

Participant Information Sheet (PIS):

Study Title:

A randomized controlled trial comparing the efficacy of high-fidelity simulation -based teaching (HFSBT) and video-assisted teaching (VAT) in ECG learning in a cohort of preclinical medical students.

Researchers involved:

PI: Dr Ratnadeep Saha (Senior Lecturer, NUMed)

Dr Bikramjit Pal, Associate Professor, NUMed

Prof Harinarayan, Radhakrishna, Dean of Clinical Affairs, NUMed

Dr Andrew Chaytor, MBBS Degree Programme Director, Newcastle University

Dr Joanna Matthan, (Dean of Academic Affairs, NUMed)

NUMed Dr Angus Aranan, (Senior lecturer, NUMed)

Dr Prakash Manickam Kumarasamy, (Lecturer, NUMed)

Dr Kye Mon Min Swe, (Associate Professor, Education Research, NUMed)

Introduction:

You are invited to participate in a randomized controlled trial study that explores ECG learning skills through HFSBT driven by complex pathophysiological computer models and VAT. This document provides necessary information about the study protocol.

Purpose of the Study:

The study aims to compare the efficacy between HFSBT and VAT in the acquisition and retention of knowledge and skills for the interpretation of ECGs.

Procedures:

Duration: The study will be conducted over two semesters. You will meet twice (Week 1 = 1.5 hrs and week 6 = 25 minutes) in first semester and once (Week 12 = 40- 45 minutes) in second semester.

Activities:

Week 1: You will appear for a Pretest MCQ (20-minute) followed by randomization.

Randomization will allow you to form two groups (6-7 in each group); Interventional group (IG) and control group (CG). This process will allow you to join a 50- minute small group interventional session (HFSBT or VAT) under the guidance independent facilitators where teaching and discussion / hand on training will be conducted one after the other. Soon, this will be followed by first OSCE assessment (25- minute) by an independent assessor.

Week 6: You will appear for second OSCE assessment (25-minute) without having any teaching and discussion sessions like the week 1.

Week 12: You will appear for both a Post-test MCQ (20-minute), third OSCE assessments (25-minute) and provide feedback (15- minute) based on a validated questionnaire. Here you will not go through any teaching and discussion sessions like week 6.

Potential Risks and Discomforts:

No significant risks associated with this study. However, being first time user, you may experience mild stress on using the high-fidelity simulation machine and feel slight assessment related stress like typical formative academic evaluation. You are assured that the evaluation for this training course will not be a part of your first-year curriculum and would not affect the course grades.

Benefits:

By participating in this research, you will support development of improved teaching methods. This will inform the teaching in future years and also directly improve your own learning process including peers on various aspects of ECG and common cardiac pathologies for the current academic year and prime you for the learning in clinical stages.

Participation: Your participation is entirely voluntary.

What happens if you refuse to give consent: Nothing. You may withdraw at any time prior to or at any point during the activity without any consequences,

Confidentiality & Data storage:

All your data will be anonymized and kept confidential. All survey/questionnaire responses, notes, and records will be kept and stored in a secured environment (Lock and key or Password protected). The research team only will have access to your information for the purposes of completing this assignment. Only, the raw data, if required, will be offered to you within twelve months of the completion of course assignment. In case if you decide to withdraw, any data that you provide up to that point will be included for the study. **However, you are strongly encouraged to involve throughout the entire study** to make it meaningful and useful for greater benefit.

Will I have access to the resource content:

The students in the control group along with the students who have not consented for the research study will be provided access to the same high fidelity simulation sessions at the end of the course to ensure parity between the groups for their development of knowledge and skills. Similarly, the students in the intervention group along with the students who have not consented for the research study will have access to the video-based lecture at the end of the course to ensure parity.

Contact Information:

If you have any questions or concerns / file a complaint, please contact: the PI in the following e mail below:

Principal Investigator: [Dr Ratnadeep saha, Email: ratnadeep.saha@newcastle.edu.my]

Thank you for considering participation in this study.