

## Research Article

## CALM ICU guidelines: Preliminary guidelines on non-pharmacological strategies for agitation in the ICU – A Delphi study

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## ABSTRACT

**Aim:** To develop preliminary clinical practice guidelines for the non-pharmacological prevention and management of patient agitation in the intensive care unit.

**Methods:** A modified three-round Delphi study was conducted between January and May 2022 and involved 114 participants from Denmark and Australia, including clinicians, researchers, patients, and family members. The first Delphi round was built on a systematic review of non-pharmacological interventions for managing agitation, a modified umbrella review encompassing qualitative reviews on patient experiences in the intensive care unit and guidelines for managing agitation across all health care settings along with stakeholder consultation. Recommendations were included if they reached a consensus level (IQR  $\geq 1$ ) of 75 % or higher in both Denmark and Australia.

**Results:** A total of 63 recommendations for preventing and managing patient agitation in the ICU were included in the preliminary guidelines. The recommendations were grouped into nine themes, forming a new model of care. The themes include care principles, assessment of agitation, identification and treatment of causes of agitation, caregiver behaviours and developing trusting relationships, family involvement, psychosocial needs, physical needs, individualised care and interventions related to the context. Differences in consensus were noted between the two countries and between stakeholders.

**Conclusions:** The study provides robust evidence for preliminary guidelines for the non-pharmacological prevention and management of patient agitation in the ICU. The guidelines emphasise the importance of developing trusting relationships, addressing individual patient needs and ensuring organisational support for successful implementation. The guidelines are preliminary and will be tailored to each country, graded and undergo public consultation and expert methodological reviews.

**Implications for Clinical Practice:** In the absence of established clinical guidelines, these preliminary guidelines offer a framework for ICU clinicians to manage patient agitation effectively, prioritising non-pharmacological approaches and minimising the use of physical and chemical restraints. The findings highlight the need for further research on non-pharmacological strategies to manage agitation.

## Introduction

The prevention and management of patient agitation in the intensive care unit (ICU) presents significant challenges with far-reaching consequences for patient recovery and long-term outcomes. Agitation, which is characterised by excessive motor activity, emotional tension,

cognitive impairment, disruption of care, aggression and fluctuations in vital signs [1], affects between 32–87 % of patients in the ICU [2,3,4]. The underlying causes of agitation in the ICU are multifactorial, often involving emotional distress [5], metabolic imbalance, inadequate gas exchange [6], traumatic brain injury [7,8], and substance withdrawal [9]. While agitation is frequently associated with hyperactive delirium

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[10], it is important to note that it can also occur in the absence of delirium [11].

Agitation in the ICU is associated with prolonged mechanical ventilation [12,13], extended ICU stays [14,13] and increased mortality rates [2,15,7,8], and treatment interruptions [16,17] causing distress for patients and their families [18]. Furthermore, agitation contributes to clinician fatigue and burnout, negatively impacting the overall functioning of the ICU [19]. Despite these severe consequences, there remains a lack of comprehensive guidelines for the management of patient agitation in the ICU. While sedation has long been the primary approach for managing agitation, evidence indicates that prolonged use of sedation can result in extended mechanical ventilation and longer ICU stays [20]. Additionally, sedatives may impede clinicians' ability to assess the neurological status of patients and, paradoxically, may exacerbate agitation [21]. Notably, no pharmacological agent has been identified that can reliably prevent agitation [21], underscoring the urgent need for alternative management approaches. In light of these concerns, clinicians are increasingly encouraged to incorporate non-pharmacological strategies into their management of patient agitation [22]. Despite the growing recognition of the importance of non-pharmacological strategies, existing guidelines predominantly emphasise pharmacological management of agitation [23]. This lack of recommendations on non-pharmacological interventions, coupled with the time constraints and demanding workload characteristic of ICU environments, often leads clinicians to rely on pharmacological solutions [24].

In response to these challenges, researchers from Denmark and Australia collaborated to develop clinical practice guidelines. These guidelines were based on the manuals provided by the Australian National Health and Medical Research Council (NHMRC) [25] and the Danish Health Authority [26] on developing clinical practice guidelines. To ensure an evidence based, holistic and patient-centred approach, the Joanna Briggs Institute model of Evidence Based Health Care [27] and the Fundamentals of Care framework [28,29] were incorporated into a conceptual framework [30] used to develop, analyse and understand data.

The first phase involved consultations with 51 stakeholders (ICU researchers, clinicians, patients and families from Denmark and Australia) to define the scope of clinical practice guidelines focused on the non-pharmacological prevention and management of patient agitation in the ICU [31,32]. After determining the scope of the guidelines, a comprehensive systematic review was undertaken to evaluate the effectiveness of non-pharmacological strategies in the ICU [31,32]. While 11 studies were identified, the overall quality of evidence supporting these interventions was low, making it difficult to form recommendations. The researchers, therefore, decided to carry out a modified umbrella review to examine existing guidelines from non-ICU settings and to explore ICU patients' experiences with agitation [30]. This review suggested a range of recommendations, primarily based on expert consensus and qualitative evidence. Ideally, guidelines should be grounded in robust scientific evidence; however, scholars argue for the importance of developing recommendations even when the available evidence is of low quality [33,34]. Given the difficulties in obtaining high-quality evidence and the ethical concerns surrounding delays in clinical action, the researchers used a modified Delphi study to assess and refine the identified low-quality and indirect evidence.

The overall aim of this study was to develop preliminary<sup>1</sup> recommendations for the non-pharmacological management of agitation in the ICU and to answer the research question: what non-pharmacological strategies should be offered to ICU patients to prevent and manage agitation? To achieve this, the study pursued the following objectives:

- To systematically identify recommendations for preventing and managing patient agitation in the ICU that reached a high level of consensus among Delphi participants.
- To evaluate the clinical importance and feasibility of each recommendation.
- To identify potential barriers and facilitators to the implementation of non-pharmacological strategies for preventing and managing patient agitation in the ICU.
- To analyse cross-cultural variations in clinical expertise and practice by comparing consensus patterns between Australian and Danish stakeholders.

## Methods

This study employed a modified three-round Delphi technique to synthesise expert consensus and formulate preliminary recommendations. The study was conducted by nurse researchers and clinicians in Denmark and Australia, as part of a larger project aiming to develop separate clinical practice guidelines for the non-pharmacological prevention and management of patient agitation for Danish and Australian ICUs. This study is reported in line with the DELPHISTAR reporting guidelines [35].

### Panel composition and recruitment

We defined an expert as a person who was very knowledgeable about, skilled in or had personal insights into patient agitation in the ICU. To be included in our expert panel, participants had to be 18 years or older, literate in English or Danish, have internet access, and live in Denmark or Australia, with no major conflicts of interest. ICU clinicians and managers needed extensive experience managing ICU agitation, with at least three years of clinical experience, a postgraduate qualification, or a senior managerial role in the ICU. Researchers were required to have published papers relevant to patient agitation in peer-reviewed journals within the last six years. Patients and family members needed to have personal experience with patient agitation from the ICU. The participants were recruited through professional and patient organisations and stakeholder networks. The first author also engaged with an Australian ICU survivor group and Danish ICU nurses online to recruit patients and family members. Interested individuals could learn more about the study and express interest on a bilingual webpage featuring videos and easy-to-read information. Eligible participants received an invitation letter, a participant information sheet and a link to the first Delphi survey.

