Stakeholder perspectives of a pilot multicomponent delirium prevention intervention for adult patients with advanced cancer in palliative care units: a behaviour change theory-based qualitative study

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Abstract

Background

Theory-based and qualitative evaluations in pilot trials of complex clinical interventions help to understand quantitative results, as well as inform the feasibility and design of subsequent effectiveness and implementation trials.

Aim

To explore patient, family, clinician, and volunteer ('stakeholder') perspectives of the feasibility and acceptability of a multicomponent non-pharmacological delirium prevention intervention for adult patients with advanced cancer in four Australian palliative care units that participated in a phase II trial, the 'PRESERVE pilot study'.

Design

A trial-embedded qualitative study via semi-structured interviews and directed content analysis using Michie's Behaviour Change Wheel and the Theoretical Domains Framework.

Setting/participants

Thirty-nine people involved in the trial: nurses (n=17), physicians (n=6), patients (n=6), family caregivers (n=4), physiotherapists (n=3), a social worker, a pastoral care worker, and a volunteer.

Results

Participants' perspectives aligned with the 'capability', 'opportunity' and 'motivation' domains of the applied frameworks. Of seven themes, three were around the alignment of the delirium prevention intervention with palliative care (intervention was considered routine care; intervention aligned with the compassionate and collaborative culture of palliative care; and differing views of palliative care priorities influenced perspectives of the intervention) and four were about study processes more directly related to adherence to the intervention (shared knowledge increased engagement with the intervention; impact of the intervention checklist on attention, delivery, and documentation of the delirium prevention strategies; clinical roles and responsibilities; and addressing environmental barriers to delirium prevention).

Conclusion

This theory-informed qualitative study identified multiple influences on the delivery and documentation of a pilot multicomponent non-pharmacological delirium prevention intervention in four palliative care units. Findings inform future definitive studies of delirium prevention in palliative care.

Australian New Zealand Clinical Trials Registry, ACTRN12617001070325; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=373168

Keywords

Behaviour change; neoplasms; clinical trial; delirium; inpatients; non-pharmacological; palliative care; qualitative research

Key statements

What is already known about the topic?

- Delirium leads to adverse outcomes for patients, family caregivers, and clinicians.
- Delirium is prevalent and often prolonged in patients with advanced cancer in palliative care units.
- In other hospital settings, multicomponent non-pharmacological interventions can prevent delirium in one in three patients.

What this paper adds

- We used two interrelated behaviour change frameworks - Michie's Behaviour Change Wheel and the Theoretical Domains Framework - to qualitatively explore patient, family caregiver, clinician, and volunteer ('stakeholders') perspectives of the feasibility and acceptability of a pilot multicomponent non-pharmacological delirium prevention intervention for patients with advanced cancer in four Australian palliative care units.
- Influences on stakeholders' perspectives, delivery and documentation of the pilot delirium prevention intervention aligned with the applied frameworks' components of 'capability', 'opportunity', and 'motivation'.
- Qualitative findings helped to explain low adherence to the intervention.

Implications for practice, theory or policy

- A multicomponent non-pharmacological delirium prevention intervention for patients with advanced cancer in four Australian palliative care units appears feasible and acceptable for stakeholders, in principle.
- However, certain study amendments may promote sufficient delivery and more precise measurement in future effectiveness and implementation trials of delirium prevention in palliative care units. For example, protocolised steps towards authentic family engagement in delivering delirium prevention interventions and reforming study documentation proformas into smaller and simpler parts.
- The applied behaviour change frameworks have utility for future studies aiming to build and integrate delirium evidence in palliative care.

Introduction

Delirium is a serious, acute and common neurocognitive condition for patients in palliative care units.[1,2] Delirium in hospital is associated with increased risk of complications, length of admission, nursing home admission, and death.[3] Affected patients often experience intense fear, anxiety and incomprehension;[4] family caregivers can feel uncertain and anxious;[5,6] and clinicians suffer too when patients are delirious.[4] Clinical management of delirium is complex in palliative care as it is sometimes difficult to predict whether it is reversible or gravely prognostic,[7] and because there is no proven medication to relieve patients' related distress.[8]

For these reasons, efforts to *prevent* delirium during palliative care may prove worthwhile. Addressing patients' fundamental human needs for sleep, vision and hearing, hydration, communication, orientation and cognition and mobility has reduced delirium incidence in other inpatient settings.[9,10] Family and volunteers played important roles alongside clinicians in these previous studies.[6,10] However, family members have reported unmet needs for anticipatory and responsive information about delirium from clinicians, and hospital volunteers have been found to require certain skills and supports for their input to be meaningful and consistent.[6,11] Clinicians as well often lack requisite knowledge and environmental resources to reduce patients' risk of delirium.[12,13]

Cognisant of both the potential for and barriers to preventing delirium, in 2017-18 we conducted a phase II cluster randomised controlled trial of a multicomponent non-pharmacological delirium prevention intervention for patients with advanced cancer in four Australian palliative care units ('the PRESERVE pilot study').[14,15] Recruitment and implementation were at the site level, with 65 patients across the four sites enrolled for quantitative data collection. Ethical approach was obtained for waiver of patient consent for this data collection, with opt-out available and the explicit expectation that clinical staff would inform and involve patients and their family caregivers re the delirium prevention strategies according to their needs, wishes and capabilities. The intervention aligned with best evidence-based delirium care but was complex and novel in palliative care, so we sought to determine if it was feasible, acceptable, and deliverable with high adherence and fidelity, using both quantitative and qualitative methods.

