Description of Individualized Delirium Intervention in Intensive Care Unit (IDI-ICU) for critically ill patients delivered by mobile health care system

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Abstract

Background
Delirium is a preventable and reversible complication for intensive care unit patients, which can be linked to short-term and long-term negative outcomes. Early intervention to cope with risk factors of delirium are necessary. Yet no specific description of IDI-ICU following the Template for Intervention Description and Replication (TIDieR) were reported. This study aimed to describe individualized delirium intervention in intensive care unit (IDI-ICU) for critically ill patients.

Methods
This descriptive research describes the evidence-based ICU delirium interventions for improving cognitive load and adherence of nurses and reducing ICU delirium incidence. Therefore, both nurses and researchers would benefit from the replication of the interventions for clinical approach or experimental research.

Results
The TIDieR checklist improved the description of ICU delirium interventions, including several key features (duration, dose or intensity, essential processes, and tailoring) for improved implementation of the intervention. The IDI-ICU library includes delirium screening, risk factor assessment, ABCDEF bundle intervention. We (1) standardized the flow chart of ICU delirium assessment tools; (2) formed an evaluation sheet of ICU delirium risk factors; and (3) translated the evidence-based ABCDEF bundle intervention into practice.

Conclusions
The TIDieR checklist provided a systematic approach for reporting the complex ICU delirium interventions delivered in a clinical interventional trial. Future well-designed RCTs are needed to examine the effectiveness of the IDI-ICU on improving cognitive load and adherence of nurses and reducing ICU delirium incidence and duration.

Introduction
Incorporation of evidence-based interventions into clinical settings requires a comprehensive set of descriptions, which not only serve to offer reliable implementation of interventions, but also to allow replication in other studies\textsuperscript{[1, 2]}. However, numerous reports of randomized controlled trials (RCT) lack sufficient description of the interventions due to limited space in an article\textsuperscript{[1\textendash}3], therefore, a better way to
report the interventions is in a separate paper. The Template for Intervention Description and Replication (TIDieR) checklist, was developed based on the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement\[^4\] and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement\[^5\], is a guide to report the detailed interventions in a trial and ensure the replicability of interventions.

This checklist can be useful in reporting complex interventions, for example, intensive care unit (ICU) delirium, which is triggered by multiple risk factors\[^6\]. The individualized delirium intervention in intensive care unit (IDI-ICU) is aimed to assist ICU nurses implement evidence-based delirium interventions. For the purpose of reporting the trial results for replication and further studies, the details of IDI-ICU are reported here. A complex set of IDI-ICU contains multiple detailed procedures. These procedures include (1) the use of the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) or Intensive Care Delirium Screening Checklist (ICDSC) for ICU delirium assessment; (2) risk factors evaluation and use of an ICU delirium prediction model to classify patients into different risk levels; (3) early prevention or management interventions for ICU delirium\[^7\], use of the ABCDEF bundle, which is recommended by the Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption (PADIS) Guidelines in adult patients in the ICU, as a way to reduce the incidence of ICU delirium or a management intervention once ICU delirium occurs\[^8\,\,9\].

However, adherence to ABCDEF bundle intervention is sub-optimal in routine clinical care\[^10\,\,11\]. Previous studies demonstrate that various barriers may hinder the adherence in implementing the delirium intervention, e.g., unfamiliarity with assessment tools\[^12\,\,13\], and increased work burden\[^14\]. The most important reason for lower adherence is that health-care providers are unclear about why, how, who and when to implement the effective intervention\[^15\]. The above reasons could result in slowing down of receiving and information processing, and the decreased capacity of cognitive resources\[^16\]. When the cognitive resources are less than the requirement of cognitive tasks, there may be increased cognitive load and a lower level of performance adherence of nurses\[^16\].

To overcome those barriers, the Clinical Decision Support System (CDSS) was designed to aid clinical decision making and reduce nurses' cognitive load\[^17\,\,18\]. PoLiang et al.\[^16\] and Grace et al.\[^19\] found that medical staff had less clinical information to remember using the the CDSS, which reduced the cognitive resources and led to a significant reduction in cognitive load and improvement in adherence. Therefore, we developed an Artificial Intelligence Assisted Prevention and Management for Delirium (AI-AntiDelirium) based on Cognitive Load Theory (CLT), which aimed to reduce cognitive load and promote adherence to delirium intervention among ICU nurses, and thus improve delirium-related clinical outcomes.

