from some designs (e.g. Randomised Control Studies) are more credible. A disadvantage of this method is that qualitative studies are either excluded from the hierarchy or rated lowest (Hong & Pluye, 2019), validated tools for qualitative studies are rare, and there is a lack of consensus on how their quality assessment should be performed (Hong et al., 2019). The strength of the MMAT, version 2018, is that it allows for the assessment of the five main type of studies; qualitative, randomised controlled trial, nonrandomised, quantitative descriptive and mixed methods, assessed. The MMAT (2018) has five core criteria to appraise the methodological quality of studies with each criterion scored on a nominal scale (Yes/No/Can't tell) (Hong et al., 2019).

Quality improvement publications were assessed using the Quality Improvement Minimum Quality Data Set (QI-MQCS) (Hempel et al., 2015). QI-MQCS has been developed to be applicable to a broad range of quality improvement intervention evaluations in healthcare across 16 content domains: It provides an overall quality score and is a valid and reliable tool (Hempel et al., 2015). The results of the selected studies critical appraisals are described and are used to guide and strengthen the interpretation of study findings.

6. Data Extraction

Eligible articles were retrieved in full text, classified and reviewed by nominated members of the research team (GSS, AA, MC, MP, LG) into a data template according to research aim(s), project design, procedures or interventions under study, implementation

components, falls outcomes and evidence of methodological quality. Data from each article was extracted independently by two team members. Disagreements during the data extraction process were resolved by discussion, with reference to the original publication for clarification, and involvement of an experienced researcher as arbiter.

7. *Data Synthesis*

A convergent qualitative synthesis was used, where the results of the included quantitative, qualitative and mixed methods studies and quality improvement projects were transformed into qualitative findings (themes, configurations, theories, concepts, and patterns) (Pluye & Hong, 2014). The review synthesis used an inductive theory-building approach with themes derived from data. Analysis commenced with an aggregation of findings, during which key concepts were defined and formed as themes under which data extracted from the studies were summarised, consistent with Munn and colleagues (2014).

Rigor in the thematic synthesis process was based on documenting the movement from textual data to themes which took place through discussion and consensus between two members of the research team (LG & GSS), and arbitration by a third researcher when needed. The themes were then discussed and validated within the broader research team, which includes clinicians as well as experienced researchers.

Results

The initial database search yielded 1852 records, with 42 additional articles identified through citation review and 10 through forward searching (Scopus). Figure 1 outlines the process of selecting the final 10 articles. The articles described projects conducted in Australia (n=3), United States of America (n=3), and one each from Canada, Brazil, England, and Singapore. Of these, five were quality improvement (Babine, Farrington, & Wierman,

2013; Beasley & Patatanian, 2009; Healey et al., 2014, Isaac et al., 2018; Maia, Cruz, Shimoda, Sichieri & Iida, 2018).

Table 2 summarises the included projects, and associated interventions and falls outcomes. The projects were focused on ward-based interventions across one or more wards within a single institution (n=5), with several including more than one component (n=5), but only one was delivered by a multidisciplinary team.

The methodological quality of included research studies as indicated by the MMAT was mixed. Two studies reported quantitative findings only (Ang et al., 2011; Ferguson et al., 2018) and two met the MMAT definition for mixed method studies (Groshaus et al., 2012; Wong Shee et al., 2014). Both clarified the use of qualitative and quantitative (non-randomised) methods but neither included an adequate rationale for using a mixed method design, although this omission may be due to the short format of the research article. Study strengths included good target group representation, and the use of appropriate measures (clearly defined & measured, valid and reliable measures) across all studies. A single randomised controlled trial (Ang, Mordiffi, & Wong, 2011) reported effective randomisation, comparable baseline groups and complete outcome data, but did not disclose researcher influence on data collection or analysis and it was unclear if or how intervention adherence was maintained. A lack of complete outcome data (Ang et al., 2011; Ferguson et al., 2018; Groshaus et al., 2012; Toye et al., 2017; Wong Shee et al., 2014) and poorly reported intervention adherence (Ang et al., 2011; Groshaus et al., 2012; Toye et al., 2017) was a methodological issue for most studies. A detailed report of the research study quality is found in Supplementary file 2.

The methodological quality of the quality improvement projects as measured by QI-MQCS was high; most projects met the minimum standard for 14 out of a possible 16 domains. All included projects met the sustainability domain by including reference to

organisational resources and policy changes needed to sustain the intervention after withdrawal of study personnel and research resources. None of the included quality improvement projects met the penetration/reach domain which describes the proportion of all eligible units who participated. Three projects did not meet the study design domain (Babine et al., 2013; Beasley & Patatanian, 2009; Healey et al., 2014), one did not meet the adherence/fidelity domain (Maia et al., 2018) and one the comparator domain (Isaac et al., 2018). The quality appraisal of included studies is available in Supplementary file 3.