Quantitative results included low adherence, where the *a priori* endpoint - at least 60% or more patients having full delivery of all required strategies in at least four domains for at least five of the first seven days of admission - was not achieved. All other outcomes were positive, including: successful and timely enrolment, sufficient delirium screening and diagnostic assessment, no related adverse event, and a signal of effect, whereby 20% intervention patients became delirious by Day 7 compared to 32% controls.[15] The intervention was mostly delivered by nurses (67%), followed by doctors (16%), and less so by family (7%) and volunteers (0.5%). Overall adherence was higher at waitlist intervention sites and lowest six months post-intervention (Figure 1) as well as for most strategies (Figure 2). Family partnership strategies were least delivered.[15]

This paper reports the PRESERVE pilot study's qualitative component, which aimed to understand patient, family caregiver, clinician, and volunteer ('stakeholders') perspectives of the feasibility and acceptability of the multicomponent non-pharmacological delirium prevention intervention in the participating palliative care units.

Methods

Design

A trial-embedded qualitative study, reported according to the consolidated criteria for reporting qualitative research (COREQ).[16] We employed this design to determine, in conjunction with quantitative methods, whether and how to proceed to definitive trials of the intervention in palliative care units.[14,17]

Theoretical framework

Theory-based evaluations of complex health care interventions help to frame and understand what is required for their successful uptake.[18] We applied the Behaviour Change Wheel to guide site engagement and training in the PRESERVE intervention,[14] as well as qualitative data analysis in conjunction with the Theoretical Domains Framework.[19-21] These theoretical frameworks for understanding and changing individual health-related behaviours incorporate three overarching components - capability, opportunity and motivation - along with explanatory detail. *Capability* refers to an individual's psychological and physical capacity to engage in the examined behaviour; *opportunity* encompasses factors outside of the individual that prompt or make their behaviour possible*;* while *motivation* is all brain processes that energise and direct the individual's behaviour.[19-21] We used these frameworks for a more theoretical (and hence more transferable) understanding of the feasibility and acceptability of multicomponent non-pharmacological delirium prevention intervention trials in palliative care units, applying them at the data analysis stage.[18]

Setting and participants

Participating sites were four hospital-based specialist palliative care units in metropolitan Australia. The focus of care in these units is symptom management, psychosocial support, and terminal care for patients with life-liming illness. At the time of the trial, most admitted patients were aged over 70 years and had advanced cancer (59% and 91%, respectively).[15] Patients were eligible for *trial enrolment* if they were aged 18 years or over and had advanced cancer. Those eligible for the *qualitative study* were trial-enrolled patients (except those with an Australian-modified Karnofsky

Performance Status[22] score of less than 30 and/or in the ‘terminal’ Palliative Care Phase[23]) and adult family caregivers, clinicians and volunteers. Qualitative study participants were required to have been involved in the intervention, English speaking or with an available healthcare interpreter, and able to give informed written consent.

Overview of PRESERVE pilot study methods

Participating sites were randomised to intervention (n=2) or control + waitlist intervention (n=2) (Figure 3). Pre-implementation included two-months of site training and engagement via interdisciplinary implementation working groups, face-to-face clinician training, and study information manuals.[14] Working groups determined how their own site would implement the intervention, including assigning roles and obtaining requisite equipment such as otoscopes, wall clocks and whiteboards. Training also informed clinicians about the key adherence measure: a daily paper-based checklist to document delivery (and reasons for non-delivery) of 36 delirium prevention strategies (Supplementary file 1). Of note, and in line with the pilot study objectives, preliminary learnings from intervention sites resulted in waitlist intervention site teams receiving more emphatic instruction on using the checklist.[15] Throughout the study, site teams were encouraged to tailor the intervention strategies to each patient’s assessed needs and preferences to ensure person-centred care.

Research team

Authors are researchers, clinicians, consumers, and a health policy expert with collective expertise and interest in palliative care, delirium, medicine, nursing, and social science. Interviews were conducted by site-based research nurses (JH, JW), a site-based social worker and associate investigator (CPh), and a university-based research assistant (LE), all with qualitative research experience plus study-specific training in recruitment, consent, and interviewing.

Recruitment

Within one-two weeks of intervention delivery, interviewers checked with clinical teams about eligibility of trial-enrolled patients and family caregivers and their willingness to be approached for an interview; and similarly consulted with the site investigator before approaching clinicians or volunteers. Participant information sheets formed the basis for discussion between the researcher and potential participants, with voluntariness of participating emphasised. All participants provided written consent, and no participants withdrew after consenting.

Data collection

Semi-structured interviews were in June – October 2018 at each site using an interview guide with open-ended questions about feasibility and acceptability of the delirium prevention intervention and the potential to fine-tune it (Supplementary file 2). Field notes were taken during the interviews. Interviews were audio-recorded and transcribed verbatim, except for participants who preferred written recording (three patients, two clinicians). Transcripts were not returned to participants. Because of the need to interview participants shortly after the intervention, data were collected via a convenience sample only, although representation of diverse roles was sought.

Data analysis

We used the directed content analysis method, which combines deductive and inductive qualitative analysis.[24,25] First, an unconstrained matrix[25] was created according to the capability, opportunity, and motivation components of the Behaviour Change Wheel framework and the interrelated domains of the Theoretical Domains Framework (Figure 4).[19] AG, AH, and LE conducted independent parallel coding of three transcripts using the matrix, then met to crosscheck and discuss preliminary coding. Remaining transcripts were deductively line-by-line coded against the matrix (AG, AH, LE) using NVivo 12 software. Inductive analysis of constructs arising from preliminary coding was next undertaken following a process of grouping, categorisation, and abstraction to formulate themes, with AG, AH, LE, and MA meeting regularly to progress analysis. Themes and sub-themes with exemplar quotes were presented to the full team, who provided additional insights and nuance that informed the interpretation of the findings.

Ethical considerations

Interviews were designed to be brief and low burden for participants. Ethical approval of the study was granted by the South Western Sydney Local Health District and University of Technology Sydney Human Research Ethics Committees (HREC/17/LPOOL/224 and ETH17-1697). Data were de-identified and securely stored at the sites and coordinating university to protect participants' confidentiality and privacy.

