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Effectiveness of a virtual reality-based sensory stimulation intervention in preventing delirium in intensive care units: a randomised-controlled trial protocol

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ABSTRACT

Introduction Delirium is a common acute cognitive impairment characterised by confusion, disorientation and attention deficits, particularly prevalent in intensive care unit (ICU) settings. Given its significant impact on patients, caregivers and healthcare resources, preventing delirium in patients in the ICU is of paramount importance. This is the first randomised-controlled trial designed to evaluate the effects of a virtual reality-based sensory stimulation intervention on preventing delirium in ICU patients.

Methods and analysis We employed a paired randomisation method to match eligible participants based on a validated delirium risk scoring model for patients in the ICU. The study will commence in September 2024 and conclude in June 2026. A consecutive sample of 198 patients in the ICU admitted to the study setting will be recruited. Eligible participants will be randomly allocated to receive either virtual reality-based sensory stimulation in addition to usual care or usual care alone. The virtual reality-based sensory stimulation intervention will last for up to 14 days, with all interventions administered by a research team. We define delirium-free days over a 14-day period as the primary outcome. The secondary outcomes will include delirium incidence, duration and severity; patients' psychological well-being (post-traumatic stress disorder, sleep quality and ICU memory); patients' clinical outcomes and other outcomes (quality of life, independence and cognitive function). Data will be collected at baseline, post-intervention and 6 months post-intervention. Two independent t-tests or Wilcoxon-Mann-Whitney tests will be used for continuous variables, while χ^2 or Fisher's exact tests will be employed for categorical variables. The analysis will adhere to both the intention-to-treat and per-protocol principles. Additionally, mixed-effects models and subgroup analysis will be planned.

Ethics and dissemination This protocol was approved by the Research Ethics Committee of Shenzhen Hospital of Southern Medical University (NYSZYYEC20230068). All participants or their family caregivers will provide written informed consent. Results will be disseminated through scientific publications, and presentations at local and international conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study evaluates a virtual reality-based sensory stimulation for preventing delirium and improving patients' psychological well-being (specifically post-traumatic stress disorder, sleep quality, and intensive care unit (ICU) memory), patients' clinical outcomes (including ICU length of stay), and other outcomes (such as quality of life, independence and cognitive function).

⇒ This study uses a rigorous randomised-controlled trial design, incorporating a virtual reality-based sensory stimulation intervention for preventing delirium in ICUs. The methodological rigour of this design enhances the reliability and validity of our findings, providing valuable insights into the effectiveness of such interventions in clinical settings.

⇒ Due to the nature of the intervention, blinding was only possible for the outcome assessors, while blinding for the participants and those delivering the intervention was not feasible.

Trial registration number ClinicalTrials.gov NCT06153472. Trial registration date: 22 November 2023.

INTRODUCTION

Delirium is a common acute state of cognitive confusion. Intensive Care Unit (ICU) delirium is highly prevalent, with an incidence ranging from 31%[1] to 56%,[2] and it can be as high as 81%[3] in patients in the ICU undergoing mechanical ventilation. A preliminary analysis of data from 375 patients admitted to the ICU for more than 24 hours revealed an occurrence rate of 44% for ICU delirium.[4] Moreover, delirious patients in the ICU had 1.33 times longer ICU stays and a 9.57-fold increase in mortality compared with non-delirious patients in the ICU.[5] Patients in the ICU who experience delirium may suffer

from post-traumatic stress disorder, anxiety, depression and cognitive impairment for up to 2 years.[6]

