Refreshing medical students' i.v.-cannulation skills: a blinded observer three-arm randomised comparison of mental imagery, part-task trainer simulation, and written instructions

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Abstract (297/300)

Introduction: Intravenous (i.v.) cannulation is a core competence in medicine, but is considered challenging to learn. This study investigates the effectiveness of three educational strategies used to refresh the i.v. cannulation skills of first-year medical students: mental imagery, part-task trainer simulation, and written instructions.

Materials and Methods: In this single-centre randomized controlled trial, first-year medical students were assigned to one of three different refresher tutorials on i.v. cannulation. Six months after their compulsory 4-hr instructor-led i.v.-cannulation course, each student was randomized to a 6-min self-learning tutorial: a mental imagery audio-guide session, hands-on i.v. cannulation on a part-task trainer, or reading written instructions.

Immediately after the refresher tutorials, trained evaluators who were blinded to the randomized group assessed the students' performance. Each evaluator completed a 15-item standardized checklist in an Objective Structured Clinical Examination (OSCE) station for i.v. cannulation. We performed a descriptive analysis of the data and a one-way ANOVA. Additionally, we investigated the influence of previous i.v. cannulation experience on the total OSCE score.

Results and Discussion: On analysing the 309 students' results, we did not find differences in the total rating of the performance (in percentage) between the three groups at the OSCE station (mental imagery group: 72.0±17.9%; part-task trainer group: 74.4±15.6%; written instructions group: 69.9±16.6%, p=0.158). Multiple linear regression showed a small but statistically significant effect of students' previous i.v. cannulation experience on OSCE performance. With the same outcome, written instructions and mental imagery had a better return on effort, compared to resource-intensive hands-on training with part-task trainers.

Conclusion: A single, short refresher seems to have a limited effect on i.v.-cannulation skills in first-year medical students. Less resource-intensive interventions, such as written

instructions or mental imagery, are equally effective compared to hands-on part-task trainer simulation for refreshing this simple but important skill.

Article summary

Strengths and limitations of this study

- Randomized adequately powered three-armed study design
- Use of mental imagery as a form of non-physical simulation
- Single-centre study in first-year medical students, therefore results might not be generalizable

Introduction:

Patient participation in healthcare education remains an essential part of student training, but practising on real patients raises ethical issues, particularly if it involves training of invasive procedures [1]. Additionally, technological, economic and regulatory changes, not only in anaesthesiology but in most medical specialities, have led to a considerable reduction in bedside teaching opportunities for medical students [2]. This has led to simulation as an educational approach in current competency-based curricula.

Simulation designed for the acquisition of technical skills aims to reproduce reality with varying levels of physical fidelity. It offers an alternative approach to learning complex psychomotor and procedural skills, with the opportunity to rehearse them in near-life scenarios in a safe, protected, learner-centred, simulated clinical setting [3].

One of the most frequently performed basic medical skills is intravenous (i.v.) cannulation [5, 6]. Although this is an invasive skill and challenging to learn [7], proficiency may prevent serious complications, such as infiltration, phlebitis, pain, or severe systemic infection [8-10]. Traditionally, medical students were taught this skill through didactic instruction, followed by practice on either an arm part-task trainer or on students or patients [5]. However, these traditional i.v.-cannulation teaching methods are time-consuming, expensive, and the opportunities for practising the technique are often unavailable [11].

Recently, mental imagery – a form of non-physical simulation – has been introduced in medical education to teach and maintain skills. Mental imagery is a structured process of mental rehearsal before a procedure [13], and involves visualization, prompted by the use of the senses, and recall, leading to a re-experiencing the initial stimulus at the moment of first exposure. Mental imagery is widely used and recognized as effective in the realms of stroke rehabilitation, cognitive behavioural therapy, high-performance athletics, and professional musicianship [14-16], as a means to improve performance and reduce procedural error.

Several studies have investigated mental imagery in postgraduate settings [4, 12, 17, 18], but only one small study used it during i.v. cannulation performed by undergraduate students [19]. Mental imagery, due to its simplicity, could facilitate learning and skill maintenance in undergraduate medical student curricula, and release educators from the physical and temporal presence of bedside teaching. Furthermore, it may provide an economic alternative to the more costly low-fidelity simulator model design.

This randomized study compared the effectiveness of three non-instructor-led teaching methods– mental imagery, low-fidelity part-task trainer simulation, and traditional written instructions –in refreshing a simple medical psychomotor procedural skill (i.v. cannulation) in first-year medical students.