Results

Thirty-nine stakeholders from four sites participated: 28 clinicians, six patients, four family caregivers and one volunteer. Clinicians were nurses (n=17), physicians (n=6), physiotherapists (n=3), a social worker and a pastoral care worker. Interview duration ranged from 6-30 minutes and averaged 15.

Influences on intervention delivery and documentation aligned with capability, opportunity, and motivation. Of seven themes, three pertained to alignment of the delirium prevention intervention with palliative care and four were about study processes more directly related to adherence to the intervention. Although stakeholders were interviewed from both the intervention and control + waitlist intervention sites, findings were similar across all participants with no systematic differences related to their site allocation. Themes are outlined below with illustrative quotes (see Supplementary file 3 for additional illustrative quotes).

Alignment of the delirium prevention intervention with palliative care

Theme 1: The intervention was considered routine care (Motivation)

Several clinicians were motivated to deliver delirium prevention strategies they perceived as routine:

> *“I think it is important to have the curtains open so people are orientated to day and night, obviously you have got to offer people drinks if they are able to tolerate it, I think that’s what we do anyway.”* (Registered nurse (RN) #1)

Many delirium prevention strategies were thought feasible as they did not add to or change clinicians’ work:

> *“There wasn’t any terribly new things that I needed to do.”* (Pastoral care worker #1).

However, perceiving the delirium prevention strategies as routine made some question how the PRESERVE intervention was different to usual care:

> “*And I mean we do it anyway, I think we do it anyway. I don’t think we have to have these set rules to know that we have to do that, you know*.” (Volunteer #1)

This line of questioning raised doubts about how seemingly routine strategies would prevent delirium:

> “*Can I link [assisting with activities of daily living and eating/drinking] to preventing delirium? I’m not sure I could.*” (RN #2)

Theme 2: The intervention aligned with the compassionate and collaborative culture of palliative care (Opportunity)

Clinicians expressed how they valued the compassion of palliative care: *“It is a very empathetic and giving service*” (Physiotherapist #1), and considered it complementary to the intervention:

> *“These prevention strategies are already ongoing and they exist here because we provide compassionate care and have the time to do that...A lot of this stuff is going on based on the kind of compassionate people we already have who work in palliative care.”* (Physician #1)

Interdisciplinary collaboration within palliative care also supported the intervention:

> *“It’s really a group effort, you get the physio in to mobilise and speech is involved, dietician is involved to make sure* [the patients] *have food that is appropriate for them to eat.”* (RN #2)

The norms of palliative care were described as different to other settings, such as acute care:

> "*I've seen physiotherapists with patients opening their milk, add in* [chocolate powder] *and shaking it up and giving it back to them - you don't get that in an acute care hospital"* (Physician #1)

Theme 3: Differing views of palliative care priorities influenced perspectives of the intervention (Motivation)

Despite interdisciplinary collaboration, clinicians' differing viewpoints on palliative care priorities influenced their perspectives of the intervention's feasibility and acceptability. For example, some physicians discounted the appropriateness and/or potential benefit of delirium prevention strategies for patients in the last weeks or days of life:

> *"If* [patients] *wanted five coffees between 2* [pm] *and 6* [pm] *because they were in the last few weeks of life, we wouldn't really limit that. I don't think I…emphasised* [the strategy to avoid caffeine after 4pm to preserve natural sleep] *at all because it wasn't really appropriate."* (Physician #3)

The proximity of death and related pressing concerns de-motivated some to talk to patients and their families about the PRESERVE intervention:

> *"*[The eligible patients'] *stays were between 48 hours and 5 days was the longest, it was very quick and in that time it was more approaching their loved one is dying, what is that going to look like, what's coming next, what symptoms might occur. So it probably wasn't the highest priority to talk about and spend any time talking about preventative strategies when you are sitting in the room with a tearful relative."* (Physician #1)

In contrast, other clinicians believed that "*The strategies should just be gold standard in a hospital, especially a unit such as ours where we see delirium very commonly*" (Physician #4). Others thought the delirium prevention strategies were fundamental care and therefore important:

> *"To be acknowledged formally as a good standard of care, not just something that 'kind people' do, and that it's what we would expect to be a basic standard of care…I'm hoping that by this being more of a formalised process that other people will realise that it's what we would expect from everyone."* (Physician #5)

Some clinicians said they tailored the delirium prevention strategies to individual patients rather than ruling them out; for example, teaching patients with limited mobility to move themselves in the bed. One physiotherapist observed that while it could be challenging to help patients to keep moving, it should be a key focus and that motivation to do so might increase if there was better understanding of its link with preventing delirium:

> *"Especially with patients who are palliative, delirium is a big risk because they are lying in bed…immobilisation can lead to a higher risk of delirium, especially with psycho-active medications or medications that have adverse side effects which a lot of cancer drugs do have. In palliative care, it's quite easy to say 'Well yeah fair enough, we will leave you alone for today so you can rest in bed', but sometimes that might actually be the worst thing for that patient…but if there was a bit more education and gentle encouragement around, 'Well you're resting in bed right now but if you're resting in bed for a week you might not be the same person as before, it might do you good just to get yourself around so that at least you can get to the toilet'."* (Physiotherapist #2)

Other clinicians said that family were keen to be involved in the intervention and that it had helped to "*make sure that their loved one had the best care*" (Enrolled nurse #1).

