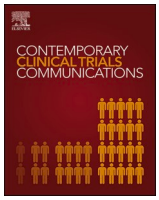
Contemporary Clinical Trials Communications 38 (2024) 101263

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



Decreasing the incidence of delirium via multi-sensory stimulation in patients receiving mechanical ventilation in the intensive care unit: A protocol for a randomized feasibility study

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ARTICLE INFO

Keywords:
Delirium
Mechanical ventilation
Family
Multi-sensory stimulation

ABSTRACT

Introduction: Delirium is a common acute brain dysfunction syndrome in patients admitted to intensive care units (ICUs). Family engagement strategies, based on the theory of multi-sensory stimulation to ameliorate sensory deprivation in patients, may be an effective and scalable method to reduce the burden of delirium.

Methods: /design: This is a assessor-blinded, randomised controlled trial of the feasibility of multi-sensory stimulation (MS) in patients with delirium. A total of 72 mechanically ventilated patients (n = 24 in each group) admitted to the ICU will be randomised to routine non-pharmacological delirium care (control), family multi-sensory stimulation and nurse multi-sensory stimulation groups. All participants except the control group will receive multi-sensory stimulation, including visual, auditory, tactile and kinesthetic stimulation, for 5 days. Our primary aim is to determine the feasibility of the study procedure (recruitment, eligibility, retention and attrition rates, appropriateness of clinical outcome measures), feasibility, acceptability and safety of the intervention (adverse events, satisfaction and other). Our secondary objective is to assess the preliminary efficacy of the MS protocol in reducing the incidence, duration and severity of delirium. Sedation levels and delirium severity will be assessed twice daily. Enrolled participants will be followed in hospital until death, discharge or up to 28 days after treatment.

Ethics and dissemination: The current study was approved by the Ethics Review Board of Huazhong University of Science and Technology Union Shenzhen Hospital, China (KY-2023-031-01). The results of this study will be presented at scientific conferences and submitted for publication in peer-reviewed journals.

Trial registration number: ChiCTR2300071457.

Strengths and limitations of this study

The mechanism of delirium in ICU patients is unclear, and the use of non-pharmacological interventions to prevent and improve the incidence of delirium is controversial worldwide. Interventions involving family members are more common in studies that prolong visiting time and increase the study population, and there are no intervention studies based on multi-sensory stimulation theory. This study integrates family members and sensory stimulation methods to prevent and improve delirium. The intervention will be delivered in a familiar environment created by family members to improve patients' cognitive function, orientation and avoid sensory deprivation. The protocol will provide multi-sensory stimulation to mechanically ventilated ICU patients, including visual, tactile, auditory and kinesthetic stimulation to improve the potential effect on delirium. This study is not only a multivariate non-pharmacological intervention study of delirium, but also an in-depth study of individualised family empowerment visitation, which may be a good countermeasure to non-pharmacological intervention in delirium management.

This study is a phase II randomised controlled trial that will only contribute to a preliminary analysis of the effects of MS on delirium prevention in mechanically ventilated patients.

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https://doi.org/10.1016/j.conctc.2024.101263
Received 14 August 2023; Received in revised form 9 January 2024; Accepted 15 January 2024
Available online 17 January 2024

1. Background

Delirium is an acute brain dysfunction syndrome characterised by sensory deprivation, impaired attention, altered consciousness, abnormal sleep–wake cycles, thought disturbances, and uncontrolled behaviour [1]. Although the mechanism of delirium is unclear, research has found that confusion of cognitive orientation and sensory deprivation in patients may be key problems leading to delirium [2,3].

