

Co-designing a digital family-led intervention for delirium prevention and management in adult critically ill patients: An application of the double diamond design process

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ABSTRACT

Background: Co-designing healthcare interventions is gaining recognition as a novel and collaborative method. Co-design involves end-users from the start, ensuring that an intervention best meets their needs. Despite its potential benefits, this approach is not yet widely used in developing clinical interventions within intensive care units where the perspectives of patients, family members, and clinicians are crucial.

Objective: To describe the application, benefits and challenges of the Double Diamond model to co-design a digital family-led voice reorientation intervention for delirium prevention and management in critically ill adult patients.

Methods: The co-design process was guided by the Double Diamond model over a period of 12 months. Development involved patients, family members, and nursing and medical staff as co-designers and decision-makers in the iterative development of the intervention. Data from field notes and group meetings were audio recorded, transcribed verbatim, and content analysed at each phase, which were then presented to the co-designers for verification and refinement.

Findings: Co-designers included people with lived experience of the ICU as patients (n = 5) and family members (n = 1) and clinical experts (nursing staff n = 3; medical staff n = 3). Co-designers were highly engaged and reported positive experiences and collaboration in the co-design process. Sharing the diversity of their own personal ICU experiences was found to be beneficial as it not only validated individual feelings but also strengthened intervention development. Differences in interpretations and meanings of the voice messages proposed as part of the intervention were challenging. Maintaining sufficient focus on each phase of the Double Diamond was difficult due to the complexity of the context in which the intervention was being co-designed and the resulting challenges of maintaining the engagement of the co-designers throughout the process.

Conclusions: There were benefits and challenges of engaging people with lived experience in an intensive care unit as co-designers through the Double Diamond design process to develop a digital family-led intervention for delirium prevention and management. Overall, applying the Double Diamond to co-design a clinical intervention is recommended, whereby the collaboration process benefits patients, family members, and clinical staff.

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What is already known

- Co-design can be successfully used to design healthcare interventions.
- Co-design is recommended to minimise misalignment between

researchers and end-user needs and priorities for healthcare intervention development.

What this paper adds

- Applying the Double Diamond model to co-design a digital family-led voice reorientation intervention for delirium in adult ICUs.

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- Engaging individuals with first-hand experience of intensive care units, including patients, family members, and clinicians, in a collaborative process spanning four structured phases, each focusing on a distinct aspect of intervention design.

1. Background

Co-design as a participatory research method has emerged over recent years as a way to improve the quality of healthcare services (Slattery et al., 2020). Co-design approaches to healthcare delivery have been shown to provide safety assurance and optimise high-quality care through collaborative design processes such as the Double Diamond (DD) model (Ford et al., 2022; Masterson et al., 2022; Silvola et al., 2023). Many of these approaches leverage the significant impacts of engagement with partners, stakeholders, and leadership to bring culture change (Istanboulian et al., 2023; Manafo et al., 2018; Masterson et al., 2022; Robert et al., 2015). The focus on engagement and leadership transforms challenges into sustainable solutions through the simplified and engaging processes employed (Fusco et al., 2020; Masterson et al., 2022).

There are many different approaches to co-design methodologies, including the DD model (Design Council, 2019; Robert et al., 2022). The DD model was launched in 2005 by the Design Council United Kingdom (Design Council, 2019), and is an innovative framework that provides a visual description and presentation of the design process for users to follow and apply (Kochanowska et al., 2022). The DD provides a structured and straightforward framework that can be applied in any context to support the development of innovative research or quality improvement projects (Ford et al., 2022; Melles et al., 2021). One essential principle of the DD is its focus on involvement and partnership with the stakeholders for whom an innovation is developed (Design Council, 2019). The DD has been beneficial in designing healthcare projects and transforming the delivery of services and programmes that improve health outcomes (Ford et al., 2022; Zhao et al., 2023; Zhang et al., 2019). The DD model has continued to gain popularity over the years as a co-design research method to improve healthcare services and bring about social change (Ford et al., 2022; Zhao et al., 2023). As a design model that employs participatory methods, the DD addresses the gaps in inclusive user-centred design of healthcare interventions (Zhao et al., 2023). It is important to uphold intercultural principles that promote mutual respect and reduce conflict in participatory research (Lachner et al., 2015; Soehnchen et al., 2023). Mistakenly adopting a strictly linear approach to the DD model could

create a rigid process that makes it difficult to exchange meaningful and clear messages across cultural boundaries (Soehnchen et al., 2023).

