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Research paper

# The development of a family-led novel intervention for delirium prevention and management in the adult intensive care unit: A co-design qualitative study

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## ARTICLE INFORMATION

## ABSTRACT

*Aim:* The aim of this study was to codesign a Family Members' Voice Reorientation Intervention (FAMVR) for delirium prevention and management in critically ill adult patients through collaborative process with previous patients, families, and clinical staff.

*Background:* Delirium is a common consequence of intensive care admission, and there is limited evidence to support family-led interventions to prevent or minimise delirium in intensive care. People with lived experience of intensive care are seldom involved in codesigning delirium prevention and management interventions despite the identified benefits of their involvement in delirium care.

*Design:* Codesign qualitative study.

*Methods:* The process of co-designing was undertaken using the four stages of the Double Diamond model. Participants included people with lived experience of the intensive care unit, family members, and intensive care clinicians. The codesign approach was utilised, and data were gathered from a series of focus groups and individual interviews. Data were digitally recorded, transcribed verbatim, and analysed using thematic analysis.

*Findings:* Of the 26 people who indicated their interest in participating, 12 (46%) completed the first and second stages, and nine (35%) completed the third and fourth stages of the Family Members' Voice Reorientation Intervention development. All participant groups were represented in the fourth stage: patients (n = 4), family members (n = 1), nurses (n = 2), and medical staff (n = 2). Four themes were identified: message content, wording, reactions, and tone, all of which informed the prototype of the intervention and its associated domains.

*Conclusion:* A codesign approach was important for developing a delirium management intervention. This process enabled participants to provide their feedback in the context of their unique experiences, which in turn enhanced the authenticity and appropriateness of this unique intervention.

## 1. Introduction

Delirium is a common brain dysfunction, which in the context of acute illness is associated with high mortality and morbidity rates.[1] Within the critical care environment, delirium management is challenging due to the complexity of presentation and the lack of a standardised approach to management.[2] A high proportion of patients in the intensive care unit (ICU) environment will develop delirium at some point during their ICU stay,[3,4] with prevalence postulated to be as high as 33%–55%.[5,6] Delirium increases the risk of long-term cognitive impairment after critical illness and is associated with increased length of hospital stay, morbidity, and mortality, with associated impact on healthcare costs and reduction in quality of life.[7]

The presentation of delirium as a syndrome varies, and the pathophysiology remains unclear; it is thought to be associated with genetic abnormalities, older age, male gender, low socioeconomic status, and previous episodes of delirium.[8] The severity of a

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critical illness has also been recognised to precipitate the development of delirium,[1] as well as increased brain inflammation, reduced cerebral blood flow, and neurotransmitter imbalance.[4] Due to the diverse range of causative factors and presentation of delirium, a multifaceted approach to prevention and management is important to alleviate the effects on patients.[9] The standard approach recommended for delirium prevention and management in the ICU comprises nonpharmacological strategies summarised as an ABCDEF bundle, which comprises the following: assessing, preventing, and managing pain, spontaneous breathing trials, choice of analgesia, delirium assessment and management, early mobilisation, and family involvement.[2] The development of interventions that facilitate these approaches could, therefore, have an important role in minimising the factors that contribute to delirium development.

The experience of delirium is unique to each patient and family member, and so the involvement of those with lived experience of delirium in the ICU is valuable in the design of suitable interventions. A collaborative design approach is a powerful strategy in the development of interventions that meet the needs of those who have experienced the phenomena.[10] The utilisation of this approach may also promote the acceptability and authenticity of delirium interventions to patients, families, and staff.[10] A collaborative design approach to ICU care has been successful, including the development of a patient communication bundle.[11]

The evidence to support the most effective management of delirium in the ICU is not well established. Pharmacological therapies, including antipsychotics, have been routinely prescribed to manage symptoms of delirium; however, these therapies have limited efficacy.[12,13] While the long-term effects of antipsychotic medications are well-known in other populations,[14] the long-term effects of antipsychotic medications such as haloperidol and ziprasidone in managing ICU delirium have only recently been identified and potentially predispose patients to detrimental outcomes.[15–17] Evidence suggests that non-pharmacological interventions can be effective in the management of delirium. Family-centred care approaches have evolved in recent years, with an emergence of non-pharmacological interventions involving family members considered effective in delirium prevention and management, with high acceptability by patients, family members, and clinicians.[18–20] A scoping review,[21] conducted as a foundation for this study, identified that family-delivered interventions including orientation practices, the provision of memory cues, extended visitation, and sensory stimulation were commonly utilised in delirium prevention and management.[22–25] However, these approaches are inconsistently applied and evaluated within ICUs, making it challenging to recommend their application in delirium management in this context.[26] This inconsistency, in addition to a limited evidence base, has led to an increased reliance on pharmacological therapies, which in themselves lack rigorous evaluation of the required evidence base.

