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Research paper

# Clinical practice guideline for nonpharmacological prevention and management of patient agitation in the adult intensive care unit (CALM ICU)☆

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ABSTRACT

*Background:* Agitation affects 32–70% of adult patients in the intensive care unit (ICU) and is associated with disruption of life-saving treatment, prolonged hospitalisation, and psychological trauma. While nonpharmacological interventions are increasingly encouraged to reduce the reliance on sedatives, existing guidelines predominantly focus on pharmacological management. This contributes to inconsistent practices and underutilisation of effective person-centred nonpharmacological alternatives.
*Objective:* The objective of this study was to develop evidence-based recommendations for the non-pharmacological prevention and management of patient agitation in the adult ICU.
*Method:* The clinical practice guideline for non-pharmacological prevention and management of patient agitation in the adult ICU (CALM ICU) was developed following the Australian National Health and Medical Research Council Guidelines for Guidelines and the Danish Health Authority's manual on guideline development. The process included stakeholder consultation with ICU clinicians, researchers, patients, and family members on the initial scope of the guideline, a systematic review and an umbrella review, a three-round modified Delphi study involving 114 participants from Denmark and Australia, and finally, stakeholder and methodological reviews of the draft guideline. The Grading of Recommendations Assessment, Development, and Evaluation approach was used to assess the certainty of the evidence.
*Results:* The guideline offers 14 recommendations, including four conditional recommendations and 10 consensus recommendations. These address early and systematic assessment, identifying and treating underlying causes of agitation, prioritising nonpharmacological interventions, and using multicomponent interventions. The recommendations also include using de-escalation strategies, reorientation, promoting sleep, adjusting stimuli, supporting comfort and relaxation, encouraging mobilisation, and involving family members. The guideline also includes two additional recommendations highlighting the importance of fundamental person-centred care and organisational support for ICU staff.
*Conclusions:* The CALM ICU guideline provides the best available evidence for reducing patient agitation through nonpharmacological strategies. It should be integrated into standard ICU care and serve as a foundation for education and practice. Further research is needed to strengthen the evidence base and

☆ This clinical practice guideline has been endorsed by the Australian College of Critical Care Nurses.

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explore implementation in diverse ICU settings. This guideline has been endorsed by the Australian College of Critical Care Nurses.
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## 1. Introduction

Patient agitation is a complex and common challenge in the intensive care unit (ICU), affecting 32–70% of patients.[1–5] It is characterised by a cluster of behaviours including excessive motor activity, emotional tension, cognitive impairment, disruption of care, and sometimes aggression and changes in vital signs[6].

Agitation can lead to serious consequences, including accidental extubation and dislodgement of life-sustaining devices,[6] disruption of treatment, and prolonged hospitalisation.[7,8] Agitation may also cause psychological trauma for patients, including fear, confusion, shame and guilt,[9,10] and distress for family members.[10–12] For ICU clinicians, managing agitation can contribute to burnout and increase the risk of injury.[13,14]

Agitation is typically multifactorial, arising from a combination of factors, including the patient's critical illness and its associated physiological disturbances such as hypoxia, metabolic imbalances, organ dysfunction, and drug withdrawal.[6] It may also be triggered by discomfort, pain, anxiety, unmet needs, psychiatric history and previous experiences, and even uncaring staff behaviours.[6] Understanding these drivers is essential for guiding targeted prevention and management strategies.

Management of agitation has evolved significantly over time. Historically, deep sedation was commonly used to facilitate mechanical ventilation. However, when not clinically indicated, deep sedation is associated with a higher risk of prolonged mechanical ventilation, extended ICU stays, and increased mortality,[15–19] delirium,[20,21] and agitation.[22] Over the last decade, guidelines have increasingly emphasised the importance of light sedation (Richmond Agitation-Sedation Scale [RASS] +1 and −2),[15,23] and recent studies show promising outcomes with no-sedation strategies.[24]

Despite these recommendations, many ICU patients continue to be oversedated.[25–27] Some ICU clinicians believe that sedation protects patients from psychological harm.[28,29] However, research shows that it is frightening ICU experiences and not factual memories that are associated with post-traumatic stress disorders.[30] Importantly, it has also been argued that reduced sedation approaches are more person centred, allowing patients to be more awake, communicate, and participate in care.[31] Another barrier to reducing sedation may be related to uncertainties around nonpharmacological approaches. Interventions such as massage therapy and animal-assisted interventions have shown promising results in other healthcare settings,[32] yet ICU clinicians often lack knowledge and confidence in using alternative strategies for addressing patient agitation.[14,33,34]

Existing ICU guidelines predominantly focus on the pharmacological management of agitation largely due to limited empirical evidence on nonpharmacological alternatives.[15] This gap can lead to ineffective and inconsistent practices, disagreements among interdisciplinary healthcare staff, inappropriate use of medication and physical restraints, and underutilisation of effective nonpharmacological interventions.[14,34,35] Agitation is often discussed within the context of delirium. While agitation and delirium often co-occur in the ICU,[36] they are distinct phenomena. Patients can be agitated without being delirious[37] and delirious without being agitated.[36] Current guidelines offer little tailored advice for managing agitation as a standalone issue, leaving clinicians without clear direction—especially for patients who fall outside the delirium spectrum.

In response to these challenges, this guideline provides evidence-based recommendations for the nonpharmacological prevention and management of patient agitation in the adult ICU. Developed collaboratively across Denmark and Australia, the clinical practice guideline for non-pharmacological prevention and management of patient agitation in the adult ICU (CALM ICU) draws on pooled expertise and contextual knowledge from both countries. This publication presents the version contextualised for Australian ICUs.

## 2. Methods

### 2.1. Overview of the clinical practice guideline development

The CALM ICU guideline was developed through a four-phase process (see Fig. 1) following the Australian National Health and Medical Research Council[38] and the Danish Health Authority's manuals for guideline development.[39] These manuals were chosen for their international recognition and rigorous standards, serving as cornerstones for evidence-based practices in both Denmark and Australia. The certainty of the evidence and the strength of the recommendations were assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach,[40] and the final guideline was reported following the Appraisal of Guidelines for Research and Evaluation (AGREE) II reporting checklist.[41]

The first phase involved initial **consultation on the scope** through workshops, written feedback, and interviews with stakeholders to define the scope of the guideline.[42] A guideline's scope outlines why the guidelines are needed, the areas it will cover, and what it intends to achieve.[43] This process included input from 36 nurses, five physicians, four researchers, two physiotherapists, one occupational therapist, and three patient representatives from Denmark and Australia. Their feedback confirmed the need and helped shape the clinical focus, target population, and priorities for the guideline.[42]

In the second phase, the team focused on **identifying the evidence**. We systematically identified and reviewed the existing literature to answer the following guideline question: *in the adult ICU, what nonpharmacological interventions should healthcare professionals use to prevent and manage patient agitation*? A systematic review[44] following Joanna Briggs Institute (JBI)'s Systematic Review of Effectiveness[45] was conducted to evaluate the effectiveness of nonpharmacological interventions for managing agitation in the ICU. Due to risk of bias and limited available evidence, a modified umbrella review following JBI's Umbrella Review[46] was also undertaken. This review synthesised existing guidelines from non-ICU settings and qualitative literature on patient experiences with agitation, providing a broader foundation for recommendation development. All searches were conducted with the support of a university-based librarian. The searches were carried out in 2021 and updated in 2024. See Supp 4 and 9 for an overview of