Methods:

Participants and setting:

All 1st-year medical students from the Medical Faculty of the University of Bern were invited to participate in the study. All participants provided written informed consent to participate, and the Bern Cantonal Ethics Committee (Req-2021-00096, 26.01.2021) waived the need for ethical approval as no patients were involved. Students who refused to participate or were late for the Objective Structured Clinical Examination (OSCE) were excluded from the study. Refusal to participate did not affect their formative assessment or any grades arising thereof. All procedures from this investigation met the criteria of the 1964 Declaration of Helsinki and its amendments [20]. All researchers complied with the Data Protection Act [21] and the Swiss Law for Human Research [22]. This study was registered in the AEA RCT Registry with the number AEARCTR-0008043. This article adheres to the CONSORT checklist.

The compulsory i.v.-cannulation course for 1st-year medical students at the University of Bern took place between late October and mid-December 2020 in the Bernese Interdisciplinary Skills and Simulation Center (BiSS). All students attended two small-group teaching sessions, each two hours long. The first session consisted of practice on an arm part-task trainer (EZ-7010, Erler Zimmer, Germany), and the second consisted of practice on simulated patients using an armband part-task trainer (R16614, Erler Zimmer, Germany), and on fellow medical students. A short course and its learning outcomes are displayed in Table 1. The physical practice of the students was individually supervised by trained course tutors (all medical students in their final years of university) and overseen by experienced intensive care unit nurses.

Table 1: Interprofessional i.v.-cannulation Course Outline & Learning Outcomes

<table>
<tr><td colspan="2">Flipped Classroom (student effort: 1h):
(1) Preparation with E-Book - The e-book contains the basics that are required for both parts (basics of hygienic hand disinfection, basics of venipuncture), combined with work assignments and study questions).
• Module 1: Hand disinfection: Theory and short MCQ questionnaire
• Module 2: Taking blood samples: where and how, pitfalls, tutorial video, 8 min (in German). (https://www.nanoo.tv/link/v/fuzPhkqU, CC BY-NC-ND 4.0)
• Module 3: I.v. cannulation: where and how, contraindications, pitfalls, complications, with tutorial video, 9 min (in German). (https://www.nanoo.tv/link/v/vnfRZMCs, CC BY-NC-ND 4.0)</td></tr>
<tr><td>Course Part 1 (Duration: 2h)</td><td>Course Part 2 (Duration: 2h)</td></tr>
<tr><td>Theory
15 minutes i.v.- cannulation
15 minutes taking blood samples</td><td rowspan="2">Practice (2h)
Practice on model /Practice on peers (voluntary)</td></tr>
<tr><td>Practice (90 min)
Practice on model
Practice on peers</td></tr>
<tr><td colspan="2">Available materials: Positioning aids for the patient's arm, gauze, alcohol swab, tourniquet, i.v cannulas (18G, 20G), cannula dressing, disposal container, gloves</td></tr>
<tr><td>Tutor concurrent feedback</td><td>Tutor concurrent feedback</td></tr>
<tr><td colspan="2">Further practice: Room and practice model provided for further practice</td></tr>
</table>

Knowledge	• List the indications, risks and complications of the procedure; • Name the materials and preparatory steps necessary for the intervention; • Explain the criteria for choosing a suitable location for the procedure; • List and justify the hygiene guidelines for the procedure;

	• Explain important basic rules of the technique; • Describe common principles underlying the different standard operating procedures from institutions.
Skills	• Adequately inform normal adults in a standard situation about the indications, risks and procedure of the intervention; • Prepare for the procedure (including providing the necessary materials, labelling tubes, checking the patient's identity, positioning, etc.); • Determine a puncture site for the procedure; • Correctly perform the intervention, following the hygiene guidelines; • Assess own abilities and determine when to call for help in case of problems; • Constructively exchange ideas with other participants.
Attitudes	• Assess the patient's fears and apprehensions about the procedure; • Assess how the procedure is experienced from the patient's point of view; • Support a climate of constructive cooperation between different professions; • Reflect on one's function and tasks within an interprofessional team

Study design and interventions

We carried out a three-armed, assessor-blinded randomized trial (Figure 1, flowchart). Six months after the first-year medical students underwent standard i.v.-cannulation training, they received an invitation explaining the goals of the study. Participants were asked to be on-site 30 minutes before a formative OSCE at the end of the first semester. Upon arrival, all participants completed a questionnaire to ascertain previous experience in i.v. cannulation, including attempts and demographics. After that, they were randomly assigned to one of three groups:

1) Group A: a ***6 min. mental imagery audio-guided tutorial:*** Students listened to a mental imagery audio recording of an i.v. cannulation procedure, in a dimmed room and using earphones, while lying down on a lounger. No i.v.-cannulation materials were available.

2) Group B: a ***6 min. part-task trainer simulation tutorial***: Students practised on a low-fidelity arm part-task trainer like the one they had in their previous course sessions (EZ-7010, Erler Zimmer, Germany). All materials used during the course sessions were available.

3) Group C: a ***6 min. tutorial with written instructions***: Students revised the i.v.-cannulation steps individually, with the aid of a laminated instruction sheet.