### Survey development and the first Delphi round

The first Delphi survey was developed based on input from stakeholders during the consultation phase [30,31,32], a systematic review of effectiveness [31,32], and a modified umbrella review [30]. All recommendations identified in the reviews were included in the first Delphi survey. A five-point Likert scale was selected for its user-friendliness [36], as well as its demonstrated reliability, internal consistency, and validity [37]. The first Delphi survey was tested by Danish and Australian laypeople and health professionals through four cognitive interviews [38]<sup>2</sup> and 15 pilot tests to ensure clarity and consistency. To ensure accuracy and linguistic appropriateness, the surveys were rigorously translated [39,40] using a two-step process: two independent forward translations to Danish and two independent back translations to English (see Appendix A).

<sup>1</sup> Preliminary because according to guideline manuals by NHMRC and the Danish Health Authority, they must be graded and go through stakeholder consultation and methodological expert review before they can be finalised.

<sup>2</sup> Cognitive interviews were conducted to assess how survey respondents understand and interpret questions. Participants verbalise their thought process as they answer questions. The technique ensures clarity and validity of the questions.

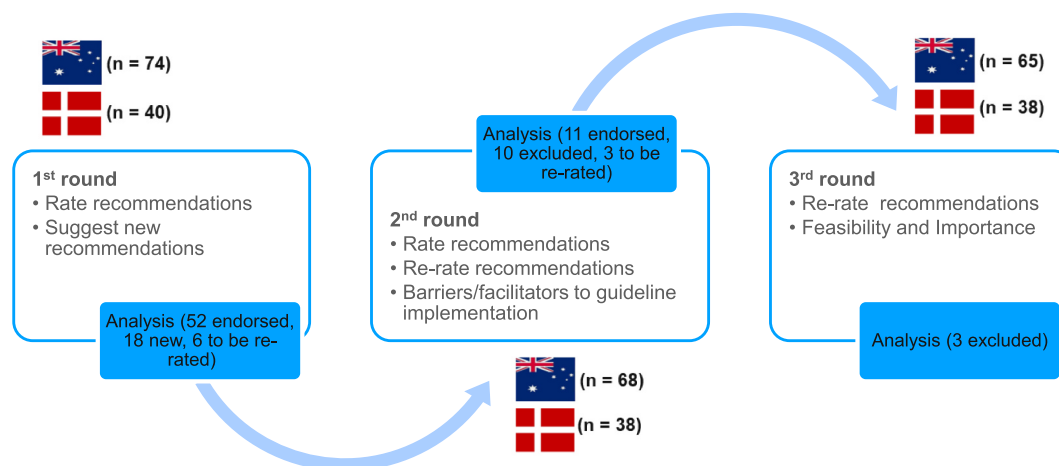


Fig. 1. Three-round modified Delphi study (n = number of participants).

The first round survey aimed to determine which items reached consensus and to assess the level of agreement for each. Participants rated either their agreement with recommendations<sup>3</sup> on a scale (from *strongly disagree* to *strongly agree*) or the usefulness<sup>4</sup> of interventions (from *not useful at all* to *very useful*). Participants were also encouraged to justify their ratings and propose additional non-pharmacological strategies [41,42]. To ensure the trustworthiness of the evidence, participants were required to have prior experience with an intervention before rating it. Questions deemed less relevant to patients and family members (e.g. relating to work processes in the ICU, staff need for education and debriefing and feasibility of recommendations) were removed from their surveys in discussion with the research team, a health professional and a layperson to ensure meaningful engagement and avoid response fatigue. The surveys were distributed via the Qualtrics platform in two languages [43].

#### Delphi rounds two and three

The researchers were mindful to avoid influencing participants' views through feedback between rounds [41]. Feedback was provided through short videos in Danish and English, thanking participants, summarising findings and outlining the objectives for the upcoming round. Participants were encouraged to contact the primary investigator for more detailed results.

In the second and third rounds, participants revisited items that had reached a high level of consensus in only one country and rated all new items from the previous round. Additionally, in these rounds, participants were asked to suggest and rate barriers and facilitators to the implementation of the guidelines, as well as evaluate each endorsed item for its importance and feasibility.<sup>5</sup> The second survey, was tested through cognitive interviews and pilot tests in Danish and English. The last survey, containing no new items, was only pilot tested.

An overview of the three Delphi rounds can be seen in Fig. 1.

<sup>3</sup> For example, "please rate the extent to which you agree or disagree with the following recommendations. Clinicians should identify and, when possible, treat causes of agitation".

<sup>4</sup> For example, "please rate how useful you believe the following strategies are for either reducing or managing agitation in the intensive care unit. How useful is using a bed-bike?".

<sup>5</sup> Feasibility was defined as the extent to which the panel member believed a recommendation could be successfully carried out within the ICU setting (s) they were familiar with.

#### Defining consensus and level of consensus

The interquartile range (IQR) was selected for its accuracy and robustness to measure the spread of data [44,45]. Consensus was defined as an IQR of one or less, with a high level of consensus established at 75 % or more, a commonly accepted threshold for high-quality recommendations [46,47,48]. Confidence intervals (lower 95 % CL and upper 95 % CL) were measured using the Wilson method [49] via the online Epitool [50] to help understand the certainty of the data.

It was decided *a priori* that an item was endorsed if it reached consensus (IQR  $\leq 1$ ) and a consensus level of  $\geq 75$  % in both countries. Items were re-rated once if they only reached a high level of consensus  $\geq 75$  % in one country only (see Table 1 for an overview of the rating criteria).

#### Data analysis

Statistical data were analysed using the Statistical Package for Social Science (SPSS) version 28.0.1 [51]. Demographic data were reported with descriptive statistics, including frequency counts, percentages, means and standard deviations. Non-parametric tests were used due to the non-normal distribution of Likert scale data, varied group sizes and the ordinal nature of the scale. IQRs and percentages were used to measure consensus, importance, feasibility, barriers and facilitators. All "don't know" responses were excluded to accurately reflect the opinions of those who had experience with an approach. The means were used to rank data. The non-parametric 2-sample Z test on proportions (2-tailed) determined significant differences in consensus between the two countries on the excluded items [52,53]. The Kruskal-Wallis H test, a non-parametric alternative to one-way analysis of variance ANOVA, was used to determine whether the stakeholder groups<sup>6</sup> differed significantly (p values  $< 0.05$  considered significant) in their ratings of the included items [54,55,56,57]. Missing data were minimal (0–2.9 %), and Little's Missing Completely at Random MCAR test [58] indicated data were missing at random, allowing for analysis without exclusion or imputation [59].

The qualitative data from open-ended questions were analysed using directed content analysis [60]. The research team reviewed participants' justifications and suggestions for re-wording, removing or adding items. Given the large volume of qualitative data, and to ensure analytical

<sup>6</sup> Stakeholder groups sharing characteristics were merged to allow enough representation in each group. The groupings were discussed and agreed upon before analysis of data.

**Table 1**  
Criteria for inclusion in the guidelines.

Criteria	Decision
Consensus established (IQR $\leq 1$ ) AND consensus level* $\geq 75$ % in both countries.	Endorsement
Consensus of $\geq 75$ % established in only one country.	To be re-rated
Items not fulfilling the criteria above.	Rejected
OR	
Items re-rated once and still do not fulfil the criteria above.	
<b>NOTE</b> If less than 25 % of all participants rate an item, it will be excluded.	

\* Percentage of participants rating either *somewhat agree* or *strongly agree* to a recommendation or state that an intervention is *somewhat useful* or *very useful*.

rigour, coding was managed by using the NVivo software [61]. In the early stages of coding, intercoder agreement was established between researchers to ensure analytical credibility. The research team discussed all new or re-worded items to ensure they accurately captured the participants' intended meanings. See Appendix A for coding rules and examples.