Non-pharmacological preventive measures aim to reduce one or more modifiable risk factors for ICU delirium.[7] Previous research identified sensory stimulation as a key and effective non-pharmacological intervention in preventing ICU delirium.[8 9] Sensory stimulation involves activating one or more senses,[10] with visual and auditory stimuli being particularly effective for patients in the ICU.[11] To further investigate the effectiveness of sensory stimulation in preventing ICU delirium, the research team conducted an initial study to assess the implementation of sensory stimulation in preventing delirium in the ICU and subsequently developed a sensory stimulation intervention plan.[12 13] This plan involved daily sessions of 30 min each for 7 days, including visual stimuli (displaying personal or family photos) and auditory stimuli (playing recordings of family members). The results of the study showed that sensory stimulation reduced the duration and severity of ICU delirium but did not significantly decrease the incidence of ICU delirium.[8 9] The limited effectiveness of sensory stimulation may be attributed to the narrow range of stimuli, insufficient stimulus intensity and inadequate dosing and implementation methods.[9]

In contrast, virtual reality (VR) technology, characterised by its three-dimensional and highly immersive qualities, has the potential to provide more effective sensory stimulation by immersing participants in three-dimensional dynamic environments.[14] International research[15–17] suggests that VR offers significant advantages in sensory stimulation and could be a promising approach for preventing ICU delirium. However, it is important to note that studies on the use of VR in this context are still in the feasibility testing stage. The DREAMS project at the University of Florida in the USA investigated the effectiveness of VR and found that 95.6% of participants found it very comfortable, 51.9% reported improved sleep quality and 81.5% experienced reduced pain.[16] This team further conducted a study with 46 patients in the ICU, implementing a 7-day VR intervention, which resulted in reduced stress, pain, anxiety and improved cognitive function and attention in the participants.[17] Additionally, Jawed and colleagues conducted a preliminary trial that showed VR could alleviate anxiety in patients in the ICU.[15] However, since those studies were in the feasibility testing stage, they were unable to measure the effects on reducing ICU delirium.

The stress recovery theory and attention restoration theory explain the principles behind preventing ICU delirium using VR-based sensory stimulation.[18 19] The stress recovery theory suggests that natural environments support positive changes in emotional states and psychophysiological recovery, primarily by relaxing the parasympathetic nervous system.[19] In stressful ICU environments, cognitive and attentional resources can become fatigued, which is especially crucial for critically ill patients facing stressors. The cognitive demands and overstimulation in the ICU environment contribute to mental fatigue and stress responses.[19] On the other hand, the attention restoration theory suggests that exposure to natural environments requires fewer cognitive resources and promotes a sense of disengagement from stressors, allowing attention to rest and recover.[18] Therefore, VR-based visual and auditory stimuli, by immersing patients in relaxing VR environments, may provide a protective effect against environmental stress and support the recovery of physiological, emotional and attentional functions, thereby helping prevent delirium. Chirico and colleagues further elucidated the mechanisms of VR-based sensory stimulation in delirium prevention: exposure to VR-based natural environments can trigger a specific psychophysiological pattern activated by the parasympathetic nervous system, leading to intense emotional reactions.[20] Emotion responses increase with higher levels of immersion, which can be used to alleviate symptoms like anxiety, pain and fear, effectively reducing patient stress, improving sleep quality and consequently reducing the incidence of delirium.[20]

Aim and hypothesis

This study aims to evaluate the effects of a VR-based sensory stimulation in preventing delirium, and improving patients' psychological (post-traumatic stress disorder, sleep quality, ICU memory), patients' clinical (ICU length of stay) and other outcomes (quality of life, independence and cognitive function). The comparator in our study is 'usual care', representing the standard treatment or practices typically provided in similar clinical settings.

It is hypothesised that on patients' 14th day of ICU hospitalisation or the day of discharge (if the ICU stay is less than 14 days), they will experience the following improvements compared with those receiving usual care.

1. Patients in the ICU receiving the VR-based sensory stimulation intervention will have
   a. A reduction in the incidence, duration and severity of delirium.
   b. An improvement in their post-traumatic stress disorder.
   c. An improvement in factual memories.
   d. A shorter length of ICU stay.
   e. An improvement in the quality of life, independence and cognitive function.

