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The effectiveness of a comprehensive package based on a serious game for improving nurses' adherence to clinical practice guidelines and the healthcare quality of intensive care units in China

Submission date
12/06/2024

Recruitment status
No longer recruiting

Registration date
26/06/2024

Overall study status
Ongoing

Last Edited
18/06/2024

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Non-adherence to clinical practice guidelines in intensive care units (ICUs) poses a serious risk to patient health outcomes and health systems. An effective strategy for addressing this issue is the implementation of comprehensive training programs based on serious games. However, there is limited research on the impact of serious game-based training on the nurses' adherence to clinical practice guidelines and the healthcare quality of ICUs in China. This study aims to evaluate the effectiveness of a comprehensive serious game-based intervention for enhancing nurses' adherence to clinical practice guidelines for ventilator-associated pneumonia (VAP) and improving the quality of healthcare provided in ICUs in China.

Who can participate?

Adult nurses aged 18 years old and over in the ICU who have gained a certificate indicating their status as intensive care specialist nurses

What does the study involve?

The study will be implemented in two cities from each of the eastern, central, and western regions of China and will include ICUs in both secondary and tertiary hospitals. The intervention group nurses will receive training through a serious game. Key elements of VAP prevention, such as ICU nurses' hand hygiene, head-of-bed elevation, subglottic secretion drainage, cuff pressure monitoring, oral care, enteral nutrition management, effective airway secretion clearance, and ventilator circuit management, will be integrated into this game following current clinical practice guidelines. A team, including five nursing administrators with over ten years of clinical teaching experience, ten clinical teachers, one software engineer, one technical support staff member, and five nurses, will develop a game-based mobile app. The development team will use literature, teaching theory, and clinical experience to create adaptable simulations. Nurses in the intervention group will be required to play the serious game at least once a week. The game will

also feature a competitive element, allowing nurses to invite others within the intervention group to join the competition. Regular discussions on quality issues will be organized to address any potential problems during the intervention's implementation. The control group will not receive any intervention. The intervention period will last for one year.

What are the possible benefits and risks of participating?
This study has the following policy implications. Firstly, employing a serious game-based intervention will introduce an innovative method for training ICU nurses, potentially transforming traditional educational practices and enhancing engagement with and the effectiveness of learning. This approach is beneficial for rapidly improving nurses' adherence to clinical practice guidelines and enhancing the quality of care, thereby strengthening the overall responsiveness and healthcare service quality of the healthcare system. Additionally, nurses trained using this method will be better equipped to adapt to the digital healthcare environment, promoting modernization and sustainable development in the healthcare sector. Secondly, this study will promote the implementation of clinical practice guidelines by identifying barriers and facilitators to their adoption and developing an intervention package based on a serious game. This approach will provide actionable insights and strategies for integrating evidence-based practices into daily ICU operations, ensuring adherence to best practices and enhancing the overall quality and consistency of patient care. The consequent findings will inform policy decisions aimed at standardizing care protocols and improving healthcare outcomes across various ICU settings. Finally, this study will develop a crucial strategy for scaling and generalizing the intervention, which will help ensure the useful development of clinical practice guidelines and provide a model for other quality improvement initiatives for China and other low- to middle-income countries. There will be no potential harm to the participants.

Where is the study run from?
Inner Mongolia University

When is the study starting and how long is it expected to run for?
January 2023 to February 2027

Who is funding the study?
1. The National Social Science Fund
2. The National Natural Science Foundation of China

Who is the main contact?
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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
National Social Science Foundation of China: 22&ZD143; National Natural Science Foundation of China: 72164031 and 72204128)

Study information

Scientific Title
Improving nurses' adherence to clinical practice guidelines via a comprehensive package based on a serious game in intensive care units in China: protocol of a multicenter randomized controlled trial

Study objectives
Based on the aims of implementation research and the utility of multicenter randomized controlled trials, this study will be conducted to develop and implement a comprehensive package based on serious gaming, integrating clinical practice guidelines for ventilator-associated pneumonia (VAP) prevention and control in the ICU.

The aim is to evaluate the effectiveness of such serious game-based interventions in enhancing nurses' adherence to clinical practice guidelines and improving the quality of healthcare provided in ICUs in China. More specifically, the goals are: 1) to identify the barriers and facilitators regarding the implementation of clinical practice guidelines for VAP in Chinese ICUs; 2) to develop and implement a comprehensive package based on a serious game, evaluating its acceptability, cost-effectiveness, and long-term effects; and 3) to develop strategic options for scaling and generalizing such serious game-based interventions to better integrate ICU clinical practice guidelines into daily practice, thereby improving the overall quality of ICU healthcare services.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/03/2023, The Peking University Health Science Center's Ethics Committee (No. 38 Xueyuan Road, Haidian District, Beijing, 100191, China; +86 010-82805751; llwyh@bjmu.edu.cn), ref: IRB00001052-23020