The objective of this article is to report the details of IDI-ICU following the TIDieR checklist\[^1\]. In order to allow replication of each component of the intervention, the description of interventions should involve sufficient details such as procedures, materials, number of times, duration, mode of delivery, how and when to administer essential processes.
Methods

Description of IDI-ICU According to the TIDieR Checklist

The interventions reported here are following the TIDieR checklist[1]. The Ethics Committee of the University approved this study.

Development of the Intervention

There are three steps to develop the IDI-ICU in order to support successful implementation by ICU nurses, including: (1) needs assessment; (2) intervention development; (3) formulation of the intervention library.

Step1: Needs assessment

Designation of the IDI-ICU aims to reduce cognitive load and enhance the adherence in implementing the methods by ICU nurses, and minimize the negative effects of the ICU delirium. The needs of nurses about the understanding of delirium interventions were carefully assessed. A literature review was carried out to assess the needs of nurses, including the content of the intervention, presentation mode of the interventions (e.g., pictures, text, voice), and procedure of the interventions (e.g., who carries out, how to do, duration, and frequency).

Step2: Intervention development

We developed the IDI-ICU protocol according to the results of needs assessment. We performed a comprehensive search to identify guidelines and articles related to delirium.

Step 3: Formulation of the library of IDI-ICU

1. Expert Discussion Meeting

The evidence-based protocol of the IDI-ICU contains delirium diagnostics, risk factor recognition, prevention and treatment strategies. In order to make sure the protocol is appropriate for clinical application, expert discussion meetings were held, six well-known clinical experts (each with more than 10 years of experience in nursing care of neurological or critically ill patients) were invited to discuss and revise the draft version of the protocol. After the expert discussion meeting, the expert opinions were collected and integrated to refine the protocol into its final version.

2. Translating evidence-based interventions into practical applications

After approval by the experts, the evidence-based interventions were translated into practical application. We used the computer logic program method to tailor individualized interventions. The following are required in this method: (1) a library containing all the interventions; (2) a series of “IF-THEN” trigger rules; (3) a channel that forms tailored intervention for each patient based on his/her condition; and (4) a data source. Additionally, detailed content and delivery of each interventions were clearly described, including
the content of the interventions, the persons to deliver or receive the interventions, the time, dose and frequency of the interventions.

3. Theory for the designing of the IDI-ICU

In 1980s, Sweller proposed the Cognitive Load Theory based on the research about the limitation of cognitive resources in the field of psychology\(^\text{[20]}\). The theory assumes that human cognitive resources are limited, and a certain number of resources are needed to process and maintain information. Based on the theory, cognitive load of ICU nurses that arise from ICU delirium assessment, risk factor evaluation and preventive and management interventions can be reduced by optimized modes of presentation.

Results

Item 1. Brief Name

Evidence-based, nurse-led individualized delirium intervention in ICU.

Item 2. Why: Rationale, Theory, or Goal of the Elements Essential to the Intervention

Step1: Needs assessment

Through literature review, three main needs were identified (1) a time-saving and easy-to-use assessment tool\(^\text{[12, 13]}\); (2) an informational hand-out of delirium risk factors\(^\text{[21]}\), and an ICU delirium risk prediction model\(^\text{[22]}\) which can dynamically assess patients' risk levels in developing delirium\(^\text{[23]}\); (3) evidence-based interventions that can be easily tailored by the nurse.

Step2: Intervention development

(1) Flow chart of ICU delirium assessment tools

The PADIS guidelines recommend the use of CAM-ICU or ICDSC to recognize ICU delirium\(^\text{[24]}\). A flow chart of assessment tools procedures was designed based on the features of each tool. The patient's risk for developing delirium is based on the nurse's assessment of each item using the rules of each assessment tool.

(2) Formulation of risk factors assessment sheet

We performed a comprehensive search to identify the guidelines related to ICU delirium. ICU delirium is caused or exacerbated by the combination of multiple risk factors\(^\text{[25]}\), three types of risk factors were summarized in our study, patient-related factors (e.g. hearing and visual impairment), disease-related factors (e.g. pain, infection), environmental or iatrogenic factors (e.g. physical restraints, mechanical ventilation).
(3) Translating evidence-based ABCDEF bundle intervention into practical applications

The PADIS Guidelines\cite{26} have recommended to use a bundle approach, namely “ABCDEF bundle” which includes measures on managing pain, conducting spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs), maintaining light sedation, and encouraging early mobility, family participation and use of non-pharmacological interventions to prevent and manage ICU delirium. The ABCDEF bundle is targeted on eliminating various modifiable risk factors of ICU delirium, such as pain, mechanical ventilation, immobility, and can be used as either a preventive intervention to reduce the incidence of ICU delirium or as a management intervention once ICU delirium occurs. The appropriate subset of interventions from the ABCDEF bundle should be tailored to patients’ specific risk factors.