Interventions to prevent in-hospital falls in older people with cognitive impairment emerged around five themes: (1) engaging with families in falls prevention, (2) assessing falls risk to identify interventions, (3) extending nursing observation through technology, (4) conducting a medication review, and (5) initiating non-pharmacological delirium prevention interventions. Two additional themes emerged around implementation: (6) capital investment is required to initiate effective falls prevention and (7) staff education or training incorporates new techniques for practice. Table 3 outlines the implementation components described in each project.

Engaging with families in falls prevention

In the three studies that focused on older people with cognitive impairment, only one study focused on communicating with families (Isaac et al., 2018). In one quality project that recorded falls in people with dementia, the TOP5 toolkit offered a communication intervention whereby family carers of people living with dementia share up to five essential strategies that can assist health staff to provide person-centred care (Isaac et al., 2018). In some projects, when older people with cognitive impairment were a sub-group of the sample or project population, patient education was extended to include the family (Ang et al., 2011; Ferguson et al., 2018; Maia et al., 2018). Engagement with family in care may offer new insights into how to prevent falls in older people with cognitive impairment.

Assessing falls risk to identify interventions

Most studies targeted interventions on modifiable risk factors for falls. However, when used, falls risk assessment was undertaken in different ways. In several articles, falls risk was determined by an unspecified screening instrument as a study inclusion (Ang et al., 2011; Babine et al., 2013; Beasley & Patatanian, 2009; Ferguson et al., 2018; Wong Shee et al., 2014). With or without screening, in those projects with adult (not specifically cognitively impaired) patients, falls risk assessment was undertaken to identify modifiable risk factors using validated falls risk assessment tools such as the Hendrich II Falls Risk Model (Ang et al., 2011) and the Morse Fall Scale (Maia et al., 2018). The interventions subsequently were designed to address the modifiable risk factors. In one study, the John Hopkins Falls Risk Assessment Tool was used but the falls prevention program was a universal, rather than targeted, program (Ferguson et al., 2018). In a study led by pharmacists, older patients with high falls risk were further assessed using a medication falls risk score (Beasley and Patatanian, 2009).

Using a more comprehensive falls assessment, the FallSafe program (Healey et al., 2014) identified vulnerable patients by falls history and/or fear of falling, who tried to walk alone although unsteady or unsafe, and cognitive assessment for patients aged 70 years and older (Royal College of Physicians, 2012). The inclusion of cognitive assessment as part of the falls risk assessment was identified in five other articles, (Babine et al., 2013; Ferguson et al., 2018; Groshaus et al., 2012; Healey et al., 2014; Toye et al., 2017). When specified, delirium screening was conducted using the Confusion Assessment Method (CAM) (Babine et al., 2013; Ferguson et al., 2018; Toye et al., 2017). For older people, adding a specific cognition assessment may assist in determining falls risk.

Extending nursing observation through technology

Once falls risk was identified, technical equipment was used to support nurses to assess and monitor people at risk of falls. Bed, chair and floor alarms, described as a type of pressure mat, were specifically used when patients were identified as cognitively impaired (Ferguson et al., 2018; Toye et al., 2017, Wong Shee et al., 2014). Physical reminders, namely wrist bands and bedhead or room door labels were used when the falls risk score, measured using a validated instrument, was high (Ang et al., 2011; Maia et al., 2018). These technical interventions function to extend and focus the nurses' gaze onto the risk and prevention of falls through awareness and early intervention.

Conducting a medication review

The most commonly reported intervention was medication review (Babine et al., 2013; Beasley & Patatanian, 2009; Ferguson et al., 2018; Healey et al., 2014; Maia et al., 2018). Beasley and Patatanian (2009) propose a two-part process with medication screening first, followed by a medication review only if the screening score meets a prescribed cut-off. In the FallSafe project, medication review focused on avoiding night sedation (Healey et al., 2014), presumably to reduce the risk of falls at night. Medication review was justified as part of delirium prevention bundles, with the prevention of delirium related to preventing falls in two studies (Babine et al., 2013; Ferguson et al., 2018). Medication review is emerging as an important strategy for falls reduction in hospitalised older people.

Initiating non-pharmacological delirium prevention interventions

In two projects, non-pharmacologic interventions, known to prevent delirium, were included as part of the intervention bundle (Babine et al., 2013; Ferguson et al., 2018). In one study, focused on nurse-led fundamental care, the interventions were similar to those listed in non-pharmacological delirium prevention programs (Groshaus et al., 2012). The non-pharmacological delirium prevention interventions included, but were not exclusive to, orientation to time and location, assist with ambulation or range of motion exercises, assist

with food or fluids, minimise sensory deprivation, i.e. ensuring reading glasses and hearing aids are used, and monitor elimination. The justification for delirium prevention was consistent across these articles and was based on the purported relationship between delirium and in-hospital falls.