Study processes that directly influenced adherence to the delirium prevention intervention

Theme 4: Shared knowledge increased engagement with the intervention (Capability)

Participants' capability to engage with the intervention was, unsurprisingly, influenced by whether they knew about it and its rationale. Interviews revealed that, despite preliminary engagement and training, some clinicians remained uncertain about it:

> *"I got sort of a verbal hand over from someone who has sort of shrugged and said, 'Well look I'm not 100% certain but this is what we're meant to do'…I didn't have the information I needed to implement it properly."* (RN #3)

Some clinicians suggested refining the site engagement and training, with added attention to weekend, casual and new clinicians:

> "*I don't think* [some of the nursing staff] *worked out the relevance of it…why you're doing it and the evidence around it."* (Physician #3)

Whereas informed clinicians said that during the pilot trial they became more aware of patients' fundamental needs, such as for fluids and unimpeded movement, and provided such strategies more often than previously:

> *"I would often say, 'Have a drink after physio', but even with patients that were declining physio, I would say, 'Oh look, there's a drink, would you like a drink of water?'. So that's one thing that I did more of during this study."* (Physiotherapist #1)

Patient participants mostly reported they were not told about the delirium prevention intervention before being interviewed:

> "*I noticed that people went over there and fill* [the checklist] *in* [points to wall near door] *after they have been in the room. But they didn't discuss it with me at all*." (Patient #1)

Similarly, some family caregivers said they were not aware they could have been involved:

> "*I was certainly not aware that we were meant to participate*" (Family caregiver #1).

Yet, some clinicians stated that family involvement was important, and that family caregivers who were informed had welcomed the information:

> *"There was a lot of engagement, and families wanting to hear about it and wanting to have a discussion around delirium."* (RN #4)

Clinicians identified they needed more formal processes to involve family caregivers in the intervention: *"The enabling family part we try and do, but if we formalise that* [process]*, that would really help."* (Physician #3)

Theme 5: Impact of the intervention checklist on attention, delivery, and documentation of the delirium prevention strategies (Capability)

The intervention checklist helped clinicians to remember and attend to the delirium prevention strategies:

> *"It's reminding us what strategies we can take to prevent delirium. When we are busy, we forget to do some things…like encourage to drink water but when we see the* [checklist] *here we can say 'Oh yeah, let's do that'."* (RN #5)

*S*ome clinicians stepped up to 'champion' intervention delivery and documentation:

> *"It was leaders that were important, and the drivers, having someone who could go round daily and just be checking and then at hand-over, just reminding staff."* (Physician #2)

Yet even highly engaged clinicians described neglecting to document some of the delirium prevention strategies they delivered. The care delivery-documentation gap seemed due to a combination of busyness, no formal study "coordinators", and views that the checklist was too long and complex:

> *"When they were doing it, they were naturally doing things on the form, but actually remembering to fill out that they had done I think was a problem because of just busyness and that's why a coordinator person would have been good to remind them."* (Physician #3)

Patients also thought the checklist too long and onerous for clinicians:

> *"Yeah, well as I was saying there is a lot on here that shouldn't be on here anyways* [points to checklist] *and the thing is I don't think they need to fill in this checklist. Maybe in a simple form in the file, at the end of the shift, something that says nothing was noticed today and she signs it, simple you know. You need a simple solution, not more work."* (Patient #2)

Others suggested that they needed more training and practice in documenting the delirium prevention strategies: *"I wasn't trained or practiced enough at doing it, just to remember all the time"* (Physiotherapist #1).

Theme 6: Clinical roles and responsibilities (Motivation)

Uncertainty about roles and responsibilities for some of the delirium prevention strategies, particularly family partnership, decreased motivation:

> *"I don't think* [whose role it was to talk to family caregivers] *was clear, I suppose I would like to but I am very conscious when I clock someone in not to burden someone with too much information at the initial consult."* (Physician #1)

The need for role clarification differed between the delirium prevention strategies, as clinicians saw some - such as encouraging oral fluids and reorientation - as everyone's responsibility:

> "*Making sure they [patients] have access to water – that is everyone's job, very clearly*" (Physician #1)

Clinicians' role influenced whether other strategies were acceptable to them. For example, one felt that manning a 'leisure trolley' for patients' access to cognitively stimulating activities had diminished their professional role, and that this strategy would be more appropriately delivered by volunteers:

> "*When I went back as a social worker, they* [patients] *kind of saw me as a trolley person and didn't take my actual social work role seriously." (Social worker* #1*)*

Clinicians noted that some family may have been reluctant to contribute to the checklist because they perceived it as *"nurses' business"*, and suggested that distinguishing clinician and family roles might address the delivery-documentation gap:

> *"Defining the roles to each individual or team and splitting up the* [documentation tool] *would help, get more compliance, I think. And a specific one for the family to fill in, with all family-related things to fill out."* (Physician #3)

Theme 7: Addressing environmental barriers to delirium prevention (Opportunity)

Several clinicians said workload had sometimes impeded intervention delivery and documentation. In particular, the checklist was thought unsustainable in its current format, despite its utility as a reminder:

> *"It's the constant reminder of optimising the vision, hearing, hydration, they are such pillar-stones but how you make sure* [the strategies] *are done every day without more paperwork. I understand that this* [refers to checklist] *was here to see what's feasible but what I am wondering is how do we maintain this."* (Physician #1)

Patients and family also considered clinicians' workload to be a barrier: *"I would hate to be a nurse, so much paperwork, nurses are like the little ants, they keep the nest going"* (Patient #2). Family and volunteer involvement in the intervention was posed as one way to overcome this barrier:

> *"Sometimes we're not always in the room…so I think having the family and other members coming through and filling out the documentation is helpful for me."* (RN #6)

Other environmental issues included access to equipment, resources, volunteers, and weekend physicians, for example:

> "*I've been to the kitchen a couple times in the week to get drinks, of the special drink. It was not forth coming. Because we just can't use ordinary water, so we had to go and get thicker water…And I suspect that they didn't have a lot of stock in the first place when we first arrived. And the other thing I think, and I didn't understand this, but in the diet section, we would tick thick-milk tea in the morning and it never arrived. They actually just gave her water. So we had been getting teas or coffees and using our own thickening powder. We bought it at the other hospital*." (Family caregiver #1)

