DEVELOPMENT, VALIDATION, AND EVALUATION OF THE EFFECTIVENESS OF SIMULATION IN BASIC LIFE SUPPORT TRAINING (SBLST), ON NEWLY EMPLOYED NURSES IN GOVERNMENTAL JORDANIAN HOSPITALS

Study Protocol

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Study title:

DEVELOPMENT, VALIDATION, AND EVALUATION OF THE EFFECTIVENESS OF SIMULATION IN BASIC LIFE SUPPORT TRAINING (SBLST) ON NEWLY EMPLOYED NURSES IN GOVERNMENTAL JORDANIAN HOSPITALS

Objective

The general objective of this study is to develop, validate and evaluate the effectiveness of simulation in basic life support training (SBLST) among newly employed nurses in Jordanian governmental hospitals; the study design is a basic experimental study design, randomized control trial (RCT) design, the dependant variables measure in this study; knowledge, practice and confidence by using a pre-test and two follow up tests, two groups are participating in this study; experimental and control group. The control group treatment is the standard intervention (brochure), and the experimental group intervention is a simulation in basic life support training (SBLST); researchers' hypothesized that there are no significant differences between the control and experimental group in the inclusion criteria and pre-test score; furthermore, the simulation in basic life support training intervention significantly improves knowledge, practice and confidence level among newly employed nurses (NEN) in Jordanian governmental hospitals; moreover, the is a significant difference between control and experimental group in the post-test scores in all dependant variables. The study process include four steps

- Perform the pre-test (assess knowledge, practice confidence surveys
- Education intervention knowledge and practice
- Perform the post-test 1 (assess knowledge, practice confidence surveys
- Perform post-test 2 (assess knowledge, practice confidence surveys

Research Hypotheses

i. The simulation in basic life support training intervention effectively improves knowledge among newly employed nurses (NEN) in Jordanian governmental hospitals.

ii. The simulation in basic life support training intervention effectively improves practice among newly employed nurses (NEN) in Jordanian governmental hospitals.

iii. The simulation in basic life support training intervention effectively improves the confidence level among newly employed nurses (NEN) in Jordanian governmental hospitals.

iv. There is no significant difference in means between the pre-test among the newly employed nurses (NEN) among interventional and the control groups in all dependent variables.

v. There is a significant mean difference between PRE-SBLST and all POST-SBLST results among NEN in all dependent variables.

Study Design

The study design was a prospective, longitudinal, single-blind basic experimental design, randomized control trial (RCT) design.

Study Location

The study was carried out in Jordan; Amman and Al-Zarqa City. The accessible population was NEN in five hospitals. The researchers selected three Jordanian hospitals. The selection was according to the capacity, capability of the institution and eligibility criteria. Computer-generated randomization (Random Allocation Software, version 1.0) was applied in blocks to allocate the hospitals by distributing them into two arms. The first arm was the control group; selected from three hospitals; Prince Hamza Hospital, AL-Basheer Hospital, and AL-Zarqa Governmental Hospital (n=51); the second arm was the interventional group from two hospitals; Prince Faisal Governmental Hospital and Dr.Jameel AL-Totanji Hospital.

Randomization of the Hospitals

To prevent data contamination between the control and interventional groups, computer-generated randomization (Random Allocation Software, version 1.0) was applied in blocks to allocate the hospitals by distributing them into two arms. The first arm was the control group; selected from three hospitals; Prince Hamza Hospital, AL-Basheer Hospital, and AL-Zarqa Governmental Hospital (n=51); the second arm was the interventional group from two hospitals; Prince Faisal governmental hospital and Dr.Jameel AL-Totanji hospital. The control and interventional groups were selected from different hospitals because the researchers are always worried about data contamination and try to minimize it between the control and intervention groups; if the sample was selected from the same area and both groups worked closely together, the data would be contaminated.

Inclusion Criteria

The researchers tried to maintain homogeneity and minimize any variations among the participants by

1. selecting both interventional and control groups from newly employed nurses
2. Male and female participants
3. Participants only who understand the questionnaires and interventions in English
4. Participants who were previously on-seat undergraduate nursing students last two years, 2020 (4th year nursing bachelor level) and 2021 (3rd year nursing bachelor level) in the period of COVID-19 pandemic and receive basic and clinical learning by online method, and now became a newly employed nurse (NEN) in hospitals and delivered care to the patient.
5. Participants can attend five to seven hours of SBLST session.
6. For more control, we selected nurses who rarely face CPR and do not attend BLS raining the last two years.