### Ethical considerations

The Delphi study received ethics approval from the Central Adelaide Local Health Network (reference 15710) and cross-institutional approval from Flinders University Social and Behavioural Research Ethics Committee (ID 4928). Informed consent was obtained from all participants. A formal ethics approval was not required in Denmark, as according to the Danish law (§14, subsection 2), research not involving biological material, such as surveys and interviews, does not require approval from a research ethics committee [62]. However, the authors ensured the study was carried out in accordance with the Declaration of Helsinki [63] and the ethical guidelines published by the Nordic Nurses Federation [64].

### Results

A total of 114 participants joined the Delphi panel between January and May 2022, representing all regions of Denmark and all States and Territories in Australia except the Northern Territory. The study included 103 ICU health professionals and researchers and 11 patients and family members (see Table 2). The participants' mean age was 44.53 ( $\pm 11.95$ ), and 86 % were females. Most ICU health professionals

**Table 2**  
Characteristics of ICU Health Professionals.

ICU Health Professionals	Denmark	Australia	Total
Physician	6	4	10
Nurse	21	51	72
Researcher	4	2	6
Allied health <sup>1</sup>	6	9	15
<b>Total</b>	<b>37</b>	<b>66</b>	<b>103</b>
<b>Years working in the ICU</b>			
2–4 years	5	3	8
5–7 years	5	14	19
8–10 years	1	10	11
11–20 years	13	26	39
20+	13	13	26
<b>Highest level of education</b>			
Bachelor	8	5	13
Graduate Certificate		21	21
Graduate Diploma		8	8
Danish Intensive Care Nursing (2 years full-time)	9		9
Master	5	24	29
Danish Kandidat	5	0	5
PhD	5	5	10
Fellowship	3	3	6
Other *	2	0	2

<sup>1</sup>Includes physiotherapist, occupational therapist, ICU manager and ICU chaplain

(63 %) had over 10 years of ICU experience, and 87 % held a post-graduate qualification (see Table 3). Retention rate was high: 90 % (n = 114) completed round 1, 93 % (n = 106) Round 2, and 90 % (n = 103) Round 3.

### Endorsed recommendations

A total of 63 recommendations were included in the guidelines. Due to the large number of recommendations, they were grouped into nine themes based on their similarity in meaning and informed by the Fundamentals of Care framework [28,29].

#### Theme 1: Care Principles

This theme, including eleven recommendations, outlines four major care principles that should guide healthcare professionals' non-pharmacological management of patient agitation (see Table 3). The first principle describes the importance of prioritising safety. Participants highlighted that organisational priorities did not always align with safety. An Australian nurse shared:

*"Sometimes, bedside staff are just told, 'You just need to manage' even though the patient's behaviour is escalating to an unsafe point"* (Australian nurse, ID 1019).

Participants noted an over-reliance on drug therapy, leading to the second principle, encouraging clinicians to always prioritise non-pharmacological strategies. Given the multifaceted nature of patient agitation, the fourth principle advises clinicians to avoid relying on a single approach and instead use multi-component non-pharmacological strategies. The use of physical restraint was particularly contentious, as it could undermine trust between clinicians and patients, exacerbate agitation and cause harm. An Australian researcher reflected:

*"Over my many years of clinical work, I came to realise that physical restraints gave an illusion of safety for the clinical team while actually making the critically ill person even more agitated"* (Australian researcher, ID 1006).

There was consensus that physical restraints should only be reserved for safety reasons when other methods had failed. Danish participants noted that physical restraint was not practised in Danish ICUs.

#### Theme 2 Assessment of agitation

This theme includes one recommendation and describes how patients should be regularly and systematically assessed for agitation (see Table 4). Early assessments allow clinicians to implement strategies before behaviours escalate. A nurse explained:

*"Missing the early signs of agitation and letting it build makes it much more difficult to manage"* (Australian nurse, ID 1057).

#### Theme 3 Identification and treatment of causes of agitation, including unmet needs

This theme includes two recommendations and describes how clinicians should identify and treat causes of agitation (see Table 5). A Danish physician explained:

*"There is a reason why they are agitated, and that reason must be found and dealt with...Medication may definitely be necessary, but it should be the*

**Table 3**  
Theme 1: Care Principles.

Category	Recommendation	N <sup>1</sup> , Consensus <sup>2</sup> (CI), Median (IQR), Mean (± SD)	Feasibility/Importance <sup>3</sup> (%)	Origin of evidence	Potential harms
Safety should be of high priority	The safety of patients, staff and family/next of kin should be given high priority when managing agitation.	114, 97 % (CI 93–99), 5 (0), 4.89 (± 0.49)	93/94	[65,66].	
	Clinicians caring for and treating agitated patients should always have access to immediate practical support.	106, 99 % (CI 95–100), 5 (0), 4.91 (±0.33)	82/99	Delphi	
	Clinical staff should check that aggressive and violent agitated patients do not have access to objects that can be used to injure others (e.g. sharp objects, weapons, hard objects that can be thrown).	104, 99 % (CI 95–100), 5 (0), 4.93 (±0.29)	94/98	Delphi	
	Clinicians should consider keeping a safe physical distance from a violent patient.	112, 88 % (CI 81–93), 5 (1), 4.54 (±0.79)	78/98	[65,66].	Maintaining a safe physical distance is not always feasible, as close proximity may be necessary to prevent the removal of life-saving equipment or to calm patients.
Clinicians should always consider non-pharmacological strategies	The intensive care unit should be laid out in a way that makes observing agitated patients easier.	103, 85 % (CI 77–91), 5 (1), 4.47 (±0.94)	64/96	Stakeholder consultation	
	Non-drug approaches should be considered first when managing agitation	113, 89 % (CI 81–93), 5 (1), 4.46 (±0.94)	92/90	[65,66,67].	In highly agitated and dangerous situations, pharmacological interventions might be prioritised over non-pharmacological strategies.
Clinicians should use multiple non-pharmacological strategies	Non-drug approaches for the prevention of agitation should be an integrated part of standard care	105, 100 % (96–100), 5 (0), 4.89 (± 0.32)	98/97	Delphi	
	Clinicians should consider using several non-drug strategies for agitated patients simultaneously.	114, 89 % (81–93), 5 (1), 4.52 (±0.92)	89/91	[68,69]	
Physical restraints should be a last resort	Clinicians should use physical restraints only as a last resort to ensure patient and staff safety.	114, 85 % (CI 77–90), 5 (1), 4.38 (±1.10)	85/91	[65,66,70,71,72,73,74]	
	Physical restraints should not be used as a substitute for direct observation <sup>4</sup>	104, 93 % (CI 87–97), 5 (0), 4.64 (± 0.79)	89/94	Delphi	
	Intensive care units should have clear guidelines for the use of physical restraints.	102, 95 % (89–98), 5 (0), 4.78 (±0.75)	93/98	[65,66].	

<sup>1</sup>N = number of participants who rated the recommendation  
<sup>2</sup>Percentage rating *somewhat* or *strongly agree*, or *somewhat* or *very useful*.  
<sup>3</sup>Percentage rating *somewhat* or *very feasible/important*.  
<sup>4</sup>Re-rated recommendation.

