

Official title: The Role of Simulation Fidelity in Early Surgical Skills Education

NCT number: not yet assigned

Unique Protocol ID: RNN/193/25/KE

Date of the document: May 20, 2025

Appendix 1 - Study protocol - May 20, 2025

Study title:

A comparison of the effectiveness of learning to apply surgical sutures using different training materials amongst medical students, taking into account teaching via face-to-face and remote methods – a randomised controlled trial.

Official title: The Role of Simulation Fidelity in Early Surgical Skills Education

Study design:

Study type: Randomised controlled trial (RCT).

Study groups: 5 groups (5 experimental, 1 control):

1. Group 1: Banana skin (40 participants)
2. Group 2: Orange peel (40 participants)
3. Group 3: Pork skin (40 participants)
4. Group 4: Chicken skin (40 participants)
5. Group 5: Silicone pads (40 participants)

Assessment: A team of 4 independent, experienced surgeons assesses the sutures according to predefined criteria. Participants complete a questionnaire evaluating the material.

Study population:

Inclusion criteria:

- o Medical students.
- o No prior advanced training in surgical suturing.
- o Written consent to participate in the study.

Exclusion criteria:

- o Participation in specialist suturing courses outside the degree programme.
- o Allergy to any of the materials used in the study.
- o Refusal to take part in the study.

Randomisation:

Randomisation procedure: Participants will be randomly assigned to one of five groups using a computerised random number generator. Randomisation will ensure that each group has an equal number of participants.

Study procedure:

1. Theoretical training (for all groups):

All participants will receive identical theoretical training covering the basics of surgical suturing techniques (60-minute lecture).

2. Practical intervention: Experimental groups (1–5): Participants will carry out a practical exercise involving placing sutures on the assigned material.

3. Skills assessment: All participants will place sutures on an identical, neutral material (a standard silicone pad).

4. Assessment by surgeons: Independent, experienced surgeons, who are unaware of the participants' group allocation (blinding), will assess the quality of the sutures applied according to established criteria.

5. Participant questionnaire: Participants in the experimental groups will complete a questionnaire evaluating the material they used.

Criteria for assessing sutures:

- o Objective measures assessed by surgeons:
- o Suture tension: Assessment of whether the sutures are too loose or too tight.
- o Symmetry and spacing between sutures: Measurement of the evenness and uniformity of the sutures placed.
- o Depth and correct placement of sutures: Whether the needle was inserted and withdrawn at the correct points.
- o Stability of knots: Assessment of whether the knots are tied correctly and do not come undone under light tension.
- o Task completion time: Measurement of the time taken to place a specified number of sutures.

Participant questionnaire:

Closed-ended questions:

- o Realism of the material: Scale 1–5.
- o Ease of working with the material: Scale 1–5.
- o Satisfaction with the learning experience: Scale 1–5

Open-ended questions:

- o What did you like about working with this material?
- o What drawbacks do you see in this material?
- o Suggestions for improving the learning process.

Data analysis:

Statistical analysis of results:

- o Comparison of mean scores between groups using an ANOVA or Kruskal-Wallis test.
- o Post-hoc analysis: Identification of significant differences between specific pairs of groups.
- o Correlation of surgeons' ratings: Calculation of the correlation coefficient (e.g., Spearman's rank correlation coefficient) between the ratings of two surgeons to assess consistency.

Study protocol:

1. Recruitment of participants: Announcement to medical students. Obtaining consent to participate in the study.
2. Randomisation and group allocation: Random allocation of participants to one of five groups.

3. Theoretical training: An identical lecture for all participants.
4. Practical intervention: The experimental groups carry out practical exercises.
5. Skills assessment: All participants apply sutures to a neutral material.
6. Assessment by surgeons: Evaluation of the quality of the sutures according to established criteria.
7. Participant questionnaire: Completion of material assessment forms by the experimental groups.
8. Data analysis and reporting of results: Conducting statistical analyses