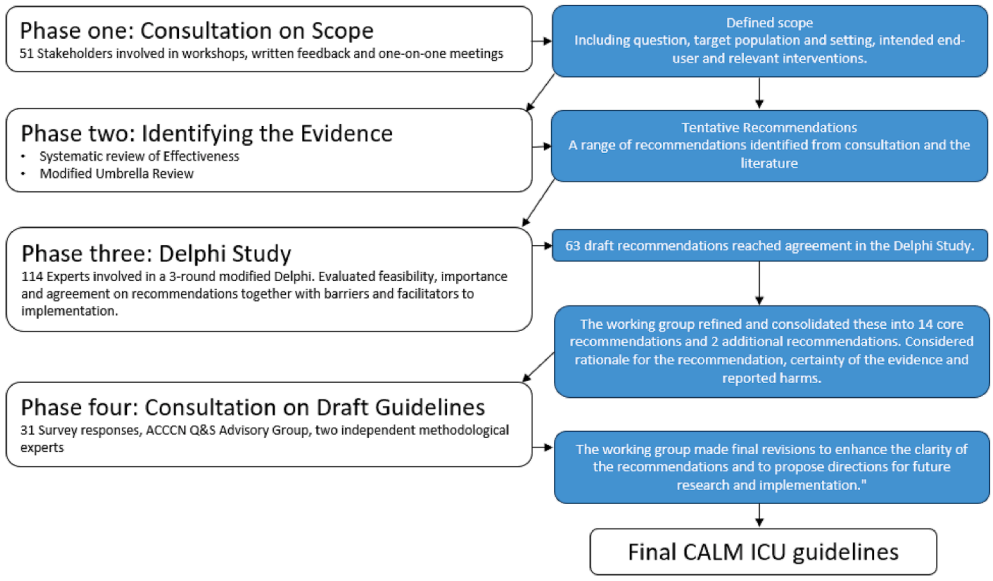


**Fig. 1.** Overview of the CALM ICU development process.

searches, critical appraisal, and extraction of data. A summary of the evidence can be found in Supp 11.

The third phase involved a **modified Delphi study** conducted in 2022.[47] The aim of this study was to determine which tentative recommendations would reach a high level of consensus among experts. The study also investigated the perceived feasibility and importance of interventions. An expert was defined as "a person who is very knowledgeable about or skilful in a particular area".[48] Experts included 11 patient representatives who had experienced patient agitation in the ICU, six researchers who had published in the field, and 10 ICU physicians, 74 nurses, and 15 allied health clinicians who all had at least 3 years of clinical experience, a managerial position in the ICU, or a postgraduate qualification in intensive care. The Delphi study received ethics approval from Central Adelaide Local Health Network (reference: 15710) and cross-institutional approval from the Flinders University Social and Behavioural Research Ethics Committee (ID 4928). A total of 114 participants from Denmark and Australia took part in the study. The first Delphi round included nonpharmacological interventions and recommendations to prevent and manage agitation identified in the initial consultation, systematic review, and modified umbrella review. The participants were also able to suggest additional interventions and evaluate if interventions were patient-centred and safe. All interventions were evaluated by the study investigators between Delphi rounds. A recommendation was endorsed if it reached consensus (interquartile range $\leq 1$), and the consensus level was $\geq$75% in both countries. Sixty-three recommendations reached consensus among the participants. All interventions that reached consensus in both countries were evaluated in terms of their importance and feasibility.[47] A summary of the Delphi study can be found in Supp 10 and a detailed overview in the published article.[47]

Before the final phase, the guideline working group grouped similar recommendations through an amalgamation process resulting in 14 consolidated core recommendations with sub-recommendations (see Table 5) and two additional recommendations (see Tables 6 and 7) that, while not directly answering the guideline question (see section 3.15), provide valuable insights into the importance of fundamental patient-centred care for this group of patients and organisational strategies for implementation.

The last phase involved **consultation** of the draft guideline by 31 Australian stakeholders (24 ICU nurses, one physician, one allied health, two patient representatives, one manager, one researcher, and one academic, the Australian College of Critical Care Nurses Quality and Safety Panel, and two independent methodological experts not involved in the development process). Feedback from these consultations was used to refine the recommendations, enhance clarity, and propose directions for future research and implementation. Supp 14 provides an overview of the feedback received, including AGREE II scores, and how the feedback was managed.

### 2.2. Working group and stakeholder involvement

The working group consisted of Danish and Australian ICU clinicians, researchers, guideline development experts, and a patient representative (see Supp 14 for more details). As described in point 2.1, stakeholder input was embedded throughout the process, with contributions informing the scope, evidence synthesis, recommendation development, and the final revisions. All members of the steering committee and stakeholders declared no conflicts of interest (see Supp 14 and 16).

The studies published by the steering committee include a systematic review of nonpharmacological interventions,[44] a concept analysis of ICU agitation,[6] a mixed-method study on ICU experiences of managing patient agitation in the ICU,[14] a methodology study on ethical and feasible stakeholder engagement in guideline development,[42] and a Delphi study.[47] More information on early stakeholder consultation and the modified umbrella review can be found in an unpublished open-access doctoral thesis.[49]

### 2.3. Health question covered by this guideline

What nonpharmacological interventions should be offered to adult patients in ICUs to prevent and manage agitation? (see Supp

8 for a detailed overview of the Population, Intervention, Comparison, Outcome (PICO) elements).

### 2.4. Target population and setting

This clinical guideline addresses adult patients (aged 18 years or older) admitted to an ICU.

### 2.5. Intended end-users

This guideline is intended to be used by clinicians who care for and treat patients in the adult ICU. Other intended users include educators, hospital leaders and managers, policy makers, funders, and organisations. Family members may also find the guideline useful, although a plain-language version should ideally be developed in the future.

### 2.6. Understanding the recommendations and the evidence behind them

The recommendations include *Conditional recommendations* and *Consensus recommendations* (see Table 1 for definitions of these). Each recommendation is presented with its rationale and the certainty of the supporting evidence.[m] In line with the Grading of Recommendations Assessment, Development and Evaluation approach,[40,50] certainty of the evidence reflects our overall confidence in the findings and their relevance to the guideline question, including both quantitative effect estimates and qualitative or consensus-based insights. It includes an assessment of limitations in the design or execution of the study (risk of bias), inconsistency (variation in study results), indirectness (applicability, generalisability, external validity, translatability, and transferability of research findings), imprecision (certainty in relation to effect estimates), and dissemination bias (selective reporting).[50] The certainty of the evidence is graded as high, moderate, low, or very low, as shown in Table 2.

The AGREE II tool[41] was used in this study to appraise the existing guidelines (see Supp 9), and it was used by methodological experts to appraise this guideline (see Supp 14). AGREE II evaluates six domains, including scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, and editorial independence.[41] Higher scores indicate stronger adherence to recognised standards of guideline development.

## 3. Recommendations

### 3.1. Early, regular, and systematic assessment

#### 3.1.1. Consensus recommendation

It is considered good practice to implement early, regular, and systematic assessments of ICU patients for agitation.

Early assessment refers to an initial evaluation performed as soon as clinically feasible after ICU admission using a validated tool such as the RASS scale.[51] Regular assessments should be performed at least once per shift (every 8–12 h) depending on the patient's condition, behaviours, and healthcare professional–initiated management of agitation.

#### 3.1.2. Rationale for the recommendation

This recommendation is based on the Delphi study. Early assessment of agitation helps prevent escalation and supports healthcare professionals in evaluating the effectiveness of implemented interventions. The recommendation originates from ICU guidelines[52,53] and guidelines established for health professionals outside the ICU setting.[54–57]

#### 3.1.3. Certainty of the evidence: very low

The AGREE II[41] scores for the guidelines were between 38% and 63%. The certainty of the evidence was rated as very low due to indirectness, risk of bias, and the limited availability of primary research evidence on this topic. As a result, the recommendation was evaluated in a Delphi study, where it achieved a high level of expert consensus.