The proportion of patients requiring mechanical ventilation in the intensive care unit (ICU) ranges from 39 % to 74 % [1]. In these patients, the focus has been on managing their illness. Statistical data have shown that the incidence of delirium is as high as 70 % in patients receiving mechanical ventilation for >72 h [4]. The average duration of delirium is approximately 5–6 days. This factor may be associated with a high risk of complications including nosocomial pneumonia, prolonged duration of mechanical ventilation, prolonged ICU stay, and the development of high-risk adverse events such as unplanned extubation and bed falls [1]. It is also an independent predictor of mortality in ICU patients [5]. A previous study showed that delirium-related mortality rates in Australia and the United States increased by 16.35 % and 4.04 % per year, respectively, from 2006 to 2016. Thus, the mortality rate has been increasing [6]. Based on domestic studies in China, the mortality rate of delirium in elderly patients with community-acquired pneumonia during hospitalisation was 31 %. In addition, ICU delirium is associated with prolonged sequelae. A previous study [7] showed that 25–78 % of patients with delirium have significant cognitive dysfunction after ICU admission, causing psychological distress to family members. In addition, delirium represents a significant financial burden for the healthcare system. In the United States, total health care costs for delirium exceed $150 billion annually. In Australia, the total economic impact of delirium in 2016–2017 was approximately $8.8 billion [8,9].

In 2018, the American Academy of Intensive Care Medicine published clinical practice guidelines for the prevention and management of pain, agitation/sedation, rehabilitation, and sleep disturbance in adult patients in the ICU [5]. The guidelines recommend the use of non-pharmacological interventions to prevent and manage delirium, including daily wakefulness, early mobilisation, sleep promotion, provision of information, music, reduction of light and noise at night, and more. Sensory stimulation is a core component of many non-pharmacological interventions [10]. There is evidence that multi-sensory stimulation is beneficial in the prevention and management of delirium. For example, four cycles of visual stimulation [11,12] can reduce delirium scores and the incidence of delirium-related adverse events. Researchers [13,14] used auditory speech stimulation twice daily for 30 min, which reduced the incidence of confusion in the ICU to 24 % and the average duration of confusion to 39 %. A 30-min daily session of auditory and visual stimulation [15] for one week reduced the duration and severity of delirium; Mohammad A [16] used the five-sense stimulation programme, which includes auditory, visual, tactile, olfactory and motor stimulation, for 1 h per day during ICU stay to effectively reduce the incidence of delirium in brain-injured patients admitted to ICU. Its potential mechanism of action is to provide visual, auditory, olfactory, tactile and other sensory stimulation, activate the unimodal sensory area and associated area of the brain, regulate various biological mechanisms, increase the activity of the cerebral cortex, increase attention and response to stimulation, effectively promote cognition and restore sensory deprivation, and prevent delirium in patients [17,18]. However, the above research on the frequency, intensity, combination of multi-sensory stimulation and who provides the stimulation is controversial and further research is needed.

At the same time, the guidelines suggest that family involvement in care can enhance the patient's defences and resistance to stressors [19] and is of great importance in the management of delirium [20,21]. However, the guidelines do not elaborate on the specific projects and content of family involvement. Research [22] has shown that the voice of a family member can create a familiar environment that can provide intimate care in a way that medical staff cannot, and that family members who are familiar with the patient's behavioural changes are more likely to observe subtle changes in the patient's awareness, cognition and behavioural expression. Therefore, multi-sensory stimulation provided by family members may be beneficial in the prevention of delirium in mechanically ventilated patients, but there is a lack of research in this area.

Based on the theory of multi-sensory stimulation and the perspective of family involvement in preventing delirium and improving delirium symptoms in patients receiving mechanical ventilation in the ICU, we developed the multi-sensory Stimulation (MS) protocol (Visual-Aural-Tactile-Kinesthetic) through a literature review, stakeholder interviews and Delphi expert correspondence. The protocol needs to be tested for effectiveness in a rigorously designed randomised controlled trial (RCT). According to the Medical Research Council (MRC) [23] framework, it is necessary to conduct a pilot study prior to the main RCT to explore the feasibility, acceptability and safety of the newly designed MS intervention. The proposed study follows the MRC framework for the development and evaluation of complex interventions. The results of this study can be used to inform the design of a future main RCT in terms of sample size calculation, feasibility planning and safety management of the MS intervention. The study findings may also be useful to clinicians, researchers and health policy makers in making decisions about non-pharmacological interventions for effective delirium management in mechanically ventilated patients.