Despite the broader integration of co-design in improving healthcare services, the application of the DD model in the design of clinical interventions is still emerging, particularly for vulnerable populations including those with lived experience of the intensive care unit (ICU). As the DD is a relatively new approach to developing interventions in the ICU environment, an evaluation of the impact and applicability of the DD in this area is important especially considering stakeholders' engagement, personal and professional experiences as a fundamental tenet of the model (Twamley et al., 2023). Technology is an important component of care and support in the ICU environment. In order to advance the management of the critically ill patient and optimise outcomes, technological innovation must also continue to advance (Mao et al., 2023), and the inclusion of key stakeholders in the design processes of any advancements is a vital component. Involving stakeholders is essential to ensure that new technologies are of clinical relevance and that their potential risks are identified and addressed to ensure patient safety is maintained (Robert et al., 2015). Utilising a DD co-design approach to create technological interventions which engages stakeholders from the outset can ensure that the results of the interventions meet the needs of the people for which they have been designed, as well as potentially increase the acceptance, adoption, adherence and satisfaction of users and enhancing the overall experience (Fylan et al., 2021; Slattery et al., 2020; Raynor et al., 2020; Robert et al., 2015).

The DD comprises four phases (Fig. 1): discover, define, develop and deliver (Design Council, 2019). The first diamond in the DD model represents a process of exploring an issue more deeply and broadly by understanding the problem from the perspectives of people who have lived experience of it, gathering their insights to help define the problem and seek solutions (Design Council, 2019; Robert et al., 2022). The second diamond represents the development of potential solutions to clearly defined problems, improving on them and rejecting ideas that do not contribute to the solution (Design Council, 2019; Robert et al., 2022). In this way, both diamonds represent a process of moving from divergent to convergent thinking. The DD is not a linear process; it is iterative where new ideas lead to a return to earlier stages, creating an opportunity for continuous feedback and improvement of the process (Design Council, 2019; Shen et al., 2024). Participating as a co-designer in a study using the DD method does not require designer skills, however, ensuring the inclusion of appropriate stakeholders with lived experience and effective management of the collaborative processes required are central to being a



Fig. 1. The Double Diamond model (Design Council, 2019).

successful co-designer (Banbury et al., 2021; Kochanowska et al., 2022; Tanay et al., 2022). The core principles of DD include prioritising people (co-designers), visual and inclusive communication, collaboration and iteration, which lead to an equal balance of power between researchers and participants (co-designers) that is mutually beneficial (Banbury et al., 2021; Melles et al., 2021).

Delirium is a common and serious condition in critically ill patients, characterised by acute confusion and cognitive disturbances (Mart et al., 2021). Recent evidence has highlighted the role of familiar voice reorientation in preventing and managing delirium (Johnson et al., 2024b). Involving family members in delirium care and using familiar voices to reorientate and comfort patients leverage the emotional connection to promote cognitive stability. A study has shown that incorporating family voices digitally into patient care resulted in delirium-free days in critically ill patients compared to those without family voices (Munro et al., 2017). Given these benefits, involving family members in designing delirium interventions is crucial to ensure the approach is effective and feasible in real-world settings. This highlights the importance of the co-design process employed in developing our digital family-led intervention, aligned with the principles of the Double Diamond design process.

The researcher conducted a two-phased implementation study of a family member's voice reorientation (FAMVR) intervention in the ICU. The findings from this study have been reported elsewhere (Johnson et al., 2024a). Phase one of the study comprised the development of the FAMVR programme, and phase two comprised a mixed-methods pilot study to explore the acceptability and feasibility of the FAMVR intervention (Johnson et al., 2024c). The current paper reports specifically on the application of the DD model as a co-design method, including the visual illustrations of the four stages of the DD and stakeholder engagement. The paper reports on the experiences of the co-designers as well as the benefits and challenges of employing the DD method in this context.