The potential for prompts and information in patient rooms was identified:

> *"If we had exercises up for them…the volunteers started helping, and the nurses can look at that, and family members can look at that…they can continue doing that even when physios are not around encouraging it."* (Physiotherapist #1)

Lastly, this participant expressed appreciation for the opportunity to be involved in the study:

> *"It was a privilege to be part of the team that was implementing the project here. It was fun having the opportunity to produce this checklist, so it felt purposeful from that point of view."* (Pastoral care worker #1)

Discussion

The value of qualitative research in pilot studies[17] was reflected in our findings, which helped to explain low adherence to the PRESERVE intervention (Figures 1, 2). Theory-based assessment of the implementation of health care interventions to improve patient outcomes is important in gaining a deeper understanding of the process required to bring about behaviour change.[18] Behaviour change theories can assist in identifying barriers and target behaviours for implementation strategies to increase the likelihood of successful delivery of complex interventions.[18] Our findings thus also demonstrate the usefulness of applying Michie's Behaviour Change Wheel and the Theoretical Domains Framework to evaluate the feasibility and acceptability of a complex intervention to prevent delirium in inpatient palliative care units.

While stakeholders supported the interdisciplinary approach, their perspectives of the feasibility and acceptability of the delirium prevention strategies in palliative care were somewhat mixed, and some did not even know of them or understand how they might prevent delirium. While many participants were enthusiastic about the intervention, not all clinicians thought that preventing delirium was a priority or possible for all patients in this setting, especially at critical junctures like admission and the last days of life. These findings help to inform how to promote sufficient delivery and precise documentation in trials in palliative care of multicomponent delirium interventions - which are critical to internal validity and demonstration of effectiveness[26, 27] - as is now outlined below.

Capability

Incomplete understanding of delirium is well documented in the palliative care literature,[6,12] and here too impeded some stakeholders' capability for the intervention. There were also gaps in knowledge about the PRESERVE pilot study, despite site training, engaged working groups, and provision of written information. Higher adherence at the waitlist intervention sites, the staff of which were provided with more emphatic instructions on completing the checklist, reinforces the importance of knowledge as an influence. Capability findings indicate the need to further broaden the reach and fine-tune the content of information in future delirium prevention trials in this setting, especially to increase the awareness and understanding of patients, family, volunteers, and clinicians who work fewer or outside office hours. While waiver of consent for collection of quantitative data helped to ensure a representative sample in the main trial, future in-person provision of study information by research staff (rather than relying on clinicians alone) to patients and family caregivers would support their knowledge of delirium prevention strategies. Activities to enhance capability could include multifaceted training that measures participation plus pre- and post-test delirium knowledge;[28,29] skills training in communication about delirium and its prevention with patients and family; and revising delirium information brochures to add content about preventive strategies.[30-32] Site adaptation of prompts and documentation, practice runs, audit and feedback, repeated training in case of staff turnover, study champions/coordinators, and greater involvement of family and volunteers may also build palliative care team capability in future delirium prevention trials.[11,33-35]

Opportunity

Clinicians saw their compassionate, collaborative ways of working as aligned to the intervention and its intention, indicating a supportive social environment[20] that will be 'grist to the mill' for future trials. Site teams also enthusiastically obtained new equipment and helped innovate implementation methods. However, environmental barriers, such as competing demands, workload, and reduced staff on weekends, remained. Such barriers to delirium care in hospitals are not extraordinary (as are, for example, ward relocations and the current COVID-19 restrictions[11,36,37]); but rather are common and therefore important to pre-empt. Other authors have suggested that clinical time constraints are best addressed by closely aligning new delirium interventions with existing workflow plus breaking them down into "*manageable chunks*".[38] Our study identified that the checklist too requires reforming into smaller and simpler parts. Both patients and family caregivers wanted family to contribute to care and were keenly aware of clinicians' workloads, as found elsewhere.[39,40] Protocolised steps for authentic family engagement in delirium prevention trials will likely be required to achieve this opportunity.[41,42]

Motivation

Clinicians' perceptions of routine and basic care, priorities, and roles and responsibilities influenced their willingness to deliver and document the intervention, as in other similar studies.[43,44] Findings build on a study of clinicians' delirium treatment practices, which found distress and safety concerns *during* delirium were predominant motivators, especially for palliative care clinicians when the patient was in the last days of life.[13] In the current study, some clinicians described how other sources of distress at admission and during dying took priority over seeking to prevent delirium, or even to raise the possibility with patients and family. These findings suggest palliative care clinicians are more strongly motivated to enact responsive care than anticipatory,[45] and perhaps also explain why delirium prevention has been less studied in this setting, relative to its treatment.[46] The need to better understand and support clinicians' anticipatory care for delirium amidst other distressing issues at the end of life is indicated. Other steps forward include streamlining the intervention and its delivery by *distinguishing* whether strategies are routine (i.e., regularly done) or fundamental (i.e., essential and hence requiring nimble tailoring);[47] *delineating* who in the team will deliver and document each (as per roles and responsibilities); and *defending* fundamental care - both in principle and its actual delivery via within-trial auditing and/or time-series measures.[11] Lastly, stakeholders' motivation might be boosted by study messaging that more clearly conveys the biological plausibility and evidence for delirium prevention through the intervention.[9,10]

Limitations

Having different interviewers across sites, some with professional relationships with participants, may have influenced interviews and responses. This possibility was addressed by training interviewers in study-specific consent processes and data collection and use of a standardised interview guide. Convenience sampling and predominance of clinician participants highlight the need to purposively recruit patients, family, and volunteers in future qualitative studies of delirium in palliative care.[12] The study being conducted in only four Australian palliative care units limits its transferability to other countries, specialities, settings and health care systems, although the theory-based analysis may moderate this limitation.