Orientation practices and cognitive rehabilitation by family members are effective in delirium prevention and management of critically ill adults,[18,19] but there is limited wider evidence about the effectiveness of integrating family members' voices as a method of orientation for ICU patients.[27] The complexity of a critical care environment can pose challenges to the integration of family members into the care of their loved ones; however, studies have identified that this approach can be effective in managing delirium and have a positive impact on the family members themselves.[19,27] The aim of this study was to develop a novel intervention to incorporate a family-delivered intervention into delirium care in the ICU. The goal was to design an intervention focussed on using the voices of family members to prevent delirium. The intervention was called the Family Member's Voice Reorientation Intervention (FAMVR). This paper will discuss the codesign process that was undertaken in this study and resulted in the collaborative development of a delirium prevention intervention using family members' voices.

## 2. Aim

The aim of this study was to codesign the FAMVR for delirium prevention and management in critically ill adult patients through engagement with people with lived experience of ICU as a patient, family member, and clinical staff.

## 3. Methods

### 3.1. Research design

The content and focus of the FAMVR were developed through a codesign approach[10] that included collaboration with people with lived experience of the ICU, as a patient, family member, nursing and medical staff. A co-design method is a validated research design involving end-users of the intended intervention and which has been extensively used in health care.[10] The co-design Double Diamond model[28,29] was applied to the stages of the process, which is reported elsewhere. The Double Diamond model is a design-thinking and problem-solving framework used to provide a structured approach to innovation that encourages exploring a wide range of ideas (divergence) and then narrowing it down to select and refine the best solutions (convergence) to address complex problems[28] (Fig. 1). The reporting of this study adhered to the Standards for Reporting Qualitative Research.[30]

The codesign approach (Fig. 1) comprised four stages: (i) gathering insights and exploration of the identified concept; (ii) refinement via focus-group discussions with participants; (iii) the creation and exploration of different perspectives via a focus group; and (iv) implementing and evaluating the prototype intervention.[10,31]

The co-design approach recognises the benefits of power-sharing in developing research interventions[10] and involves a shift from protecting individual participants towards developing a mutually advantageous relationship between the researcher and community partners,[32,33] where research is not simply 'being done' to them.[10] Codesign approaches are particularly important in ensuring that the goals of interventions are achieved for the benefit of vulnerable communities, which may be considered to include adult ICU patients and their families.[10,32,33] To enable this power-sharing, the stakeholder group of end-users were actively involved from the outset and throughout intervention development. This enhances credibility and acceptability, as well as facilitates a two-way learning process for researchers and stakeholders.[10]

### 3.2. Population

Two groups of participants were involved in this study: people with lived experience of the ICU as a patient or family members (group 1) and the clinicians expert group (group 2). Participants in group 1 comprised people with lived experience of delirium either as a patient or family member in the ICU. Group-2 participants comprised nursing and medical staff employed in senior clinical positions from the study site at a National Health Service trust in the United Kingdom.
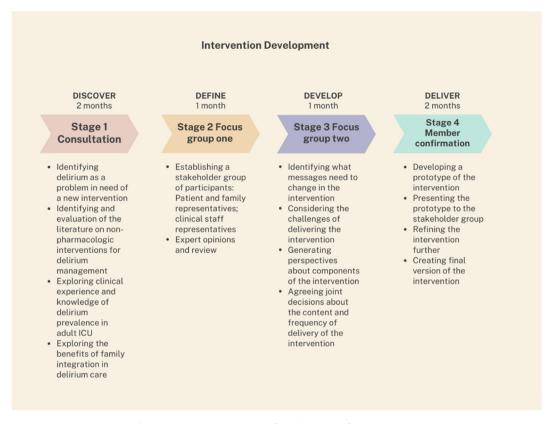
**Intervention Development**