Capital investment is required to initiate effective falls prevention

Capital investment included purchase of information technology software (Groshaus et al., 2012; Maia et al., 2018), equipment such as low beds (Toye et al., 2017), non-slip socks (Healey et al., 2014), pressure mat alarms (Ang et al., 2011; Ferguson et al., 2018; Wong Shee et al., 2014), licenses for products such as the CAM instrument (Babine et al., 2013; Ferguson et al., 2018; Toye et al., 2017), and provisions to make environmental changes such as paint and refurbishment (Babine et al., 2013). Staff release to lead local hospital policy development, either adaptation or new policy, was required to accommodate new procedures (Beasley & Patatanian, 2009; Isaac et al., 2018; Maia et al., 2018). Like other organisational change, organisational investment appears critical to falls prevention in older adults with cognitive impairment.

Staff education or training incorporates new techniques for practice

Staff training in specific techniques for assessment or interventions was reported in seven articles (Babine et al., 2013; Ferguson et al., 2018; Groshaus et al., 2012; Healey et al., 2014; Isaac et al., 2018; Maia et al., 2018; Wong Shee et al., 2014). In two research studies, staff education was supported with hard copy (Groshaus et al., 2012) or on-line (Toye et al., 2017) materials. One study focused on how staff would work with new team members such as volunteers (Babine et al., 2013). In one project, the education focused on identified clinical leaders only, assuming that they would support staff learning through their work (Healey et al., 2014). Those studies that reported sustainability relied on peer learning and support strategies including reminders about specific interventions during rounding (Beasley &

Patatanian, 2009) and allocation of responsibility for implementation monitoring and staff education to one nurse (Wong Shee et al., 2014).

In order to embed new techniques into practice, two research studies were guided by an implementation framework, using the Theoretical Domains Framework (in Toye et al., 2017) and Plan, Do, Study, Act (in Ferguson et al., 2018). Using the Theoretical Domains Framework, researchers expanded staff education to include information about the policy framework that supports the intervention and conducted joint sessions for nursing and allied health staff (Toye et al., 2017). Using Plan, Do, Study, Act, the implementation included an executive led project management team and a Project Manager (Ferguson et al., 2018). Only one of the quality improvement projects indicated that an implementation approach was used but did not elucidate a specific model (Healey et al., 2014).

Discussion

In this review, strategies for falls reduction that were unique for the population of older people with, or at risk of developing, cognitive impairment were identified. Engaging families in falls prevention, assessing falls risk to identify interventions, extending nursing observation through technology, conducting a medication review, and initiating non-pharmacological delirium prevention interventions were the strategies that appeared to reduce falls in older people with cognitive impairment while in hospital. While implementation was not consistently addressed in the reviewed articles, achieving positive change in falls reduction was associated with a capital investment to initiate falls prevention. Staff education was commonly used as an implementation strategy, however the focus was often limited to how to use new techniques. Very few of the articles addressed sustainability of falls prevention initiatives.

Engaging with families of older people with cognitive impairment emerged as an effective strategy through inclusion in patient education, when the patient exhibited cognitive impairment, and the use of the ‘TOP 5’ communication strategy, whereby the family share important information about the person with dementia. Engagement of the family was not raised in any of the earlier literature reviews on falls (Cameron et al., 2018; Hempel et al., 2013; Lach, Harrison & Phongphanngam, 2017; Oliver et al., 2007; Rubenstein & Josephson, 2006; Tricco et al., 2017) and appears to be an important inclusion in falls prevention in this population. The inclusion of families as part of in-hospital falls prevention for older people with cognitive impairment reflects emerging research (Boltz, Chippendale, Resnick & Galvin, 2015) and policy (Australian Commission on Safety and Quality in Health Care, 2019), and offers a new line of inquiry for falls prevention research in hospital.

Including families in patient education activities may be one way for hospital staff to develop a stronger relationship, or partnership, with family caregivers for the longer-term care of the person with cognitive impairment. However, in a three-group randomised trial, researchers found that an educational falls prevention intervention that included multimedia and health professional follow up for families of older people with cognitive impairment did not reduce falls (Haines et al., 2011). Suitable educational interventions for families requires further development and investigation.

While the use of the ‘TOP 5’ communication tool could promote a collaboration between family caregivers and hospital staff to provide care that is person-focused, the implementation of caregiver communication tools for families of people living with dementia remains a challenge (Toye et al., 2019). Ways to include families of patients with cognitive impairment in hospital-based care requires further investigation to confirm the reduction in adverse outcomes for patients.