Conclusion

This qualitative study gained value in using behaviour change frameworks to identify multiple influences on delivery and documentation of a pilot multicomponent non-pharmacological delirium prevention intervention in four palliative care units. A next step in our research program is to integrate these qualitative findings with quantitative trial results, which will contribute to a more decisive understanding of the most feasible and acceptable study processes and strategies for delirium prevention trials in palliative care. We are also currently applying these theory-based learnings in a feasibility study of a modified PRESERVE intervention for Māori and non-Māori patients in New Zealand hospices, with particular attention to wh**ā**nau (family) involvement**.** This preliminary research in delirium prevention in palliative care will inform future definitive studies.

Abbreviations

Consolidated criteria for reporting qualitative research (COREQ); Registered nurse (RN).

Authorship

Conceptualisation and co-leading of the study (MA, AH, JP); study coordination (AG); data collection (LE, JH, JW, CPh); data analysis (AG, MA, AH, LE); manuscript drafting (AG, AH); and manuscript revision (MA, AH, JP, LE, SK, BN, MB, AC, PGL, SHB, JMD, ML, EWE, CP). All authors read and approved the final manuscript.

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Declaration of conflicts of interest

The authors declare that there is no conflict of interest**.**

Research ethics and patient consent

Ethical approval for this study was granted by the South Western Sydney Local Health District Human Research Ethics Committee on 19 July 2017 (HREC/17/LPOOL/224) and the University of Technology Sydney Human Research Ethics Committee on 22 September 2017 (ETH17-1697). Participants provided written informed consent.

Data management and sharing

Raw data are contained within this manuscript in the form of de-identified participant quotes. The corresponding author can be contacted for further information.

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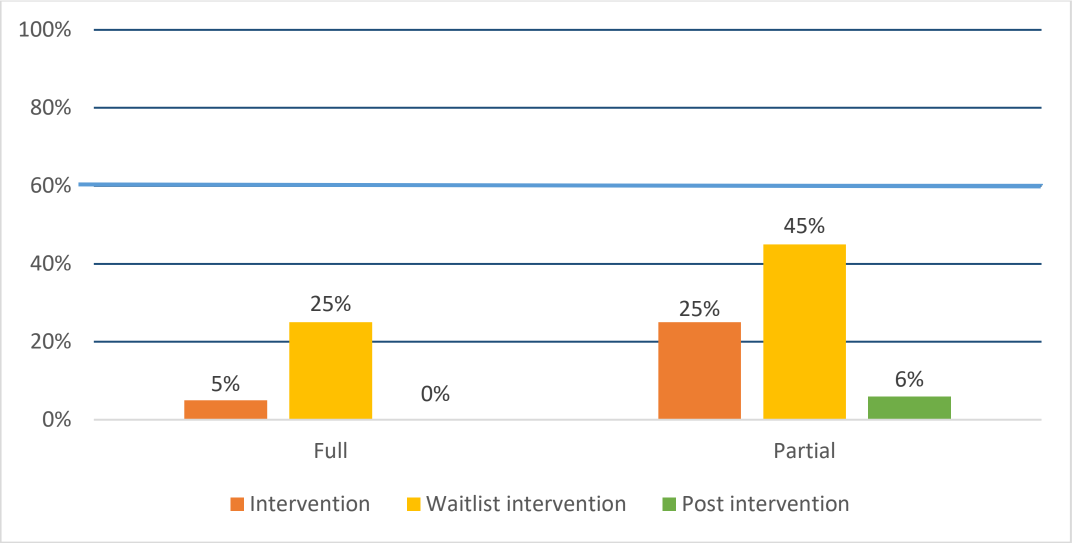
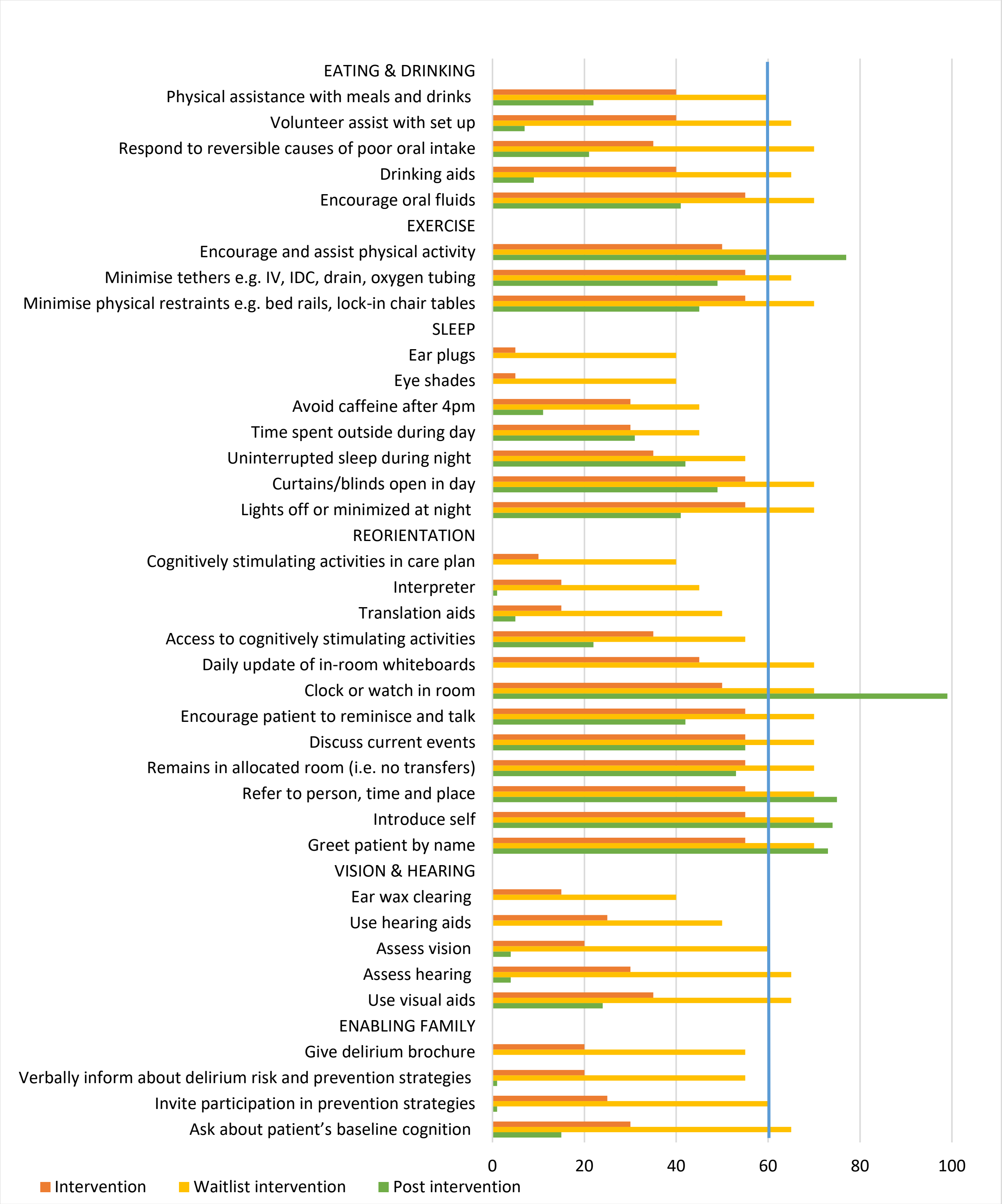