| DISCOVER 2 months | DEFINE 1 month | DEVELOP 1 month | DELIVER 2 months |
|---|---|---|---|
| **Stage 1 Consultation** | **Stage 2 Focus group one** | **Stage 3 Focus group two** | **Stage 4 Member confirmation** |
| • Identifying delirium as a problem in need of a new intervention<br>• Identifying and evaluation of the literature on non-pharmacologic interventions for delirium management<br>• Exploring clinical experience and knowledge of delirium prevalence in adult ICU<br>• Exploring the benefits of family integration in delirium care | • Establishing a stakeholder group of participants: Patient and family representatives; clinical staff representatives<br>• Expert opinions and review | • Identifying what messages need to change in the intervention<br>• Considering the challenges of delivering the intervention<br>• Generating perspectives about components of the intervention<br>• Agreeing joint decisions about the content and frequency of delivery of the intervention | • Developing a prototype of the intervention<br>• Presenting the prototype to the stakeholder group<br>• Refining the intervention further<br>• Creating final version of the intervention |

**Fig. 1.** These actions were taken before pilot testing of the intervention.

### 3.3. Sampling strategy

All participants were selected using purposive sampling. Inclusion criteria included being aged 18 years and above with lived experience of delirium in the ICU as a patient or family member and nursing or medical staff employed in the ICU at the study site. A minimum of six participants (two patients, two family members and two clinical staff) were recruited to ensure a broad range of perspectives. Participants in group 1 were invited to participate with or without family members. Recruitment of participants continued until data saturation was reached.[34]

### 3.4. Recruitment

#### 3.4.1. People with lived experience and family members

Group-1 participants were invited to participate in the study via an invitation from the ICUsteps[35] website. The ICUsteps organisation is a registered charity led by people with lived experience of the ICU as patients and family members, which supports patients and relatives affected by critical illness in the UK.[35]

#### 3.4.2. Clinical staff

The researcher shared posters about the study at the site and also approached staff members individually to participate in the study. Clinical staff who expressed an interest in participating could then contact the researcher via email, phone, or face-to-face when further information was provided and have any questions answered.

#### 3.4.3. Recruitment process

The use of a combination of recruitment strategies maximised engagement with potential participants.[36,37] Potential participants were provided with the participant information consent form and were given a minimum of 24 h to decide whether to participate before written consent was obtained. When participants consented to participate, they commenced stage one of the study. The researcher reconfirmed consent before commencement of each focus group. Recruitment commenced in April 2023 and concluded in May 2023.

As a senior ICU nurse, the researcher was cognisant of potential power imbalances with participants. They therefore ensured that they did not work in the same ICU as the participants at the time of the study. Before the commencement of the study, the researcher started a reflexive journaling process in which they reflected on their experience and recorded all potential biases that could have an impact on it.[38] The researcher revisited this reflective process throughout the research process to ensure that personal biases did not impact on the development or outcomes of the study.

### 3.5. Ethical approval

Ethical approval was obtained from the Research Ethics Committee (REC ref: 23/LO/0057) and reciprocal ethical approval from the University Human Research Ethics Committee (REMS NO: 2023-04186-JOHNSON), where the researcher is a student. Approval was also obtained from the Health Research Authority and Health and Care Research Wales (HCRW) and Confirmation of Capability and Capacity from the study site.

### 3.6. Data collection

This codesign element was the first phase of a larger study. Fig. 1 outlines the stages applied for the data collection of this study phase. The stages employed in this codesign process enabled

flexible engagement and collaboration with a range of stakeholders by providing multiple time options for participants to select their preferred time for the focus group and by utilising video conferencing, which enabled participants to contribute in their natural settings.

The initial meetings with participants were via telephone, email, and Microsoft Teams, where those with lived experience as patients were encouraged to obtain support from family members in this process. An iterative and systematic codesign approach followed to integrate stakeholder knowledge and experience to develop the FAMVR.[39] As a base for discussions with the participants, the researcher combined the experiences of all participants and other formative work, including a literature review, into a series of draft-scripted messages as a component of FAMVR (See Appendix 1 Supplementary Material Draft Scripted Message).[27]

In the initial step of the codesign process, these draughted scripted messages from a literature review were provided to all participants for their feedback before the focus groups, either to comment, approve, or make changes to the messages. In total, participants (patients n = 78, family n = 18, nurses n = 21, medical staff n = 8) made 125 changes. The updated messages were presented to the participants in an initial focus-group discussion to identify which should be a component of the final scripted messages in the prototype of FAMVR. The researcher collated all participants' responses, which then guided the second focus group. Both focus groups with the same participants were conducted online via Microsoft Teams. The format was semi-structured to ensure the flow of ideas and capture any suggestions from participants that were not researcher-driven.[40] The first focus group lasted 60 min, and the second one lasted for 45 min until data saturation was achieved. These were recorded using a 32-GB digital voice recorder and the Microsoft Teams recording function.