Randomization procedure

Students were allocated according to a 1:1:1 ratio to either the mental imagery group (n=105), the part-task trainer simulation group (n=105) or the written instructions group (n=106) using block randomization with a fixed block size of 9. The randomization sequence was created through randomization software (www.sealedenvelope.com). The allocation sequence was concealed from the students and the evaluators, as well as from those involved in the statistical testing of the data.

Construction of the mental imagery audio script and the audio guide

RG, RB and CCG (an anaesthesia-certified nurse), considered specialists in i.v. cannulation, recorded a 45-min online focus group, facilitated by JBE, to develop the mental imagery script. They were asked to describe visual and kinesthetic clues at each step of i.v. cannulation and common pitfalls during i.v. cannulation. The focus group recordings were transcribed and analysed using iterative content analysis to create the mental practice script. This script was subsequently audio recorded.

The guided mental imagery tutorial that was presented to the randomized group of students consisted of a 6-min audio guide with instructions for i.v. cannulation embedded in relaxing breathing exercises. Students were advised to imagine the technique as if they were performing i.v. cannulation themselves. Instructions were delivered at a slow pace and emphasized the correct technique.

The i.v.-cannulation OSCE assessment

The i.v.-cannulation skill was assessed six months after the initial training, during the 1st year formative OSCE at the University of Bern's Faculty of Medicine. This OSCE comprised three different stations assessing 1) i.v.-cannulation skills, 2) basic life support, and 3) history taking. Each station lasted 8 minutes and the students' distribution to one of these stations occurred randomly.

In the 8-min i.v.-cannulation OSCE station, a simulated patient used an i.v.-puncture model strapped to their arm (R16614, Erler Zimmer, Germany) for puncture. The assessment was conducted by trained evaluators using a 15-item OSCE checklist in use at the University of Bern, which was tested for internal consistency. This setting and the structure of the checklist ensured that procedural flow, psychomotor skills as well as communicative aspects of the students' i.v.-cannulation performance could be assessed. Evaluators were all experienced anaesthesia nurses blinded to the students' group rehearsal assignment. All evaluators took part in a 30-min training session on completing the checklist.

Statistical analysis

Our primary outcome was the total score in percentage of the OSCE assessment for the i.v.-cannulation station. Additionally, the influence of previous i.v.cannulation experience on the total OSCE score was examined.

We performed a multi-arm sample size calculation, aiming to demonstrate superiority of one of the educational strategies using an *a priori* power analysis with G*Power V.3.1.[23] Assuming an effect size (f=0.305) for a one-way analysis of variance with three groups (α=0.01, 1-β=0.80), we found that the minimum required sample size for three groups was n=156. To compensate for 20% of non-responders, we aimed for 180 participants.

Statistical analysis was performed using SPSS 27 (IBM Corp, Armonk, NY, USA). Categorical variables were described as absolute (n) and relative frequencies (%). Continuous variables were described using mean and standard deviation. In order to control for possible confounding effects, interdependence of categorical variables with the three groups was tested using a Chi-squared test for contingency tables, and one-way ANOVAs were used to test possible differences in the means of continuous variables between the three groups. For reliability testing of the checklist, internal consistency was evaluated with Chronbach´s alpha.

A one-way analysis of variance (ANOVA) was conducted to compare the means of the total OSCE score in percentages of the three groups. The number of previous attempts at i.v. cannulation using part-task trainer simulation and the number of previous attempts at live i.v. cannulation served as predictors in a multiple linear regression with the total score in percentage as dependent variable. An a priori probability of less than 0.05 was considered to be statistically significant.

Patient and Public Involvement

No patient involved.

Results

Three hundred and sixteen students were invited to participate in the study. After excluding students who did not attend the OSCE or arrived late, 309 students were enrolled (participation rate of 97.8%). The participants' characteristics did not differ between the three groups (Table 2). Overall, the items in the checklist showed an internal consistency of α= 0.691, which is considered acceptable [24].

204 **Table 2:** Participants' characteristics

	Total (n=309)	**Mental Imagery (n=104)**	**Part-Task Trainer (n=100)**	**Written Instructions (n=105)**	**p-value**
Age, years (mean±SD)	21.3±1.9	21.1±1.9	21.2±1.7	21.6±2.2	0.500
Female sex, n (%)	189 (61.2)	64 (62.1)	69 (68.3)	56 (53.3)	0.085*
German mother tongue, n (%)	282 (91.0)	92 (89.3)	92 (91.1)	98 (92.5)	0.545*
No previous experience in healthcare, n (%)	301 (97.4)	101 (98.1)	96 (95.0)	104 (98.1)	0.563*
Previous attempts at i.v.-cannulation in part-task trainer simulation, n (mean±SD)	3.0±1.9	3.1±1.9	2.9±1.9	3.0±1.9	0.693
Previous attempts at live i.v.cannulation, n (mean±SD)	3.2±8.0	2.3±1.9	3.8±9.0	3.6±10.4	0.372

205 *Chi-square

206

207 There was no statistically significant difference between groups in the one-way ANOVA on 208 our primary outcome the students' overall i.v.-cannulation performance rating: mental imagery 209 scored 72.0±17.9%, part-task trainer simulation scored 74.4±15.6%, and written instructions 210 scored 69.9±16.6% ($F_{2,306} = 1.856, p = 0.158$).