Step 3: Formulation of the library of IDI-ICU

We established an interdisciplinary team of clinical nurses, physicians, and researchers, to determine what modifications are necessary to streamline the delivery the protocol. This team kept touch online daily and meet weekly throughout the project, and discuss a set of change requests based on cognitive load theory and design requirements, including modifying document templates, creating new viewing fields, and revising algorithm between delirium risk factors and interventions. The modification requests are an iterative, ongoing input and cooperative process between clinical staff and the research team to optimize the delirium intervention. Finally, a set of delirium intervention to reduce the ICU delirium incidence were formulated (see Table S1).

Item 3. Materials: Physical and Informational Materials Used in the Intervention, Including Those Provided to Participants or Used in Intervention Delivery or in Training of Intervention Providers

The manual of IDI-ICU was developed to ensure that ICU nurses understand the use of these delirium intervention, which consists of three main parts (1) assessment tools, the rule to judge whether the patient having delirium were clearly made; (2) risk factors evaluation sheet, the definition/criteria of each factor has predefined; and (3) risk factor targeting interventions, detailed nursing interventions with duration or frequency were included in the instructions. These interventions are described as clearly as possible, so nurses can learn them with minimal training (Table S1).

Item 4. Procedures, Activities, and/or Processes Used in the Intervention

Intervention group

Nurses in the intervention group provide delirium intervention based on the Al-AntiDelirium. Firstly, an educational program is delivered by researchers, eligible nurses are trained on how to operate the Al-AntiDelirium. The Al-AntiDelirium consists of four main modules: assessment tools, risk factor assessment, nursing care plan and nursing checklist. Briefly introduction of the steps to use the Al-
AntiDelirium: (1) logging into the system on a mobile phone; (2) diagnosing ICU delirium: nurses choose one instrument (CAM-ICU or ICDSC) and complete the items according to the prompts, the AI-AntiDelirium automatically presents whether the patient has delirium or not; (3) assessing risk factors: the AI-AntiDelirium automatically retrieves risk factors of ICU delirium from the hospital information system, nursing information system and laboratory test results. Risk factors that cannot be obtained from other systems are evaluated by the nurse. Additionally, the AI-AntiDelirium automatically calculates a predictive risk value for developing ICU delirium based on the prediction model[25]; (4) viewing nursing care plan: the AI-AntiDelirium can automatically tailor personalized ICU delirium prevention or management interventions based on the risk factors identified; (5) viewing nursing checklist: nurses view the nursing checklist which including frequency of the intervention and carry out the interventions for each patient and record reasons why patients did not receive these interventions.

Control group

Nurses in the control group provide delirium intervention based on the paper-version of assessment tools (CAM-ICU, ICDSC), delirium risk factors and ABCDEF bundle interventions. Prior to the study, an educational program related to ICU delirium is delivered by researchers to train nurses on how to use the paper-based materials. During the study, nurses use the paper-version of CAM-ICU or ICDSC to assess ICU delirium, use evaluation list to assess risk factors, and use the appropriate subset of interventions from the ABCDEF bundle targeted to patients’ specific risk factors.

Item 5. Description of the Expertise, Background, and Specific Training Given to Intervention Providers

ICU nurses are positioned best to provide early delirium detection and early management intervention for critically ill patients when necessary, because they are always at the patient’s bedside and monitoring the changes in the patient’s condition. The IDI-ICU has been used by ICU nurses who are qualified registered nurses, with a minimum of 1-year experience in intensive care.

ICU nurses in the intervention group attend a one-hour training session according to a standardized manual, that describes how to operate the AI-AntiDelirium, including logging on to the system, using the delirium assessment tools, recording risk factors, and providing individualized interventions. Additionally, the ICU nurses and the researchers are required to attend regular meetings to discuss and troubleshoot the use of the interventions. The purpose of these procedures is to ensure minimal deviation from the manual. Nurses in the control group provide ICU delirium related nursing care based on the paper-version of assessment tools, risk factors, and the ABCDEF bundle. Prior to the study, an educational program related to the use of a paper-based ICU delirium materials is delivered by researchers with the same content delivered to the intervention group.