Data captured focussed on participants' views and attitudes towards family members' voice interventions for delirium care, difficulties experienced with family integration in the ICU, views of the initial scripted messages, and thoughts on what helped or would help integrate patients and family members in delirium care. Ideas were also sought from the participants for the delivery of the intervention, as well as the relevant components, such as the frequency and duration of the intervention. The focus groups were invaluable to gather rich data and these lived experiences into the intervention. New messages suggested in the first focus group were explored and refined in the second focus group until no new messages emerged.

The activities in the second focus group centred on participants' feedback including the content, duration, and frequency of delivery of the intervention. Participants also identified and discussed potential challenges in relation to acceptability, usability, and feasibility of the intervention from their individual perspectives. Data from this second focus group were analysed using thematic analysis, and refinements to scripted messages were undertaken. This ensured that modifications were centred around evidence-based family integration into delirium care. The final messages were sent to all participants for confirmation of what was agreed during the focus groups.

### 3.7. Data analysis

Focus-group recordings were transcribed verbatim. Data analysis was conducted in parallel with data collection to ensure that any new issues raised were explored in the second focus group. Data from participants with lived experience as patients and family members were analysed separately from the staff participants to capture the uniqueness of both perspectives. An inductive thematic analysis using Braun and Clarke's[41] technique was used to analyse

the data to identify the views and experiences of participants. The researcher independently transcribed data from the focus groups to become familiar with the raw data and noted initial codes during the process.[41] The transcribed data were uploaded to the QRS International's NVivo software (V.12, 2018), which supported the steps of the thematic analysis.[42] Initial codes were generated, and data relevant to each code were added. Codes were collated into potential themes, after which the themes were checked against the entire data set. Further analysis was conducted to refine the themes, and the final themes were generated before the final report was produced. The research team agreed upon the initial codes and final themes before they were finalised.

### 3.8. Techniques to enhance trustworthiness

Triangulation of data was achieved from various sources including field notes, verbal feedback during phone calls with participants, written and verbal responses in the focus groups, Microsoft Teams presentations, and discussion among participants.[43] A purposive sampling technique enabled targeted recruitment of participants with lived experience of delirium, which added richness to the gathered data.[43] Although the predetermined number of participants was a minimum of six, data were gathered until data saturation was reached. The nine participants who completed the fourth stage of the study provided sufficient depth of messages to enable final development of the FAMVR.

## 4. Findings

### 4.1. Description of participants

Twenty-six potential participants expressed an interest in participating in the study, including 10 people with lived experience as patients, two as family members, nine nurses, and five medical staff members. The total number of those who expressed an interest who went on to participate in the first and second stages of the study and who reviewed and returned comments on the draft-scripted messages was 12 overall: five people with lived experience as patients, one family member, three nurses, and three medical staff members. Three participants withdrew following the second stage; one medical staff participant withdrew due to work commitments, one nurse withdrew due to illness, and one person with lived experience as a patient withdrew due to other commitments. Overall, nine participants completed the development phase of the intervention. Of the nine participants, four were patients, one was a family member, two were nurses, and two were medical staff members, all aged between 30 and 60 years (Table 1).

### 4.2. Themes from the focus groups

Four key themes emerged from the analysis (Table 2). The first theme was message content, including type, frequency, and duration of orientation messages. The second theme was message wording, which included choice and order of words. The third theme was reactions to messages from patients, and the fourth was message tone, which centred on compassion and delivery. The content and application of the FAMVR were refined as a result. The initial draft-scripted messages (see Supplementary Materials Appendix 1, 2 and 3) were modified to form the prototype of the FAMVR intervention.