At 6 months after completing the intervention, compared with those receiving usual care, patients in the ICU undergoing the VR-based sensory stimulation intervention will experience an improvement in quality of life, independence and cognitive function.

METHODS AND ANALYSIS

Design

A multicentre assessor-blinded two-arm parallel group randomised-controlled trial (RCT) will be conducted.

Setting

Participants will be recruited from general ICUs of Shenzhen Hospital of Southern Medical University and Shenzhen Hospital of Beijing University, two comprehensive tertiary A-level hospitals in Shenzhen, Guangdong Province, Mainland China. Tertiary A-level hospital provides specialist tertiary care in a large hospital after a referral from primary and secondary care.[21]

Participants

All patients in the ICU admitted to the study setting will be recruited if they are/have (1) aged 18 years or older, (2) first-time admission to the ICU and (3) a Richmond Agitation-Sedation Scale (RASS) score of ≥−3.[22] Patients will be excluded if they have (1) been diagnosed with dementia, delirium or acute psychiatric illness at admission, (2) been diagnosed with end-stage cancer, (3) severe hearing impairment and cannot be corrected by hearing aids and (4) been admitted to ICU with radioactive material.

Sample size determination

The sample size calculation was conducted to assess the difference in delirium-free days (the primary outcome) between the experimental and control groups, using GPower 3.4. A similar study evaluating the impact of sensory stimulation on delirium-free days (the primary outcome) indicated a moderate effect size between groups (i.e., d = 0.45) .[8] Utilizing GPower for a priori power analysis with a two-tailed independent samples t-test (means: difference between two independent means of two groups), we set the significance level at 0.05, the effect size at 0.45, and the power at 0.8, with a group allocation ratio of 1:1. The analysis estimates that a total of 158 participants are needed, with 79 participants in each group. Based on another similar study examining the effects of VR on critically ill patients, considering an estimated dropout rate of 20%, the total sample size for this study is estimated to be 198.

Randomisation and allocation concealment

We employed a simple randomisation method by generating random numbers through the randomization.com website. Based on these generated numbers, participants were then randomly assigned to either the intervention or control group. To ensure allocation concealment, consecutively numbered, sealed and opaque envelopes will be used. This process will be conducted by a research assistant who will have no further involvement in the study after participant enrollment.

Blinding

Owing to the nature of the intervention, the researchers responsible for delivering the intervention will be aware of the group assignment. However, the outcome assessors will remain blinded to the group allocation and will not participate in data analysis or result reporting.

Intervention

Participants allocated to the intervention group will receive a VR-based sensory stimulation intervention plus usual care. This intervention is designed to provide VR-based visual and auditory stimulation to patients in the ICU, with additional support from family caregivers. The intervention will be administered by researchers who are trained ICU nurses. It will commence on the patient's admission and continue until the 14th day of their ICU hospitalisation or the day of discharge if their stay is less than 14 days. Each day, a 30 min session will be conducted.[23–25]

The investigator will provide a delirium knowledge leaflet and a sample reorientation message to family caregivers in the intervention group. The investigator will spend 30 min explaining the contents to family caregivers during their first meeting. Family caregivers will be asked to prepare the family photographs, family video or recordings at their earliest convenience. The leaflet contains information about the definition, prevalence and risk factors of delirium, along with practical steps family caregivers can take to support the patients. These steps include engaging in simple conversations, reminding patients of the current time, date and location, providing glasses or hearing aids when necessary, decorating patient beds with family photographs and discussing familiar topics. The reorientation messages serve to help patients understand their surroundings and offer encouragement. Each segment of the message requires 2 min for recording, following the sample message. The leaflet was designed by the investigator, and the sample reorientation message was adapted from a previous study.[25] Both the leaflet and the sample orientation message were reviewed by a committee comprising three ICU nurse specialists, two nurse academics, one physician and two family caregivers.