Exclusion Criteria

1. The researchers excluded the NEN participants working in intensive care units because ICU nurses face CPR and perform BLS daily.
2. Excluded participants with medical or physical health problems (e.g., pregnant women and participants complaining of lower back pain).
3. Participants who attended CPR training less than two years previously were also excluded. Finally,
4. NEN who upgraded their educational degree from a diploma to a bachelor's degree were excluded.

Research Instruments

The study consists of a pre-test, intervention, immediate post-test-1 after the intervention, and finally, the post-test-2 three months after the intervention. This study measured knowledge, practice, and confidence through pre- and post-tests in control and experimental groups. This study used two interventions: SBLST for the interventional group and AHA-BLS 2020 brochure as a standard treatment for the control group. Data collection proceeded using the Google Form Platform (A web-based instrument Copyrighted by Google application).

The evaluation process includes a pre-test and two follow-up assessments to measure knowledge, practice and confidence. The researcher will analyse the means of each test; the total dependent variables were 30 questions listed in.

Languages of the Tools

According to the HCP educational level, all four sections of the tools assessment are written in English; furthermore, the researchers' assistance clarified any misunderstanding points or need for translation to the participants.

Tools Sections

The tools consist of five sections; research information sheet and consent forms, demographical data, knowledge assessment tools, skills assessment tools, and confidence level assessment tools.

Research information sheet and Consent Forms

The research information sheet is a piece of brief researcher information and contact details; it also includes subject information and a consent form with an area for the participant's signature when they are approved to participate in this study. Furthermore, the research information sheets include a participant's publication consent form.

Demographical data

Demographic parts are attached in; these data consist of dichotomous questions (Yes\NO), nominal data, ordinal data, and interval measurement questions. Nominal measurements include sex and ordinal assessment as educational level and area of experience; interval assessment questions include age and work experience. Dichotomous assessments (Yes\NO), asking if the participant previously participated in a CPR episode or observed any CPR before, if the participants had finished training the BLS using simulation previously, and if the participant gained the certification of BLS training from formal and accredited institutions previously.

Knowledge and practice

Nursing knowledge is the interaction of science and research to improve practice. Researchers use a 13-question MCQ tool to assess knowledge. Nursing practice is performing the knowledge learned before; the researchers assessed skills using a tool consisting of ten MCQ. The participants got zero for each wrong answer and one mark for each correct answer.

Confidence

Confidence is the build and accomplishment of the nursing profession through knowledge acquisition, skills, and critical thinking. Confidence is the positive feeling of faith and dependability to perform BLS without fear and free from risk to the patient. The researchers assessed confidence level using seven statements rated as a dropdown in percent value from the lowest value of 5% to the highest value of 100%.

Study Process

Pre-test

After NEN enrolled according to the inclusion criteria for both the control group and experimental group (n= 102), the participants started by signing the informed consent, filled out the demographical data and pre-test as proactive steps before the intervention; many sessions of pre-test data collection and intervention were performed according to the availability of NEN, the arrangement of the hospital's nursing director. The estimated time to fill in the demographical data and pre-test is around 30 minutes. Oermann et al. (2020) addressed that the trainer performs a pre-test assessment to assess the effectiveness of SBLST. The investigators discussed the purpose of the study with the control group and explained to them the procedure to prevent any data contamination and minimize the interpretation of the survey content with the other

Intervention

The control group read the brochure containing a brief guideline about basic life support for 30-60 minutes before taking the post-test. Standard treatment ran from Dec 2022 to Jan 2023. One full day for SBLST intervention, from 5 to 7 hours for SBLST intervention is required based on the recent research and uses AHA-2020 guidelines. The number of participants was ten NEN in each session. The

interventional treatment consists of theoretical and practical parts. The SBLST intervention was conducted in an educational lab according to the hospital's capability; SBLST ran for seven days, from 22 Nov 2022 to 20-Dec, 2022.