**Table 4**  
Theme 2: Assessment of Agitation.

Category	Recommendation	N, consensus, (CI), Median (IQR), Mean (± SD)	Feasibility/Importance (%)	Origin of evidence
Assessment	ICU patients should be regularly and systematically assessed for agitation.	100, 97 % (CI 92–99), 5 (0), 4.75 (± 0.46)	100/96	[65,66,74,75,76]

**Table 5**  
Theme 3: Identification and treatment of causes of agitation including unmet needs.

Category	Recommendation	N, Consensus <sup>a</sup> (CI), Median (IQR), Mean (± SD)	Feasibility/Importance (%)	Origin of evidence
Treat causes including unmet needs	Clinicians should support patients' fundamental care needs to reduce and manage agitation.	102, 99 % (CI 95–100), 5 (0), 5 (± 0.35)	95/100	Stakeholder consultation
	Clinicians should identify and, when possible, treat causes of agitation.	103, 100 % (CI 96–100), 5 (0), 4.97 (±0.16)	89/99	[65,66,67,74,76]

**Table 6**  
Theme 4: Caregiver behaviours and developing trusting relationships.

Recommendation	N, Consensus <sup>a</sup> (CI), Median (IQR), Mean (± SD)	Feasibility/Importance (%)	Origin of evidence
Develop a relationship with the patient based on empathy, respect and trust.	114, 95 % (CI 89–98) 5 (0), 4.73 (± 0.55)	98/99	[65,70,74,75,77,78].
Become familiar with the patient's background (e.g., likes, dislikes, culture, history, values, fears and routines).	113, 99 % (CI 95–100) 5 (0), 4.86 (± 0.38)	94/98	Stakeholder consultation
Clinicians should be trained to use de-escalation techniques.	106, 99 % (CI 95–100) 5 (0), 4.89 (±0.40)	92/97	[65,66,67,74,75]
Use clear and concise language.	114, 96 % (CI 90–98) 5 (1), 4.65 (±0.68)	99/98	[65,74,75].
Use "active listening".	113, 93 % (CI 0.96–87) 5 (1), 4.61 (± 0.67)	96/96	[65,74,75].
Use alternative communication methods.	109, 95 % (CI 0.89–0.97), 5 (1), 4.47 (±0.75)	93/94	Stakeholder consultation

last in the line of options. Otherwise, the agitation will most likely just occur again when you stop sedating – and it will keep happening, at least until the patient has become so weak that he does not have the strength to be agitated anymore” (Danish physician, ID 2033).

Special attention should be paid to unmet needs, as these could lead to agitation. A patient illustrated how unrecognised pain and an uncomfortable position led to agitation:

“They [nurses] thought I purposely tried to annoy them...but I was lying uncomfortably with my right leg, and I couldn't talk...they gave me a drug to make me relax. They didn't consider that perhaps there was another reason for my agitation...I struggled with pain in my leg for a long time after the incident” (Danish patient, ID 2003).

**Theme 4 Caregiver behaviors and developing trusting relationships**

This theme includes six recommendations (see Table 6). Participants explained how non-pharmacological strategies were more likely to have an effect when patients trusted healthcare professionals and when these professionals had a holistic understanding of the patient, their needs, likes and dislikes. Effective communication was seen as crucial in making patients feel heard, seen and encouraged to express their needs.

**Table 7**  
Theme 5: Family involvement.

Category	Recommendation	N, Consensus <sup>a</sup> (CI), Median (IQR), Mean (± SD)	Feasibility/Importance (%)	Origin of evidence
Communication with families	Clinicians should establish how much the family would like to and are able to be involved in managing patient agitation	113, 89 % (CI 81–93), 5 (1) 4.52 (±0.80)	95/97	Stakeholder consultation [67]
	Clinicians should offer family members information about agitation	114, 98 % (CI 94–100), 5 (0) 4.85 (±0.50)	99/95	
Family in care	Teach family members/next of kin to use non-drug strategies.	109, 91 % (CI 84–95), 5 (1), 4.48 (± 0.74)	80/92	Stakeholder consultation [70,77,78]
	Involve family members/next of kin in care.	114, 90 % (CI 85–96), 5 (0), 4.39 (±0.72)	77/86	
	Use telephone and/or video conferencing when family members/next of kin are unable to visit the patient in person.	96, 83 % (CI 75–95), 4 (1), 4.19 (±1.03)	89/94	

Participants also noted that certain staff behaviours could trigger agitation. Negative behaviours included speaking over the heads of patients in a non-confidential manner, arguing, being 'bossy', shouting, ignoring, not listening or involving patients, standing over them and mirroring their agitated behaviours. An Australian family member shared:

“Sadly, some staff seem only to be clinical and abrupt, and this can, in fact, escalate distress and agitation in patients” (Australian family member, ID 1063).

Due to reduced levels of consciousness, confusion, and mechanical ventilation, communication with agitated ICU patients requires staff to use clear and concise language and sometimes alternative communication methods.

**Theme 5 Family involvement**

This theme includes five recommendations and describes the importance of partnering with families (see Table 7). Participants emphasised how relatives helped patients through their ICU stay by providing critical information about patient preferences and needs and by making patients feel safe. A patient explained:

“But if they had talked to my husband and asked what I was like as a person, then they would have known that I have difficulties with such things” (Danish patient, ID 2003).

Not all families had capacity to be involved, and some could exacerbate patient agitation or feel unnecessary responsibility and guilt.

“It is easy to put undue stress on the family, who may feel that they are 'letting the patient down' if they feel they can't do what is asked” (Australian nurse, ID 1012).

While family involvement in care reached a high level of consensus in both countries, some Danish participants emphasised that family members should not assume caregiving roles or engage in personal care activities, as this could compromise their identity as relatives, such as a spouse or parent, and potentially undermine the patient's dignity and well-being. As a Danish physiotherapist explained:

“Culturally, in Denmark, we do not have a tradition of involving relatives in tasks related to personal care, out of respect for the patient's dignity and long-term wellbeing” (Danish physiotherapist, ID 2029).

Another added:

“I mostly recommend family members not being involved in care, their primary purpose is to be family members when they are visiting” (Danish physiotherapist, ID 2043).

**Theme 6 Psychosocial needs**

Theme six includes 22 recommendations focusing on helping patients feel safe, comfortable, empowered, relaxed and re-orientated (see Table 8). Participants described how reassurance and being present signalled care and connection, while consistent care from the same team provided stability and continuity. Empowering and involving patients in their care made it more meaningful and supported their confidence. It was explained how supporting comfort and relaxation also reduces