Assessing falls risk to identify specific falls prevention interventions was used in most studies. The use of a validated falls assessment instrument is widely understood as the standard for falls prevention in hospital (Cameron et al., 2018). However, in the projects focused on people with cognitive impairment, the assessment included fear of falling (Healey et al., 2014) and cognition (Babine et al., 2013; Ferguson et al., 2018; Groshaus et al., 2012; Healey et al., 2014; Toye et al., 2017). When fear of falling is understood, specific actions to support ambulation can be developed (Resnick & Boltz, 2019). Cognitive screening was often focused on detecting delirium, and usually delivered with a bundle of delirium prevention interventions as outlined later. Recognising fear of falling and detecting delirium offers new areas for developing falls risk for older patients.

Nursing observation was extended through technologies, such as bed and chair exit alarms, and reminders to observe for falls risks, such as wristbands and door labels. The principle of continuous observation is considered important to clinical nurses caring for people with delirium and at risk of falls (Grealish et al., 2019) but whether technical extensions of the nursing gaze delivers better patient outcomes, such as reduced falls, is unclear. While alarms are identified as an important falls prevention strategy in this review, the need for further studies to develop a body of evidence of effectiveness is required. For example, the inclusion of floor alarm mats as part of a complex falls prevention intervention initiated in six US Veterans hospitals did not alter the falls rates (Quigley, Barnett, Bulat, & Friedman, 2016). Further, while nursing observations can be extended through technologies, how the extended nursing gaze translates to decreasing falls is not directly evident (Resnick & Boltz, 2019).

Medication review emerged as a core feature in falls prevention bundles for people with cognitive impairment. Medication review is widely recognised as important to patient safety (Blenkinsopp, Bond & Raynor, 2012) and is identified as an important falls prevention

strategy in an earlier review focused on falls in people with cognitive impairment (Oliver et al., 2007). Of note, the development and usefulness of a medication screening tool (Beasley & Patatanian, 2009) may assist non-pharmacy staff to quickly identify medications that place an older person at higher risk of a fall and prompt a pharmacy referral. In the Cochrane review, Cameron and colleagues (2018) suggest that general medication review in care homes may make little difference in falls but this is not explored in hospitals. Further research into the use of medication review in older people with cognitive impairment to reduce in-hospital falls is required.

While cognition assessment is a key element of many validated falls assessment tools, delirium prevention is less well acknowledged as an approach to reduce in-hospital falls in older patients. Non-pharmacological delirium prevention activities were clearly identified in two projects (Babine et al., 2013; Ferguson et al., 2018), with a set of non-pharmacological nursing interventions focused on older person care in a third study (Groshaus et al., 2012) closely resembling those used for delirium prevention.

Delirium, an acute disorder of attention and cognition (Oh, Fong, Hsieh & Inouye, 2017) is a common hospital-acquired complication and in Australia, accounted for 13% of all hospital-acquired complications in 2017-18 (Australian Institute of Health and Welfare, 2019). The prevalence of delirium is difficult to determine as it is often under recognised by all hospital staff (Steis & Fick, 2012). In a systematic review of the literature, reports of the delirium occurrence rate per admission varied between 11 and 42% (Siddiqi, House & Holmes, 2016). Delirium is more common in older people with dementia. In a retrospective cohort study of NSW hospital discharge data for 2006/7, the relative risk of delirium for people living with dementia is nearly three times as high as for people without delirium (Bail et al., 2013). For people living with a cognitive impairment such as dementia, the

complication of delirium presents another assault on their cognitive processing, further increasing their risk of falling.

There is a growing body of evidence to suggest that delirium can be prevented using a non-pharmacological bundle of interventions. In a Cochrane Review, researchers found that in 39 trials with over 16,082 participants, non-pharmacological multicomponent interventions reduced the incidence of delirium compared to usual care in hospital medical and surgical settings, noting that the effect for patients with pre-existing dementia is less certain (Siddiqi et al., 2016). Further investigation into the relationship between delirium prevention interventions and falls prevention in older people with cognitive impairment is recommended (Silner, Holle & Rudolph, 2019).

In selecting only studies with positive changes in reported falls or falls rates, there is a risk of overlooking evidence that suggests the named strategies do not work. For example, the finding that low-low beds reduced falls in people with high falls risk (Ang et al., 2011) contrasts with the findings of a pragmatic matched cluster randomised trial (paired wards), which found that providing one low-low bed for every 12 for use by people with cognitive impairment or high falls risk did not reduce falls (Haines, Bell & Varghese, 2010). Of note is that the Ang study used a sample of patients at higher risk of falls whereas Haines reports for all in-patients. The inconsistency of sampling approaches appears to confound the evidence on what works. Sampling is also an issue when comparing the included study on medication review, which specifically targets patients 70 years and over (Babine et al., 2013) that found a decline in fall rates and a medication review, conducted as part of a complex falls prevention intervention targeting all patients in six Veteran's hospitals (Quigley et al., 2016), that found relatively stable falls rates. Thus, our review provides a foundation to better understand promising interventions, but does not replace the need for high quality systematic reviews of

interventions that either researchers may be considering testing in future research or quality improvers may be considering implementing in practice.