Study design
12-month multicenter parallel-group individually randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Enhancing ICU nurses’ adherence to clinical practice guidelines and improving the quality of healthcare provided in ICUs in China

Interventions
This study is a 12-month multicenter, parallel-group, individually randomized controlled trial with one intervention and one control arm, using a 1:1 allocation ratio, to evaluate whether the serious game-based comprehensive intervention is superior to usual training programs. After recruitment, randomization will be conducted using a random list generated by STATA 17.0 software. A 1:1 ratio of nurses will be randomly assigned to the intervention group or the control group. Sealed envelopes containing the group numbers will be kept by the research manager, who is not directly involved in participant recruitment or follow-up matters. The research designer will retain the group assignment results until the end of the data analysis period.

The study will span 38 months, comprising a 3-month preparation and pilot phase, a 6-month participant recruitment phase, a 12-month intervention implementation phase, and a 5-month data analysis and write-up phase. Following the intervention, a 12-month follow-up study will be conducted to compare outcomes and implementation strategies between the intervention and control groups.

The intervention group nurses will receive training via a serious game. Following current clinical practice guidelines, key elements of ventilator-acquired pneumonia (VAP) prevention will integrate into the serious game. These elements include ICU nurses’ hand hygiene, head-of-bed elevation, subglottic secretion drainage, cuff pressure monitoring, oral care, enteral nutrition management, effective airway secretion clearance, and ventilator circuit management. A game-based mobile app will be developed by a team of authors, including 5 nursing administrators with over 10 years of clinical teaching experience, 10 clinical teachers, 1 software engineer, 1 member of technical support staff, and 5 nurses. The software development team will draw on literature, teaching theory, and clinical experience to simulate adaptable operations. Nurses in the intervention group will be required to play the serious game at least once a week. Additionally, the game includes a feature for inviting others to join the competition, with an algorithm limiting the invited individuals to those within the intervention group and enabling competition among members of this group. Regular discussions will also be organized around quality issues to address potential issues during the implementation of the intervention. The control group will receive no intervention. The intervention period will last for one year.

The primary study hypothesis is that a comprehensive package incorporating serious gaming can significantly improve ICU nurses' adherence to clinical practice guidelines. Therefore, the primary outcome will be the adherence to clinical practice guidelines. The adherence rate will be identified using the scores obtained from the serious gaming component.

The study will utilize Donabedian's structure-process-outcome quality assessment model to define secondary outcomes. Firstly, it will examine the structural components, including ICU staffing, medical equipment, quality management systems, and financial status. Secondly, it will

assess process-based components, such as adherence to clinical practice guidelines, patient monitoring frequency, implementation of infection control measures, nurse game scores, and nurse satisfaction. The adherence of nurses to clinical practice guidelines will be measured based on their game scores. Finally, it will analyze outcome indicators, including patient survival rates, treatment success rates, reoperation rates, complication rates, healthcare-associated infection (HAI) rates, and patient satisfaction.

Intervention Type
Behavioural

Primary outcome(s)
Adherence rate to clinical practice guidelines measured using the scores obtained from the serious gaming component at baseline and 6 and 12 months

Key secondary outcome(s))
The following secondary outcome measures will be assessed at baseline, 6 months, and 12 months:
1. Structural components: ICU staffing, medical equipment, quality management systems, and financial status measured using an institutional questionnaire
2. Process-based components:
2.1. Adherence rate to clinical practice guidelines and nurse game scores measured using the data obtained from the serious gaming component
2.2. Patient monitoring frequency measured using patient medical records
2.3. Implementation of infection control measures assessed using a pre-designed questionnaire
2.4. Nurse satisfaction measured using the Minnesota Satisfaction Questionnaire

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Certification indicating their status as an intensive care specialist nurse
2. Have a mobile phone or computer
3. Internet access

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
01/01/2024

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
China

Study participating centre
Peking University
38 Xueyuan Road, Haidian District
Beijing
China
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Sponsor information

Organisation
National Natural Science Foundation of China

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
National Social Science Fund of China

Alternative Name(s)
Chinese National Funding of Social Sciences, , National Social Science Foundation of China, National Social Science Foundation, NSSFC

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
National Natural Science Foundation of China

Results and Publications

Individual participant data (IPD) sharing plan
The anonymized patient-level data and statistical code generated during and/or analyzed during the current study will be available upon reasonable request to Prof. Min Su (sumin1227@126.com) or Prof. Weiyan Jian (jianweiyan@bjmu.edu.cn) after all papers of this study have been published and within 5 years after the trial ended. The data can only be used for research purposes and shared with research organizations/qualified researchers. Consent for data use will be obtained during patient recruitment.

IPD sharing plan summary
Available on request