**Table 8**  
Theme 6: Psychosocial needs.

Category	Recommendation	N, Consensus <sup>a</sup> (CI), Median (IQR), Mean ( $\pm$ SD)	Feasibility/ Importance (%)	Origin of evidence	Potential harms
Help patients to feel safe	Reassure the patient that they are safe.	114, 94 % (CI 88–97), 5 (0), 4.46 ( $\pm$ 0.61)	99/96	[70,73,75,77,78].	
	Hold a patient's hand.	114, 89 % (CI 81–93), 4 (1), 4.3 ( $\pm$ 0.80)	94/83	[77]	
Empower the patient	Involve patients in personal care activities.	111, 92 % (CI 85–96), 5 (0), 4.49 ( $\pm$ 0.72)	91/95	[70,73,74,75,77,78,79]	
	Debrief the capable patient after an episode of agitation.	85, 88 % (CI 80–93), 5 (0), 4.46 ( $\pm$ 0.81)	85/89	[65,74,75].	
	Use neuropaedagogy.	45, 82 % (CI 69–91), 5 (1), 4.24 ( $\pm$ 0.96)	72/69	Delphi	
	Involve a psychologist or psychiatrist in the treatment plan.	91, 77 % (CI 67–84), 4 (1), 4.13 ( $\pm$ 0.96)	51/70	[67]	
	Respect patients' need for personal space.	112, 94 % (CI 88–97), 5 (0), 4.69 ( $\pm$ 0.59)	85/95	[65,66,73,75]	Respecting personal space is not always feasible, as close proximity may be necessary to prevent the removal of life-saving equipment or to calm patients.
	Ensure patient dignity.	113, 99 % (CI 95–100), 5 (0), 4.83 ( $\pm$ 0.40)	97/99	[73]	
Comfort and relaxation	Ensure comfortable surroundings (i.e. by optimising room temperature, ventilation and/or design).	106, 84 % (CI 76–100), 5 (1), 4.41 ( $\pm$ 0.80)	73/94	[65,66,75]	
	Offer a fidget toy.	80, 83 % (CI 73–89), 4 (1), 4.11 ( $\pm$ 0.87)	73/74	Stakeholder consultation	Objects, like fidget toys, can become projectiles or infection sources.
	Play classical or relaxing music, preferably adjusted to patient preferences.	99, 89 % (CI 81–94), 4 (1), 4.23 ( $\pm$ 0.81)	85/84	[80,81]	
	Take the patient outdoors.	105, 92 % (CI 86–96), 5 (1), 4.52 ( $\pm$ 0.80)	70/86	Stakeholder consultation	Taking very agitated patients outside can be dangerous for both clinicians and patients.
	Use pet therapy.	79, 86 % (CI 77–92), 5 (1), 4.29 ( $\pm$ 0.95)	42/78	Stakeholder consultation	Pet therapy can pose infection and allergy risks
	Use therapeutic touch.	102, 82 % (CI 74–89), 4 (1), 4.09 ( $\pm$ 0.91)	89/81	[77,78,82]	
Re-orientation	Inform the patient about the plan for the day.	113, 88 % (CI 80–92), 4 (1), 4.4 ( $\pm$ 0.80)	95/95	Stakeholder consultation	
	Use a personalised fixed daily schedule with familiar activities.	105, 89 % (CI 81–93), 5 (1), 4.38 ( $\pm$ 0.89)	82/87	Stakeholder consultation	
	Irrespective of how much the patient appears to understand, explain to them their circumstances.	113, 95 % (CI 98–98), 5 (0), 4.48 ( $\pm$ 0.72)	96/94	[70,75,77,78]	
	Use hearing aids in the hearing-impaired patient.	106, 100 % (CI 97–100), 5 (0), 4.92 ( $\pm$ 0.24)	98/99	Stakeholder consultation	
	Use visual aids in the vision-impaired patient.	106, 97 % (CI 92–99), 5 (0), 4.83 ( $\pm$ 0.45)	100/98	Stakeholder consultation	
	Use appropriate lighting adjusted according to the time of the day.	109, 97 % (CI 92–99), 5 (0), 4.77 ( $\pm$ 0.63)	93/98	[65]	
	Create familiar surroundings (e.g. with pictures or other items from the patient's home).	111, 94 % (CI 88–97), 5 (1), 4.5 ( $\pm$ 0.65)	94/93	Stakeholder consultation	
Have a clock and calendar visible to the patient.	111, 93 % (CI 86–96), 5 (1), 4.62 ( $\pm$ 0.64)	94/98	[65]		

patient agitation, sometimes through distraction and keeping restless bodies occupied. Interventions such as music tailored to patient preferences, fidget toys, pet therapy, therapeutic touch or taking the patient outdoors were described as useful for reducing agitation. An Australian nurse explained:

*“Taking them out to an open space and getting some sun exposure during the morning will help improve their mood and, somehow, calm patients down and improve their behaviours”* (Australian nurse, ID 1044).

Re-orientation strategies included informing patients about the daily plan, offering information, and creating familiar surroundings. Tools like hearing aids, visual aids, appropriate lighting, and visible clocks and

calendars were also essential. A physician explained the importance of using re-orientation strategies:

*“Sensory deficits may decrease the patient's awareness and understanding of their surroundings, increasing distress and potentially making them appear agitated or non-compliant”* (Australian physician, ID 1070).

#### Theme 7 Physical needs

This theme includes eight recommendations (see Table 9). Supporting patients in being physically active was seen as important for preventing agitation by improving sleep while also calming, distracting, and stimulating them. A physiotherapist explained:

**Table 9**

Theme 7: Physical needs.

Category	Recommendation	N, Consensus <sup>a</sup> (CI), Median (IQR), Mean ( $\pm$ SD)	Feasibility/ Importance (%)	Origin of evidence	Potential harms
Mobilise patients	Support capable patients to be physically active (e.g. by supporting patients to sit on the edge of the bed or take small walks)	113, 99 % (CI 95–100), 5 (0) 4.78 ( $\pm$ 0.44)	92/99	Stakeholder consultation	
Ensure the right level of stimuli	Minimise unnecessary stimuli.	104, 97 % (CI 92–99), 5 (1), 4.68 ( $\pm$ 0.60)	80/98	Delphi	
	Group care and treatment activities, rather than disturbing the patient several times.	113, 96 % (CI 90–98), 5 (0), 4.72 ( $\pm$ 0.55)	92/97	Stakeholder consultation	
	Clinicians should minimise routine interventions and monitoring that are less important to the outcomes of patients (stimuli can be auditory, e.g. sounds, visual, e.g. lights or moving objects, tactile, e.g. lines or equipment, social, e.g. interacting with people)	102, 87 % (CI 79–92), 5 (1), 4.46 ( $\pm$ 0.94)	92/90	Stakeholder consultation	Minimising routine interventions can be fatal if not done carefully.
Promote sleep	Offer quiet surroundings for the patient, for example a single bed room.	112, 95 % (CI 89–98), 5 (0), 4.71 ( $\pm$ 0.61)	83/95	Stakeholder consultation	Moving hemodynamically unstable patients can be dangerous for both clinicians and patients.
	Use mental stimulation such as Lego, jigsaws, radio, TV, internet, magazines, pictures <sup>1</sup>	101, 88 % (CI 80–93), 4 (1), 4.21 ( $\pm$ 0.78)	80/85	Stakeholder consultation	Too much stimulation may result in increased agitation
Promote sleep	Preserve patients' usual sleep-wake cycle.	103, 98 % (CI 93–99), 5 (1), 4.68 ( $\pm$ 0.55)	80/97	[5,67,78]	
	Minimise interruptions at night from noise, light and activities.	114, 100 % (CI 97–100), 5 (0), 4.94 ( $\pm$ 0.24)	91/100	[70]	

<sup>1</sup>Re-rated recommendation.**Table 10**

Theme 8: Individualised care.

Category	Recommendation	N, Consensus <sup>a</sup> (CI), Median (IQR), Mean ( $\pm$ SD)	Feasibility/ Importance (%)	Origin of evidence
Importance of individualised care	Develop care plans based on patient preferences and values.	105, 91 % (CI 85–95) 5 (0), 4.61 ( $\pm$ 0.74)	88/93	[73,74,75,79].
	Non-pharmacological interventions must be adjusted to the individual patient (e.g., patient needs, history, preferences, level of agitation, previous experiences).	106, 100 % (CI 97–100), 5 (0), 4.89 ( $\pm$ 0.32)	94/97	Delphi

**Table 11**

Theme 9: Interventions related to the context.