In the included projects, capital investment was required to initiate falls prevention activities. As argued by Ferguson and colleagues (2018), an intervention that can reduce the number of falls can not only benefit patients but also provide cost and efficiency savings to the institution. However, interestingly none of the projects addressed sustainability, and specifically how to sustain the practice through continued resources including training. Based on our review, we suggest that future research into falls prevention for older patients with cognitive impairment should consider costs for initiation as well as sustainability.

Staff education was commonly used as an implementation strategy. However, the focus was short-term, usually limited to how to use new techniques or technologies. One exception was the research project by Toye and colleagues (2017), where the education program is clearly outlined and addresses staff capability to enhance practice and staff opportunity to enhance practice, as well as training on the intervention itself.

Very few of the articles addressed sustainability of falls prevention initiatives. When they did, sustainability appeared to be related to policy development and implementation and peer learning. The two studies that were guided by an explicit implementation framework were published in the last two years. Framing research and quality improvement work using an implementation model can help teams to explain how and why implementation succeeds or fails (Nilsen, 2015). The 'TOP5' project (Ferguson et al., 2018) used the plan-do-study-act model and identified strategies for sustainability, whereas using the theoretical domains framework did not lead to conclusions about sustainability. Further research and development in the area of falls prevention in older patients with cognitive impairment should identify the implementation framework to assist with explaining how implementation strategies were effective. Strategies to support sustainability were not commonly reported. Those that were

reported included policy development and peer learning through sharing information at rounds. How information is shared beyond the implementation period, and how practices are sustained, is an area for further research.

Limitations

This mixed studies review adopted a constructivist approach to a meta-narrative about falls prevention. There were several limitations to this review. Firstly, only projects with an improvement in falls rates were included. Such an approach risks excluding reports on projects where the same interventions produced contrary results, and therefore the findings are not definitive. The aim of this review was exploratory, to identify interventions that were found to reduce falls in populations that included older people with cognitive impairment. This approach aimed to extend the types of literature reviewed from strictly research studies, a method adopted by other reviews, to include quality improvement projects that report clinical, rather than only statistical, reductions in falls rates. Using this method, we have identified a range of interventions that may be worthy of further investigation for this population.

Secondly, the interventions described in this review have been found at a minimum to clinically reduce falls, as noted earlier, the statistical significance of any reductions has not been consistently demonstrated. Further, our definition of falls did differentiate falls from falls with injury. Differentiating falls from falls with injury as an endpoint is recommended in future studies, to determine the specificity of interventions for falls outcomes. On these grounds, the findings should be used tentatively to guide practice, noting that they provide a foundation to guide further research into the problem of falls in older people with cognitive impairment.

Thirdly, the inclusion of studies that included people with cognitive impairment and people without may have skewed results. Rather than take the findings as definitive recommendations for practice, we suggest that they are used critically, with monitoring for feasibility and effectiveness, before widespread implementation. More importantly, these findings offer a clear direction for further research into how non-pharmacological delirium prevention interventions may have broader benefits for falls prevention, particularly in people living with dementia.

Finally, while the inclusion of quality improvement studies in this review revealed new strategies for investigation, the heterogeneity of the included projects is a limitation. The interventions were inconsistently described across studies. In order to compare interventions, particularly multi-component interventions, greater attention to detail is required. The use of a template for intervention description, such as TIDier (Hoffman et al., 2014) is recommended.

Conclusion

This review offers a constructivist narrative about falls prevention in hospitalised older people with cognitive impairment. The identified prevention interventions offer a range of options for further research and evaluation but as this was not a systematic review of intervention effects, it is not intended to be used as a foundation for practice guidelines. Groups and organisations could use this review as one foundation to identify priorities for future research in falls prevention in vulnerable older patient populations. One important intervention emerging from this review is to implement non-pharmacologic delirium prevention interventions for older people in general, and those with dementia specifically. Further evaluation of communication devices that promote partnership between staff and families, such as the ‘TOP 5’ holds promise for falls reduction. Medication review and

possibly, medication screening, are also worthy of exploring as part of falls prevention programs targeting older patients. Falls risk screening is a highly regarded assessment practice, and for patients aged 65 years and older, using a validated falls risk assessment is critical to identify specific falls prevention interventions in this population.

Importantly, this unique approach to reviews has produced specific falls prevention interventions for older patients with cognitive impairment that can drive further research and quality activities. The projects did not often clearly describe implementation or sustainability. Understanding how implementation works through using theories, models or frameworks will be important and examining work-based learning strategies, such as pedagogic practices, more closely may yield important insights for sustainability of practice change.