Each daily session will commence at the earliest available daytime hour, typically between 12:00 and 16:00, following the completion of family recordings. During the pre-bedside phase, the investigator will gather family photographs, recordings and videos either digitally recorded or retrieved from previous family collections stored on electronic devices. Subsequently, the investigator will spend 30 min with each patient in the intervention group, tailoring the intervention based on the patient's ability to engage with auditory or visual stimulation (figure 1). Notably, the intervention will be discontinued for trial participants under conditions such as participant requests or fluctuations in disease status.

Implementation content

The intervention consists of the following stages: (1) guidance stage (5min): introducing the content and purpose of the VR scenes to be played in the next 30 min; (2) relaxation stage (12 min): selecting natural scenery VR scenes accompanied by soothing background music to help patients relax; (3) family and friends support stage (8 min): playing VR scene videos provided by family and friends, selecting happy moments and conveying

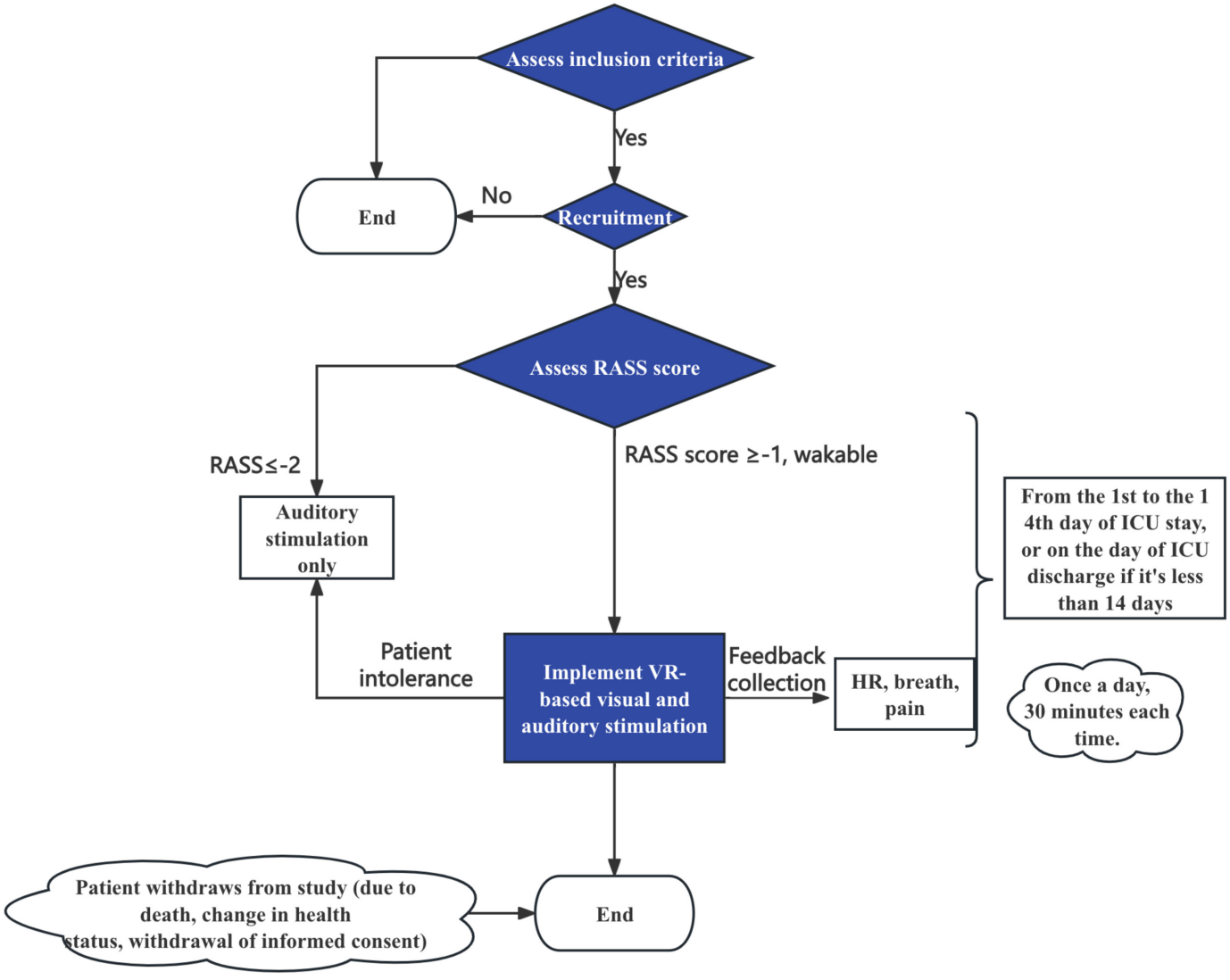

Figure 1 Flowchart of virtual reality (VR)-based sensory stimulation implementation. ICU, intensive care unit; RASS, Richmond Agitation-Sedation Scale.

family wishes and blessings; (4) feedback stage (5 min): guiding patients to provide feedback and collecting relevant parameters, such as heart rate, respiration and pain.

Control group

Participants in the control group will receive the usual care, consistent with their existing or planned treatment routines. Registered ICU nurses will administer the same nursing care, which includes, but is not limited to, sedation, analgesia, spontaneous breathing trials, indwelling catheter management, feeding and bowel care.

Outcome and outcome measures

The research will measure the following outcomes (see table 1).

Primary outcomes

Delirium-free days