### 3.2. Identifying and treating the cause of agitation

#### 3.2.1. Consensus recommendation

It is considered good practice to identify and, when possible, treat the causes of agitation.

#### 3.2.2. Subrecommendations

- Become familiar with the patient's background (e.g., likes, dislikes, culture, history, values, fears, and routines).
- Develop care plans based on the patient's preferences and values.

#### 3.2.3. Rationale for the recommendation

Various factors can trigger, cause, or minimise agitation.[6] Delphi participants agreed that it was helpful to understand, through the patient or their relatives, the patient's background, including their preferences, aversions, culture, medical history, values, fears, and routines, as well as their fundamental care needs. Multiple assessments, such as delirium, pain, and substance withdrawal assessments, may be needed to better understand causes of agitation. This recommendation is based on the Delphi study. It originates from an ICU guideline[52] and three guidelines developed for healthcare professionals outside the ICU.[54,55,58]

#### 3.2.4. Certainty of the evidence: very low

The AGREE II[41] scores of the guidelines ranged from 40% to 63 %. The certainty of the evidence was seen as very low due to risk of bias and limited primary research. The recommendation was subsequently evaluated through a Delphi study, where it reached high level of expert consensus.

### 3.3. Nonpharmacological strategies as the first choice

#### 3.3.1. Consensus recommendation

It is considered good practice to use nonpharmacological strategies before pharmacological treatment to manage agitation.

#### 3.3.2. Rationale for the recommendation

This recommendation is based on the Delphi study. While medication may be necessary for treating agitation, it should be a last resort after evaluating other treatment measures. The recommendation derives from three guidelines developed outside the ICU.[54,55,58] The working group also noted that nonpharmacological interventions typically have fewer side effects than medications[15–18,59] and that they often address the underlying causes of agitation rather than just the symptoms.[60,61]

#### 3.3.3. Certainty of the evidence: very low

The guidelines scored between 40% and 63% with the AGREE II tool.[41] The certainty of the evidence was downgraded due to risk of bias, indirectness, and limited primary evidence, so the

[m] A summary of the evidence can be found in Supplementary Material 11.

**Table 1**
Definitions of types of recommendations (see the full list of recommendations in supplementary material 2).

| Type of recommendation | Description |
|---|---|
| Strong recommendation | A strong recommendation is given when there is high-quality evidence showing that the overall benefits of the intervention clearly outweigh the disadvantages. This means that all, or almost all, patients will accept the recommended intervention. |
| Conditional recommendation | A conditional recommendation for the intervention is given when the benefits of the intervention are greater than the disadvantages or the available evidence cannot rule out a significant benefit of the intervention while it is assessed that the harmful effects are few or absent. This recommendation is also used when there is evidence that patients' preferences vary. |
| Consensus recommendation | Consensus recommendation is a good practice recommendation used when there is no or little relevant evidence and the recommendation reached agreement among experts in a large Delphi study. |

**Table 2**
Definitions of GRADE ratings of the certainty of the evidence (see the full basis for the recommendation in supplementary material 3).

| GRADE certainty of the evidence | Description |
|---|---|
| High | We are very confident that the true effect is close to the estimated effect. |
| Moderate | We are moderately confident in the estimated effect. The true effect is likely close to this, but there is a possibility that it is substantially different. |
| Low | We have limited confidence in the estimated effect. The true effect is likely to be substantially different from the estimated effect. |
| Very low | We have very little confidence in the estimated effect. The true effect is likely to be substantially different from the estimated effect. |

GRADE: Grading of Recommendations Assessment, Development and Evaluation.

recommendation was evaluated through a Delphi study, where it reached a high level of expert consensus.

### 3.4. De-escalation

#### 3.4.1. Consensus recommendation

It is considered good practice to use de-escalation techniques to minimise agitation.

De-escalation techniques involve the use of verbal and nonverbal communication to help calm patients and prevent a situation from becoming more intense or violent.

#### 3.4.2. Subrecommendations

- Prioritise the safety of patients, staff, and relatives when managing agitation.
- Ensure that patients who are aggressive and violent do not have access to objects that can cause harm to themselves or others (e.g., sharp objects, weapons, or hard objects that can be thrown).
- Maintain a physical safety distance from patients who are violent.
- Develop a relationship with the patient based on empathy, respect, and trust.
- Respect the patient's need for privacy.

#### 3.4.3. Rationale for the recommendation

This recommendation is based on the Delphi study. Delphi participants highlighted how staff behaviours can trigger or exacerbate patient agitation. The recommendation stems from four guidelines[54–57] for healthcare professionals in emergency departments and psychiatry. Ten domains for de-escalation include respecting personal space, avoiding provocation, establishing verbal contact, being concise, identifying wants and feelings, listening closely, agreeing or agreeing to disagree, setting clear limits, offering choices and optimism, and debriefing the patient and staff.[57] Additionally, the importance of cultivating "a trusting relationship" between patients and healthcare professionals is highlighted,[56] and healthcare professionals are advised to be aware of their own behaviours, move slowly, and maintain a safe distance.[54]

#### 3.4.4. Certainty of the evidence: very low

The guidelines received an AGREE II[41] score between 38% and 63%. The certainty of the evidence was rated as very low due to indirectness, risk of bias, and the limited availability of primary research evidence on this topic. The recommendation was included in the Delphi study, where it reached a high level of expert consensus.

### 3.5. Use of multicomponent nonpharmacological strategies

#### 3.5.1. Conditional recommendation

Consider using multicomponent nonpharmacological treatments for the prevention and management of agitation.

Studies on multicomponent interventions included reorientation, therapeutic activities, interventions that promote sleep, early mobilisation, hydration and nutrition, music, and support for patients with hearing or vision impairments as components.[62]

#### 3.5.2. Rationale for the recommendation

This recommendation is supported by a meta-analysis of two smaller studies[63,64] (see Table 3 and Supp. p. 48), which showed a standardised mean difference of −0.73 (95% confidence interval: −1.06 to −0.41) on the RASS scale. This indicates a medium to large reduction in patient agitation compared to usual care,[65] suggesting that multicomponent interventions may be more effective in reducing agitation. The recommendation also reached consensus in the Delphi study. Given the multifactorial nature of agitation,[49] the working group emphasised the importance of using diverse strategies rather than relying on a single intervention.

#### 3.5.3. Certainty of the evidence: very low

The certainty of the evidence is very low. The meta-analysis included only two studies with small sample sizes and short follow-up periods. The studies differed in patient populations (elderly postsurgical ICU vs cardiac ICU) and intervention components, introducing clinical heterogeneity and limiting comparability. Additionally, there was imprecision in the reporting of psychoactive medication use and the distinction between intervention and standard treatment was not clearly defined. Although

**Table 3**
Summary of findings table for multicomponent nonpharmacological intervention.

| Multicomponent nonpharmacological care intervention compared to usual care on ICU patient agitation | | | | | | |
|---|---|---|---|---|---|---|
| **Patient or population:** Adult patients in the ICU<br>**Intervention:** Multicomponent care intervention<br>**Comparison:** Usual care<br>**Outcome**: Patient agitation | | | | | | |
| Outcomes | **Anticipated absolute effects*** (95% CI) | | Relative effect (95% CI) | Number of participants (studies) | Certainty of the evidence (GRADE) | Comments |
| | **Risk with no multicomponent intervention** | **Risk with multicomponent intervention** | | | | |
| Patient agitation as assessed with RASS | | SMD: −0.73, SMD (−1.06 to −0.41) | – | 220 (two RCTs) | ⊕○○○<br>Very low[a,b,c] | |

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**GRADE working group grades of evidence**
**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect.
**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

CI: confidence interval; RASS: Richmond Agitation-Sedation Scale; RCT: randomised controlled trial; SMD: standard mean difference.
Higher scores indicate increased agitation.
[a] Unclear differences between the intervention and usual care.
[b] Lack of precision with uncertainty about whether psychoactive medication was given before or during the intervention.
[c] Imprecise results due to small sample sizes, short intervention periods, and short follow-up periods.

heterogeneity was assessed using $I^2$, this measure is not considered reliable with only two studies and should be interpreted with caution. As such, the pooled estimate should be considered indicative rather than definite and not generalisable to all ICU settings. These limitations informed the decision to evaluate the recommendation through a Delphi study, where it achieved a high level of expert consensus.