2. The project: developing a family member's voice reorientation (FAMVR) intervention to prevent and manage delirium in critically ill adult patients

Patients in the ICU on mechanical ventilation via an advanced airway experience psychological and physical difficulties with communication (Guttormson et al., 2015; Ijssennagger et al., 2018; Istanboulian et al., 2020). Patients also experience the unfamiliar ICU environment, supportive treatments for critical illness, procedures and routines which are unfamiliar and difficult to understand, all of which can contribute to the development of delirium which can yield deleterious short- and long-term outcomes for those who experience it (Mart et al., 2021; Tilouche et al., 2018). The barriers around limited visitation in ICUs can further compound these challenges, making some patients feel distant from their loved ones (Mohsen et al., 2022; Rose et al., 2022; Secunda and Kruser, 2022). In this context, we hypothesised that the development of a digital family-led voice orientation programme to provide ongoing orientation, reassurance, and comforting words to critically ill patients on mechanical ventilation may play a role in preventing delirium and/or minimising anxiety because orientation is important as it supports connection with patients and their families during a vulnerable time in the ICU. Whilst family-led interventions have been identified as beneficial in delirium care, gaps exist in creating and implementing user friendly and user managed interventions that can be consistently utilised (Johnson et al., 2024b). To accomplish this objective, it was crucial to involve people with lived experience of the ICU as patients, family members and clinicians as co-designers in a collaborative co-design process to ensure the intervention met the needs of those for whom it was intended. The co-designers' unique experiences and professional insights were explored to produce the digital family-led programme (FAMVR) to address this gap in ICU delirium care.

3. Method: the DD model

3.1. Setting

The intervention was designed for a 32-bed general adult ICU of a large metropolitan hospital in the United Kingdom (UK), where the clinical co-designers worked (Johnson et al., 2024c). The design period occurred between April and July 2023, after which the intervention was implemented in the ICU between August 2023 and March 2024. The design process occurred via virtual platforms (Microsoft videoconferencing). The patient and family member co-designers were members of the ICUsteps organisation, a registered charity in the UK that provides support to critically ill patients and their families during and after hospital discharge (ICUsteps, 2005). The study received ethical approval from the London – Camden & Kings Cross Research Ethics Committee (REC ref.: 23/LO/0057) (registration number: ACTRN12622001568707; ANZCTR – Registration).

3.2. Recruitment and participants

There were two groups of co-designers: the patient and family member co-designers, and the clinical expert co-designers. A purposive recruitment strategy was used to recruit co-designers to ensure maximal experience-based diversity in the groups (Green et al., 2020; Raynor et al., 2020). A target of six co-designers was set, including two ICU clinicians, two family members, and two patients. Eligible co-designers were provided with participant information which made clear that participation was voluntary, and written consent was obtained.

3.2.1. Recruitment of patient and family member participants

The co-designer group was recruited via ICUsteps (ICUsteps, 2005). The researcher used email and electronic posters to contact the ICUsteps organisation, which, in turn, advertised the study on its website. Inclusion criteria were people aged 18 years and over who had experienced delirium or were family members of someone who experienced delirium in the ICU, could understand English, have access to the internet to support virtual meetings and were able to provide informed written consent. Interested co-designers initially contacted the researcher directly and more information was provided about their participation in the study, as well as the participant information and consent forms. Participants had at least 24 h to consider participating in the co-design process after receiving this information.

3.2.2. Recruitment of clinical staff participants

This co-designer group was recruited via email and poster distribution on staff notice boards at the study site. The researcher also attended face-to-face staff meetings, where details of the study were shared with clinical staff, and face-to-face recruitment occurred if they were interested. The inclusion criteria comprised those who held permanent clinical positions as senior nurses or medical practitioners in the ICU. This was to ensure that extensive experience of the ICU was captured in the design process. Participants had 24 h to consider their participation before responding to the researcher. Interested participants contacted the researcher directly, who engaged with them by sharing more information and the participant information form and consent.

3.3. DD phases and adaptation to the FAMVR development

The four phases of the DD model provide a distinct focus for the design process, and each comprises a set of activities to ensure the structure and clarity at each stage (Design Council, 2019).

3.3.1. Phase one: the discovery phase

This phase aims to enable people with lived experience of the problem or phenomenon to understand the problem. In the FAMVR project, the goal of this phase was to consult with the co-designers to explore

and generate ideas to form the basis of the key messages that could provide orientation, reassurance, and comfort to patients with delirium. Co-designers were requested to write about their experiences of reorientation in the ICU as patients, family members, nurses and medical staff. Participants were also asked to comment on the appropriateness of 30 pre-designed draft messages, drawing upon their own experiences. The 30 draft messages were adapted from a literature review (Johnson et al., 2024b) and the researcher's clinical experience at various periods of engagement with service users.

3.3.2. Phase two: the define phase

This phase aims to refine the findings gathered from phase one to clarify the challenge in a focused format. In this project, the focus of messages generated from phase one was defined and refined, providing a basis to be incorporated into the FAMVR intervention. Co-designers were presented with the collated information from phase one during a recorded online audio-visual (Microsoft Teams) 60-minute semi-structured focus group.