211 Stepwise multiple linear regression showed that i.v.-cannulation experience during part-task 212 trainer simulation had a significant but small effect on the OSCE performance (R^2 213 $= 0.015, p = 0.031$). Students reported the number of previous attempts at cannulation as 214 6.5±8.5, without differences between the three groups (p=0.224). The live i.v.-cannulation 215 experience showed no contribution to the OSCE performance.

Discussion

Our study shows that the performance of i.v. cannulation, assessed at an objective, structured skills exam, did not differ after three different refresher tutorials (mental imagery, part-task trainer simulation, and written instructions).

Our results differ from those of several randomised controlled trials on mental imagery in postgraduate education. Studies that involved surgical trainees' "warming up" with mental imagery [17, 18] described significantly improved performance with a warm-up before laparoscopic surgery. However, when considering the effects of warm-up on the different aspects of psychomotor performance, Paschold et al. [25] found that these were affected by the nature of the warm-up, the type of surgery, and the expertise of the surgeon. This suggests that optimal warm-up strategies are task- and procedure-specific and may change with varying expertise [4], consequently yielding conflicting results.

Use of mental imagery in anaesthesia studies also showed conflicting findings. A 2016 study reported improved fiberoptic intubation skills after a 5-minute mental imagery warm-up on a virtual reality bronchoscopy simulator when compared with a control group [26]. In contrast, anaesthetists practicing mental imagery did not manage crises better during simulation [27]. The reasons proposed by the study authors for the negative results were the nature of the task, the limited "dose" effect (20 min vs. the 30–90 min reported in successful interventions), and the number reduced of cues in the mental script.

More recently, comparable effects of mental imagery and low-fidelity simulation were described in anaesthesiology residents learning to administer epidural anaesthesia [28]. Our study results align with the latter, as all three "warm-up" methods resulted in similar student performance in an objective, structured skills exam.

It is of more interest to compare our results with the study by Sanders et al. [19]. They also did not find a significant difference in medical students' venipuncture performance with or without mental imagery. But they did find a significant difference in student performance between part-task trainer simulation and a control. Those authors assessed their students immediately after their training session, while our assessment occurred following the refresher, at 6 months after the initial training. Thus the two studies might not be readily comparable.

The number of previous i.v.-cannulation part-task trainer simulation attempts had a small but significant effect on the OSCE performance. Students in our study performed, on average, more than six attempts at i.v. cannulation in the 6 months before their first-year OSCE. This number is considered as the number of attempts necessary to achieve a plateau level of the learning curve for this procedure [7, 29]. That might partly explain why the three different refresher strategies resulted in comparable results. As our study participants reached the critical mass of medical students who had already acquired the necessary skills in i.v.-cannulation before the study took place, an improvement might be hard to detect, and our students probably did not necessarily profit from these refreshers. That might explain the puzzling finding in our study that the written instructions group was just as effective as the other two interventions, and questions the need for such a refresher shortly before an OSCE at all.

Although we did not formally assess the cost of our three interventions, it seems obvious that written instructions and mental imagery are far more economical than the purchase and maintenance of a low-fidelity part-task arm, including the instructor's salary and time spent teaching). This cost-effectiveness argument needs to be further investigated in a properly performed cost-effectiveness analysis.

Our study has several other limitations. It assessed the effectiveness of different refresher techniques for i.v.-cannulation skills, but its successful transfer to clinical practice could not be ascertained. We assume that our results can be applied to related techniques which require venipuncture, like taking blood samples, but despite our robust design, our results may not be generalizable to other cohorts. Additionally, due to the post-test methodology of the study, no conclusion can be taken regarding the student's performance of i.v. cannulation before the intervention. Finally, it is possible that the 6-minute intervention was simply too short to detect a difference in the teaching strategy and its effect on the performance of the skill.

In summary, these results suggest that all interventions were similarly successful at refreshing i.v.-cannulation procedures in undergraduate medical students.

Conclusions:

Medical schools currently seek to offer more efficient, cost-effective and innovative methods to enhance learning. Our study comparing three 6-minute refresher strategies, indicates that part-task trainer simulation is not superior to mental imagery and written instructions for refreshing i.v.-cannulation skills in first-year medical students. Both mental imagery and written instructions have a far better effort-return ratio than resource-intensive hands-on training with part-task trainer simulation. Mental imagery and written instructions cannot completely replace physical clinical skills training in i.v. cannulation, but may effectively supplement it, similar to other fields involving complex psychomotor skill learning.