### 3.6. Involvement of relatives

#### 3.6.1. Conditional recommendation

Consider involving relatives in the prevention and management of agitation.

#### 3.6.2. Subrecommendations

- Assess the extent to which relatives wish to and are able to be involved in managing the patient's agitation.
- Provide relatives with information about agitation.
- Teach relatives to use nonpharmacological strategies.
- Involve relatives in patient care.
- Use phone and/or video meetings when relatives are unable to visit the patient.

#### 3.6.3. Rationale for the recommendation

This recommendation originates from three qualitative systematic reviews.[9,10,66] Interviews with patients and relatives suggest that relatives offer comfort, guidance, and orientation and can engage patients in meaningful activities and assist with care. The recommendation is also supported by an ICU guideline[53] and a guideline developed for patients with traumatic brain injury.[58] Finally, this recommendation reached consensus in the Delphi study. Delphi study participants highlighted how relatives can provide crucial information about patient preferences and needs and often help patients feel safe.[47]

It is important to note that two studies, a randomised controlled trial (RCT) with 70 patients and a quasi-experimental study with 31 patients,[67,68] did not find significant effects of family presence. However, due to small sample sizes, lack of intervention details, and issues with the reliability of agitation measurements, it was not possible to draw definitive conclusions from the studies. Finally, it was noted that one ICU guideline[15] called for more research on the role of families in order to make recommendations.

#### 3.6.4. Certainty of the evidence: very low

The working group identified limited evidence for involving relatives in managing patient agitation. An RCT and a quasi-experimental study were appraised as moderate and adequate, respectively, and the three qualitative reviews were rated as high methodological quality using the appropriate JBI tools.[45,69] The guideline scores ranged from 39% to 94% using the AGREE II tool.[41] Based on the limited available evidence, indirectness, and risk of bias, the certainty was rated as very low. The recommendation was included in a Delphi study, where it achieved a high level of expert consensus.

### 3.7. Helping patients feel safe and involved

#### 3.7.1. Conditional recommendation

Consider helping patients feel safe and involved in their treatment to prevent and manage agitation.

#### 3.7.2. Subrecommendations

- Reassure the patient that they can feel safe.
- Create familiar surroundings with photographs or other items from the patient's home.
- Use "active listening". Active listening means listening carefully and showing interest in what the person has to say.
- Respect and protect the patient's dignity.
- Engage the patient in personal care activities.

- Debrief with the patient after an episode of agitation if they are able to participate.
- Incorporate neuropaedagogy into care strategies. Neuropaedagogy encourages clinicians to have a holistic approach to patient care by considering patient behaviours in light of their illness and how their brain and body work in specific environments.[70,71]
- Involve a psychologist or psychiatrist in the treatment when appropriate.
- Hold a patient's hand.
- Use therapeutic touch.
- Use trauma-informed care principles. (A trauma-informed care approach acknowledges the effects of trauma on physical and mental health and aims to provide care that promotes healing and prevents retraumatisation. This recommendation only reached consensus in Australia.)

#### 3.7.3. Rationale for the recommendation

This recommendation is based on three qualitative systematic reviews[9,10,66] that describe patients' experiences with agitation, including feelings of helplessness, the real risk of death, surreal experiences, and delusions. These reviews illustrate how patients experience an overwhelming sense of dependency, powerlessness, and loss of control and how being more involved in care can calm a patient with agitation.[9,10,66] The recommendation is also supported by guidelines developed for healthcare professionals working in emergency and psychiatry departments.[54,55,57,72] Finally, this recommendation reached consensus in the Delphi study. Delphi study participants noted that patients often became calmer when they felt staff members were present and cared about them.[47] Consistent care from the same team provides stability and continuity in treatment and relationships, which is crucial for patients with confusion and agitation.[47]

#### 3.7.4. Certainty of the evidence: very low

The certainty of the evidence was rated as very low. The three qualitative reviews[9,10,66] were of high methodological quality according to JBI's checklist.[69] The guidelines received AGREE II[41] scores ranging from 41% to 69%. Due to the limited available evidence, indirectness, and risk of bias, the subrecommendations supporting this recommendation were included in the Delphi study, where they all reached a high level of consensus.

### 3.8. Music

#### 3.8.1. Conditional recommendation

Consider playing music to prevent and manage agitation.

Positive effects have been found with relaxing, classical, and live music tailored to the patient's preferences (acoustic guitar, humming, and soft singing).

#### 3.8.2. Rationale for the recommendation

This recommendation is supported by a meta-analysis of two smaller studies,[73,74] which showed a mean difference of −0.60 (95% confidence interval: −0.81 to −0.38) on the RASS scale. This indicates a medium effect size[65] or a medium reduction in patient agitation compared to usual care, suggesting that listening to music may be an effective nonpharmacological strategy in the ICU. The recommendation also reached consensus in the Delphi study, where it was seen as important and feasible.

#### 3.8.3. Certainty of the evidence: very low

The certainty of the evidence is very low due to several limitations. The meta-analysis included only two small RCTs,[73,74] with small sample sizes (n = 188), no blinding, short intervention durations, and different delivery methods (live vs recorded music), which introduces clinical heterogeneity and limits generalisability. These factors contribute to serious risk of bias, indirectness, and imprecision in the effect estimate. Although heterogeneity was assessed using $I^2$, this measure is not considered reliable with only two studies and should be interpreted with caution. As such, the pooled estimate should be considered indicative rather than definite and not generalisable to all ICUs. Given the very low certainty of evidence (see Table 4), the recommendation was included in the Delphi study, where it reached a high level of consensus.

### 3.9. Supporting patient comfort and relaxation

#### 3.9.1. Consensus recommendation

It is considered good practice to use methods that support patient comfort and relaxation to prevent and manage agitation.

#### 3.9.2. Subrecommendations

- Ensure a comfortable environment (e.g., optimising room temperature, ventilation, and room design).
- Offer the patient a fidget toy.
- Take the patient outdoors.
- Pet therapy, such as certified therapy animals (typically dogs). Alternative approaches, such as showing photos or facilitating video calls with the patient's own pets, may also provide comfort.

#### 3.9.3. Rationale for the recommendation

This recommendation is based on the Delphi study. It originates from guidelines[54,55,57,58] developed for healthcare professionals outside the ICU. The different sources highlight the importance of supporting the patient's physical comfort, such as adjusting temperature, lighting, noise, ventilation, and colours. Delphi study participants noted that fidget toys, taking patients outside, and involving pets could distract patients from discomfort and restlessness.[47]

#### 3.9.4. Certainty of the evidence: very low

The guidelines received AGREE II[41] scores ranging from 41% to 63%. The certainty of the evidence was rated as very low due to indirectness, risk of bias, and the limited availability of primary research evidence on this topic. As a result, the recommendation was evaluated in a Delphi study, where it achieved a high level of expert consensus.

### 3.10. Reorientation and using situation-oriented communication techniques

#### 3.10.1. Consensus recommendation

It is considered good practice to reorientate the patient and use situation-oriented communication techniques to prevent and manage agitation.