3.3.3. Phase three: the development phase

This phase encourages people with lived experience of the problem to provide different potential solutions for the problem using their unique insights and perspectives and drawing upon a wide range of perspectives. This was achieved through a second focus group which was held online for 40 min. During this discussion, the details of the approach, technique, and messaging were developed in order to finalise how the intervention should be delivered and enable finalisation of the FAMVR intervention.

3.3.4. Phase four: the deliver phase

This final phase focuses on trialling the solutions at a small scale, refining the solutions and eliminating those that are not feasible. In this project, the FAMVR intervention was tested and evaluated in a small patient population as a pilot study, and further refinement was made following feedback. The findings from the pilot study are reported elsewhere (Johnson et al., 2024c).

3.4. Data collection and analysis

Table 1 outlines the activities that occurred within each of the four phases of the DD model. At the end of each phase, the data collected were analysed to inform the next phase and maintain the iterative process (Design Council, 2019; Shen et al., 2024). All co-design meetings were audio and video recorded. Data collected included focus group transcripts, written feedback on the draft scripted messages, and field notes (the researcher's notes during the telephone consultation). The researcher also recorded a reflexive journal where feedback and presumptions were documented. Data were transcribed verbatim and analysed using deductive thematic analysis to summarise the contents of the intervention, the experiences of participating in the co-design project, and the benefits and challenges of adopting the DD method (Naem et al., 2023). The research team agreed on the predetermined themes based on the purpose of the design process. For each phase of the DD, the researcher generated initial codes based on the defined themes, reviewed codes to ensure the themes were adequately captured, and refined the themes to clarify what each represented (Naem et al., 2023).

4. Findings

4.1. DD phases

Twelve co-designers completed phases one and two of the DD process, and nine completed phase three after three (patient $n = 1$; nurse $n = 1$; medical staff $n = 1$) withdrew due to work and personal commitments. Four co-designers who were clinical experts contributed to phase four of the DD. The co-designers comprised people with lived

Table 1
DD phases and methods adapted to FAMVR development.

DD phases	Methods used in FAMVR development
Discover	<ul style="list-style-type: none"> Co-designer consultation Email Phone call Face-to-face Videoconferencing Shared findings from literature review identifying needs for family integration in delirium care. Feedback on draft scripted messages. Collation and categorisation of feedback into messages needing changing, messages without changes, and messages with new suggestions.
Define	Focus group (clear electronic agenda shared via email before the meeting) <ul style="list-style-type: none"> Video platform for home or work location Audio transcripts Excel spreadsheets PowerPoint slides Transcript content analysed. Messages are refined and categorised into three domains.
Develop	Focus group (clear electronic agenda shared via email before the meeting) <ul style="list-style-type: none"> Video platform for home or work location Audio transcripts Digital illustrations Acknowledgement of differing perspectives and resolutions discussed. Transcript thematically analysed. The FAMVR prototype was agreed upon and presented.
Deliver	Co-designers were thanked and appreciated for participation by email. Training and staff support. Meeting with host study site. Test the FAMVR intervention as a pilot study with 15 patients and 15 family members.

experience of the ICU as patients ($n = 5$), family members ($n = 1$), nurses ($n = 3$) and medical staff ($n = 3$). Seven of them identified as females, and five identified as males.

4.1.1. Discover

Co-designers provided direct input to the draft scripted messages by suggesting new messages and recommending the order of delivery of the messages. Table 2 illustrates how one of the messages changed, detailing two co-designers' personal and emotional experiences of delirium and the ICU care environment, which resulted in the final message. All co-designers recommended a series of new messages and conveyed what each meant to them and what they could mean to patients and family members in the ICU context in relation to auditory reorientation. The researcher and individual co-designers held in-depth discussions, after which the draft messages were further reviewed and amended upon agreement with the co-designers.

The co-designers recommended 125 messages (patients $n = 78$, family $n = 18$, nurses $n = 21$, medical staff $n = 8$). Following the collection of all the responses, the researcher collated and categorised the data into three key domains: general ICU orientation, ICU routine care, such as providing hygiene care to the patient; and a domain associated with ICU procedures such as weaning off mechanical ventilation and spontaneous breathing trials.