2. Methods/design

2.1. Study design

This study will be a phase II, three-arm, assessor-blinded RCT. After eligibility assessment, all consented participants will be randomly allocated to three parallel groups: family-delivered multi-sensory stimulation (MS-F), nurse-delivered multi-sensory stimulation (MS-N) and control, with an allocation ratio of 1:1:1. The study will include a 5-day MS intervention and a follow-up 4 weeks after the end of the intervention. The proposed study is expected to start on 1 January 2024 and end on 31 December 2024. The design and conduct of the study is shown in Fig. 1.

The study protocol was reported according to the Standard Protocol Items: Recommendations for Interventional Trial Checklist. The intervention report in this paper follows the TiDier guidelines.

2.2. Study setting

The study samples are from patients with respiratory failure requiring mechanical ventilation in the ICU of Huazhong University of Science and Technology Union Shenzhen Hospital, a 2500-bed tertiary hospital in China with 38 ICU beds (20 surgical beds, 18 medical beds) and an average of 100 patients per month.

2.3. Sample

2.3.1. Eligibility criteria

2.3.1.1. Inclusion criteria. Inclusion criteria were patients: 1) aged 18 years or older; 2) receiving mechanical ventilation and admitted to the ICU for ≥24 h; 3) with Glasgow Coma Scale score >9, with Richmond Agitation-Sedation Scale (RASS) sedation score ≥ −3 (meeting assessment criteria for delirium); 4) had no history of delirium, alcohol abuse or psychotropic substance abuse prior to admission to the ICU; 5) did not have a diagnosis of dementia, advanced cancer, brain injury, mental disorder; 6) did not have severe visual impairment, hearing impairment, skin integrity without missing damage; 7) gave informed consent to participate in the study and should have a family member aged 18 years