#### 4.2.1. Theme 1: Message content
Participants considered that understanding the ICU context was important in order for the messages to be suitable and acceptable to

**Table 1**
Participant description.

| Participant | Contribution | Role | Condition | Gender |
|---|---|---|---|---|
| 1 | First, second, third, and fourth stages | Patient | Delirium | Male |
| 2 | First, second, third, and fourth stages | Patient | Delirium | Male |
| 3 | First, second, third, and fourth stages | Patient | Delirium | Female |
| 4 | First, second, third, and fourth stages | Patient | Delirium | Female |
| 5 | First, second, third, and fourth stages | Family member | Caregiver | Female |
| 6 | First, second, third, and fourth stages | Nursing staff | Senior ICU nurse | Female |
| 7 | First, second, third, and fourth stages | Nursing staff | Senior ICU nurse | Female |
| 8 | First, second, third, and fourth stages | Medical staff | Senior medical | Female |
| 9 | First, second, third, and fourth stages | Medical staff | Senior medical | Male |
| 10 | First and second stages | Nursing staff | Senior ICU nurse | Female |
| 11 | First and second stages | Patient | Delirium | Male |
| 12 | First-stage medical staff | Medical staff | Senior medical | Male |

Abbreviation: ICU: intensive care unit.

patients, family members, and clinicians. The dynamic ICU environment necessitated that the messages focussed on providing ongoing orientation by nursing staff to orientate patients to the current time and date instead of recording time and date that could result in incorrect orientation provided to the patients. An example of this was suggested by a patient [Table 2, Quote 1].

Participants suggested that orientation messages in the current time, even if the date and month could not be captured, allowed flexibility to include individual circumstances, enabling an individualised approach to the content of the messages, which could lead to effective orientation. It was considered that nurses' providing information about the patient's illness would reassure them. Hence, the content of the FAMVR included two messages, where nurses would include current information. A patient reflected [Table 2, Quote 2].

This was supported by a nurse participant who also felt that the message should be situated in the present time [Table 2, Quote 3]. One patient participant felt that incorporating an element of flexibility into the catalogue of messages was important [Table 2, Quote 4]. Repetition of information was viewed as important by one medical staff participant [Table 2, Quote 5].

Each group of participants had similar perspectives and suggested that the content of the FAMVR had been designed to be played three times a day to allow for ongoing orientation and, whenever necessary, during routine nursing care and weaning from ventilation. Importantly, the messages are designed to be a guide to the family members who will be recording the messages, whereby they are encouraged to speak in their natural words whilst describing the fundamental elements of the messages. This flexibility in the content enhances the family-centred approach to the intervention. A patient participant viewed FAMVR as helping with memory recall whilst in the ICU [Table 2, Quote 6]. Another patient participant suggested that the FAMVR be played at least twice a day [Table 2, Quote 7]. A nurse participant suggested playing the intervention three times a day and observing closely for any adverse events that may occur so that the frequency it is played with is minimised [Table 2, Quote 8].

#### 4.2.2. Theme 2: Message wording

The FAMVR also focussed on messages around nursing care, such as bathing and oral hygiene. Patient and family member participants suggested that moving patients during routine nursing care can be distressing; therefore, messages designed around orienting patients during these activities could alleviate the anxieties experienced by the patients. It was also important to incorporate correct words that focussed on reassuring the patients and not exacerbating distress or fear. The original scripted messages were modified following multiple suggestions until the final messages

were agreed upon. The message "do not be scared" was altered to "I know that this may be confusing, but you are being looked after in the hospital", which is clearer and reassuring for patients. The tone of messages can promote a compassionate approach to care and be beneficial to nurses when included as a preventive strategy whilst caring for patients. A patient reflected that [Table 2, Quote 9]. A nurse participant viewed the FAMVR intervention within nursing care would improve compassion [Table 2, Quote 10].

Participants shared that the ICU environment can create fear in patients, but hearing a loved one's voice can reassure patients about their fears. Using gentle words would be more productive because some patients may not be frightened, and using words that infer fear may create fear for them and would be counterproductive. Confusing, calm, and relaxed words emerged as preferable for messages as they conveyed reassurance without exacerbating distress. This was reinforced by a patient participant [Table 2, Quote 11]. A patient participant felt that they were peaceful and calm during their ICU admission and would not have wanted their family members to feel they were in distress [Table 2, Quote 12].

#### 4.2.3. Theme 3: Reactions to messages

Participants shared that it can be distressing and frightening for family members to see their loved ones in the ICU or suffering from delirium; hence, it is important to include messages that recognise this reaction and reassure family members to minimise their distress and anxieties. Knowing that their family members are safe can also reassure patients. The experience shared by participants suggested that patients in the ICU may perceive nursing and medical staff as a threat to them, which may worsen their delirium; therefore, it was important to include messages that reassured patients about staff roles and that their family members were safe.