4.1.2. Define

Co-designers discussed their underlying values as former patients or family members and current clinical experts, which gave rise to new ideas and further elaborated the messages for the intervention. The group agreed that the most crucial aspect of the FAMVR intervention would be the compassion demonstrated in delivering the messages and in providing flexibility for the family members to use natural words to convey these messages. One of the co-designers contributed by reflecting upon their experience:

Table 2

Example of how the Double Diamond model enabled changes to the FAMVR messages.

Initial message	Co-designer suggestions	Final message
Message 1: Do not be scared	[Patient] "Speaking about the word scared and that would have triggered me even more." [Family] "Please don't be frightened and you are being looked after in a hospital. I think that sounds much more how you say reassuring to the patient rather than just saying don't be scared."	Message 4: I know that this may be confusing, but you are being looked after in the hospital.

"Obviously with me I had no familiar surroundings and the compassion could have been better. I was being a bit rebellious, but if there had been a bit more hands on, bit more softer approach maybe I would not have felt like a prisoner."

[Patient]

Another co-designer emphasised a personalised approach to the intervention, which the group agreed upon would be beneficial to patients and family members:

"I think that we've talked about this before, about it being an individual experience, it has to be an individual experience."

[Patient]

The contributions at this phase culminated in the development phase, where Table 3 was presented, showing the general orientation domain of the FAMVR intervention messages functioning as a guide and prompt to family members when recording on the iPad rather than being pre-determined and the same for all. However, where family members may not feel confident in using their own words, the presented script may be useful for them to help record the messages.

4.1.3. Develop

Agreement was reached on the final version of the FAMVR messages (Table 3) and prototype as a sketch (Fig. 2), including aspects related to duration, frequency and arrangement of the messages. One of the co-designers considered the impact that the duration of the messages could play in reorienting patients:

"I'm quite happy with the length of what you have. I really am and it's because time is so completely warped and it's kind of non-existent like a second can be a day."

[Patient]

Another co-designer viewed the length of the messages as comparable to the frequency that the group agreed upon:

"I think the messages was a good length and it's not very lengthy like for hours and hours. So we should be able to accommodate first thing in the morning once we are like beginning the shifts and during the day and like again in the evening time."

[Clinician]

Table 3

Domain one of the FAMVR messages.

<p>Domain 1 – General Reorientation to the ICU Scripted Messages for ICU Reorientation to be played 3 times a day (Morning, afternoon and bedtime)</p> <p>Please speak in a soft tone. These messages are a guide for you and you may use your own natural English words.</p> <p>Introduction</p> <p>Hello/Hi/Hey ----- (Say patients name with any familiar or usual endearment or word). This is ----- (your name or endearment) your ----- (your relationship to the patient). I'm sending you this message to help you understand where you are and what is happening around you.</p> <ol style="list-style-type: none"> 1. Your nurse is going to tell you the current date and time (The nurse will insert time of the day, day of the week, date, month, year). 2. Your nurse will also tell you how long you have been unwell for (The nurse will insert length of time in ICU, illness, disease or accident that the patient is experiencing based on what you think would help). 3. You are in ----- (Insert name of the hospital). 4. I know that this may be confusing, but you are being looked after in the hospital. 5. Your doctors and nurses care about you and are looking after you. 6. You might hear noises and beeps that are coming from the machines that you may or may not be able to see, but they are helping you to get better. 7. Please try to stay calm and relax ----- (endearment) as the nurses and doctors work to help you feel better. 8. I feel safe that you are in good hands here. 9. (Specific family member or our family) know you are here and have visited you (Past tense) and thinking of you. 10. I Love You (Usual endearment, closure or how you would usually end a conversation with them).
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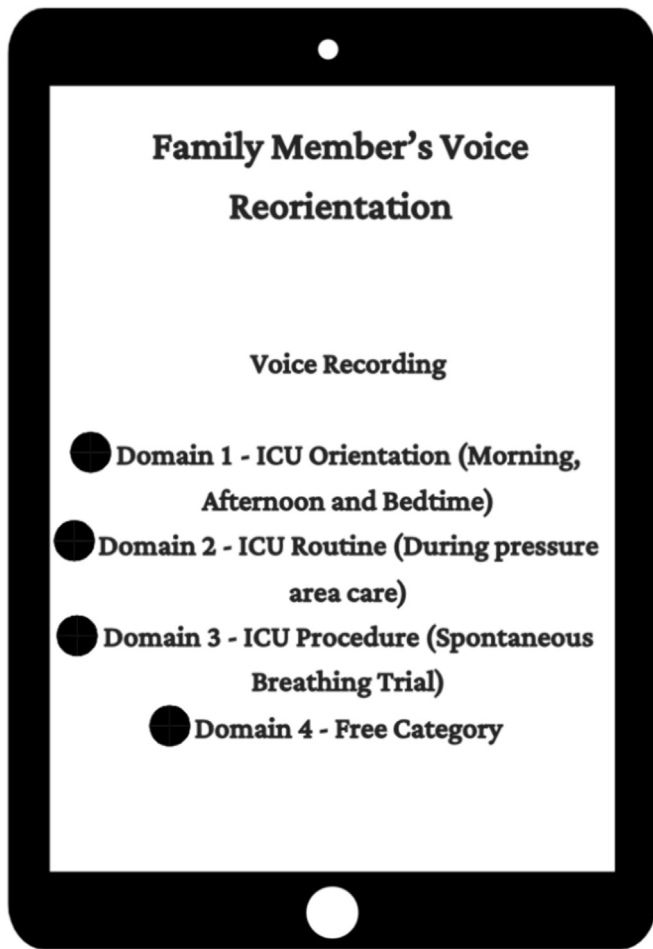