Relevance to clinical practice

The key strategies for reducing falls in older people with cognitive impairment will require nurses to partner with clinicians from other disciplines. Processes for routine medication review can be co-developed by nurses and pharmacists. Delirium prevention, and particularly the importance of meaningful engagement for people with cognitive impairment, can be discussed with occupational therapists to produce a range of accessible activities that are suitable for the specific ward context. Emerging communication technologies that promote sharing of information and enhance partnership with families of people living with dementia, may be co-developed with social workers. Complex and collaborative solutions that bring together different health disciplines are required. As we move forward in our shared understanding about falls prevention globally, it is timely for clinicians to partner with researchers to develop a body of evidence around what works in falls prevention for older people living with cognitive impairment.

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Table 2: Included projects, falls outcome

Authors (Country)	Research Aim	Project Design	Participants	Sample Size	Intervention	Reported falls
Ang et al., 2011 (Singapore)	Examine the effectiveness of a targeted multiple intervention strategy to reduce the number of patient falls in an acute care hospital	Randomised control trial	Patients aged ≥ 21 with a Hendrick Falls Risk Model score of ≥ 5	1822	<p>Falls screening based on history</p> <p>Identify patients at risk using wrist band and bedhead label</p> <p>Follow up assessment using the Hendrich II Falls Risk Assessment</p> <p>Interventions specific to the falls risks identified</p> <p>Educate patient education (30 min) regarding awareness of their specific risk of falling</p> <p>If patient cognitively impaired, educate family</p>	The proportion who fell was significantly lower in the intervention group (n=4/910, 0.4%, 95% CI: 0.2-1.1) compared with the control group (n=14/912, 1.5%, 95% CI: 0.9-2.6).
Babine et al., 2013 (USA)	Observe whether a delirium prevention program can prevent falls	Pre-post intervention comparison	Inpatients aged ≥ 70 yrs identified as falls risk, taking potentially inappropriate medications or prescribed a sedative	95	<p>Delirium screening</p> <p>Deliver non-pharmacological delirium prevention bundle[^]</p> <p>Conduct a medication review</p>	A decline in average fall rates from 5.15 per 1000 occupied bed days in the 8 months prior and 2.49 per 1000 patient days during the 3-month pilot.

Authors (Country)	Research Aim	Project Design	Participants	Sample Size	Intervention	Reported falls
Beasley & Patatanian, 2009 (USA)	To develop, implement and evaluate a pharmacy fall prevention program	Pre-post intervention	All admitted patients with high falls risk (focus on patients aged ≥ 65 years)	204	Pharmacist assesses medication falls risk score: <ul style="list-style-type: none"> • High risk - analgesic, antipsychotics, anticonvulsants and long acting benzodiazepines (3 points each) • Medium risk - antihypertensive, cardiac, antiarrhythmic, antidepressant (2 points each) • Low risk - diuretics (1 point each). Conduct medication review for people with medication fall risk score ≥ 6	30% decline in fall rate from a mean of 4.69 patient falls per 1000 bed days pre-intervention to 1.75 patient falls x 1000 bed days post-intervention
Ferguson et al., 2018 (USA)	The effectiveness of a hospital wide intervention on delirium-associated falls	Pre-post intervention	All patients admitted to participating wards, focus on high risk patients (aged ≥ 65 , pre-existing cognitive impairment,	Patients of a 336-bed tertiary care hospital setting	Delirium screening Universal falls precautions Deliver nurse-led non-pharmacological delirium prevention bundle [^] Conduct medication review if delirium present Educate patients and families Use bed and chair alarm if person has cognitive impairment	Decrease in the rate of delirium-associated falls from 0.91 per 1000 patient days pre-intervention to 0.50 post intervention.

Authors (Country)	Research Aim	Project Design	Participants	Sample Size	Intervention	Reported falls
			history of delirium)			
Groshaus et al., 2012 (Canada)	To evaluate a knowledge translation intervention, namely a nurse-initiated computerised clinical decision support tool to reduce harms in the care of older medical patients	Step wedge trial	All patients ≥65 study units	All patients ≥65 on the study units (ranging from 17 – 44 patients per unit per data collection period)	Delirium screening Nurse led fundamental care program	Odds of a fall was 9.3 times higher before than after the intervention (95% CI 0.9-100; p=0.065), a clinical, rather than statistically significant, difference.