Researchers combined two frameworks in the SBLST. Miller's Pyramid and Kolb's Cycle; Miller's Pyramid focuses on teaching theoretical and practical aspects of the task through simulation and allowing trainees to perform the procedure independently with guidance; Kolb's Cycle suggests giving learners a scenario to practice until they eliminate errors before moving to another scenario. The SBLST intervention was reviewed by three experts in BLS and approved by the Jordanian Ministry of Health-Life Support Center. It was found to be compliant, safe and covered all aspects of AHA-2020. English experts provided feedback to improve clarity. A pilot study was conducted on 20 nurses to calculate SBLST time, identify errors, monitor the progress and calculate Cronbach's Alpha.

Adult half-body manikin and a pediatric full-body manikin are necessary; with lung bag inflation and deflation characteristics, palpable carotid pulse, the chest includes spring inside to facilitate chest recoil, and chest compression board, bag-valve-mask-ventilation, chest compression performed on the Charlie simulator to relieve choking. The principles investigator (PI) had a master's degree in critical care nursing, eighteen years of experience between ICUs, lecturers and clinical instructors, valid BLS and ACLS, training of trainers in nursing education, and randomized control trial training. The facilitator must have CPR certifications in BLS and ACLS, enough expertise in education and training, and good communication skills the investigator had a master degree in critical care. Two research assistants supported the

PI in collecting data; one research assistant for the control group and the other for the interventional group.

Post-test

All participants completed the immediate post-test-1 after the interventions. The post-tets-2 was conducted by providing the participants with a Google Form Platform link through their phone and email addresses. The post-test after three months evaluates whether the participants' level stayed at the same level or minimized by comparing the mean value between all post-tests. Forty-eight participants in the experimental group completed post-test-2 with a response rate of 94%, and 45 participants in the control group with a response rate of 88%.

Sample Size Estimation

Sample size calculation is performed by using G*POWER software (version 3.1); sample size calculation is summarized and consists of the following steps (1) Select the test family (F-test family), (2) Select the statistical test (Select ANOVA-repeated test, between factors), the preliminary test analysis the researchers used in this study, the rationale for using the Select ANOVA-repeated test between factors due to measure many dependent variables means at different time points. (3) The parameters selected to calculate sample size include one side tail, alpha (α) and equals (0.05)- type one error, Power (P) and equal (0.8), effect size, the number of groups is two (each group = n\2) n= the estimated sample size, number of measurements were four measurements (Pre-test, Post-test immediately, Post-test after two months, and Post-test after three months).

Effect Size (ES) = 0.26, automatically calculated by G*Power software, depending on the sample size of the previous study, the effect size is calculated, the

Control group's post-test result M±SD was equal (25.03±3.04) with a sample size of 28 participants, and the interventional group (26.64±2.64) with sample size 29 participants. The sample size is 72 participants; because the research study continued for three months, we added a 10% drop rate for each month, so the drop rate is 30%. Final sample size estimation including drop rate (n\1-dropout rate) = 72/(1-0.30) = 102 participants, the intervention group arm is 51 participants, and The largest sample size was obtained from the interventional group, more than the Control Group and the Control group arm 51 participants.

Simple Random Sampling of the Participants

After obtaining ethical approval and permission to conduct the study from the Ministry of Health in Jordan, approval letter (Education/Info\ 15177) and ethical approval letter (MOH/REC/2022/340), The researchers started the formal face-to-face visits to arrange with the nursing director and a continuous education office in the selected hospitals about the study objective and how the study would proceed; The researchers received the activation letter to initiate the study and prepared the list of the available participants who met the study's eligibility criteria. The number of participants depends on the availability of newly employed nurses in the institution who meet the inclusion criteria. The researchers randomly selected the participants from the participants' list by randomly sampling from newly employed nurses in each hospital for interventional and control groups.

. The response of the control group hospitals was as the following; the nursing director and continuous education in AL-Zarqa Governmental Hospital responded by providing all the information about participants and selecting a time and day to perform the Pre-test, standard treatment and the immediate post-test. Prince Hamzah Hospital and AL-Basheer Hospital gave the researcher the names of departments in the

hospital, including those with NEN, and we visited these departments to select the available NEN randomly and performed Pre-test, standard treatment, and immediate post-test in their departments.