While reorienting refers to helping a patient regain awareness of their surroundings, time, situation, and identity, situation-oriented communication refers to the use of strategies that are adapted to the specific situation and needs of the patient, ensuring

**Table 4**
Summary of findings of music therapy.

| Summary of findings | | | | | | |
|---|---|---|---|---|---|---|
| Music therapy for 30 min compared to no music therapy for minimising patient agitation | | | | | | |
| **Patient or population:** Adult patients in the ICU<br>**Intervention:** Music therapy 30 min<br>**Comparison:** No music therapy<br>**Outcome:** Patient agitation | | | | | | |
| Outcomes | **Anticipated absolute effects*** (95% CI) | | Relative effect (95% CI) | Number of participants (studies) | Certainty of the evidence (GRADE) | Comments |
| | **Risk with no music therapy** | **Risk with music therapy 30 min** | | | | |
| Patient agitation as assessed with RASS | | MD: −**0.6 SD** (−0.81 to −0.38) | – | 188 (two RCTs) | ⊕○○○ Very low[a,b,c] | |

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**GRADE working group grades of evidence**
**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect.
**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

CI: Confidence interval; GRADE: Grading of Recommendations Assessment, Development and Evaluation; MD: mean difference; RASS: Richmond Agitation-Sedation Scale; RCT: randomised controlled trial; SD: standard deviation.
Higher scores indicate increased agitation.
[a] Risk of bias. No blinding in the studies.
[b] Imprecision. Only two studies with 188 participants were included.
[c] Indirectness. Differences in interventions, as one study included live music and the other used recorded music played via an MP3 player.

communication is clear, relevant, and effective given the specific situation.

#### 3.10.2. Subrecommendations

- Inform the patient about the day's plan.
- Use clear and accurate language.
- Employ alternative communication methods (e.g., methods such as pen and paper, boards with icons and pictures, alphabet boards, and computer communication systems).
- Use a personal daily schedule with familiar activities.
- Explain the situation to the patient, regardless of their level of understanding.
- Use hearing aids for patients with hearing impairments.
- Use visual aids for patients with visual impairments.
- Adjust lighting according to the time of day.
- Ensure the time and date are visible to the patient.

#### 3.10.3. Rationale for the recommendation

This recommendation is based on the Delphi study and stems from three qualitative reviews[9,10,66] and existing guidelines for emergency and psychiatric health professionals.[54,57] This literature and the Delphi study[47] describe how reorientating patients by using situation-orientated communication can be crucial as confusion, a disturbed sense of time, and misunderstandings of the ICU environment can lead to agitation.

#### 3.10.4. Certainty of the evidence: very low

According to JBI's checklist for systematic reviews and research synthesis,[62] the three reviews[9,10,66] were considered to be of high methodological quality (10–11 criteria met out of 11). The existing guidelines[54,57] were rated at 41% and 45% using the AGREE II tool.[41] The certainty of the evidence was rated as very low due to indirectness, risk of bias, and the limited availability of primary research evidence on this topic. As a result, the recommendation was evaluated in a Delphi study, where it achieved a high level of expert consensus.

### 3.11. Mobilisation

#### 3.11.1. Consensus recommendation

It is good practice to mobilise the patient to prevent agitation.

Patients can be supported to be physically active, e.g., by mobilising to the bedside or taking short walks.

#### 3.11.2. Rationale for the recommendation

This recommendation is based on the Delphi study, where participants described physical activity as an important way to prevent agitation by stimulating the patient, calming them, and ensuring better sleep through natural tiredness.[47] It was also described how changing from a lying to a sitting position, with both feet on the floor, can have a calming and grounding effect.[47] Physical activity was also described as a way to distract patients and promote their wellbeing and self-control.[47]

#### 3.11.3. Certainty of the evidence: very low

The working group has not identified any direct evidence for the use of mobilisation to prevent agitation. Due to the lack of evidence, the recommendation was included in the Delphi study, where it reached a high level of consensus.

### 3.12. Adjusting the amount of stimuli

#### 3.12.1. Consensus recommendation

It is considered good practice to adjust the amount of stimulation to prevent and manage agitation.

#### 3.12.2. Subrecommendations

- Minimise unnecessary stimuli. Stimuli can be auditory (sounds), visual (light and moving objects), tactile (wires and equipment), or social (interacting people).

- Group care and treatment activities to avoid disturbing the patient multiple times.
- Minimise routine interventions and monitoring that are less critical for patient outcomes, such as unnecessary glucose monitoring, endotracheal suctioning, and neurological assessments.
- Offer the patient a calm environment, e.g., a private room.
- Use mental stimulation (engage the patient with activities such as Lego, puzzles, radio, TV, internet, magazines, and photos).

#### 3.12.3. Rationale for the recommendation

This recommendation is based on the Delphi study and originates from guidelines[54–58] developed for health professionals outside the ICU. The Delphi study and guidelines indicate that overstimulation from light, sound, heat, and cold can exacerbate agitation. Therefore, it is crucial to modify the environment to minimise external stimulation.

#### 3.12.4. Certainty of the evidence: very low

The guidelines received AGREE II[41] scores ranging from 38% to 63%. The certainty of the evidence was rated as very low due to indirectness, risk of bias, and the limited availability of primary research evidence on this topic. As a result, the recommendation was evaluated in a Delphi study, where it achieved a high level of expert consensus.

### 3.13. Promoting sleep

#### 3.13.1. Consensus recommendation

It is considered good practice to promote sleep to prevent and manage agitation.

#### 3.13.2. Subrecommendations

- Support the patient's usual circadian rhythm.
- Minimise nighttime disruptions from noise, light, and activities.

#### 3.13.3. Rationale for the recommendation

This recommendation is based on the Delphi study and originates from a guideline for managing traumatic brain injury[58] and three qualitative reviews.[9,10,66] One review by Ortega et al.[66] highlights a vicious cycle where sleep deprivation due to critical illness and the ICU environment leads to agitation and delirium, further worsening sleep. It is suggested that changing the environment in ICUs by reducing noise at night and promoting natural light could help mitigate these issues.[10]

#### 3.13.4. Certainty of the evidence: very low

The three qualitative reviews were rated as high methodological quality according to JBI's checklist for systematic reviews and research synthesis.[69] The guideline, focusing on patients with traumatic head injuries,[58] received an AGREE II[41] score of 53%. Due to the limited available evidence, indirectness, and risk of bias, the recommendation was included in the Delphi study, where it reached a high level of consensus.

### 3.14. Physical restraint as a last resort

#### 3.14.1. Consensus recommendation

It is considered good practice for physical restraint to be used only as a last resort to ensure safety of patients and staff.

#### 3.14.2. Subrecommendations

- Do not use physical restraints as a substitute for direct observation.
- ICUs should have clear, well-defined guidelines for the use of physical restraints.

#### 3.14.3. Rationale for the recommendation

This recommendation is based on the Delphi study. While physical restraint may be necessary for ensuring the safety of patients and staff, it should be a last resort when other strategies have failed. The recommendation derives from one ICU guideline[15] and four guidelines developed outside the ICU.[54–56,72] These guidelines highlight that there is a lack of evidence related to the therapeutic effect of physical restraint that the intervention can be traumatic for patients, negatively affect trusting relationships between patients and staff, and paradoxically exacerbate agitation, increase the use of sedatives, and increase adverse events such as self-extubation. A qualitative review also describes patients' distressing experiences with being physically restrained, and based on this finding, the authors recommend minimising or ceasing the use of physical restraints.[10]

#### 3.14.4. Certainty of the evidence: very low

The guidelines scored between 38% and 94% with the AGREE II tool.[41] The qualitative review was rated high methodological quality.[46] The certainty of the evidence was rated as very low due to indirectness, risk of bias, and the limited availability of primary research evidence on this topic. As a result, the recommendation was evaluated in a Delphi study, where it achieved a high level of expert consensus.