As the FAMVR can be played in the family member's absence, this became important for reassuring patients when family members were not present. This may prevent adverse reactions to the messages and also allow family members to both personalise their messages to specific family members who are visiting the patient or generalise it to their whole family [Table 2, Quote 13].

A patient participant felt that the familiar voice orientation would be helpful as their auditory senses remained active [Table 2, Quote 14]. Another patient participant felt that witnessing a patient manifesting delirium symptom could be distressing for family members [Table 2, Quote 15].

A patient participant felt that it was important to generalise the messages about family members [Table 2, Quote 16]. Another patient participant viewed it as important to allow the family members flexibility to say what they feel more comfortable with [Table 2, Quote 17]. An important consideration was that the family

**Table 2**
Themes and participants' quotes from the findings.

| Theme 1: Message content | Theme 2: Message wording | Theme 3: Reactions to messages | Theme 4: Message tone |
|---|---|---|---|
| **Quote 1** "This is where you are. You are in hospital, and now, the nurse will tell you the current date, time, and how long you have been unwell and then move on to the prerecording". {P1} | **Quote 9** "So I was fortunate enough to have, you know, my loved ones visiting me and being able to tell me lovely reassuring things in person, but whatever they said was being twisted by my brain and turned into something that just fed into the narrative of the delirium, really". {P3} | **Quote 13** "I'm a family member who visited my brother every day in intensive care and critical care. And but five years ago now. But even now, it's a struggle sometimes to talk about it because it was really distressing for me to see the delirium effects because I didn't know what it was". {P5} | **Quote 20** "There were times amidst the horror where I, too was having a nice time, and I thought I was on a train journey, and the sounds were the sounds of the train. So for somebody to say this isn't a train, that these are machines that are keeping you alive. I think again it's a very, very difficult thing". {P1} |
| **Quote 2** "I would love to have the time of day if possible, and of course, we are hearing the nurses' voices sometimes anyway. It is just so important for reorientation to know whether it's morning or it's night. Is it the same day, is it not". {P4} | **Quote 10** "I really like the message. I think we talked about compassion quite a bit, and actually, for me as a nurse, hearing a family member saying what we're about to do is quite humanising, and it actually will probably make the nurses aware of that compassion bit". {P7} | **Quote 14** "I just wanted to say that a very good point is that certainly when I was in the coma, I could hear things, and I could see lights and things. So, all of that, my brain was trying to make sense of it." {P1} | **Quote 21** "People might not hear loud noises and beeps, so it's just maybe something like you might be aware of some noises and beeps. They're coming from the machines that you may or may not be able to see, but they're helping you to get better". {P6} |
| **Quote 3** "Yeah, I think that is quite nice to have that nurse input. That particular date and time". {P6} | **Quote 11** "I think I did say in the suggestions that telling somebody not to be scared probably and certainly makes me more scared, and you know, especially because in my experience, I had feelings of paranoia anyway, so everybody was trying to kill me. So, I was in ICU for three weeks during the early stages of the pandemic in 2020. So nobody could come and visit me, but I do think that being able to hear a loved one. I think it would have helped me, and I can only speak for me if I'd been able to hear my wife's voice or my family's voice telling me, giving me that context". {P1} | **Quote 15** "I think the difficulty and I would have been certainly very upsetting, you know, for loved ones seeing the person experiencing the delirium". {P3} | **Quote 22** "I believe if we can add the function of the tube in a simple way that can be understood just to the patient and not in any medical term, just a simple way of explaining to the patient what is the reason of this tube". {P8} |
| **Quote 4** "I think if you can be flexible and have a certain level of flexibility around the formulation of the message, maybe based on the patient circumstances; that could help". {P3} | **Quote 12** "My husband had no idea where I was, you know, I looked peaceful, but I was asleep as far as he was concerned, there was no never any thought that you know of the terror that I was putting myself through, and I wouldn't have liked him to have thought that I might be frightened either. I wondered if it was possible as a prompt. Maybe a better prompt to say, you know, this may be very confusing, but you're being looked after in the hospital". {P4} | **Quote 16** "I would say give the option to generalise it because sometimes it's good to say the whole family are thinking of you and wishing you well and hoping that you're going to get better". {P4} | **Quote 23** "If it is possible. Take a normal breath as we prepare to take this breathing tube out of your mouth. To take a normal breath and also mention that there is something that's going to happen about the tube so that they are aware and trying to put both together in the same context". {P6} |
| **Quote 5** "Knowing that your illness is gone or that part is gone. The distressing event is gone is something which I got connected to or perceived quite easily and assuring that again and again repeatedly". {P8} | | **Quote 17** "I think it may be confusing to say that somebody is actually in the room and they're not in the room, and so I think just allowing the opportunity for the family member to say may be more appropriate for them". {P1} | |
| **Quote 6** "If it was, you know, morning, noon, and evening. I would like to hope that it's a point of drawing me back and I would get used to that". {P4} | | **Quote 18** "I don't have a problem with the specific family member as long as they're visiting. And if not, then I would go for, you know, the whole family".{P3} | |
| **Quote 7** "During the day, during the night sort of thing, we will be quite good, a good start". {P1} | | **Quote 19** "Rather than generalising family members instead, name one particular family person. Like for example, if I'm there on the ventilator, I'm recovering. I'm in delirium. The first closest person is my partner? I think that will be something which is been there always and that is the most comforting person for me". {P7} | |
| **Quote 8** "So I think that would perhaps be a good place to start in terms of orientation sort of morning, afternoon, and night, but I think we just need to be mindful that if people don't react positively to it, then perhaps we just try it once a day". {P6} | | | |