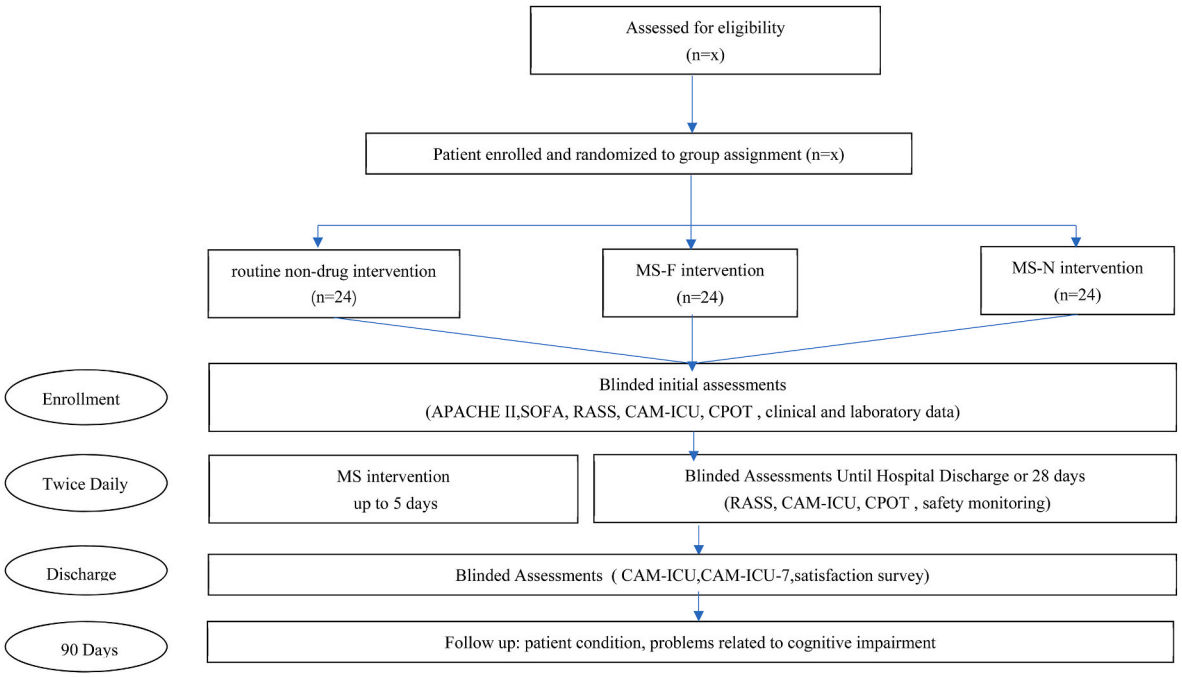

Fig. 1. MS study flowchart, interventions, and assessments.

or older who acts as a caregiver and gives informed consent to participate in the study.

2.3.1.2. Exclusion criteria. Exclusion criteria were patients: 1) ICU stay <144h; 2) severe disease progression, death, treatment discontinuation and non-cooperation.

2.3.2. Sample size estimation

We established criteria for the sample recruitment rate based on previous studies [24]. Based on the recruitment experience of the team in the ICU where the trial was conducted, the recruitment rate was close to 90 %.We expect that a sample size of 72 will be sufficient to determine feasibility.

2.4. Recruitment methods

Potential participants will be recruited from the Department of Intensive Care Medicine, Union Shenzhen Hospital, Huazhong University of Science and Technology. Study flyers will be displayed in the ICU consultation room to generate interest. Patients will be assessed against the inclusion/exclusion criteria by the principal investigator. If the patient is deemed eligible, a recruitment letter will be sent to the patient and family. If the patient and family agree, the investigator will interview the patient and family and provide them with further information about the intervention and study participation.

2.5. Randomisation and blinding

Sequence randomisation is performed using a random number table. Select column 3, row 4 of the random numbers table, read the random numbers sequentially. Arrange the generated 72 numbers in the order of reading and note the order 1 to 72 , then arrange the generated 72 numbers from small to large, with the 24 order numbers corresponding to the smaller random numbers as MS-F group, the 24 numbers corresponding to the meidium random numbers as MS-N group, the 24 numbers corresponding to the larger random numbers as control group. These sequence numbers will be encoded in sealed, opaque, stapled envelopes. This sequence will only be available to a researcher not involved in the recruitment of volunteers and will be concealed from the researcher enrolling and assessing participants. Each participant will be sequentially assigned a number corresponding to a stapled envelope and will be randomised (on the same day after written informed consent, screening, and completion of baseline measures) to the MS-F, MS-N, or control groups in a 1:1:1 allocation ratio. Due to the nature of the study, it is not possible to blind the implementer of the intervention, so data collection and statistical analysis are blinded. The non-blinded research coordinator is aware of the randomisation of patients and the video playback equipment, and coordinates and differentiates the visiting times of the different groups of family members entering the ward. The study nurse responsible for protocol data collection is unaware of the patient groupings.

2.6. Intervention

2.6.1. Development of MS

The MS programme was developed by the research team after literature review, semi-structured interviews with stakeholders (health care workers and patients' families), and then determined by Delphi expert correspondence method.

The research group searched four Chinese and eight English databases: CNKI, Wanfang Medical Network, SinoMed, VIP China Science and Technology Journal Database (VIP), PubMed, Web of Science, Embase, ScienceDirect, The Cohrane Library, OVID LWW, Clinical Key for Nursing, CINAHL Complete, using the search terms "family/dependents/family-centred care" "ICU" "delirium" "multisensory stimulation/multimodal interaction" "non-drug/non-medicine/intervention/care/nursing". Literature summaries and weighted full-text reading were carried out using NoteExpress software, and two members of the group independently analyzed and screened the literature and guidelines for inclusion and exclusion indicators. For controversial articles, a third researcher was invited to provide objective arbitration and 14 valid documents were finally identified, including 2 guidelines, 2 clinical decision making, 4 systematic reviews, 1 review and 5 randomised controlled trials. The research team extracted the active intervention components including visual, auditory, kinesthetic and tactile stimulation modalities, as well as the intervention dosage and mode of delivery reported in the literature, which informed the development of a

preliminary intervention protocol.