### 3.15. Additional recommendations

While the additional recommendations described later in the text did not directly answer our health question, they all reached consensus in the Delphi study and provide valuable insights into the importance of fundamental patient-centred care for this group of patients, as well as organisational strategies for implementation.

#### 3.15.1. The importance of fundamental person-centred care

Delphi participants agreed that healthcare professionals should become familiar with each patient's background (e.g., preferences, culture, personal history, values, fears, and daily routines) in order to better support their basic care needs.[47] While unmet basic needs can trigger or intensify agitation,[49,52,55,76] ICU patients often struggle to communicate these needs due to mechanical ventilation, physical weakness, and confusion.[9,10,66] To bridge this gap, healthcare professionals should use situation-oriented communication techniques and engage with relatives to learn more about the patient. Building trusting relationships is essential and helps patients feel safer and better able to express their needs.[56] This person-centred, fundamental care approach aligns with the broader healthcare guidelines for agitation[54,56,57] feedback from former ICU patients[77,78] and endorsement by the Delphi panel (see Table 6).

#### 3.15.2. Recommendations for organisations aiming to implement the guideline

Delphi study participants agreed that health professionals in the ICU should receive organisational support to effectively prevent and manage patient agitation.[47] It can be physically and mentally challenging for nurses caring for patients with agitation.

**Table 5**
Summary table of recommendations.

| | Recommendation | Subrecommendations | Origin of evidence | Consensus N, percentage (95% CI), Median (IQR) | Feasibility/ importance (percentage[f]) | Undesirable effect/ comments | Certainty of the evidence | Strength of recommendations |
|---|---|---|---|---|---|---|---|---|
| 1. | It is considered good practice to implement early, regular, and systematic assessments of ICU patients for agitation. | | 52,54–57,47 | N = 100, 97% (CI: 0.92–0.99), 5 (0) | 100/96 | Assessments should be done without disrupting patients. | | Good practice recommendation |
| 2. | It is considered good practice to identify and, when possible, treat the causes of agitation. | | 52,54,55,58,47 | N = 103, 100% (CI:. 0.96–1.0), 5 (0) | 89/99 | | | Good practice recommendation |
| | | Become familiar with the patient's background (e.g., likes, dislikes, culture, history, values, fears, and routines). | | N = 113, 99% (CI: 0.95–1.0), 5 (0) | 94/98 | | | |
| | | Develop care plans based on patient preferences and values. | | N = 105, 91% (CI: 0.85–0.95), 5 (0) | 88/93 | | | |
| 3. | It is considered good practice to use nonpharmacological strategies before pharmacological treatment to manage agitation. | | 15–18,54,55,58–61,47 | N = 113, 89% (CI: 0.81–0.93), 5 (1) | 92/90 | Some situations may require urgent medical treatment to ensure the safety of patients and staff. Medical treatment must still be considered for other psychological comorbidities. | | Good practice recommendation |
| 4. | It is considered good practice to use de-escalation techniques to minimise agitation. | | 54–57,47 | N = 106, 99% (CI: 0.95–1.0), 5 (0) | 92/97 | Effective use requires staff training and practice (e.g., simulation). | | Good practice recommendation |
| | | Prioritise the safety of patients, staff, and relatives when managing agitation. | | N = 114, 97% (CI: 0.93–0.99), 5 (0) | 93/94 | | | |
| | | Ensure that aggressive and patients who are violent do not have access to objects that can cause harm to themselves or others (e.g., sharp objects, weapons, or hard objects that can be thrown). | | N = 104, 99% (CI: 0.95–1.0), 5 (0) | 94/98 | Staff may not have the right to search patients' personal belongings for objects that could be used as weapons. | | |
| | | Maintain a physical safety distance from patients who are violent. | | N = 112, 88% (CI: 0.81–0.93), 5 (1) | 78/98 | Close contact with patients may be necessary to reduce agitation and increase patient safety, e.g., for administering medication and avoiding extubation. Physical distance should be applied cautiously and only for short periods. | | |
| | | Develop a relationship with the patient based on empathy, respect, and trust. | | N = 114, 95% (CI: 0.89–0.98), 5 (0) | 98/99 | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Respect patients' need for privacy | | N = 112, 94% (CI: 0.88–0.97), 5 (0) | 85/95 | | | |
| 5. | Consider using multicomponent nonpharmacological treatments for the prevention and management of agitation. | | 49·63,64,47 | N = 114, 89% (CI: 0.81–0.93), 5 (1) | 89/91 | | ⊕◯◯◯ Very low[a,b,c] | Conditional/Weak |
| 6. | Consider involving relatives in the prevention and management of agitation. | | 9,10,15,66–68,47 | N = 114, 90% (CI: 0.84–0.95), 5 (1) | 77/86 | Relatives may not have capacity to be involved. They should never feel responsible for care. It is essential to protect the patients' dignity when involving relatives.[17] In some cases, relatives might exacerbate patient agitation. | ⊕◯◯◯ Very low[a,c,e] | Conditional/weak |
| | | Assess the extent to which relatives wish to and are able to be involved in managing the patient's agitation. | | N = 113, 89% (CI: 0.81–0.93), 5 (1) | 95/97 | | | |
| | | Offer relatives information about agitation. | | N = 114, 98% (CI: 0.94–1.0), 5 (0) | 99/95 | | | |
| | | Teach relatives to use nonpharmacological strategies. | | N = 109, 91% (CI: 0.84–0.95), 5 (1) | 80/92 | | | |
| | | Use phone and/or video meetings when relatives are unable to visit the patient. | | N = 96, 83% (CI: 0.75–0.89), 4 (1) | 89/94 | | | |
| 7. | Consider helping patients feel safe and involved in their treatment to prevent and manage agitation. | | 9,10,54,55,57,66,72,47 | | | | ⊕◯◯◯ Very low[a,c,e] | Conditional/weak |
| | | Reassure the patient that they can feel safe. | | N = 114, 97% (CI: 0.88–0.97), 5 (0) | 99/96 | | | |
| | | Create familiar surroundings (e.g., with pictures or other items from the patient's home). | | N = 111, 94% (CI: 0.88–0.97), 5 (1) | 94/93 | | | |
| | | Hold a patient's hand. | | N = 114, 89% (CI: 0.81–0.93), 4 (1) | 94/83 | | | |
| | | Use "active listening". Active listening means listening carefully and showing interest in what the person has to say. | | N = 113, 93% (CI: 0.87–0.96), 5 (1) | 96/96 | | | |
| | | Respect patient dignity. | | N = 113, 99% (CI:.0.95–1.0), 5 (1) | 97/99 | | | |
| | | Engage patients in personal care activities. | | N = 111, 92% (CI: 0.85–0.96), 5 (0) | 91/95 | | | |
| | | Debrief with the patient after an episode of agitation if they are able to participate. | | N = 85, 88% (CI −0.80–0.93), 5 (0) | 85/89 | | | |

(*continued on next page*)