Declarations

Ethics approval and consent to participate: All participants provided written informed consent to participate and the Bern Cantonal Ethics Committee (Req-2021-00096, 26.01.2021) waived the need for ethical approval as no patients were involved.

Consent for publication: Not applicable

Availability of data and materials: The data generated and analysed during the current study are available in the manuscript and the Supplemental Digital Content. Datasets containing student information are available after anonymization from the corresponding author on reasonable request. More information on the study can be found at https://doi.org/10.1257/rct.8043-1.0.

Competing interests: RG is the Director of Training and Education of the European Resuscitation Council, the Task Force Chair Education, Implementation, and Team of ILCOR, and a member of the Direction of the MME Program of the University of Bern. The remaining authors report no declarations of interest.

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Author contributions:

JBE wrote the outline and performed the data collection, demographic statistical analysis and interpretation of the data.

RB and MB contributed to the outline, performed the data collection, and helped in data interpretation and the writing process.

DS performed the bivariate statistical analysis and helped interpret the data.

RG initiated the study, supervised the creation and adaptation of the outline, and critically reviewed the manuscript.

CB supervised the creation and adaptation of the outline, performed data collection and helped in data interpretation and the writing process.

All of the authors have read and approved the final version of the manuscript.

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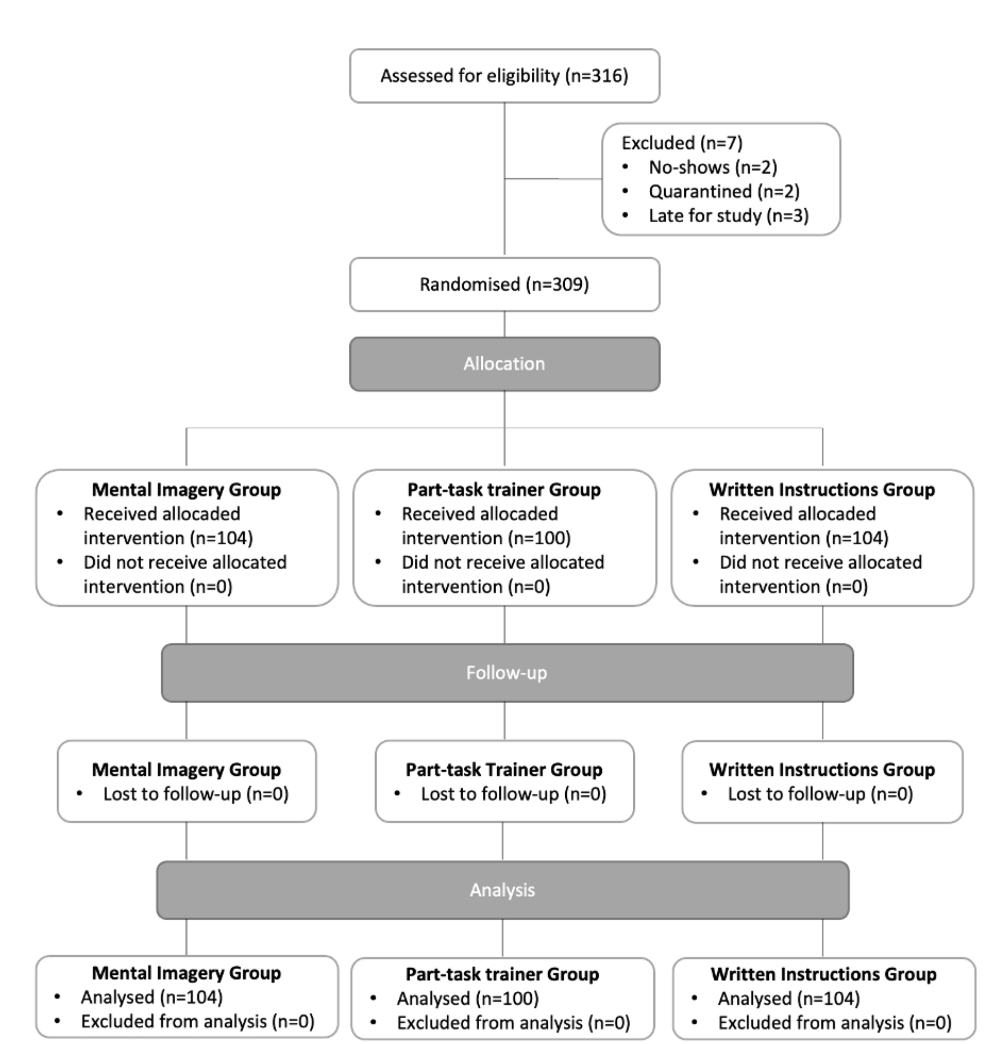
Figures:

Figure 1: Study Flowchart



Study Flowchart

159x167mm (150 x 150 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	13
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Refreshing medical students' i.v.-cannulation skills: a blinded observer three-arm randomised comparison of mental imagery, part-task trainer simulation, and written instructions

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Title: Refreshing medical students' i.v.-cannulation skills: a blinded observer three-arm randomised comparison of mental imagery, part-task trainer simulation, and written instructions

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Keywords: mental imagery, simulation, venous cannulation, medical education, anaesthesia

Trial registration: AEARCTR-0008043

Word count: Abstract 296 words, manuscript 2542 words

Abstract (297/300)

Introduction: Intravenous (i.v.) cannulation is a core competence in medicine, but is considered challenging to learn. This study investigates the effectiveness of three educational strategies used to refresh the i.v. cannulation skills of first-year medical students: mental imagery, part-task trainer simulation, and written instructions.

Materials and Methods: In this single-centre randomized controlled trial, first-year medical students were assigned to one of three different refresher tutorials on i.v. cannulation. Six months after their compulsory 4-hr instructor-led i.v.-cannulation course, each student was randomized to a 6-min self-learning tutorial: a mental imagery audio-guide session, hands-on i.v. cannulation on a part-task trainer, or reading written instructions.

Immediately after the refresher tutorials, trained evaluators who were blinded to the randomized group assessed the students' performance. Each evaluator completed a 15-item standardized checklist in an Objective Structured Clinical Examination (OSCE) station for i.v. cannulation. We performed a descriptive analysis of the data and a one-way analysis of variance. Additionally, we investigated the influence of previous i.v. cannulation experience on the total OSCE score.

Results and Discussion: On analysing the 309 students' results, we did not find differences in the total rating of the performance (in percentage) between the three groups at the OSCE station (mental imagery group: 72.0±17.9%; part-task trainer group: 74.4±15.6%; written instructions group: 69.9±16.6%, $p=0.158$). Multiple linear regression showed a small but statistically significant effect of students' previous i.v. cannulation experience on OSCE performance. With the same outcome, written instructions and mental imagery had a better return on effort, compared to resource-intensive hands-on training with part-task trainers.

Conclusion: A single, short refresher seems to have a limited effect on i.v.-cannulation skills in first-year medical students. Less resource-intensive interventions, such as written

instructions or mental imagery, are effective compared to hands-on part-task trainer simulation for refreshing this simple but important skill.

Article summary

Strengths and limitations of this study

- Randomized adequately powered three-armed study design
- Use of mental imagery as a form of non-physical simulation
- Single-centre study in first-year medical students, therefore results might not be generalizable

Introduction:

Patient participation in healthcare education remains an essential part of student training, but practising on real patients raises ethical issues, particularly if it involves training of invasive procedures [1]. Additionally, technological, economic and regulatory changes, not only in anaesthesiology but in most medical specialities, have led to a considerable reduction in bedside teaching opportunities for medical students [2]. This has led to simulation as an educational approach in current competency-based curricula.

Simulation designed for the acquisition of technical skills aims to reproduce reality with varying levels of physical fidelity. It offers an alternative approach to learning complex psychomotor and procedural skills, with the opportunity to rehearse them in near-life scenarios in a safe, protected, learner-centred, simulated clinical setting [3].

One of the most frequently performed basic medical skills is intravenous (i.v.) cannulation [4, 5]. Although this is an invasive skill and challenging to learn [6], proficiency may prevent serious complications, such as infiltration, phlebitis, pain, or severe systemic infection [7-9]. Traditionally, medical students were taught this skill through didactic instruction, followed by practice on either an arm part-task trainer or on students or patients [4]. However, these traditional i.v.-cannulation teaching methods are time-consuming, expensive, and the opportunities for practising the technique are often unavailable [10].

Recently, mental imagery – a form of non-physical simulation – has been introduced in medical education to teach and maintain skills [11]. Mental imagery is a structured process of mental rehearsal before a procedure [12], and involves visualization, prompted by the use of the senses, and recall, leading to a re-experiencing the initial stimulus at the moment of first exposure. Mental imagery is widely used and recognized as effective in the realms of stroke rehabilitation, cognitive behavioural therapy, high-performance athletics, and professional musicianship [13-15], as a means to improve performance and reduce procedural error.

Several studies have investigated mental imagery in postgraduate settings [16-19], but only one small study used it during i.v. cannulation performed by undergraduate students [20]. Mental imagery, due to its simplicity, could facilitate learning and skill maintenance in undergraduate medical student curricula, and release educators from the physical and temporal presence of bedside teaching. Furthermore, it may provide an economic alternative to the more costly low-fidelity simulator model design.