Item 6. Mode of Delivery

The IDI-ICU are used individually with face-to-face, mainly delivered by ICU nurses; a few interventions are implemented by family members during visiting hours.
Item 7. Type(s) of Location(s) Where the Intervention Occurred, Including Any Necessary Infrastructure or Relevant Features

IDI-ICU were delivered in the ICU.

Item 8. Number of Times the Intervention Was Delivered and Over What Period of Time Including the Number of Sessions, Their Schedule, and Their Duration, Intensity or Dose

IDI-ICU is delivered 7 days a week, until the patient’s discharge. Nursing care activities varied with specific frequency, duration, intensity or dose. For example, assessment of delirium is recommended at least one time per shift. If the patients have the ability to exercises, nurses will guide the patient to do the active range-of-motion exercises, 10 times for each joint, three times a day. ICU nurses provide as much intervention as the patient could tolerate based on the patient’s condition. Some factors may result in lowered dose of the intervention including patients’ illness, patients’ family members, and staff shortages. The actual implementation of interventions for each patient was recorded on a separate report form.

Item 9. Tailoring of the Intervention

IDI-ICU is designed for adult patients with an expected ICU stay of at least 48 hours. On the first day of admission, the nurse assesses the patient’s basic characteristics, vital signs, disease history, diagnosis, test results, medications, etc. Each day, different nursing interventions are provided for patients based on their daily assessment. In the manual, interventions for different delirium risk factors are tailored into detailed nursing interventions respectively (see Table S1).

Item 10. Modifications of the Intervention During the Study

Before the IDI-ICU trial, a pilot study was conducted to examine the feasibility of the intervention, and modifications were made according to providers’ feedback. No modifications were made on the current intervention protocol during the IDI-ICU trial.

Item 11. Planned Procedures for How Adherence or Fidelity Was Assessed, Describe How and by Whom, and if Any Strategies Were Used to Maintain or Improve Fidelity, Describe Them

The detail of the intervention providers’ training is presented in item 5. In this section, adherence to IDI-ICU by study nurses was described. The head nurse for each study units, received training of the intervention, serves the role of supervisor for the nurses’ fidelity to the manual. In addition, the principal investigator of this project acts as an observer during the implementation of the study in each center and do not provide any feedback to ICU nurses, because we record the authentic adherence without any interference.

11.1. Planned Procedures to Assess Feasibility in the Ongoing Trial.

The feasibility of IDI-ICU is assessed in a pilot study, therefore, no specific procedures are implemented to examine feasibility of the IDI-ICU in the large-scale clinical study.
Item 12. Actual Adherence or Fidelity

The fidelity of IDI-ICU protocol in the trial is measured by the intervention recording form, which is used in the pilot study to record frequency, duration, intensity or dose of intervention. These data are reported in an article with the clinical effect data and submitted to a peer-reviewed journal at the end of the study.

Patient and public involvement

No patient involved.

Discussion

To the best of our knowledge, this is the first study to report a detailed process for development of theory-based and evidence-based IDI-ICU, which aims at reducing cognitive load and improving adherence of ICU nurses, as well as reducing ICU delirium incidence and other negative outcomes in ICU patients. Following the cognitive load theory, interventions are formed in this study which integrate the nurses’ needs, evidence-based measures and experts’ opinion. ICU delirium intervention are described in detail following the TIDieR checklist. Therefore, it will be easy for the clinical staff and researchers to replicate the IDI-ICU. However, in order to better evaluate the pros and cons of the intervention, we suggest that the interventions described in the manual be delayed from clinical implementation until the study results are published.

The major advantage of this study is that the TIDieR checklist, which has rarely been applied to delirium trials before, was adopted to describe IDI-ICU. The TIDieR checklist has been developed to provide a systematic way to report key items of the IDI-ICU used in clinical trials, including the following main headings: why (rationale and underlying theory), what (materials and procedures), when (how often and how much), how (mode of delivery, tailoring and modifications), where (location and infrastructure), and who (providers). Several points are worthy of discussion with regard to the feasibility of the TIDieR checklist to describe a complex IDI-ICU. First, the TIDieR checklist emphasizes the facilitators and obstacles that promote or compromise delivery of interventions[27]. Second, TIDieR requires the detailed description of the intervention nurses such as their background, competencies and training received, which would benefit other hospital staffs to replicate the interventions. Third, the TIDieR checklist serves as a universal norm for describing interventions, making it useful at the stage of study design[28]. Above all, the TIDieR checklist guides the authors to report their interventions in a more effective manner, so help clinical staff can apply the interventions and help researchers to replicate the evidence in further studies[27].