**Table 5** (*continued*)

| | Recommendation | Subrecommendations | Origin of evidence | Consensus N, percentage (95% CI), Median (IQR) | Feasibility/ importance (percentage[f]) | Undesirable effect/ comments | Certainty of the evidence | Strength of recommendations |
|---|---|---|---|---|---|---|---|---|
| | | Use neuropaedagogy.[b] | | N = 45, 82% (CI: 0.80–0.93), 5 (1) | 72/69 | Neuropedagogy was seen as less important and feasible. The reason for this is unclear. However, introductory training is needed to apply principles in practice. | | |
| | | Involve a psychologist or psychiatrist in the treatment plan when appropriate. | | N = 91, 77% (CI: 0.67–0.84), 4 (1) | 51/70 | Involving a psychologist or psychiatrist was deemed less important and feasible due to their limited availability in the ICU and potential lack of knowledge about the complex issues in treating ICU agitation | | |
| | | Use trauma-informed care principles (this only reached consensus in Australia) | | N = 41, 83%, 4 (1) | Not rated | | | |
| | | Use therapeutic touch. | | N = 102, 82% (CI: 0.74–0.89), 4 (1) | 89/81 | Some patients may not appreciate this form of touch from healthcare professionals. Touch may be inappropriate for patients who are very agitated. Health professionals must feel comfortable with this method. | | |
| 8. | Consider playing music to prevent and manage agitation. | | 47,73,74 | N = 99, 89% (CI: 0.81–0.94), 4 (1) | 85/84 | Playing music requires devices such as MP3 players, tablets or hospital-approved speakers, headphones or earbuds and playlists. | ⊕◯◯◯ Very low[a,c,d] | Conditional/weak |
| 9. | It is considered good practice to use methods that support patient comfort and relaxation to prevent and manage agitation. | | 54,55,57,58,47 | | | | | Good practice recommendation |
| | | Ensure a comfortable environment (e.g., optimising room temperature, ventilation, and room design). | | N = 106, 84% (CI: 0.76–0.90), 5 (1) | 73/94 | May not be feasible due to limitations to adjust temperature, light, noise, ventilation, and colours of the room. | | |
| | | Offer the patient a fidget toy. | | N = 80, 83% (CI: 0.73–0.89), 4 (1) | 73/74 | Hygienic principles and safety should be prioritised. The cost of fidget toys varies. Simple toys such as stress balls, acupressure rings, and simple spinners are relatively cheap, whereas other more interactive toys | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | are more expensive. Clinicians should opt for toys that are easy to clean. | |
| | | Take the patient outdoors. | | N = 105, 92% (CI: 0.86–0.96), 5 (1) | 70/86 | Patients should only be taken outside if their condition is stable and their behaviour does not pose a risk to themselves and others.[41] Not all ICUs have facilities to take patients outdoors. | |
| | | Pet therapy, such as certified therapy animals (typically dogs). Alternative approaches, such as showing photos or facilitating video calls with the patient's own pets, may also provide comfort. | | N = 79, 86% (CI: 0.77–0.92), 5 (1) | 42/78 | Staff should consider local guidelines, the risk of infections and allergies, and patient/staff safety when involving animals. | |
| 10. | It is considered good practice to reorientate the patient and use situation-oriented communication techniques to prevent and manage agitation. | | 9,10,54,57,66,47 | | | | Good practice recommendation |
| | | Use clear and accurate language. | | N = 114, 96% (CI: 0.90–0.98), 5 (1) | 99/98 | | |
| | | Employ alternative communication methods (e.g., methods such as pen and paper, boards with icons and pictures, alphabet boards, and computer communication systems). | | N = 109, 95% (CI: 0.89–0.97), 5 (1) | 93/94 | | |
| | | Inform the patient about the day's plan. | | N = 113, 88% (CI: 0.80–0.92), 4 (1) | 95/95 | | |
| | | Use a personalised fixed daily schedule with familiar activities. | | N = 105, 89% (CI: 0.81–0.93), 5 (1) | 82/87 | Fixed daily schedules should be flexible to adapt to the patient's needs. Fixed schedules are most beneficial for patients who are hospitalised for extended periods. | |
| | | Explain the situation to the patient, regardless of their level of understanding. | | N = 113, 95% (CI: 0.89–0.98), 5 (0) | 96/94 | | |
| | | Use hearing aids for patients with hearing impairments. | | N = 106, 100% (CI: 0.97–0.1), 5 (0) | 98/99 | | |
| | | Use visual aids for patients with visual impairments. | | N = 106, 97% (CI: 0.92–0.99), 5 (0) | 100/98 | | |
| | | Adjust lighting according to the time of day. | | N = 109, 97% (CI: 0.92–0.99), 5 (0) | 93/98 | | |
| | | Ensure the time and date are visible to the patient. | | N = 111, 93% (CI: 0.86–0.96), 5 (1) | 94/98 | | |

(*continued on next page*)

**Table 5** (*continued*)

| | Recommendation | Subrecommendations | Origin of evidence | Consensus N, percentage (95% CI), Median (IQR) | Feasibility/ importance (percentage[f]) | Undesirable effect/ comments | Certainty of the evidence | Strength of recommendations |
|---|---|---|---|---|---|---|---|---|
| 11. | It is good practice to mobilise the patient to prevent agitation. | | 47 | N = 113, 99% (CI: 0.95–1.0), 5 (0) | 92/99 | Moving a patient with agitation can be dangerous and should be approached with caution | | Good practice recommendation |
| 12. | It is considered good practice to adjust the amount of stimulation to prevent and manage agitation. | | 54–58,47 | | | | | Good practice recommendation |
| | | Minimise unnecessary stimuli. Stimuli can be auditory (sounds), visual (light and moving objects), tactile (wires an equipment), or social (interacting people)[b]. | | N = 104, 97% (CI: 0.92–0.99), 5 (1) | 80/98 | | | |
| | | Group care and treatment activities to avoid disturbing the patient multiple times. | | N = 113, 96% (CI: 0.90–0.98), 5 (0) | 92/97 | | | |
| | | Minimise routine interventions and monitoring that are less critical for patient outcomes, such as unnecessary glucose monitoring, endotracheal suctioning, and neurological assessments. | | N = 102, 87% (CI: 0.79–0.92), 5 (1) | 92/90 | Minimising routine interventions and monitoring should be guided by professional judgement, experience, and knowledge of healthcare professionals | | |
| | | Offer the patient a calm environment, e.g., a private room. | | N = 112, 95% (CI: 0.89–0.98), 5 (0) | 83/95 | May not be feasible depending on the ICU | | |
| | | Use mental stimulation (engage the patient with activities such as Lego, puzzles, radio, TV, internet, magazines, and photos)[c] | | N = 101, 88% (CI: 0.80–0.93), 4 (1) | 80/85 | Mental stimulation must be adjusted for each individual patient as it may result in frustration and/or overstimulation. | | |
| 13 | It is considered good practice to promote sleep to prevent and manage agitation. | | 9,10,58,66 | | | | | Good practice recommendation |
| | | Support the patient's usual circadian rhythm.[b] | | N = 103, 98% (CI: 0.93–0.99), 5 (0) | 80/97 | | | |
| | | Minimise interruptions at night from noise, light, and activities. | | N = 114, 100% (CI: 0.97–1.0), 5 (0) | 91/100 | | | |
| 14 | It is considered good practice for physical restraint to be used only as a last resort to ensure safety of patients and staff. | | 10,53–56,72,75 | N = 114, 85% (CI: 0.77–0.90), 5 (1) | 85/91 | | | Consensus recommendation |

| | | |
|---|---|---|
| Do not use physical restraints as a substitute for direct observation. | N = 104, 93% (CI: 0.87–0.97), 5 (0) | 89/94 |
| ICUs should have clear guidelines for the use of physical restraints. | N = 102, 95% (CI: 0.89–0.98), 5 (0) | 93/98 |

CI: confidence interval; ICU: intensive care unit; IQR: interquartile range.

Explanations

[a] Serious risk of bias (unclear differences between the intervention and usual care, blinding issues, lack of inter-rater reliability).

[b] Serious imprecision with uncertainty about whether psychoactive medication was given before or during the intervention.

[c] Serious imprecision due to small sample sizes, short intervention periods, and short follow-up periods.

[d] Serious risk of bias one study funded by a music organisation.

[e] Serious risk of bias (limitations to study design, consensus statements, and qualitative research.