This randomized study compared the effectiveness of three non-instructor-led teaching methods– mental imagery, low-fidelity part-task trainer simulation, and traditional written instructions –in refreshing a simple medical psychomotor procedural skill (i.v. cannulation) in first-year medical students.

Methods:

Participants and setting:

All 1st-year medical students from the Medical Faculty of the University of Bern were invited to participate in the study. All participants provided written informed consent to participate, and the Bern Cantonal Ethics Committee (Req-2021-00096, 26.01.2021) waived the need for ethical approval as no patients were involved. Students who refused to participate or were late for the Objective Structured Clinical Examination (OSCE) were excluded from the study. Refusal to participate did not affect their formative assessment or any grades arising thereof. All procedures from this investigation met the criteria of the 1964 Declaration of Helsinki and its amendments [21]. All researchers complied with the Data Protection Act [22] and the Swiss Law for Human Research [23]. This study was registered in the AEA RCT Registry with the number AEARCTR-0008043[24]. This article adheres to the CONSORT checklist.

The compulsory i.v.-cannulation course for 1st-year medical students at the University of Bern took place between late October and mid-December 2020 in the Bernese Interdisciplinary Skills and Simulation Center (BiSS). All students attended two small-group teaching sessions, each two hours long. The first session consisted of practice on an arm part-task trainer (EZ-7010, Erler Zimmer, Germany), and the second consisted of practice on simulated patients using an armband part-task trainer (R16614, Erler Zimmer, Germany), and on fellow medical students. A short course and its learning outcomes are displayed in Table 1. The physical practice of the students was individually supervised by trained course tutors (all medical students in their final years of university) and overseen by experienced intensive care unit nurses.

Table 1: Interprofessional i.v.-cannulation Course Outline & Learning Outcomes

<table>
<tr><td colspan="2">Flipped Classroom (student effort: 1h):
(1) Preparation with E-Book - The e-book contains the basics that are required for both parts (basics of hygienic hand disinfection, basics of venipuncture), combined with work assignments and study questions).
• Module 1: Hand disinfection: Theory and short MCQ questionnaire
• Module 2: Taking blood samples: where and how, pitfalls, tutorial video, 8 min (in German). (https://www.nanoo.tv/link/v/fuzPhkqU, CC BY-NC-ND 4.0)
• Module 3: I.v. cannulation: where and how, contraindications, pitfalls, complications, with tutorial video, 9 min (in German). (https://www.nanoo.tv/link/v/vnfRZMCs, CC BY-NC-ND 4.0)</td></tr>
<tr><td>Course Part 1 (Duration: 2h)</td><td>Course Part 2 (Duration: 2h)</td></tr>
<tr><td>Theory
15 minutes i.v.- cannulation
15 minutes taking blood samples</td><td rowspan="2">Practice (2h)
Practice on model /Practice on peers (voluntary)</td></tr>
<tr><td>Practice (90 min)
Practice on model
Practice on peers</td></tr>
<tr><td colspan="2">Available materials: Positioning aids for the patient's arm, gauze, alcohol swab, tourniquet, i.v cannulas (18G, 20G), cannula dressing, disposal container, gloves</td></tr>
<tr><td>Tutor concurrent feedback</td><td>Tutor concurrent feedback</td></tr>
<tr><td colspan="2">Further practice: Room and practice model provided for further practice</td></tr>
</table>

Knowledge	• List the indications, risks and complications of the procedure; • Name the materials and preparatory steps necessary for the intervention; • Explain the criteria for choosing a suitable location for the procedure; • List and justify the hygiene guidelines for the procedure;

	• Explain important basic rules of the technique; • Describe common principles underlying the different institutional standards;
Skills	• Adequately inform normal adults in a standard situation about the indications, risks and procedure of the intervention; • Prepare for the procedure (including providing the necessary materials, labelling tubes, checking the patient's identity, positioning, etc.); • Determine a puncture site for the procedure; • Correctly perform the intervention, following the hygiene guidelines; • Assess own abilities and determine when to call for help in case of problems; • Constructively exchange ideas with other participants.
Attitudes	• Assess the patient's fears and apprehensions about the procedure; • Assess how the procedure is experienced from the patient's point of view; • Support a climate of constructive cooperation between different professions; • Reflect on one's function and tasks within an interprofessional team

Study design and interventions

We carried out a three-armed, assessor-blinded randomized trial (Figure 1, flowchart). Six months after the first-year medical students underwent standard i.v.-cannulation training, they received an invitation explaining the goals of the study. Students were unaware of the specific skill or interventions of the study. Participants were asked to be on-site 30 minutes before a formative OSCE at the end of the first semester. Upon arrival, all participants completed a questionnaire to ascertain previous experience in i.v. cannulation, including attempts and demographics. After that, they were randomly assigned to one of three groups:

1) Group A: a ***6 min. mental imagery audio-guided tutorial:*** Students listened to a mental imagery audio recording of an i.v. cannulation procedure, in a dimmed room and using earphones, while lying down on a lounger. No i.v.-cannulation materials were available.