Our primary outcome will be delirium-free days over a 14-day period, with delirium assessed using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) flow sheet. The CAM-ICU is comprised of four features, namely fluctuation of mental status, inattention, altered level of consciousness and disorganised thinking. CAM-ICU was commonly adopted in ICU settings to measure delirium and was reported to have good inter-rater reliability (overall kappa coefficient=0.71).[26]

Secondary outcomes

Delirium incidence, duration and severity

Delirium incidence refers to the number of patients exhibiting delirium. Delirium duration is calculated from the initial delirium diagnosis to the last assessment indicating the absence of delirium based on CAM-ICU evaluations conducted every 8 hours during the patient's stay. Delirium duration will be measured for each shift and summarised in days. Delirium severity will be measured using the CAM-ICU-7 Delirium Severity Scale, which is a 7-point rating scale derived from the CAM-ICU and RASS assessments. The final CAM-ICU-7 score ranges from 0 to 7, with 7 being the most severe. CAM-ICU-7 scores

Table 1 Outcomes and time schedules for data collection

Outcome measures	Data collection time points							End point
	Day 1	Day 2	Day 3	…	…	…	Day 14/discharge	6 months post-discharge
Delirium score (CAM-ICU)	XX	XX	XX	…	…	…	XX	
Sedation score (RASS)	XX	XX	XX	…	…	…	XX	
Pain score (NRS)	XX	XX	XX	…	…	…	XX	
Pain score (BPAT)	XX	XX	XX	…	…	…	XX	
Sleep (RCSQ)	XX	XX	XX	…	…	…	XX	
Post-traumatic stress disorder (PCL)							XX	
ICU memory (ICUMT)							XX	
Patient clinical outcomes							XX	
Quality-of-life score (EuroQol)	XX						XX	X
Independence function (motor-FIM)	XX						XX	X
Cognitive function (cognitive-FIM)	XX						XX	X

BPAT, behaviour pain assessment tool; CAM-ICU, Confusion Assessment Methods for Intensive Care Units; EuroQol, European Health Index; FIM, Functional Independence Measure; ICUMT, Intensive Care Unit Memory Tool; NRS, numerical rating scale; PCL, Post-traumatic Stress Disorder Checklist; RASS, Richmond Agitation-Sedation Scale; RCSQ, Richards-Campbell Sleep Questionnaire.

are further categorised as 0–2: no delirium; 3–5: mild-to-moderate delirium and 6–7: severe delirium. CAM-ICU-7 showed a high internal consistency (Cronbach's α=0.85) and good correlation with Delirium Rating Scale-Revised-98 (correlation coefficient=0.64).[27] The highest CAM-ICU-7 score recorded over the 14-day period will represent delirium severity.