Blue line denotes 60% *a priori* adherence endpoint

Figure 1. Adherence to delirium prevention strategies at intervention, waitlist intervention, and 6 months post-intervention, full (all strategies of ≥4 domains for ≥5 days) and partial (any strategy in ≥4 domains for ≥5 days)



Blue line denotes 60% *a priori* adherence endpoint

Figure 2. Adherence (%) by delirium prevention domain and strategy at intervention, waitlist intervention, and 6 months post-intervention

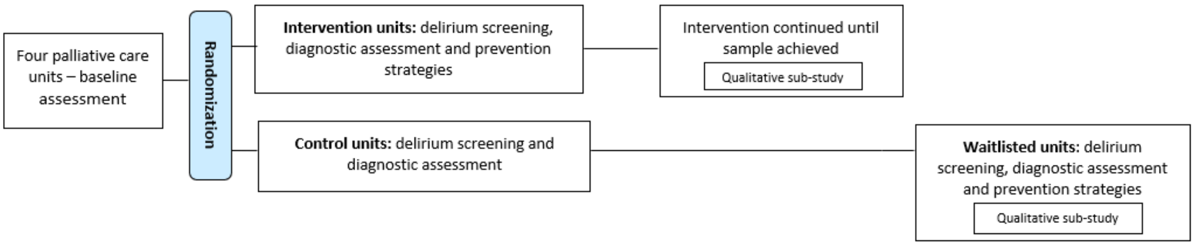


Figure 1: Study Diagram
Standardized delirium screening and diagnostic assessment at all units + delirium prevention strategies at intervention units (May-Jun 2018); control units were waitlisted to the intervention (Aug-Sep 2018)

Figure 3. PRESERVE pilot study design

Capability		
a.	Physical	- Skills
b.	Psychological	- Knowledge - Skills - Memory, attention and decision processes - Behavioural
Motivation		
a.	Automatic processes	- Social/professional role and identity - Optimism - Reinforcement - Emotion - Goals
b.	Reflective processes	- Social/professional role and identity - Beliefs about capabilities - Optimism - Beliefs about consequences - Intentions
Opportunity		
a.	Social	- Social influences
b.	Physical	- Environmental context and resources

Figure 4. Unconstrained coding matrix[19]

Supplementary Files

Supplementary file 1. PRESERVE Checklist Single Day

The Delirium Prevention Research Project (The PRESERVE pilot study)

PaCCSC UNIVERSITY OF TECHNOLOGY SYDNEY

Patient ID Sticker

Please record the interventions you have offered and provided

Use the following codes to denote completion/witness of activity:

F family	**M** medical	**N** nursing	**SW** social worker	**PC** pastoral care	**PT** physiotherapy	**S** self (patient)
DT diversional tx	**V** volunteers	**SP** speech path.	**D** dietician	**MT** massage tx	**OT** occupat tx	

Reason for non-completion:

NR not required	**C** patient choice	**O** other
NA not approp.	**NP** not possible	

DATE

PID: 036/_ _/_ _ _ _
(To be inserted by study team)