It is also noteworthy that all the interventions used in this study are evidence-based bundle intervention, which increases the reliability and feasibility of interventions to improve the delirium related outcomes. The evidence-based bundle intervention are aimed at facilitating nurses early recognition of ICU patients at high-risk for delirium, and addresses multiple delirium risk factors in either prevention and/or
management interventions, which make a potential difference to clinical outcomes of ICU patients. Information on the impact of bundle intervention will offer knowledge to clinical staff for providing individualized measures to critically ill patients.

Another strength of this study is that CDSS is adopted to support the translation of evidence-based interventions into practical clinical applications. Several studies have shown that CDSS can reduce cognitive load of nursing staff\textsuperscript{[17,18]}. ICU nurses are always in a state of over workload and dealing with complex decision making, which lead to psychological distress and mental fatigue\textsuperscript{[16]}. PoLiang and colleagues\textsuperscript{[16]} found that medical staff needed more cognitive resources to complete activities, such as recalling information, collecting information from multi-channel and real-time monitoring, which when lacking resulted in poor adherence to clinical practice guidelines. Therefore, a CDSS which assists clinical staff to decrease cognitive load and enhance adherence to ICU delirium interventions is needed.

Several limitations should also be noted. One is that there is still need for a randomized controlled trial to verify the effectiveness of the intervention. The other limitation is that the needs assessment was limited to only literature review and interview. Multi-aspect needs assessment methods that integrated individual interviews, focus group discussions and literature review should be applied in future studies to identify more problems regarding implementation of delirium interventions. Finally, the bundle interventions only focused on several important delirium risk factors (e.g. pain, mechanical ventilation, immobility, and family members absent) rather than targeting other risk factors such as hypotension and metabolic acidosis. Further studies are needed that focus on expanded delirium risk factors and related interventions. Despite these limitations, this paper is the current best description of evidence-based ICU delirium intervention which followed TIDieR checklist.

**Conclusion**

The IDI-ICU is described according to the TIDieR checklist, which contributes to the clinical practice for the standardization of interventions. The results from this study also serve as a theoretical and methodological basis for exploring the application of Cognitive Load Theory in designing delirium interventions which delivered by ICU nurses for critically ill patients. Future well-designed RCTs are needed to examine the effectiveness of the IDI-ICU on reducing ICU delirium incidence and duration.

**Abbreviations**

**RCT**: Randomized Controlled Trials;

**TIDieR**: Template for Intervention Description and Replication checklist;

**CONSORT**: Consolidated Standards of Reporting Trials;

**SPIRIT**: Standard Protocol Items: Recommendations for Interventional Trials;
ICU: Intensive Care Unit;

IDI-ICU: Individualized Delirium Intervention in Intensive Care Unit;

CAM-ICU: Confusion Assessment Method for the Intensive Care Unit;

ICDSC: Intensive Care Delirium Screening Checklist;

PADIS: Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption Guideline;

CDSS: Clinical Decision Support System;

AI-AntiDelirium: Artificial Intelligence Assisted Prevention and Management for Delirium;

CLT: Cognitive Load Theory;

SATs: Spontaneous Awakening Trials;

SBTs: Spontaneous Breathing Trials.

Declarations

Ethics approval and consent to participate

The Ethics Committee of the University approved this study (Z2019SY21). Informed consent was obtained from all subjects. All methods were performed in accordance with the Template for Intervention Description and Replication (TIDieR) checklist.

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article [Supplementary Table S1].

Competing interests

The authors declare that they have no competing interests

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Authors’ contributions
SZ contributions to the conception, design of the work, interpretation of data, have drafted the work and substantively revised it. MJ contributions to interpretation of data, have drafted the work and substantively revised it. WC contributions to interpretation of data, have drafted the work. YW contributions to have drafted the work and substantively revised it. All authors read and approved the final manuscript. All authors have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work.

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References


**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- TIDieRChecklist.pdf
- TableS1.pdf