Richards-Campbell Sleep Questionnaire (RCSQ)

RCSQ is employed to assess the sleep quality of patients in the ICU. Originally developed for evaluating sleep in critically ill patients, this questionnaire is designed to capture various aspects of sleep during the ICU stay. The scale evaluates perceptions of sleep depth, sleep onset latency, number of awakenings, time spent awake and overall sleep quality. The content validity of the Chinese version of the RCSQ questionnaire is 0.840, and the Cronbach's α coefficient is 0.874.

Post-traumatic stress disorder(PTSD)

The 17-item PTSD Checklist (PCL) corresponds to the DSM-III-R symptoms of PTSD and serves as a self-report scale for assessing PTSD.[28 29] Patients will be asked to rate their agreement with each item on a scale from 1 (not at all) to 5 (extremely). PTSD symptoms are categorised into re-experiencing (flashback, nightmare, emotional cue reactivity and physical cue reactivity), avoidance and emotional numbing (avoidance of thoughts and reminders, amnesia, loss of interest, detachment, restricted affect and foreshortened future) and hyperarousal (irritability/anger, sleep disturbance, difficulty concentrating, hypervigilance, exaggerated startle response). The total score ranges from 17 to 85.[30]

A previous study confirmed the good reliability and validity of the PCL, including test-retest reliability of 0.96, internal consistency reliability of 0.94 and predictive validity of 0.64.[31] High correlations with the Symptom Checklist-90 further confirm its reliability and validity.[32]

ICU memory

The ICU-Memory Tool (ICU-M) will be used to measure ICU experience of patients in the ICU.[33] This tool includes 14 questions (five open-ended questions and nine closed-ended questions) and is primarily divided into three parts: memories before admission to the ICU, memories during the ICU stay and memories after transferring out of the ICU. Memories during the ICU stay are categorised into three subscales: factual memories (lights, alarms, voices, families, faces, breathing tube, suctioning, darkness, clock, tube in your mouth and wound care), memories of feelings (discomfort, confusion, sadness, anxiety/fear, panic and pain) and memories of delusions (feeling that people were trying to hurt you, hallucinations, nightmares, dreams). The total number of memories in each of the three subscales will be summed. The Chinese version of ICU-M has a Cronbach's α coefficient of 0.823 and a scale-level content validity index of 0.946, confirming its good reliability and validity.[34]

Patients' clinical outcomes

Medical outcomes will be extracted by the outcome assessor from the electronic healthcare system on participants' discharge. This information includes (a) ICU length of stay: the total number of days a patient stays in the ICU; (b) 30-day mortality: the total death cases among all eligible cases at 30 days after admission to the ICU; (c) duration of mechanical ventilation: the registered time in hours that the patients are on the mechanical ventilator; (d) the duration of use of physical restraint: the recorded time in hours that the patients are receiving physical

restraint; (e) sedation use: the documented total amount and average doses (mg/per day) of sedation by using the conversion measurement of the same quantity of dexmedetomidine; (f) analgesics use: the documented total amount and average doses (mg/per day) of analgesics using the conversion measurement of the same quantity of propofol; (g) self-extubation: the documented amount of self-extubation cases; and (h) ICU-acquired infection: the documented amount of self-acquired infection cases.