Category	Recommendation	N, Consensus <sup>a</sup> (CI), Median (IQR), Mean ( $\pm$ SD)	Feasibility/ Importance (%)	Origin of evidence
Staff support	Additional staffing should be considered when there is an agitated patient in the ICU.	103, 95 % (CI 89–98), 5 (0), 4.64 ( $\pm$ 0.54)	64/96	[67,75]
	Staff caring for agitated patients should be offered debriefing.	103, 86 % (CI 78–92), 5 (1), 4.47 ( $\pm$ 0.94)	79/89	[65,70,74,75]
	Clinicians who provide care and treatment for agitated patients should be offered frequent breaks during their shift.	106, 99 % (CI 95–100), 5 (0), 4.82 ( $\pm$ 0.41)	60/94	Delphi
Leadership support	Ongoing staff education about agitation and methods to reduce agitation should be provided.	102, 98 % (CI 93–99), 5 (0), 4.88 ( $\pm$ 0.43)	88 /97	[65,66,67,75,77].
	Nursing and medical leaders should support the use of non-drug interventions to reduce and manage agitation.	103, 93 % (CI 97–97), 5 (0), 4.64 ( $\pm$ 0.83)	99/98	Stakeholder consultation
Multi-disciplinary team collaboration	The multi-disciplinary team should collaborate to reduce and manage patient agitation.	103, 99 % (CI 95–100), 5 (0), 4.92 ( $\pm$ 0.54)	99/100	Stakeholder consultation

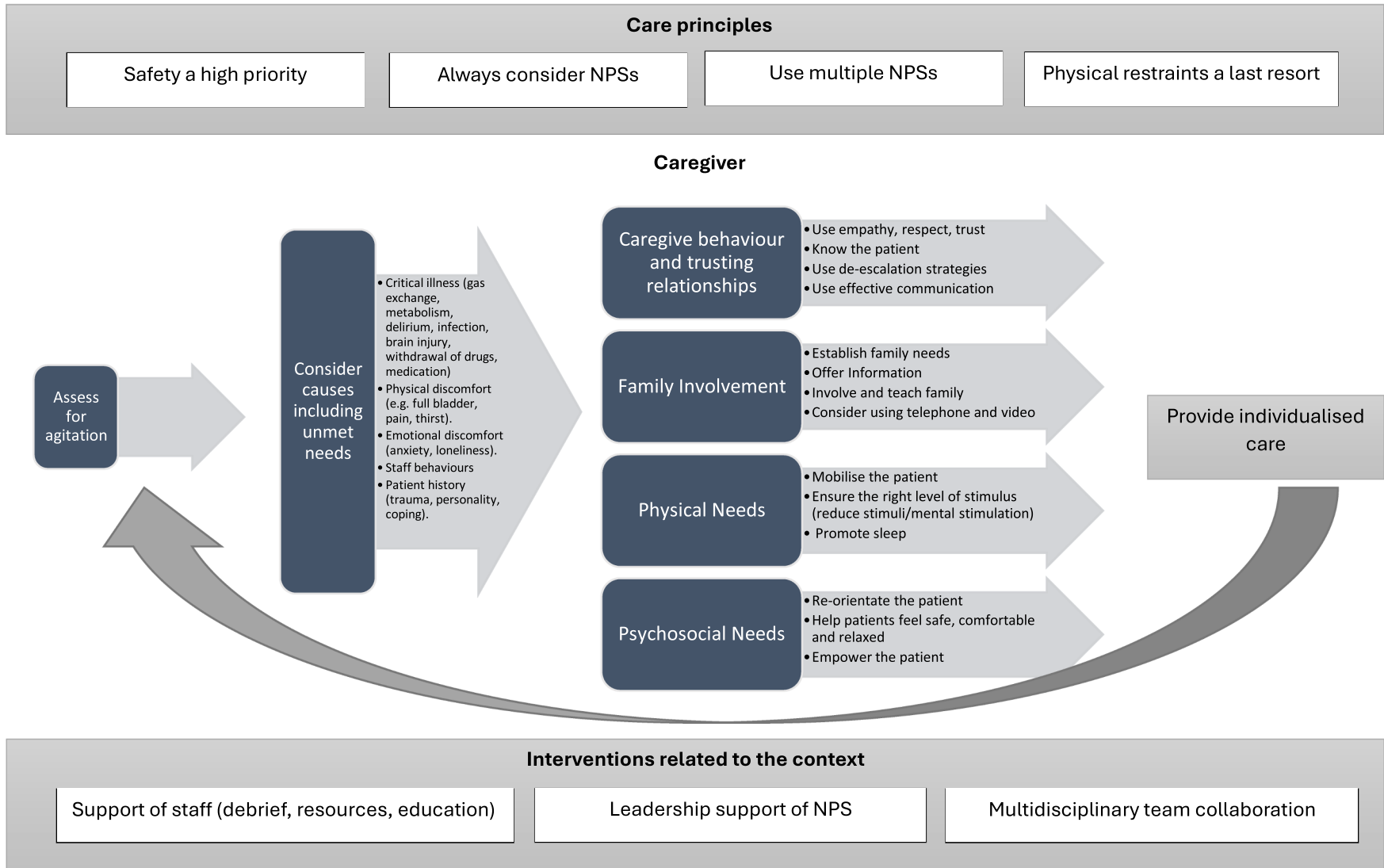


Fig. 2. Model for non-pharmacological prevention and management of patient agitation in the ICU.

**Table 12**  
Importance of interventions.

Item	Not important at all % (count)	Not very important % (count)	Neutral % (count)	Somewhat important % (count)	Very important % (count)
Fidget toy	0.0 % (n = 0)	2.2 % (n = 2)	23.3 % (n = 21)	37.8 % (n = 34)	36.7 % (n = 33)
Neuropaedagogy	1.6 % (n = 1)	0.0 % (n = 0)	29.5 % (n = 18)	29.5 % (n = 18)	39.3 % (n = 24)
Involving a psychologist or psychiatrist	2.2 % (n = 2)	6.5 % (n = 6)	21.7 % (n = 20)	32.6 % (n = 30)	37.0 % (n = 34)

**Table 13**  
Feasibility of interventions.

	Not feasible at all % (count)	Not very feasible % (count)	Neutral % (count)	Somewhat feasible % (count)	Very feasible % (count)
Offer a fidget toy	2.5 % (n = 2)	7.6 % (n = 6)	16.5 % (n = 13)	35.4 % (n = 28)	38.0 % (n = 30)
Comfortable surroundings	1.1 % (n = 1)	11.2 % (n = 10)	14.6 % (n = 13)	40.4 % (n = 36)	32.6 % (n = 29)
Neuropaedagogy	0.0 % (n = 0)	5.6 % (n = 2)	22.2 % (n = 8)	38.9 % (n = 14)	33.3 % (n = 12)
Patient outdoors	3.4 % (n = 3)	17.0 % (n = 15)	9.1 % (n = 8)	52.3 % (n = 46)	18.2 % (n = 16)
ICU layout	4.4 % (n = 4)	15.6 % (n = 14)	15.6 % (n = 14)	41.1 % (n = 37)	23.3 % (n = 21)
Trauma-informed care	2.6 % (n = 1)	12.8 % (n = 5)	20.5 % (n = 8)	41.0 % (n = 16)	23.1 % (n = 9)
Additional staffing	4.5 % (n = 4)	23.9 % (n = 21)	8.0 % (n = 7)	44.3 % (n = 39)	19.3 % (n = 17)
Frequent breaks	3.4 % (n = 3)	21.6 % (n = 19)	14.8 % (n = 13)	44.3 % (n = 39)	15.9 % (n = 14)
Involve a psychologist or psychiatrist	6.3 % (n = 5)	27.8 % (n = 22)	15.2 % (n = 12)	38.0 % (n = 30)	12.7 % (n = 10)
Pet therapy	10.3 % (n = 8)	30.8 % (n = 24)	16.7 % (n = 13)	29.5 % (n = 23)	12.8 % (n = 10)

**Table 14**  
Items with significant differences between stakeholder groups.

Group	Item	Kruskal Wallis (H)	p Value	Eta squared ( $\eta^2$ )	Effect size (d)	Rating compared to other groups
Nurses	Additional staffing	18.55	<0.001	0.148	0.835	Higher
	Staff rotation	21.16	<0.001	0.183	0.948	Higher
	Debriefing	11.70	0.008	0.088	0.621	Higher
	Prioritising safety	11.07	0.026	0.065	0.527	Higher
	Maintaining a safe distance	19.48	<0.001	0.142	0.814	Higher
Physicians	Developing a relationship w. the patient	17.10	0.002	0.12	0.739	Lower
	Using alternative communication methods	17.98	0.001	0.134	0.788	Lower
	Neuropaedagogy	14.06	0.003	0.252	1.159	Lower
Researchers	Developing care plans based on patient preferences	13.36	0.01	0.094	0.643	Lower
	Checking that aggressive and violent agitated patients do not have access to objects	12.38	0.015	0.085	0.608	Lower
Patients/ Families	Comfortable surroundings	21.06	<0.001	0.169	0.902	Higher
	Mental stimulation	10.61	0.031	0.066	0.532	Higher

“Supporting even very weak patients to a sitting position on a firm surface, of course, with massive support and firm ground under their feet, can calm down a patient. They can feel their body in a different position than the lying” (Danish physiotherapist, ID 2042).