The response of the interventional group hospitals was as the following; Prince Faisal Governmental Hospital and Dr.Jameel AL-Totanji Hospital scheduled many days and times to perform the intervention, and the hospitals arranged with the available participants who met the eligibility criteria; then, the researcher selected the participants randomly.

Ethical Considerations

Permission to Conduct the Study

Regarding ethical considerations, approval for the study was obtained from the Human Research Ethics Committee (HREC), Universiti Sains Malaysia (USM). Moreover, ethical approvals to initiate SBLST intervention in Jordanian Hospitals in Amman and AL-Zarqa city were obtained from the Ministry of Health in Jordan; the study protocol was revised and approved for implementation by Jawatankuasa Etika Penyilidikan Manusia Universiti Sains Malaysia (JEPeM-USM) with study protocol code USM/JEPeM/22110681, which compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Subject Vulnerability

There is no vulnerability group in this study. All the participants were nurses over 20 years old and working in hospitals; no participants had handicaps or physical problems. The participants made the voluntary choice to take part in the trial. The researchers discussed the study's objectives, methods, benefits and risks. The study was free from any potential hazards or adverse effects on participants, no intervention was applied in emergencies, and no medicine product will be used in this study. The procedure was simple, the devices used in the intervention were safe, and the investigator was instructed to frequently ask the participant about health and physical condition, especially during chest compression.

The participants who signed a hard copy of the consent are part of this trial study. During all study phases, the participants will be asked using the electronic method; Google Form Platform, if they would like to participate in this study, and they will answer (YES\NO) before completing the questionnaires. Furthermore, the intervention will be applied in simulation; the participant voluntarily withdraws from the study without any influence or effect on annual evaluation or salary. The institutions took full responsibility for the trial and protecting the participants and treated the participants if there were unexpected adverse effects or physical harm.

The research includes minimal risk toward participants, observable by the time length and components of the intervention; participants may be feeling discomfort. This risk is equal to the nurses' daily life activity. They can be adapted with this minimal risk; only four components require a long time to cover the knowledge and practice in the intervention, but the other four components are easy and need a short time. The researchers planned to minimize the participant's discomfort due to the time

and length of the intervention by giving the participant "break times" between the components of the intervention.

Declaration of Absence of Conflict of Interest

The researchers had declared that there was no conflict of interest, and all co-authors had no financial interest to report. We certify that the first author is purely a Ph.D. student's original work and has not been given to submit to other universities or journals.

Privacy and Confidentiality

When the study was completed, the trial master files and documents were protected and kept safe, and all records were kept confidential. Furthermore, the data collected is not associated with individuals by name but only by phone number and email to contact them later to complete the post-test; data is kept properly and handled only in the research. In addition, the researchers also emphasized that only research groups can access the relevant data in this research and not use it in the future without consent from the participants; moreover, after finishing the study, the data will archive properly according to the policy.

Community Sensitivities and Benefits

The intervention benefits of NEN as a part of a contentious education, and the knowledge and practice shared through the natural learning process in the classroom, face-to-face learning, and the questionnaires filled using an electronic method, Google Forms Platform; there is no sensitive information about the participants. The primary benefits of this study's findings toward participants are to increase newly employed nurses' knowledge, practice skills, and confidence level when facing critical situations inside or outside the hospitals, increases professionalism in all healthcare delivery systems, self-esteem, improve newly employed nurses' performance competency,

decision-making, satisfaction, to decrease turnovers and dissatisfaction. Furthermore, the benefits of this study are to develop patient care processes and enhance the victims' survival and patient satisfaction, maintain patient safety, enhance the welfare and hospital discharge outcomes, become cost-effective for patients and their families, and keep patients away from hazards.

Incentive and Reimbursement

The researcher verbally thanked all participants for their sincere cooperation following the completion. Furthermore, the researcher planned to give the control group an SBLST on a selected day; finally, the participant received feedback about the pre and post-result and a certification attendance of 4 hours from the researcher, adding to the required job development hours in the yearly self-evaluation form.