In order to adapt this preliminary intervention protocol to fit the real ICU practice setting, the research team conducted semi-structured interviews with key stakeholders including 3 ICU managers, 15 nurse managers and 10 family members. Based on the interview findings, the research team modified the specific format and implementation schedule of the intervention to allow some flexibility while ensuring fidelity. In order to validate the preliminary intervention protocol, the research team conducted two rounds of expert consultation using the Delphi method, involving 20 specialists in neurology, critical care medicine, rehabilitation science, and nursing from 15 tertiary-level hospitals in 11 provinces in China. Based on the suggestions from the experts, the research team further refined the intervention modules and dosage, resulting in a finalized intervention programme (Table 1).

Referring to previous studies [25], the research team developed scripts for the visual and auditory intervention components to provide guidance for families and intervention nurses during video recording. The script uses a simple language that can be managed by people with an elementary school education or higher: 1) Hello! This is (name of the speaker). 2) You are now in intensive care. 3) The time is (current time). Nurses and doctors are looking after you 24 h a day. 4) Please try to relax. the ECG monitor data shows that your vital signs are stable. 5) The ICU is a bit noisy, but these monitors can help you with your treatment. 6) There are some wires and tubes attached to your body. The nurse has attached them. Please do not touch them. 7) You are not able talk right now because you are on a respirator. 8) The nurse knows that you are not feeling well. The doctor can give you painkillers if necessary. 9) Please try to cooperate with the nurses and doctors. 10) I hope you will get well soon. We are all worried about you. Family members or nurses will be instructed to record a <2 min video using a mobile phone with a script. The video player is clean and functional and the volume is set to a predetermined level. The process of tactile stimulation was carried out by five ICU clinical nurse specialists [26]. When family members are admitted to the ICU, these nurses are instructed to disinfect their hands, rub them to warm them, and massage the patient from forehead to cheek to occipital bone (without touching the endotracheal tube), and then massage the patient's forearm to upper arm on both arms (without touching the peripheral venous catheter or central venous catheter). Massage the lower limbs and ankles. Avoid surrounding areas, such as the site of the femoral vein catheter. Each household member should not touch the patient for more than 15 min.

Table 1
Intervention protocol description.

Intervention content	Control	MS intervention	
		MS-F group	MS-N group
Before intervention			
Family members record videos according to the script and learn the method of tactile and movement stimulation		X	
Nurse record videos according to the same script			X
Visual stimulation			
Movie video[a] (30 min in length, once a day)	X	X	X
Family member video (2 min in length, every 2 h from 9:00 to 17:00)		5X	
Nurse video (2 min in length, every 2 h from 9:00 to 17:00)			5X
Auditory stimulation			
Music[b] (30 min in length, once a day)	X	X	X
Family member's voice (2 min in length, every 2 h from 9:00 to 17:00)		5X	
Nurse's voice (2 min in length, every 2 h from 9:00 to 17:00)			5X
Tactile stimulation			
Therapeutic touch[c]	X	X	X
Touch by a family member (15 min in length, from 16:00 to 16:30)		X	
Movement stimulation			
Therapeutic activities[d]	X	X	X
Family members assist with patient activities (>30 min in length, from 10:30 to 11:30)		X	

Abbreviations: MS, multi-sensory stimulation; MS-F, multi-sensory stimulation delivered by family member; MS-N, multi-sensory stimulation delivered by nurse; X, once a day; 5X, five times a day.

[a] Movie videos downloaded from the internet.

[b] Music downloaded from the internet, i.e. Beethoven's D major second movement, Schubert's Serenade and Chinese Classical Music.

[c] Therapeutic touch by nurses at the necessary time, i.e. touch during infusion, examination, etc.

[d] Therapeutic activities by nurses and rehabilitation therapists, i.e. ankle pump movement, limb air pressure treatment, etc.