Authors (Country)	Research Aim	Project Design	Participants	Sample Size	Intervention	Reported falls
Healey et al., 2014 (England)	Describe the impact of a complex falls prevention intervention	Interrupted time series design: Baseline Introduction Implement- ation Sustain	All patients admitted to participating wards (n=16): 8 intervention 8 comparison	>60,000 with >30,000 in each group	FallSafe Program for more vulnerable patients: <ul style="list-style-type: none"> • Call bell in sight and reach • Cognitive screen • Ask about fear of falling • Lying and standing BP • Conduct a medication review • Avoid night sedation • Safe footwear on feet • Conduct urinalysis 	Reduced fall rate in intervention units (adjusted rate ratio 0.75, 95% CI 0.68-0.84, p<0.0001) in 12 months post implementation
Isaac et al., 2018 (Australia)	Investigate whether the 'TOP5' strategy could improve the patient's hospital experience, and positively impact health service provision and outcomes (reduced falls)	Interrupted time series design: Baseline Pilot	All patients with dementia and under the care of a geriatrician admitted to participating geriatric wards	All patients on two wards in an acute teaching hospital	Use 'TOP5' toolkit to engage carers of patients with cognitive impairment, sharing up to five essential strategies to assist health staff to provide optimal person-centred care and communication.	There was a 45% reduction in falls with or without an injury between baseline and establishment phase (p<0.05)

Authors (Country)	Research Aim	Project Design	Participants	Sample Size	Intervention	Reported falls
Maia, et al., 2018 (Brazil)	Promote evidence-based practice in the prevention of falls	Pre-post intervention	Adult and older adult inpatients admitted to Intensive Care Unit	94	Adjust physical environment Provide falls prevention leaflet for patients and families Identify patients at risk using bedside signs and wristband alerts Schedule and supervise toileting Conduct medication review	Rate of falls declined from 3.99 per 1000 bed days to 0 over four months
Toye et al., 2017 (Australia)	Evaluate the effectiveness of a staff education program in reducing falls related to delirium	Pre-post intervention	Patients ≥ 65 years	23	Delirium screening Reorient patient to time and place Provide a companion Use low bed Use alarm mat Supervise when in bathroom Frequent observation	Falls per month decreased from 9 pre- intervention to 3 post intervention.
Wong Shee et al., 2014 (Australia)	To evaluate the effectiveness of an electronic sensor bed/chair-exit alarm system on fall incidence and	Repeated measures, A-B-A, single cohort design	Patients with cognitive impairment (MMSE <25) and a high falls risk	34	Electronic bed and chair sensor mats connected to call system	Significant decrease in the falls during the intervention period (1.66 falls/21 bed days) vs preintervention (3.18 falls/21 bed days)

Authors (Country)	Research Aim	Project Design	Participants	Sample Size	Intervention	Reported falls
	fall-related injury rates					
[^] Nurse led non-pharmacological delirium prevention bundle includes (but not limited to): mobilisation, adequate nutrition & hydration, cognitive engagement, use sensory devices such as glasses and hearing aid, and help with relaxation and sleep) MMSE = Mini Mental State Examination						

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Propose a short take-home title. The title should explicitly state that the review included different type of evidence	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review (e.g., a health problem) in the context of what is already known (e.g., an existing literature review paper or a reference book chapter).	3-5
Objectives	4	Formulate questions and/or objectives (qualitative, quantitative or both) being addressed by your review.	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Justification	6	Justify the use of a review of qualitative and quantitative evidence.	6
Eligibility criteria	7	Specify the inclusion and exclusion criteria and the rationale for supporting these criteria.	6-7
Information sources	8	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	8
Search	9	<ul style="list-style-type: none"> • Present full electronic search strategy for at least one database (e.g., in an appendix), including any limits used, such that it could be repeated. • Describe the process for removing duplicates. • Specify the involvement of a librarian, if applicable. 	Table 1
Study selection	10	Describe the process for selecting studies (e.g., screening based on titles and abstracts, and eligibility based on full-text, number of reviewers, software used).	8
Data collection process	11	<ul style="list-style-type: none"> • Describe the method of data extraction from included studies (e.g., number of reviewers involved, piloted forms, etc.). • List the data extracted. • If applicable, state any processes for obtaining and confirming data from investigators of included studies (e.g., initial email to the first author and reminder email). 	9-10
Appraisal	12	<ul style="list-style-type: none"> • Describe the process for appraising included studies (e.g., tools used, number of reviewers involved), and specifically for assessing the methodological quality or risk of bias of included qualitative, quantitative, and mixed methods studies. 	8-9