Ensuring the right level of stimuli was also seen as important. This involved protecting patients from unnecessary stimuli and promoting sleep, rest and privacy. An Australian nurse highlighted:

“Routine invasive devices or procedures such as IDCs [indwelling urinary catheter], arterial lines, 12 lead monitoring, daily bloods, SpO<sub>2</sub> [pulse oximetry] monitoring should be carefully considered – are they actually necessary?” (Australian nurse, ID 1082).

#### Theme 8 Individualised care.

This theme includes two recommendations (see Table 10). Multiple participants described how the effectiveness of non-pharmacological strategies always depended on the individual patient. Factors such as the level of critical illness, patient preferences and values, previous experiences, level of agitation and mood on a specific day all played a crucial role. A Danish nurse highlighted:

“We need to think of the individual patient, their needs and experiences. What works one day may not work the next. Music may work for 20 min one day but perhaps only 10 min the next day. Playing music for someone who normally does not appreciate music may not work at all” (Danish nurse, ID 2018).

#### Theme 9 Interventions relating to the context

This theme includes six recommendations (see Table 11). The consideration of additional staff, frequent breaks, debriefing of staff, staff education, leadership support for non-pharmacological strategies, and a multi-disciplinary approach to agitation all reached a high level of consensus. Participants highlighted the physical and mental exhaustion involved in caring for hyperactive, delirious patients. A Danish nurse noted:

“It is very physically and mentally draining to care for a hyperactive, delirious patient and one’s energy and strength quickly get depleted. Breaks and perhaps rotation of staff are important” (Danish nurse, ID 2018).

Adequate staffing was deemed essential for the successful implementation of non-pharmacological strategies. An Australian physician emphasised:

“Staffing ratios are perhaps the most important aspect of management, as without adequate staffing, there is no ability to deliver non-pharmacological interventions”. (Australian physician, ID 1052).

The nine themes presented above form an integrated model of care (Fig. 2) that can support clinical decision-making in the non-pharmacological prevention and management of agitation in the ICU. The model outlines core care principles, key caregiver actions, and contextual factors that influence implementation.

### Harms or special considerations of the included recommendations

The open-ended questions suggested that while most non-pharmacological strategies were perceived as safe, some were described as being potentially harmful if not considered carefully. These considerations are all described in Tables 3, 8 and 9. Participants also emphasised the importance of considering individual patient and family needs to avoid exacerbating agitation. Family involvement, phone and video conferences, holding a patient's hand, using music or therapeutic touch and informing patients about the day can all potentially trigger agitation. Establishing familiar surroundings can lead to clutter and infection control issues. Visible clocks can disturb sleep and grouping activities can exhaust and agitate patients. Mental stimulation might result in overstimulation and preserving usual sleep-wake cycles can be detrimental if patients need more sleep. Additionally, care based on patient preferences may not always align with what is best for the patient, such as not brushing teeth or mobilising if patients prefer not to.

### Importance and feasibility of interventions

While most interventions were seen as both important and feasible, some received lower ratings (see Tables 12 and 13). Open-ended questions explained how interventions were seen as less feasible due to resource restraints, local regulations, ICU layout and concerns relating to the risk of infection or staff injury. It is less clear why some interventions were seen as less important. However, some participants explained how involving a psychologist or psychiatrist was seen as less important since they sometimes struggled to understand the ICU environment and only offered treatment to patients who could communicate verbally.

### Barriers and facilitators to implementation

The main barriers to guideline implementation were lack of time ( $n = 95$ , 93 %) and changing existing habits ( $n = 96$ , 85 %). Inadequate equipment and facilities were more significant barriers in Australia ( $n = 61$ , 87 %) than in Denmark ( $n = 34$ , 71 %). Conversely, lack of trust in the guidelines was a greater barrier in Denmark ( $n = 35$ , 74 %) compared to Australia ( $n = 60$ , 50 %). Other barriers included staff lack of confidence in non-pharmacological strategies ( $n = 96$ , 73 %) and the belief that non-pharmacological strategies are resource intensive ( $n = 95$ , 75 %). Facilitators rated highly by both Danish and Australian participants included a user-friendly design of the guidelines ( $n = 95$ , 98 %), a clear plan for implementation and follow-up ( $n = 96$ , 98 %), a clear outline of the strength of the recommendation ( $n = 96$ , 92 %), supportive leadership ( $n = 96$ , 99 %), collaboration between multi-disciplinary team members ( $n = 96$ , 100 %) and a dedicated group of clinicians to support implementation ( $n = 95$ , 98 %).

### Significant differences between Australia and Denmark

While Danish and Australian participants agreed on most recommendations, notable discrepancies existed.<sup>7</sup> Bed bikes (31.3 %,  $z = 2.5$ ,  $p = 0.02$ , 95 % CI 0.07–0.56), basal stimulation (12.1 %,  $z = 2.1$ ,  $p = 0.03$ , 95 % CI 0.03–0.5), therapeutic weighted blankets (18.1 %,  $z = 1.9$ ,  $p = 0.05$ , 95 % CI 0.002 – 0.41) and 'the same staff should be allocated to care for the patient' (29.5 %,  $z = 3.4$ ,  $p = 0.001$ , 95 % CI 0.12–0.46) received significantly higher ratings in Denmark compared with Australia. Meanwhile, 'it is a good idea to rotate staff' (29.6 %,  $z = 3.4$ ,  $p = 0.001$ , 95 % CI 0.12–0.47) and trauma-informed care (44 %,  $z = 3.2$ ,  $p = 0.002$ , 95 % CI 0.17–0.70) received significantly higher ratings in Australia.

<sup>7</sup> It items were presented in two rounds, results of the second round are presented.

### Differences between stakeholder groups

The study also identified significant discrepancies between stakeholder groups (see Table 14). For example, nurses rated items related to staffing and safety higher than other stakeholder groups. One explanation may be that it is often nurses who, with their continuous presence next to the bed, are those managing agitation. Other ICU clinicians, patients and families may not fully understand the demanding nature of caring for agitated patients. Physicians, on the other hand, rated developing relationships with the patient, using alternative communication methods and neuropaedagogy lower. ICU physicians have limited time available for each patient, thus they may have seen these interventions as less useful. It is unclear why researchers rated developing care plans and checking patients do not have access to objects that can be thrown lower than other groups. Finally, the findings also suggest that patients and family members may value some interventions differently from other stakeholder groups including comfortable surroundings and mental stimulation.

### Discussion

This three-round Delphi study resulted in 63 preliminary guideline recommendations for the non-pharmacological management of patient agitation in the ICU. The study highlights the importance of fostering trusting relationships, addressing both the physical and psychosocial needs of patients and recognising the organisational support necessary to successfully implement interventions. These strategies align with the Fundamentals of Care framework [28,29], reflecting the importance of providing comprehensive person centred fundamental care for agitated patients in the ICU.