Abbreviation: ICU: intensive care unit.

members are visiting [Table 2, Quote 18]. A medical staff participant felt that personalising messages would be beneficial to some patients to ensure flexibility [Table 2, Quote 19].

### 4.2.4. Theme 4: Message tone

Participants stated that the ICU environment could be noisy due to the machines used and occasions of emergency situations; hence, it was important to include messages that reassured the patients about noises calmly. However, participants advised that not all patients may find the noises distressing, and not all may hear the noises, so the tone of the messages was designed to provide orientation to all patients. Instead of using words such as alarm, which may create a sense of urgency, words such as 'beeps' and 'noises' were recommended to provide a more reassuring message. Patient participants stated that while noises in the ICU may be distressing, it may also feel calming for some patients, particularly those who may be in a delirious state, so it was important for the messages to be communicated to patients neutrally and calmly [Table 2, Quote 20]. A nurse participant stated that some patients may not hear the noises in the ICU due to sedation [Table 2, Quote 21].

Participants advised that the message tone also determines how the messages related to different ICU procedures and devices are communicated to patients. Whilst there may be commonly used terms for staff, they may be distressing to patients and be devoid of meaning. For instance, some patients might be aware of the endotracheal tube (ETT), whereas others might not. It is uncertain whether being aware of the ETT compounds delirium; however, ETTs can add to the discomfort for critically ill patients, increasing the risk of delirium.[8] It is important to reassure patients about ETTs in a tone that may promote understanding of the support ETTs provide. A medical staff participant proposed a solution to this issue [Table 2, Quote 22]. A nurse participant suggested it was important to mention the procedure that will occur with the ETT and how this was phrased [Table 2, Quote 23].

## 5. Development of prototype FAMVR

As a result of this codesign approach, the FAMVR was developed as an intervention that enables direct communication between families and patients through voice either in real time or via recorded messages. Guided scripted messages are recorded on an iPad to provide orientation, reassurance, and comforting words from family members to their loved ones who are mechanically ventilated. These messages are then played, in the morning, afternoon and before bedtime, until the patients are no longer intubated and mechanically ventilated. This approach ensures that recorded messages in familiar voices can be played when family members are not visiting, and if family members are unable to visit, the messages can be recorded from them virtually and added to the library of messages.

The findings from this collaborative approach enabled the structure of the FAMVR intervention to be categorised into four domains: general reorientation, personal care, specific procedures, and a flexible domain where family members can record messages they feel are of value to the patients. The participants agreed upon the last domain to provide more flexibility to the family members to include messages of their choice.

The FAMVR is currently being implemented in an adult ICU as a pilot study to determine its effect on patients in real time using the Richmond Agitation and Sedation Scale score, as well as the feedback from patients, family members, and clinical staff.[3] The FAMVR will then be refined for a larger-scale study and integrated into delirium care in ICUs.

## 6. Discussion

This study applied the codesign method to develop the FAMVR for delirium prevention and management by collaborating with patients, family members, and clinical staff with lived experience of the ICU. The collaboration process enabled in-depth personal and professional insights into the key contents and format of the interventions, as well as its potential implications for the clinical practice of delirium in the adult ICU. The collaboration process was integral to the development of a family-led intervention that has the potential to prevent and manage delirium in the ICU.