2.6.2. Pre-intervention phase

At enrolment, data will be collected on demographic characteristics (admission number, age, sex, height, weight and diagnosis), vital signs (heart rate, respiratory rate, blood pressure, body temperature and oxygen saturation), laboratory and imaging data, severity of illness (APACHE II and SOFA scores), family medication, cause of admission, use of antipsychotic, analgesic, sedative and anti-anxiety drugs before admission and cumulative dose. The nurse will give a short presentation using PowerPoint to explain the clinical features and prognosis of delirium to the family. Nurses in the ICU will receive on-site training on research programmes, video players and the operation of headphones.

2.6.3. Intervention phase

All participants will receive standard clinical care for mechanically ventilated patients. The control group will receive routine non-pharmacological interventions for delirium [27]. Nurses will use the CAM-ICU scale to screen for delirium; implement goal-directed shallow sedation strategies [28]: RASS score regulation from −2 to +1, pain assessment using the Critical Care Pain Observation Tool (CPOT), and CPOT score should be less than 3; wake patients at 7:30 a.m. daily; nurses increase communication with patients, encourage early mobilisation of patients, assist patients with activities of daily living, manage patient sleep, and reduce ward noise; provide books, newspapers, or videos.

The intervention group (MS-F group and MS-N group) receives the MS programme for 5 days by nurses or family members. The heart rate and blood pressure of the participants will be recorded before and after stimulation by the nurse. The participants who are extubated within 5 days can receive the intervention if they are not transferred out of the ICU. Those who remain in the ICU after 5 days will not receive further intervention. Participants who remain in hospital will be followed up until day 28 or discharge, whichever comes first. Participants will continue to receive physician-prescribed sedatives, if needed, without interference from the study. During the stimulation process, nurses will create a conducive environment and non-urgent nursing activities will be avoided.

Family members of all patients have access to the ward for bedside visits at different times. Family visiting hours for the control and MS-N groups are 16:30–17:00 daily. Family visiting hours for patients in the MS-F group are 10:30–11:30 and 16:00–16:30 on days 1–5 of the intervention and 16:30–17:00 daily from day 6.

2.7. Outcome measures

2.7.1. Feasibility outcomes

2.7.1.1. Feasibility of the study process. This study mainly focuses on the feasibility outcomes, including 1) recruitment: i.e. the length of time taken to recruit participants, the average number of participants recruited per month, and the proportion of eligible patient-carer dyads who are eventually recruited into the study; 2) eligibility: the proportion

of screened patient-carer dyads who meet the inclusion criteria; 3) retention and attrition rates: The proportion of recruited participants who complete the study or drop out of the study with or without a reason; 4) Adequacy of clinical outcome measures: The proportion of incomplete questionnaires and the characteristics of the missing data.

2.7.1.2. Feasibility, acceptability and safety of the intervention. The feasibility, acceptability and safety of the study intervention will be assessed in terms of: 1) adverse events [29]: number of adverse events in patients, such as changes in vital signs, falls, bed falls and unplanned extubation; 2) satisfaction [30]: satisfaction of patients' family members will be assessed using the Critical Care Family Satisfaction Survey (CCFSS). The scale is divided into five dimensions: information, reassurance, comfort, acceptance and support, and consists of 27 items. According to the level of satisfaction, there are 1–5 points from very unsatisfied to very satisfied. The total score of each item ranges from 27 to 135 points, which is proportional to the level of satisfaction. The scale has a Cronbach's alpha of 0.929, content validity of 0.902 and construct validity of 0.894. The feasibility and acceptability of the intervention will be assessed during the intervention and within 24 h of patient transfer and discharge, and the other domains of feasibility and acceptability will be assessed through a process evaluation using a qualitative approach.

2.7.2. Preliminary efficacy signals

2.7.2.1. Incidence of delirium. It is measured using the Confusion Assessment Method for the ICU (CAM-ICU) [31].The scale contains four features: ①mental state, ②inattention, ③altered level of consciousness and ④disorganised thinking. If both feature①and feature②are positive and feature③or feature④is positive, the patient is considered to have delirium.The proportion of patients scoring positive on the CAM-ICU scale as a proportion of all mechanically ventilated patients in the same period.