This Delphi study highlights the challenges of ensuring continuity of care for patients who are agitated in the ICU while also balancing staff wellbeing. The recommendation 'the same staff should be allocated to care for the patient' reached consensus only in Denmark. It was described how caring for the same patient helped staff to better understand patient needs and preferences, fostered trust and ultimately helped to minimise agitation. The existing literature also suggests that continuity of care is essential for developing trusting clinician-patient relationships and ensuring the provision of patient-centred care [83,84,85]. In contrast, Australian participants raised concerns about the risk of burnout and fatigue from assigning nursing staff to the same patient for extended periods. Notably, the recommendation 'it is a good idea to rotate staff' reached consensus only in Australia. Burnout among ICU healthcare workers is well-documented with a recent systematic review [86], involving 20,723 healthcare workers, reporting burnout rates of 42 % among ICU physicians and 45 % among ICU nurses. This high rate of burnout can have serious consequences for patient safety, quality of care and staff retention [86]. Given the potential for staff burnout, it is crucial to explore strategies that balance the need for continuity of care with measures to prevent clinician fatigue. Some Danish participants described how they implemented a team based approach, where a team of clinicians rotates to care for the same patient, distributing the workload and reducing individual burnout. This model warrants further investigation to evaluate its effectiveness in balancing patient and staff needs in ICU settings.

Several participants in this Delphi study, including patients and family members, expressed concerns that the use of personal restraints could exacerbate agitation. Danish participants noted that physical restraints were not used in Danish ICUs, while Australian participants acknowledged their occasional necessity to facilitate staff breaks or complete clinical tasks while ensuring patient safety. This difference in perceptions is not surprising, as approximately 7–8 % of Australian ICUs report using physical restraints [87,88,89,90], whereas Danish ICUs

consistently do not [91,92,93]. Although physical restraint is common in ICUs worldwide [94], similar to Denmark, it is not standard practice in countries like Norway [95], Portugal and the UK [96]. A qualitative study by Perez [90] involving interviews with five patients and six family members revealed that physical restraints often led to feelings of fear, anguish, helplessness and a lack of trust. Participants reported being deprived of basic human instincts, such as hugging or wiping away tears, contributing to a sense of loss and distress. Additionally, all participants experienced post-traumatic stress symptoms and family members reported significant emotional trauma from witnessing restraints [90]. Given the negative emotional and psychological consequences associated with physical restraints, it is argued that such practices are not consistent with a patient-centered approach to care. The use of physical restraints undermines the development of trusting relationships and has shown to increase agitation while also negatively affecting overall outcomes for patients [97]. Therefore, alternatives to physical restraints, such as ensuring patient safety, comfort, empowerment, adjusting stimuli and involving family, should be prioritised in managing ICU agitation.

This study identified several perceived barriers to implementing non-pharmacological management of agitation, including lack of time and resources. Notably, the majority of non-pharmacological strategies in this study were found to be feasible, low-risk, and low-resource demanding. Multiple interventions, such as developing trusting relationships, creative supportive environments and involving family, can be integrated into standard care as they do not necessarily require more resources [98]. Although sedation may seem quicker, it does not address underlying causes, leading to recurrent issues and prolonged recovery times [99]. While medication can be important for patient comfort and safety, clinicians should also be aware of and utilise alternative strategies. Educating staff on the long-term benefits of non-pharmacological strategies, such as better patient outcomes and shorter ICU stays, can help shift the focus towards these approaches, ultimately saving time and resources.

Both the PADIS guidelines [23], focusing on pain, agitation/sedation, delirium, immobility and sleep, and the CALM ICU guidelines are grounded in rigorous methodologies and systematic reviews. However, a key difference lies in how each guideline development process responded to gaps in the evidence. When PADIS guideline developers were unable to identify primary quantitative studies, they refrained from making recommendations. In contrast, our approach incorporated not only quantitative evidence but also qualitative evidence, existing guidelines from other healthcare settings, and extensive stakeholder input. To strengthen the validity of our findings, we tested and refined the recommendations through a large Delphi study conducted across two countries. As a result, the CALM ICU guidelines offer preliminary recommendations that address an important gap in the literature and provide a foundation for future research and practice development in the non-pharmacological management of agitation in the ICU.

#### *Implications for future practice and research*

This Delphi study underscores the urgent need for further research on non-pharmacological strategies for managing patient agitation in the ICU. More research is needed to fully understand current practices and potential barriers to guideline implementation. The role of continuity of care and the methods to maintain this while preventing staff burnout, warrants additional investigation. The preliminary guidelines identified in this study need to be tailored to local contexts, graded and reviewed by methodological experts and stakeholders before being finalised and published. Clinicians who want to implement the guidelines in their unique workplace must determine whether to include items that received agreement in only one country and those with lower ratings

regarding feasibility and importance. Although the GRADE handbook advises against recommending interventions with lower feasibility [100], it can be argued that certain practices, such as using a fidget toy, can be prioritised at a low cost and made feasible. Therefore, such interventions may warrant inclusion in the final guidelines.

#### **Strengths and limitations**

This Delphi study is a rigorously designed study offering preliminary recommendations that can complement the existing PADIS guidelines [23]. The study had a substantial participant pool and a high response rate. The inclusion of experiences and perspectives from various healthcare professionals, patients and family members enhances the comprehensiveness, robustness and validity of the findings.

Several limitations should be acknowledged. Firstly, the guidelines are preliminary and require grading, stakeholder consultation on the final draft and methodological reviews as per NHMRC (NHMRC) [25] and the Danish Health Authority [26] manuals before they can be finalised.

One limitation is response bias, with the majority of participants being ICU nurses. Different recommendations might have emerged with a more diverse range of participants. However, it is important to note that the study included various other stakeholders, such as physicians, physiotherapists, occupational therapists, researchers, patients, and family members, whose perspectives were all considered throughout the project. Additionally, nurses, as primary caregivers for agitated patients, frequently engage with patients and for extended periods, making their perspectives particularly valuable.

Additionally, as an online Delphi study, this approach may have inadvertently excluded individuals without access to a computer or the internet, or those with limited reading, communication, or digital literacy skills. Due to logistical challenges and the distance between researchers and participants, face-to-face meetings were not feasible.

Finally, it must be acknowledged that the evidence underpinning the Delphi study is derived from studies of low methodological quality, qualitative research, and guidelines from outside the ICU. Consequently, the certainty of the recommendations is expected to be rated as low [101]. However, as identified during this project, there are inherent challenges in conducting rigorous studies in this field. Therefore, the preliminary recommendations are valuable as they build on the best available evidence and expert consensus from two countries.

#### **Conclusion**

This Delphi study provides valuable preliminary guidelines for the non-pharmacological prevention and management of agitation in adult ICU patients. The findings emphasise the importance of considering non-pharmacological strategies as a primary approach, utilising multiple interventions and prioritising patient safety, with physical restraints reserved only as a last resort. Key interventions include thorough agitation assessments, addressing underlying causes, building trusting clinician-patient relationships, optimising staff behaviors and involving families in care, while tailoring interventions to meet patients' physical and psychosocial needs. Additionally, successful implementation requires considering the broader context, including staff and leadership support, as well as fostering multi-disciplinary team collaboration. Notably, the study highlighted differences in the way recommendations were rated by participants from different countries and stakeholder groups, underscoring the influence of cultural and professional perspectives in shaping approaches to agitation management in the ICU. These findings lay the foundation for further research and refinement of guidelines that can enhance patient care in the ICU.

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## CRediT authorship contribution statement

**Anne Mette N. Adams:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Diane Chamberlain:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Charlotte Brun Thorup:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Mette Grønkvær:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Shalyn Rouke:** Writing – review & editing. **Tiffany Conroy:** Writing – review & editing, Supervision, Methodology, Investigation, Formal analysis, Conceptualization.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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