[f] Percentage rating somewhat or very feasible/important.

The Delphi study[47] and multiple other sources[9,14,54,56,57] suggest that ICUs must prioritise staff safety by maintaining adequate staffing levels, allowing regular staff breaks, and ensuring staff members have access to immediate practical support. Training on agitation and de-escalation techniques is essential. Debriefing sessions should be conducted by experienced staff in a safe environment. Balancing continuity of care with staff rotation is crucial to prevent fatigue and burnout. Finally, organisations should support the use of nonpharmacological interventions and encourage multidisciplinary collaboration (see Table 7).

## 4. Implementation of the guideline

While the vast majority of nonpharmacological interventions were seen as feasible and of low cost, implementation can be challenging, time-consuming, and costly.[79] Barriers include insufficient resources (e.g., devices for playing music and fidget toys), the need for staff education and training, difficulties in changing habits, infection control concerns, and lack of awareness of the importance of nonpharmacological strategies.[47] Implementation of the presented guideline requires a rigorous knowledge translation framework supporting the implementation of complex interventions.[70] Frameworks such as integrated-Promoting Action on Research in Health Services have shown promising results in offering a structured guide for engaging with stakeholders, exploring contextual factors and supporting targeted facilitation.[71] The Adaptable Framework To Evaluate Products of Participatory Research may also be beneficial, with its ability to track and evaluate stakeholder behaviours and preferences in real time, enabling iterative changes during the implementation process.[80] At Flinders Medical Centre in South Australia, researchers are currently looking at codesigning a tailored, context-specific intervention for implementing the guideline. The authors are hoping to offer a detailed description of how the guideline can be practically implemented in the ICU.

The current guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption (PADIS) guidelines predominantly offer recommendations for the pharmacological management of agitation.[81] We suggest incorporating the presented guideline into the PADIS guidelines. Agitation is linked with pain, delirium, and sleep, and some recommendations overlap with ours such as multicomponent interventions for delirium.[15] However, the PADIS guidelines lack a holistic model of care, including assessment and identification of causes of agitation, identifying causes of agitation, the establishment of trusting relationships, and promoting staff behaviours, involving families and supporting staff, which is essential for optimising care in the ICU.

The ABCDEF[n] bundle, an evidence-based approach to managing critically ill patients by addressing pain, spontaneous awakening and spontaneous breathing trials, analgesia and sedation, delirium assessment, early mobilisation, and family engagement, has shown promising results.[82,83] However, research has indicated that patient agitation is a barrier to implementing the ABCDEF bundle.83 Strengthening the bundle to include **F**undamental care to prevent and manage patient agitation, ABCEDE**F$_2$** could improve outcomes and experiences for patients, families, and staff. The ABCEDEF bundle aims to humanise care in the ICU,[84] and insights from our guideline can further this goal.

[n] ABCDEF bundle stands for **A**ssess, prevent, and manage pain; **B**oth spontaneous awakening and breathing trials; **C**hoice of analgesia and sedation; **D**elirium assessment, prevention, and management; **E**arly mobility and exercise; and **F**amily engagement and empowerment.

**Table 6**
Importance of fundamental person-centred care.

| | Consensus, percentage | Feasibility/importance |
|---|---|---|
| Healthcare professionals should support patients' fundamental care needs to reduce and manage agitation. | N = 102, 99 % | 95/100 |

**Table 7**
Recommendations for organisations.

| | Consensus, percentage | Feasibility/importance |
|---|---|---|
| Healthcare professionals caring for and treating patients with agitation should always have access to immediate practical support.[b] | N = 106, 99% | 82/99 |
| The ICU should be laid out in a way that makes observing patients with agitation easier. | N = 103, 85% | 64/96 |
| Additional staffing should be considered when there is a patient with agitation in the ICU. | N = 103, 95% | 64/96 |
| Staff caring for patients with agitation should be offered debriefing. | N = 103, 86% | 79/89 |
| Clinicians who provide care and treatment for patients with agitation should be offered frequent breaks during their shift.[b] | N = 106, 99% | 60/94 |
| Ongoing staff education about agitation and methods to reduce agitation should be provided. | N = 102, 98% | 88/97 |
| Nursing and medical leaders should support the use of nondrug interventions to reduce and manage agitation. | N = 103, 93% | 99/98 |
| The multidisciplinary team should collaborate to reduce and manage patient agitation. | N = 103, 99% | 99/100 |

## 5. Strengths and limitations

Major strengths of this guideline include significant stakeholder involvement, a robust development process including a systematic review of the existing literature, and a Delphi study meeting all key quality criteria,[85–87] including a priori definitions for consensus, endorsement of recommendations, number of Delphi rounds, stringent participant selection criteria, and clear criteria for modifying or removing recommendations.[47] A high level of consensus was required in both countries for endorsement. Validity was further strengthened through rigorously tested surveys and careful translation to ensure clarity of survey items.[47] Collaboration across countries has multiple advantages, including the pooling of resources and expertise.[88]

The primary limitation of this guideline is the very low certainty of the evidence upon which the recommendations are based. This rating reflects a limited evidence base, indirectness of recommendations that at times originated from areas outside the ICU, the risk of bias, inconsistency, and imprecision. There is a clear paucity of evidence on nonpharmacological interventions for agitation in the ICU, highlighting an urgent need to expand the evidence base to better inform clinical practice. However, it must also be acknowledged that studying nonpharmacological interventions is challenging and that some answers may not be fully uncovered through experimental designs. To support the credibility and clinical relevance of the included recommendations, each was validated through a modified Delphi study. Furthermore, the recommendations are conceptually grounded in the known causative mechanisms of agitation,[6] including biological causes, unmet needs, and lowered stress thresholds, providing a strong theoretical rationale for inclusion in ICU care.

This guideline was collaboratively developed in Denmark and Australia, with contextual adaptation for each country. This publication focuses on the guideline adapted for Australian ICUs. Since the majority of recommendations reached consensus in both countries, it is likely the guideline can be adapted for use in other countries.

## 6. Conclusion

This publication is the first to provide a guideline for the nonpharmacological prevention and management of patient agitation in the ICU. The CALM ICU guideline will equip staff with knowledge on how to reduce patient agitation using nonpharmacological strategies, thus reducing the overuse of medication and restrictive practices and improving patient experiences. Furthermore, they are designed to promote interdisciplinary collaboration and strengthen intensive care nurses' clinical decision-making and leadership in delivering person-centred care. Ultimately, the guideline can serve as a framework for educating new and existing ICU staff and encourage the continual evaluation of current practices and standards of care.

## CRediT authorship contribution statement

**Anne Mette Adams** – Conceptualisation, methodology, validation, formal analysis, investigation, Writing – original draft, **Diane Chamberlain** – Conceptualisation, methodology, validation, formal analysis, writing – review & editing, writing, supervision, **Charlotte Brun Thorup** – validation, discussion, review & editing, **Marianne W Nørgaard**-methodology, formal analysis, review & editing, **Britt Laugesen** - methodology, discussion, review & editing, **Mette Grønkjær** - validation, discussion, review & editing, **Matthew Maiden** – review & editing - **Cherie Waite** – review & editing, **Kay Bruce** - review & editing, **Cornelia Lamprecht** - review & editing, **Tiffany Conroy** - Conceptualisation, methodology, validation, formal analysis, discussion, writing – review & editing, supervision.

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## Data availability statement

The data that support the findings of this study are available from the corresponding author, AMA, upon reasonable request.

## Declaration of competing interests

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Anne Mette Adams reports financial support was provided by Australian College of Critical Care Nurses Ltd. All other 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 (see also Supp 16 for more information).

## Supplementary Data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.aucc.2025.101466.

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