		On admission day only																
	Sleep																	
1	Ear plugs are worn at night																	
2	Eye mask/shade is worn at night																	
3	Room curtains/blinds are open in the day																	
4	Room lights are off or minimised at night																	
5	Time is spent outside during the day																	
6	Only non-caffeinated drinks after 4pm																	
7	The patient reports uninterrupted night-time sleep																	
	Vision & Hearing																	
8	Assess hearing																	
9	Ear wax cleared																	
10	Use hearing aids																	
11	Assess vision																	
12	Use visual aids e.g. glasses																	
	Eating and Drinking																	
13	Encourage oral fluids																	
14	Physical assistance with meals																	
15	Drinking aids used e.g. straws, cup holders, cups with lids etc.																	
16	Respond to reversible causes of poor oral intake e.g. nausea, vomiting																	
17	Volunteer to set-up assist																	
	Reorientation																	
18	Interpreter used																	
19	Translation aids																	
20	Greet patient by name																	
21	Introduce self																	
22	Refer to person, time and place																	
23	Clock in room																	
24	Daily update of whiteboard																	
25	Remains in allocated room																	
26	Discuss current events																	
27	Encourage pt to reminisce and talk																	
28	Access to cognitively stimulating activities e.g. leisure trolley, own activities																	
29	Cognitively stimulating activities in care plan																	
	Exercise																	
30	No lines (e.g. IV, IDC, drain, oxygen tubing) restricting movement																	
31	No bed-rails, lock in chair tables etc. restricting movement																	
32	Encouragement/assistance of physical activity to highest capacity																	
	Physical activity																	
33	Level 0: None																	
34	Level 1: Active range of movement exercises in bed and/or sitting position in bed																	
35	Level 2: Assistance to sit on the side of the bed																	
36	Level 3: Sitting in a chair, standing																	
37	Level 4: Walking around room or unit (independent or assisted)																	
38	Level 5: Gym/ exercise program/walking outside of unit																	
	Enabling Family																	
39	Ask family about baseline cognition																	
40	Verbally inform of delirium risk and prevention																	
41	Give delirium brochure to family																	
42	Invite family participation in delirium prevention																	

Supplementary file 2. Interview guides

Interview guide for patients and family caregivers

1. Do you have any comments or questions about any of the strategies (you/name of patient) received?

2. Were the strategies feasible for (you/name of patient)?

    a. What, if anything, worked well?

    b. What, if anything, didn't work well?

3. Were the strategies acceptable to you?

    a. Why they were ok?

    b. Why they weren't ok?

4. Do you have any suggestions about how we could better give these aspects of care at (site name)?

5. Do you have any other comments or questions before we finish the interview?

Interview guide for clinicians and volunteers

1. What delirium prevention strategies were you involved in?

2. Do you think that the delirium prevention strategies were feasible:

    a. For your patients?

    b. In this setting?

3. Were the strategies acceptable for patients?

4. Were the strategies acceptable for family caregivers?

5. Were the strategies acceptable to you?

6. Do you have any suggestions about how the delirium prevention strategies would be best delivered:

    a. To your patients?

    b. In this setting?

7. Do you have any suggestions about how we could better give these aspects of care at (site name)?

8. Do you have any other comments or questions before we finish the interview?

Supplementary file 3. Themes and additional illustrative quotes

Alignment of the delirium prevention intervention with palliative care	
Theme 1: The intervention was considered routine care (Motivation)	*"I understand the thinking behind this, and I understand the various measures and I can see how if they were put in place correctly and early enough they could perhaps make a difference. But I felt like a lot of it was stuff that we would be doing anyway, so it wasn't new…It was things that I would be doing in my caring of a patient anyway."* (RN #7) "*I'm not sure that I could see all those questions* [referring to the intervention strategies] *relating to the delirium thing though*." (Family caregiver #2)
Theme 2: The intervention aligned with the compassionate and collaborative culture of palliative care (Opportunity)	*"I mean in my situation I go up to one of the girls and say, 'Who do you think would like to go for a walk?' or 'What can I do for anyone in here today?', and she will say, 'Look, you could go in and talk to that lady, or you could take that man for a walk'. And you know, I think that as long as we can do that that's fine."* (Volunteer #1)
Theme 3: Differing views of palliative care priorities influenced perspectives of the intervention (Motivation)	*"It's great that* [the strategies] *are actually being recognised as important things that may help prevent delirium and that's giving value to basic nursing care that we have been doing a long time. And actually saying how important it is for our patients and in the prevention of delirium particularly."* (RN #8) *"I would say most developed* [delirium] *here and it was in the context of them dying. Whereas other patients will develop delirium here through a combination of new environment, medications, being medically unwell, maybe a urinary tract infection. And that group would benefit much, much more from the delirium prevention strategies, that would be really effective for them but the ones that have that terminal delirium, where it's irreversible medical progress, benefited much less."* (Physician #1)
Study processes that directly influenced adherence to the delirium prevention intervention	

Theme 4: Shared knowledge increased engagement with the intervention (Capability)	“*Was it part of the study to have the notice boards with the days on it?*” (RN #9). *“*[Physiotherapist asking nurse for a leg bag] *was so good that it helped bring nursing care needs of a patient to a physio’s attention, in that they can ask for something that’s going to make mobilising easier for the patient. And everyone was thinking about what is around the patient, what’s in their environment that is potentially restrictive.”* (RN #4) *“I didn’t think it had anything to do with me to be honest with you. They didn’t say anything. I didn’t know it was for me. She [a nurse] just said, ‘Thank goodness this is over’ when she was taking [the checklist] down [laughs]. Oh dear, so you know.” (Patient #2)*
Theme 5: Impact of the intervention checklist on attention, delivery, and documentation of the delirium prevention strategies (Capability)	*“Having a checklist like this is very beneficial, maybe it can be streamlined…and not be as big.”* (RN #10) “*We were all thinking more about delirium and delirium prevention…it helped hone our focus on it.*” (Physician #5)
Theme 6: Clinical roles and responsibilities (Motivation)	*“I think that was a challenge as it wasn’t a fixed role* [hearing assessment] *for either* [physicians or RN’s] *and I did question that and it wasn’t given a designated role here. I would be interested to see what registered nurses felt because I wouldn’t have seen it as, my assumption was that that was formally in their admission assessment. I may think about it when I am writing someone in, informally. But my assumption was that it was formally done by them* [RNs].*”* (Physician #1)
Theme 7: Addressing environmental barriers to delirium prevention (Opportunity)	*“Nurses can only do so much…as they have other jobs to do. Family is very, very important.”* (Patient #3)