Fig. 2. The FAMVR prototype.

The participants reflected upon the prototype and considered its potential impact if it were to be implemented in practice. A co-designer conveyed the potential long-term positive outcome of the intervention to patients and their family members:

"Albeit that may distress some people, but actually I think in the long run it will help."

[Patient]

Another co-designer reflected on their experience as a family member to an ICU patient and relayed the impact of family reorientation to patients:

"You know he couldn't speak or anything like that, cause one of the effects of being in the coma, but he recognised my mum and dad even though he couldn't speak, it was reassuring for him and it was wonderful for them to see him too."

[Family]

The group discussed how the FAMVR messages would make them feel and how they might support patients and their families. The developed script of the FAMVR and a guide for the delivery were then presented to the group before the conclusion of the meeting.

4.1.4. Deliver

The FAMVR prototype (Fig. 2) was shared with experienced clinical staff and a team of ICU clinical leaders who recommended and

commended its use in the ICU. The intervention was then implemented in real time over 6 months; 15 critically ill patients and 15 family members were enrolled in the study (Johnson et al., 2024b). The FAMVR is intended to be used by nurses to assist in mechanically ventilated patients' orientation in real-time. Domain one is used in the morning, afternoon, and night to provide general ICU orientation. Domains two and three are used as needed before repositioning patients and during the weaning process from mechanical ventilation. Domain four is used as needed for patients whose family members do not visit regularly to provide them with context about everyday events in their families. During the deliver phase, feedback was obtained from family members and clinical staff on the process and the overall intervention. This feedback will enable further refinement of the FAMVR intervention, the results of which will be reported elsewhere.

4.2. Participants' experiences

Co-designers described the experience of being part of the DD co-design process as invaluable and a positive one. One of the clinicians viewed the experience as reflective and expressed gratitude for the opportunity to collaborate with former patients on such a vital project:

"I just wanted to say X, irrespective of your lovely piece of research that you're doing and it's always very welcomed when we get family members and ex-patients coming back to talk to us, as healthcare professionals it's very humbling to hear your experiences."

[Clinician]

Co-designers described the digital platform as an enabler to their engagement with the project, enhancing their contribution to the collaborative process in their natural settings without the requirement to commute to a physical location. One of the patients reflected that this collaboration process provided an opportunity to engage with clinicians by enhancing the depth of insights and experiences:

"I was actually meeting with the some other friends through the patient public involvement. A work up here in Edinburgh, and I think for us as ex patients. It is humbling that healthcare professionals are wanting to listen. You know, they wanting to hear what we have to say from our perspective and they are actually listening and taking it on board. So I think it's a two way street you know."

[Patient]

Co-designers were fully engaged at every DD model phase, exploring each other's perspectives, asking questions and providing alternative solutions. The resulting discussions gave deeper insights and meaning to the messages, where participants could draw upon their personal and professional experiences.