2.7.2.2. Duration of delirium. Time from delirium to return to normal.

2.7.2.3. Severity of delirium. It is assessed using the Confusion Assessment Method ICU-7 (CAM-ICU-7) [32]. The CAM-ICU-7 score ranges from 0 to 7 points, the higher the score the more severe the delirium, 0 to 2 is classified as no delirium, 3 to 5 is classified as mild to moderate delirium, 6 to 7 is classified as severe delirium.

2.8. Data collection and management

2.8.1. Data collection

2.8.1.1. Baseline data collection. Collect general information about the patient, including sex, age, height, weight, education level, Acute Physiological and Chronic Health Scores II, SOFA score, medical conditions, lifestyle.

2.8.1.2. Feasibility outcomes data collection. Data on the feasibility of the study procedure, including the completion rate of the MS intervention and the eligibility, recruitment, retention and attrition rates of participants from recruitment to follow-up, will be collected by the researcher throughout the study. Adverse events will be abstracted from nursing notes and electronic medical records [33]. A paper version of the Family Satisfaction Scale will be administered to family members within 24 h of patient's transfer to the general ward or before discharge.

2.8.1.3. Preliminary efficacy signals data collection. Data are collected by research assistants. Every day from 8:00 to 8:30 and from 18:00 to 18:30, the research assistant uses the CAM-ICU to assess for delirium and the CAM-ICU-7 to determine the severity of delirium. On days 1–5 of the intervention, the research assistant records the patient's vital signs, laboratory results (including white blood cell count and potassium, calcium, lactate levels, etc.), and 2 delirium scores daily. From day 6 to day 28 after the intervention, the study assistant will record delirium assessment data once a day until the patient withdraws or dies [34,35].

2.8.2. Data management

In this study, the EpiData data collection tool will be used to construct, enter, check and convert the database. Prior to the start of the experiment, the researchers will be trained in the use of this tool and will undergo separate tests of data entry and results evaluation.

2.9. Data analysis

Continuous variables will be presented as means and standard deviations or medians and interquartile ranges, and nominal variables will be presented as frequencies and percentages. Comparisons of family satisfaction scores among the three groups will be analyzed using analysis of variance (ANOVA) or corresponding non-parametric test, as appropriate. Generalized estimating equation (GEE) will be utilized to evaluate group differences for each preliminary efficacy signal, as well as the interaction effect of time and group, due to its advantage of not being constrained by data distribution. Binary response model will be used for the incidence of delirium, scale response model will be used for the duration of delirium, and ordinal response model will be used for the severity of delirium. Statistical significance for all analyses will be determined by a P value of less than 0.05.

2.10. Process evaluation

Semi-structured interviews will be used to conduct the process evaluation of the research. The interviewees will consist of patients from the MS-F group and patients from the MS-N group, as well as family members involved in the MS-F intervention and nurses providing the MS-N intervention.The researchers will ask open-ended questions based on the study objectives, i.e. to comprehend the experiences of patients in receiving the MS-F or MS-N interventions and to ascertain the perceptions of family members and intervention nurses regarding the value and delivery of the MS-F and MS-N interventions, respectively. The sample size decision is flexible and potential patients, family members and nurses will be recruited until data saturation is reached. All interviews will be conducted following the interviewee's provision of informed consent, and each interview will be audio-recorded. These recordings will be transcribed verbatim and analyzed using content analysis with NVivo Plus 12.2 software.