		<ul style="list-style-type: none"> Specify how results of this appraisal are used in the synthesis. For example, for descriptive purpose (include all studies with description of their methodological quality or risk of bias) or for analytical purpose (contrast synthesis of 'lower quality' studies vs. 'higher quality' studies using sensitivity analysis). 	
Synthesis	13	<ul style="list-style-type: none"> Describe the synthesis design used. Describe and justify the synthesis method(s) used (e.g., quantitative content analysis, meta-analysis, thematic synthesis, etc.). 	10
Additional analyses	14	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses), if done.	n/a
RESULTS			
Study selection	15	<ul style="list-style-type: none"> Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. Give numbers of quantitative, qualitative and mixed methods studies included. 	Figure 1
Study characteristics	16	<ul style="list-style-type: none"> For each study, present characteristics for which data were extracted (e.g., tables of characteristics of included studies) and provide the citations. Specify common information across all included studies. Describe the studies including their heterogeneity (variability associated with differences between studies). 	Table 2 Table 3 10-11
Result of appraisal	17	Present data on the methodological quality or risk of bias of included studies based on the appraisal done.	11
Results of synthesis	18	<ul style="list-style-type: none"> Present results of synthesis. If qualitative synthesis: <ul style="list-style-type: none"> In the text, briefly summarize the main themes or categories and refer to the appendix. Appendix (table, figure, or matrix): For each study, present the themes or categories identified. If quantitative synthesis: <ul style="list-style-type: none"> In the text, briefly summarize the data and refer to the appendix. Appendix (table, figure, or matrix): For all key variables, present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot. If qualitative and quantitative syntheses: <ul style="list-style-type: none"> Present both If applicable, present the results of the integration of both syntheses. 	12-16
Additional analysis	19	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses).	n/a
DISCUSSION			
Summary of evidence	20	<ul style="list-style-type: none"> Provide an overall summary of results (take-home messages) from the qualitative and/or quantitative synthesis. State the main results for each main theme or category, and/or key process/outcome variable. Consider their relevance and importance for knowledge users (e.g., health care providers, managers, and decision/policy makers). Take into account the methodological quality across studies (when applicable). 	16-22

		<ul style="list-style-type: none"> Describe insight gained from the integration of qualitative and quantitative evidence. 	
Contribution	21	<ul style="list-style-type: none"> Describe the contribution of the review (compared to what is already known) with respect to: Review methods, Scientific knowledge, Practice, program planning and evaluation, policy making, or else 	16-22
Limitations	22	<ul style="list-style-type: none"> Specify any element that may affect the cumulative evidence. Discuss limitations at the study and process/outcome levels (e.g., lack of rich data for qualitative synthesis, methodological quality/risk of bias, and their potential consequences on the results). Discuss limitations at the review level (e.g., dependent reviewers, incomplete retrieval of relevant studies - selective publication of reports regarding studies with positive results), and limited reporting (selective reporting of information about included studies)), and their potential consequences on the results. 	22-23
Conclusions	23	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	23-24
ACKNOWLEDGEMENTS			
Acknowledgements	27	<ul style="list-style-type: none"> Describe sources of funding and other support (e.g., supply of data) and the role of funders in the review. Acknowledge any information about potential conflict of interest 	Cover page
REFERENCES			
References		<ul style="list-style-type: none"> List all the references cited in the text 	25-28

Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000

Supplementary Table 1: Research Study Critical Appraisal according to MMAT

Study Type (No.)	Number of articles		
	Yes	No	Can't Tell
1. Qualitative Component (2) (Groshaus et al., 2012;* Wong Shee et al., 2014*)			
1.1 Is the qualitative approach appropriate to answer the research question?	2*		
1.2 Are the qualitative data collection methods adequate to address the research question?	2*		
1.3 Are the findings adequately derived from the data?			2*
1.4 Is the interpretation of results sufficiently substantiated by data?	1*		1*
1.5 Is there coherence between qualitative data sources, collection, analysis and interpretation?	1*		1*
2. Quantitative randomised control trials (1) (Ang et al., 2011)			
2.1 Is randomisation appropriately performed?	1		
2.2 Are the groups comparable at baseline?	1		
2.3 Are there complete outcome data?	1		
2.4 Are outcome assessors blinded to the intervention provided?		1	
2.5 Did the participants adhere to the assigned intervention?			1
3. Quantitative non-randomised (4) (Ferguson et al., 2018; Toye et al., 2017;Groshaus et al., 2012;* Wong Shee et al., 2014*)			
3.1 Are the participants representative of the target population?	2/ 2*		
3.2 Are measurements appropriate regarding both the outcome and intervention (or exposure)?	2/ 2*		
3.3 Are there complete outcome data?	1	1/ 1*	1*
3.4 Are the confounders accounted for in the design and analysis?	1/ 1*	1	1*
3.5 During the study period, is the intervention administered (or exposure occurred) as intended?	1/ 1*		1/ 1*
4. Quantitative Descriptive (0)			
4.1 Is the sampling strategy relevant to address the research question?			
4.2 Is the sample representative of the target population?			
4.3 Are the measurements appropriate?			
4.4 Is the risk of nonresponse bias low?			
4.5 Is the statistical analysis appropriate to answer the research question?			
5. Mixed methods (2)			

(Groshaus et al., 2012;* Wong Shee et al., 2014*)			
5.1	Is there an adequate rationale for using a mixed methods design to address the research question?		2*
5.2	Are the different components of the study effectively integrated to answer the research question?	1*	1*
5.3	Are the outputs of the integration of qualitative and quantitative components adequately interpreted?	1*	1*
5.4	Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?	1*	1*
5.5	Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?		2*
*Mixed methods study			