The efficacy of nonpharmacological delirium management interventions within adult ICU settings is not well understood and may lead to an over-reliance on pharmacological therapies.[44] Adopting a collaborative approach to the design of an intervention such as the FAMVR allows the insights from collaborators to strengthen the efficacy of such intervention and enables the individual efficacy of the intervention to be studied.[45] Implementing non-pharmacological delirium management interventions in adult ICUs can be challenging due to the heterogeneity of these interventions and the vulnerability of the ICU patient population and barriers that come with conducting research in ICUs. The successful application of co-design in this study may provide preliminary information into such exploration.

Whilst family members' interventions are effective in delirium management and in improving the family members' psychological well-being,[18,24] the integration of family-delivered interventions is still limited in adult ICUs due to the paucity of evidence relating to the feasibility, acceptability, and effectiveness of these interventions. Findings from this study demonstrate that a codesign approach working with people with lived experience of ICU as patients, family members, and clinicians can be adopted to develop person-centred interventions within the critical care environment. This collaboration can increase the fidelity, acceptability, applicability, and standardisation of interventions and, therefore, enable more straightforward application to ICU practice.

Family involvement in health care is widely accepted and has been identified to be effective in improving overall patient outcomes.[46] Conversely, the literature reveals that ethical−legal consequences of family involvement in healthcare decision-making could create further tension and challenges for critically ill patients who often lack the mental capacity to make clinical decisions.[47] However, the adverse consequences of family involvement can be mitigated by setting up supportive strategies that enable family members to understand the care implications of their loved ones, such as patient public involvement groups and become involved in the capacity they feel comfortable with. This family involvement approach was considered for this study by involving an already established patient-family involvement group and working collaboratively to develop the FAMVR, ensuring that patients and family opinions are considered and integrated into the intervention. The codesign method remains an emerging approach to research studies in health care, and there is a paucity of evidence on the application of codesign in delirium management research. However, previous studies have identified its feasibility in inpatient rehabilitation settings.[45] The feasibility of the codesign method in ICU research is worthy of further exploration as the use of codesign in ICU research is recommended.

The strength of this study lies in adopting an evidence-based, person-centred approach to codesign a delirium management intervention. We minimised selection bias by allowing all eligible patients and family members to hear about the study by advertising through ICUsteps[35] and allowing them to make their own choices as to whether they want to participate or not. Also, selecting patients and family members who are not currently in the ICU

mitigates the bias of voicing their opinions about the care they received and the concern of being judged for their opinions, which enabled thorough modification of the FAMVR. The focus group involved clinical experts, patients, and family members, allowing for dialogue and consideration of both sides' thoughts before reaching an agreement on the final intervention. We utilised several routes to recruit and engage participants, resulting in more retention than anticipated, allowing substantial data to be collected that informed the intervention.

The limitation of the study is that the patient participants and one family member participant were not current patients in the ICU. Their experiences may have occurred several years ago, and their experiences may not represent the patients who will receive the FAMVR. However, we recognised this and ensured that the clinical expert participants were those currently holding clinical positions in the ICU. This will also be mitigated in the study's second phase, when the experiences of the patients and family members who receive the FAMVR will be evaluated, ensuring more family member recruitment. This evaluation will enable us to compare and refine the FAMVR before its utility can be established in clinical practice.

## 7. Conclusion

This study demonstrated that ICU patients, families, and clinical staff can be successfully engaged in codesigning novel interventions in the ICU. The FAMVR has the potential to contribute to the care and support of patients affected by delirium by integrating family members' voices to provide ongoing orientation, reassurance, and comforting words, which may minimise anxiety and severity of delirium. Further study is needed to evaluate the impact and effectiveness of the FAMVR on critically ill patients and their family members.

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## Credit authorship contribution statement

Gideon U. Johnson: Conceptualisation, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing—original draft, Writing—review and editing, Visualisation, Project administration.

Amanda Towell-Barnard: Conceptualisation, Methodology, Validation, Formal analysis, Resources, Writing—review and editing, supervision.

Christopher McLean: Methodology, Validation, Formal analysis, Resources, writing—review and editing, Supervision.

Beverley Ewens: Conceptualisation, Methodology, Validation, Formal analysis, Resources, Writing—review and editing. Supervision.

## Conflict of interest

The authors declare no conflict of interest.

## Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.aucc.2024.07.076.

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