4.3. Benefits and challenges

As a result of the phases of the DD, five co-designers contacted the researcher to further express how they valued being involved in the study. They provided additional suggestions for the messages, sharing their lived experiences of the ICU and how the FAMVR intervention could benefit patients, families and clinical staff. Some co-designers specifically referenced the COVID-19 pandemic and the associated isolation experienced by families visiting their loved ones in the ICU, identifying how the FAMVR intervention could bridge that gap if such access restrictions occurred again in the ICU. Some participants' descriptions of their experience of having delirium whilst in the ICU highlighted the importance of the FAMVR in preventing delirium or minimising patients' anxieties through familiar voice orientation and reassurance. The group collaborative process was beneficial in creating positive group

dynamics, where co-designers questioned and clarified each other's perspectives as needed and showed compassion and understanding for each other's experiences. One co-designer reflected upon his experience in the ICU:

"Being under delirium, I can honestly say I was like a scared little girl. So just because you've got a fit young man or an old man, or you think that person's strong and doesn't need that comfort."

[Patient]

Other co-designers reassured him with their own experiences, emphasising on the importance of compassion:

"I do believe everybody should be treated with that compassion, regardless of who they are."

[Patient]

"You learn over a couple of months who you could trust and you know there are some excellent individuals, but equally, you know, there's some people who were lacking in compassion."

[Family]

Sharing the diversity of their own personal ICU experiences was crucial to validating individual feelings and strengthening the fidelity of the FAMVR intervention. This meant various perceptions could be represented in the intervention development, enhancing its acceptability. A co-designer reported their experience of family involvement worsening their delirium symptoms:

"I can't see what adverse effect it could have effectively, but certainly in my case, even music fed into the delirium."

[Patient]

Whereas another co-designer perceived family involvement as essential to them and helped to improve their delirium symptoms:

"I think something from a family member would be much more useful, actually for me would have been critical there because it would have at least given me some sort of reassurance."

[Patient]

Collaborating with different groups of co-designers with unique perspectives and experiences was challenging initially, as each one had different interpretations and meanings to the initial messages. For example, a co-designer reported that the orientation messages about the ventilator and endotracheal tube may be irrelevant. In contrast, another co-designer emphasised the importance of orientating patients about these devices:

"Personally, I would have started to panic if I had heard the words that I was on a ventilator and had tubes in me."

[Patient]

"I suppose it's playing this message for those perhaps that it is a problem. Because what we sometimes see is a lots of people who are trying to get rid of the tube before they're ready. So we have to some way let them know what it is and what it's doing."

[Clinician]

However, when the focus group discussions commenced, co-designers drew upon each other's perspectives, and ideas were clarified,

giving equal consideration to everyone's contributions. Sustaining the focus of each phase of the DD was challenging as patient and family member co-designers initially approached the focus group as a debrief session with the clinicians, which led to occasional digressions from the focus of the phase. It was apparent that most of the co-designers had not had an opportunity to talk about their ICU experiences with clinicians until that focus group. Utilising a clear agenda and semi-structured questions enabled the researcher to steer the focus group to achieve the aim of the DD phases.

5. Discussion

This paper reports on the DD model and the experiences, benefits, and challenges of applying it to co-design a digital family-led intervention for delirium prevention and management in critically ill adult patients. The application of the DD model provided a clear focus for consultation during the co-design process, and was achieved through appropriately staged contributions from participants through methods which included focus groups and the use of a virtual video conferencing platform to enhance engagement. The diversity of the co-designer group provided unique insights into the value of the DD process, which enabled positive experiences shared by the group. Challenges around initially different viewpoints from co-designers were clarified, and they could then draw upon each other's perspectives, further enhancing the co-creation process.

Applying the DD as a co-design method to develop the FAMVR programme through clear, distinct phases of co-creative development and co-evaluation ensured that the content and technology were developed and trialled as an intervention to support delirium care. Experience-based co-design emphasises the need to share power between participants and researchers, creating a mutually inclusive group whereby every participant can speak (Robert et al., 2022; Small et al., 2021; Swarbrick et al., 2019). For this reason, designing interventions in partnership with people with lived experience of a health experience is strongly supported by the broader health literature (Heaton-Shrestha et al., 2022; Raynor et al., 2020; Park et al., 2018), however, we believe that the development of a co-designed intervention is unique within an ICU environment.

The co-designers in this study benefitted from the collaboration in several ways. Sharing their lived experiences of the ICU in a supportive environment was the first opportunity for most of them to learn from other people's experiences of delirium. Several other benefits have been reported in the literature when using the co-design method, and these benefits are centred around the experience-based approach whereby people are prioritised in the co-design process (Banbury et al., 2021; Raynor et al., 2020; Robert et al., 2022; Small et al., 2021). Co-design methods have been validated in various aspects of healthcare intervention development (Banbury et al., 2021; Fusco et al., 2020). Whilst its application in the ICU is emerging, it has been identified as successful and beneficial to clinical practice in improving patient care (Istanboulian et al., 2023).