Quality of life

The EuroQol-5 Dimension will be used to assess the participants' quality of life. It assigns a grade on a scale ranging from 0 (representing the worst possible health status) to 100 (representing the best possible health status) based on one question for each of the five dimensions, including mobility, self-care, usual activities, pain/discomfort and anxiety/depression.[35]

Independence and cognitive function

Functional Independence Measure (FIM) will be used to measure both the independence and cognitive function. The FIM is comprised of 18 items, which are grouped into two subscales: motor and cognition. The motor items are adapted from the Barthel Index and are collectively known as the Motor-FIM. These items include eating, grooming, bathing, dressing (upper body), dressing (lower body), toileting, bladder management, bowel management, transfers (bed/chair/wheelchair), transfers (toilet), transfers (bath/shower), walk/wheelchair and stairs. The cognition subscale, known as the Cognitive-FIM, includes the following items: comprehension, expression, social interaction, problem solving and memory. Each item is scored on a 7-point ordinal scale, ranging from a score of 1 to 7. A higher score indicates greater independence in performing the task associated with that item. The inter-rater reliability of FIM has been established with acceptable psychometric performance, with intraclass correlation coefficients (ICCs) ranging from 0.86 to 0.88. Concurrent validity with the Barthel Index (ICC>0.83) has demonstrated strong construct validity between items on the Barthel Index and items on the FIM to measure functional limitations.[36]

Sociodemographic and clinical information

Sociodemographic and clinical information including patients in the ICU and family caregivers' age, gender, educational level, marital status, occupation, the relationship between patients in the ICU and family caregivers and the health history of patients in the ICU will be collected.

Data collection

Two research assistants, both trained consistently, will commence by explaining the study and obtaining written informed consent from the participants. Subsequently, research assistants will gather patients' demographic data from their medical records and collect information on their quality of life, independence and cognitive function prior to admission to the ICU from the participants' family caregivers. The nurses in charge of the study ICU will assess the CAM-ICU, RASS and RCSQ during daily routine. On the 14th day of a patient's ICU hospitalisation or on discharge if the ICU stay is less than 14 days, the research assistants will collect data on secondary measures (PTSD, ICU memory), clinical outcomes, independence and cognitive function. Additionally, the quality of life, independence and cognitive function will be assessed via a phone call by the research assistant 6 months after the completion of the intervention. Notably, two research centres each have two research assistants dedicated to obtaining informed consent and collecting data, respectively.

Data management

Each patient has a case report form (CRF) for data collection, initially documented on paper. Following this, the data from the CRFs are transferred to Excel spreadsheets on computers. Access to the Excel files will be restricted through password protection. Only authorised personnel participating in the study will have access to these files. All data entry and manipulation activities will be logged and tracked to maintain transparency and accountability.

To identify and rectify errors, such as missing values, outliers and typos, data cleaning strategies will be employed.[37] Several methods will be employed to detect errors and minimise the impacts on the accuracy of results. First, the original data set (in Excel) will be manually checked to identify data errors. Second, statistical graphical explorations, including box plots, histograms and scatter plots, along with descriptive statistics such as mean, frequency and percentage, will be used. Through this process, data errors, including typos, outliers and violations of integrity constraints, will be corrected.

Data analysis

This study will use R4.3.2 software for data analysis, with statistical analysis led by two master's degree-holding research personnel. All statistical tests will be two-tailed, with the significance level set at 0.05. To assess the normal distribution of continuous variables, skewness, kurtosis, Q-Q plots and histograms will be examined. Variables with skewness and kurtosis values within the range of −2.0 to 2.0 will be considered to have a normal distribution. For normally distributed continuous variables, the study will describe them using the mean±SD. For variables that do not meet the normal distribution criteria, the study will describe them using the median (IQR). Categorical variables will be described using frequency (proportion). If the assumptions for hypothesis testing of continuous variables are met, independent two-sample t-tests will be used to compare differences between different groups. Otherwise, the Wilcoxon-Mann-Whitney test will be employed. For categorical variables, χ^2 tests and Fisher's exact tests will be used to compare differences between different groups. Additionally, missing values will be imputed using multiple imputation methods. The study will follow the