3. Discussion

3.1. Theoretical basis and significance of MS scheme

The aim of this study is to assess the feasibility of MS, a method of providing multi-sensory stimulation to critically ill patients receiving mechanical ventilation, with and without family involvement. Our trial will also assess the initial efficacy of multi-sensory stimulation in reducing the incidence and severity of delirium. Our programme is based on previous research. Sensory stimulation is also known as sensory channel or multimodal interaction. In this programme, visual, auditory, tactile and other sensory stimuli are used to activate the unimodal sense and association areas of the brain. They can also regulate various biological mechanisms, increase cortical activity, improve concentration and response to stimuli, and promote recovery of cognitive and sensory function [36]. The influence of family members on cognition and emotion can improve anxiety and other negative emotions. However, no previous studies have used multi-sensory stimulation regimens in family members to prevent delirium. The advantages of our protocol include blinding of outcome assessors, twice daily assessment

of delirium, and assessment of pain and level of sedation. The extended application of our study may allow comparison of outcomes between family involvement and nurse-led arms in future studies. In this feasibility study, our protocol will allow us to test hypotheses, develop video scripts and implement multi-sensory stimulation interventions in the ICU. The results of this study can be used to inform the development of a protocol design in a larger trial.

3.2. Clinical implication

This study is based on the needs of mechanically ventilated patients in the ICU and the concept of multi-sensory stimulation with a feasible intervention for families. It can not only broaden the management of complications in mechanically ventilated patients and improve thinking, but also facilitate family participation in the intervention method and improve nurses' awareness of delirium awareness and screening. This method can improve communication between nurses and patients and their families, and improve the effectiveness of prevention and treatment, as well as patient prognosis and satisfaction. The results of the study will provide a clinical basis for the design and implementation of non-drug intervention programmes.

4. Trial registration

The full protocol of this trial, published in the Chinese core journal of Nursing Science, has been registered on Clinical Trials.gov (ChiCTR2300071457). Recruitment will start on 1 January 2024 and will end on 31 December 2024.

Funding

The MS trial is supported by the Shenzhen Nanshan District Science and Technology Project (NS2023081), the Shenzhen Science and Technology Programme (funding number: JCYJ20190809104609625), the construction project of Team Construction in Guangdong Province Teaching Quality and Teaching Reform Project (Higher Education in Guangzhou [2020] 19) and Guangdong Province Degree and Postgraduate Education Reform Research Project (2021JGXM026).

Availability of data and materials

The data results from this feasibility study are not available at the time of publication. The researchers will retain access to the final data set. There are no plans to provide compensation for the study in the event of injury. Results will be communicated to participants within our hospital system by email. Full access to the protocol or participant level datasets is available on request.

Authors' contributions

Study concept and design: Bin He,Wen-ting Liu.
Data acquisition: Si-ya Meng, Yu-Ju Qin, Zheng Yang.
Manuscript preparation: Bin He.
Critical revision of the manuscript: Yu-ying Wang, Xiao-Ling Mou, Yu-Qi Chen.

Funding

Bin He, Yu Chen.
Administrative support: Yu Chen, Bei-rong Mo.
Study Supervision: Bin He, Yu Chen, All authors have read and approved the final manuscript.

Ethical approval and consent to participate

The MS protocol was reviewed by the Ethics Committee of Huazhong University of Science and Technology Union Shenzhen Hospital (No.: KY-2023-031-01)).

CRediT authorship contribution statement

Bin He: Writing – original draft, Project administration, Data curation, Conceptualization. **Bei-rong Mo:** Project administration, Methodology, Formal analysis. **Si-ya Meng:** Project administration. **Zheng Yang:** Project administration, Funding acquisition. **Wen-ting Liu:** Conceptualization. **Yu-ying wang:** Investigation. **Xiao-Ling Mou:** Investigation. **Yu-Qi Chen:** Formal analysis. **Yu Chen:** Resources, Project administration.

Declaration of competing interest

The authors declare that they have no competing interests.

Data availability

No data was used for the research described in the article.

Acknowledgments

We would like to thank Yu Chen's delirium research team, the Association of Huazhong Universities of Science and Technology and Shenzhen Hospital for their efforts in developing this protocol.

Abbreviations

CAM-ICU: Confusion Assessment Method for the ICU.
RASS: Richmond Agitation-Sedation Scale.
CPOT: Critical Pain Observation Tool.

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