Internal Research Grant Human Ethical Protocol

Information sheet for Individuals

Title of Proposed Research Project:

Testing a Simulation Teaching Intervention in Critical Care Nursing: A randomized control trial

Specific purpose

The aim of the study was to evaluate the effectiveness of simulation teaching intervention for diabetes ketoacidosis in a critical care nursing in a public university. The findings may assist to design best educational practices in improving simulation experiences in the nursing program.

Background

You are asked to participate in a research study. We are doing research to Testing a Simulation Teaching Intervention in Critical Care Nursing: A randomized control trial

Study procedure

This letter outlines important information to help you decide whether or not you would like to take part in this research. If you agree, we will ask you to take part in a survey and a potential simulation teaching intervention. We will ask you to share information about yourself and learning. The audio recording of the simulation will be private, and your name will not be used in this study. The tapes of the simulation will only be seen by the research assistant and coordinator. The tapes and surveys will be kept in a secure storage following the research. The survey in professional journals will appear for teaching and research purposes without any identification.

Benefits

Your participation might not benefit you individually, but the information will help the teaching faculty in the nursing curriculum and program to design simulation intervention. The information that you will share with us will help us to make recommendations for this simulation teaching-learning framework.

Risks

It is not expected that taking part in this study would cause any harm to you. The only requirement from you is your time and willingness to engage in the survey and potential intervention. You will be able to opt out of any areas of discussion that are uncomfortable for you.

Confidentiality

The data will be kept confidential. All identifying information will be removed from the data. Nothing you have shared will be connected to your name. All information will be kept in a password protected and encrypted file on a computer in the researcher's office. Only the researcher, a research assistant/ and transcriber will know what you have shared. Everyone will be asked to sign a confidentiality agreement. The data will be stored for an undetermined time. When we decide to destroy or shred it, it will be in a way that ensures privacy and confidentiality. The data will also be used to write academic papers and policy information sheets. Your name will not be connected to these sharing events. We may use the data we get from this study in future research, but if we do this it will have to be approved by a Research Ethics Board.

Freedom to Withdraw

You are under no obligation to participate in this study. The participation is completely voluntary. Even if you agree to be in the study, you can change your mind and withdraw at any time. If you decide to stop participating you can ask that all information you have shared be removed and destroyed.

Additional contacts

You are welcome to ask any questions, at any time, regarding any aspect of this study, participant rights, and ethical conduct of research. The plan for this study will be reviewed for its adherence to ethical guidelines by a Research Ethics Board at the Sultan Qaboos University.

Researcher information:

Melba Dsouza, School of Nursing, Sultan Qaboos University, Email desouzamelba123@gmail.com, Cell 968-98136661

Consent Form for Participants

Part 1 (to be completed by the researcher):

Title of Project Title: Researcher information:

Testing a Simulation Teaching Intervention in Critical Care Nursing: A randomized control trial

Investigators/ Researcher. Melba Dsouza, School of Nursing, Sultan Qaboos University, Email desouzamelba123@gmail.com, Cell 968-98136661

Part 2 (to be completed by the research participant, tick any one): Yes/ No

1. Do you understand that you have been asked to be in a research study? Yes/ No
2. Have you read and received a copy of the attached Information Sheet? Yes/ No
3. Do you understand the benefits and risks involved in taking part in this research study?
4. Have you had an opportunity to ask questions and discuss this study? Yes/ No
5. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without penalty? Yes/ No
6. If you request to withdraw from the study, do you understand that all data gathered up to the point of withdraw will be destroyed on request? Yes/ No
7. Has the issue of confidentiality and anonymity been explained to you? Yes/ No
8. Do you understand that the conversations will be recorded? Yes/ No
9. Do you understand that portions of the final research may be published in professional journals or presented at conferences? Yes/ No
10. Do you understand the researcher is obligated to report any breach of professional conduct that is unethical and not legal, and that is not currently in a process of resolution? Yes/ No
11. Who explained this study to you? Yes/No? _____
12. Do you understand about the voluntary participation, withdraw from consent for the Survey, Simulation? Yes/No
13. Do you need more information about the Survey, Simulation? Yes/No
14. I will participate in the Survey ☐YES ☐NO, Simulation ☐YES ☐NO (tick mark only the boxes applicable)
15. I understand that I can withdraw at any time from the Survey, Simulation ☐YES ☐NO

I agree to take part in this study: ☐YES ☐NO

Signature of Participant _____ (Name or Code)

Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT.

Confidentiality Agreement

Title of the Project: Testing a Simulation Teaching Intervention in Critical Care Nursing: A randomized control trial

I, _____, the (student research assistant) have been hired to : _____

I agree to -

1. keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format (e.g., disks, tapes, transcripts) with anyone other than the Researcher(s).
2. keep all research information in any form or format (e.g., disks, tapes, transcripts) secure while it is in my possession.
3. return all research information in any form or format (e.g., disks, tapes, transcripts) to the Researcher(s) when I have completed the research tasks.
4. after consulting with the Researcher(s), erase or destroy all research information in any form or format regarding this research project that is not returnable to the Researcher(s) (e.g., information stored on computer hard drive).
5. Inform participants about ethics and consent in Survey, Simulation?

   (Print Name) (Signature) (Date)

Researcher(s) _____

(Print Name) (Signature) (Date) _____

The plan for this study has been reviewed for its adherence to ethical guidelines and approved by Research Ethics Board at the Sultan Qaboos University.

For questions regarding participant rights and ethical conduct of research, contact Melba Dsouza, School of Nursing, Sultan Qaboos University, Email desouzamelba123@gmail.com, Cell 968-98136661

Informed Consent Form

Study Title: Testing a Simulation Teaching Intervention in Critical Care Nursing: A randomized control trial

Greeting Participants,

You are being asked to participate in a survey about **"**Testing a Simulation Teaching Intervention in Critical Care Nursing: A randomized control trial**"**

Participation in this study requires you to complete a questionnaire which may take 30 minutes. You are NOT required to provide any personal identifying information and all information collected will be kept confidential. Only the researcher will have access to the completed questionnaires. Your teachers will not have any access to the information you have provided. Publication and presentations at the completion of the study will report only grouped findings.
Your participation in this study is absolutely voluntary and you have a right to refuse to participate. If you change your mind during the course of completing the questionnaire, you have the right to withdraw from the study at any time. If you have any questions, please feel free to ask.

Potential risks: There are no physical risks to you as a result of participating in the study.

Potential benefits: There are no immediate benefits to you from this study. However, results of this study may be used to conduct interventional studies to enhance simulation learning of students.

Participant's Declaration Statement: I have read the above information. I have also had the opportunity to ask questions about it and they have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study.

Participant Signature :_____
Date: _____

For additional information contact Melba Dsouza, School of Nursing, Sultan Qaboos University, Email desouzamelba123@gmail.com, Cell 968-98136661