intention-to-treat (ITT) and per-protocol (PP) principles for analysis. After imputing missing data using multiple imputation methods, the study will perform ITT and PP analyses and report relevant uncertainty indicators, such as CIs and SEs, in the results. This study will employ mixed-effects models for outcomes with repeated measurements. These models, also known as multilevel or hierarchical models, are effective for analysing data with a hierarchical structure, such as repeated measurements. Fixed effects will estimate population-level relationships between predictors and outcomes. Our study will include predictors like APACHE-II score, age, admission category and use of sedatives and analgesics as fixed explanatory variables. Subgroup analyses based on age, gender and length of ICU stay will be conducted.

DISCUSSION

This study evaluates a VR-based sensory stimulation for preventing delirium and improving patients' psychological well-being (specifically post-traumatic stress disorder, sleep quality and ICU memory), patients' clinical outcomes (including ICU length of stay) and other outcomes (such as quality of life, independence and cognitive function). It employs a rigorous RCT design, incorporating a VR-based sensory stimulation intervention within ICUs, which enhances the reliability and validity of findings. The methodological rigour of this design provides valuable insights into the effectiveness of such interventions in clinical settings. Previously, our primary outcome included both the incidence duration and severity of delirium. However, considering the recommendation to focus on a single primary outcome, we have designated delirium-free days as the primary outcome. Consequently, we have classified delirium duration and severity as secondary outcomes, and this update has been reflected in the trial registry.

In our study, our primary focus is on preventing delirium. However, if delirium does occur, physicians may prescribe antipsychotic medications. We will accurately document whether patients receive these medications and the dosage administered. Furthermore, we will maintain detailed records of the dosage of sedatives and analgesics administered to patients throughout the study. Additionally, in the intervention, family caregivers are involved through a 'sample reorientation message', which refers to a written communication provided to help them understand and navigate changes in care, treatment or environment. We acknowledge that family involvement may influence patient outcomes and could act as a confounding factor in our study. The observed effects may result from a combination of the VR intervention and changes in family behaviour. Due to the nature of the intervention, blinding was only possible for the outcome assessors, while blinding for the participants and those delivering the intervention was not feasible.

The study anticipates prompt availability of materials from family members and has contingency plans in place to ensure the timely initiation of the VR intervention. However, delays in obtaining materials from family members may occur, potentially impacting the initiation of the VR intervention. Additionally, the use of antipsychotic medications to manage delirium may influence study outcomes, and while their administration will be documented, their effects on study outcomes may not be fully controlled.

ETHICS AND DISSEMINATION

For patients in the ICU, obtaining informed consent can be a complex process due to the patients' health conditions. When possible, and when the patient is capable of understanding and making decisions, we will seek written consent directly from the patient. However, for those who may be too ill to provide consent, we will obtain written consent from their legally authorised representatives, typically family members. We are committed to ensuring that all potential participants, or their designated representatives, are fully informed about the study's objectives and procedures. This includes providing detailed information about the study, its potential risks and benefits, and the voluntary nature of participation.

We are dedicated to upholding the highest ethical standards in disseminating our research findings. Study outcomes will be shared through peer-reviewed publications and presented at academic conferences, ensuring that our work reaches the relevant professional and scientific audiences. We are steadfast in our efforts to safeguard the rights and confidentiality of all participants. To preserve individual privacy, all personal information will be anonymised, and the findings will be communicated in a manner that protects the identities of the participants.

Correction notice This article has been corrected since it was published online. The sample size in the abstract has been updated from 324 to 198.

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Contributors SL, YL, TW, DL, MH and JT contributed to the study's conception and design. SL led data management as the principal investigator, while MH, TW and YL developed the study methods and provided supervision. All authors participated in drafting and revising the manuscript. SL is the guarantor responsible for the integrity of the study. All authors approved the final manuscript and agreed to be accountable for the work.

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