Whilst the application of DD to intervention development is promising, it may be challenging to engage a vulnerable population such as ICU patients in the process (Locock et al., 2014a). The discovery phase has been reported to be lengthy and expensive, which can impact the progression of the various design phases and the implementation of the intervention (Donetto et al., 2013; Locock et al., 2014a; Locock et al., 2014b). Therefore, it was essential for the researchers to explore the literature extensively (Johnson et al., 2024b) and leverage their clinical expertise to illustrate an initial draft of scripted messages, which minimised barriers to engagement by the co-designers and increased uptake as they had an existing draft to work with (Locock et al., 2014a). Recounting past traumatic experiences can be difficult for some people and may be counterproductive in this process (Harlan et al., 2020; Hirshberg et al., 2020). Our experiences demonstrate that this can be transformed into a positive experience by fostering a

supportive environment for the participants whereby they feel safe to recount their experiences at a pace that they feel comfortable with and return to the focus of the DD phase when they feel ready (Reifarth et al., 2023; Robert et al., 2015; Tanay et al., 2022). This project identified that most co-designers were often ready to continue with the focus of the DD phase without prompting, and they maintained clarity of the focus throughout the engagement process.

During the co-design meetings, the use of a virtual platform presented communication barriers that made it challenging to discuss complex issues such as experiences of delirium. The virtual platform limited the ability to observe non-verbal cues, which are important for understanding the reactions and engagement levels of the co-designers (Pettersson et al., 2020). Although the platform had virtual functions that enabled participants to convey reactions via images, some co-designers did not know how to use them. This is consistent with other studies reporting computer literacy as a barrier among participants in virtual focus groups (Tran et al., 2021). To mitigate this barrier, it is important to provide adequate training and support to co-designers before using virtual platforms.

5.1. Strength and limitations

The strength of this study lies in its structured collaborative approach to designing a simplified intervention that provides representatives of family and patient populations the ability to inform the intervention from the onset. This ensured that end-user perspectives were captured and prefaced, maximising the intervention's acceptability and fidelity. Adopting a digital approach to the intervention provides an opportunity to align with emerging technologies in ICUs. Afterwards, the intervention can be refined over time via various digital platforms such as apps, other audio-visual devices or embedment within televisions if present in the ICU setting. Also, adopting virtual engagement enabled co-designers to fully engage and participate in the phases of the DD from their natural settings. Another strength of this study is successfully co-designing a clinical intervention in a challenging patient population and setting, which is transferable to other clinical areas such as aged care, paediatrics, dementia and care of the elderly and learning disability.

The first limitation of this study relates to the small number of participants involved, particularly having only one family member involved, which cannot capture all the diversity of experience in ICU care. Although data saturation was achieved, a larger number of participants may better represent ICU patient populations. Secondly, whilst the group's collaborative approach was beneficial to the co-designers, it was unclear if it provided a psychologically safe space for all co-designers to provide their opinions and perspectives. Some patient and family co-designers may have withheld vital information about their experience due to concerns about speaking in a group setting or being challenged by the clinical experts in the group. Presenting an initial draft of scripted messages to the participants during the discovery phase may pose a risk to the method as participants may provide recommendations based on the script instead of their unique experiences. This risk was mitigated by allowing participants to discuss their lived experiences during the focus groups without limiting them to the scripted messages.

6. Conclusion

The DD model as a co-design method was integral to the design of a delirium intervention for ICU patients in this study. The value of using the DD model relates to the structure and clarity it provides to create people-centred interventions to manage complex health issues, where power can be shared equally among co-designers, and co-designers are given the authority to provide constructive feedback through their experiences and insights. Interventions developed via a DD approach can strengthen applicability in ICU settings, where the DD co-design

method is an emerging approach to clinical intervention development. The report has demonstrated that safe and effective collaboration between ICU patients, family members and clinicians in developing a clinical intervention is achievable and mutually supportive.

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CRedit authorship contribution statement

Gideon U. Johnson: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Amanda Towell-Barnard:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Formal analysis, Conceptualization. **Christopher McLean:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Formal analysis. **Glenn Robert:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Formal analysis. **Beverley Ewens:** Writing – review & editing, Validation, Supervision, Resources, Methodology, Formal analysis, Conceptualization.

Data availability

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

Declaration of Competing Interest

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

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