2) Group B: a ***6 min. part-task trainer simulation tutorial***: Students practised on a low-fidelity arm part-task trainer like the one they had in their previous course sessions (EZ-7010, Erler Zimmer, Germany). All materials used during the course sessions were available.

3) Group C: a ***6 min. tutorial with written instructions***: Students revised the i.v.-cannulation steps individually, with the aid of a laminated instruction sheet.

Randomization procedure

Students were allocated according to a 1:1:1 ratio to either the mental imagery group (n=105), the part-task trainer simulation group (n=105) or the written instructions group (n=106) using block randomization with a fixed block size of 9. The randomization sequence was created through randomization software (www.sealedenvelope.com). The allocation sequence was concealed from the students and the evaluators, as well as from those involved in the statistical testing of the data.

Construction of the mental imagery audio script and the audio guide

RG, RB and CCG (an anaesthesia-certified nurse), considered specialists in i.v. cannulation, recorded a 45-min online mini-focus group [25], facilitated by JBE, to develop the mental imagery script. They were asked to describe visual and kinesthetic clues at each step of i.v. cannulation and common pitfalls during i.v. cannulation. The focus group recordings were transcribed and analysed using iterative content analysis to create the mental practice script. This script was subsequently audio recorded and piloted amongst all authors and one additional colleague, proficient in hypnosis (FL, in acknowledgements).

The guided mental imagery tutorial that was presented to the randomized group of students consisted of a 6-min audio guide with instructions for i.v. cannulation embedded in relaxing breathing exercises. Students were advised to imagine the technique as if they were performing i.v. cannulation themselves. Instructions were delivered at a slow pace (*circa* 100 spoken words/minute) and emphasized the correct technique.

The i.v.-cannulation OSCE assessment

The i.v.-cannulation skill was assessed six months after the initial training, during the 1st year formative OSCE at the University of Bern's Faculty of Medicine. This OSCE comprised three different stations assessing 1) i.v.-cannulation skills, 2) basic life support, and 3) history taking. Each station lasted 8 minutes and the students' distribution to one of these stations occurred randomly. As this was a formative OSCE, students were aware of the skills being tested. Students were not able to communicate with each other during the examination.

In the 8-min i.v.-cannulation OSCE station, a simulated patient used an i.v.-puncture model strapped to their arm (R16614, Erler Zimmer, Germany) for puncture. The assessment was conducted by trained evaluators using a 15-item OSCE checklist in use at the University of Bern, which was tested for internal consistency. This setting and the structure of the checklist ensured that procedural flow, psychomotor skills (a total of two cannulation attempts were allowed), as well as communicative aspects of the students' i.v.-cannulation performance could be assessed. All six evaluators were all experienced anaesthesia study nurses (see Acknowledgements) blinded to the students' group rehearsal assignment. All evaluators took part in a 30-min training session in the use of the rating scales and on completing the checklist. We considered the assessor effect to be negligible, since the overall performance of the three intervention groups was of interest, and candidates were randomly assigned to the three intervention groups.

Statistical analysis

Our primary outcome was the total score in percentage of the 15-item OSCE assessment for the i.v.-cannulation station. Additionally, the influence of previous i.v.cannulation experience on the total OSCE score was examined.

We performed a multi-arm sample size calculation, aiming to demonstrate superiority of one of the educational strategies using an *a priori* power analysis with G*Power V.3.1. [(26)] Assuming an effect size (f=0.305) for a one-way analysis of variance with three groups (α=0.01, 1-β=0.80), we found that the minimum required sample size for three groups was n=156 (52 per group). To compensate for 20% of non-responders, we aimed for 180 participants.

Statistical analysis was performed using SPSS 27 (IBM Corp, Armonk, NY, USA). Categorical variables were described as absolute (n) and relative frequencies (%). Continuous variables were described using mean and standard deviation. In order to control for possible confounding effects, interdependence of categorical variables with the three groups was tested using a Chi-squared test for contingency tables, and one-way analysis of variance (ANOVA) were used to test possible differences in the means of continuous variables between the three groups. For reliability testing of the checklist, internal consistency was evaluated with Chronbach´s alpha. A one-way ANOVA was conducted to compare the means of the total OSCE score in percentages of the three groups. The number of previous attempts at i.v. cannulation using part-task trainer simulation and the number of previous attempts at human i.v. cannulation served as predictors in a multiple linear regression with the total score in percentage as dependent variable. To examine the influence of prior experience with i.v. cannulation on performance, multiple linear regression was performed. The OSCE total score in percentage served as the dependent variable, while the two variables "number of previous attempts at live i.v. cannulation" and "number of previous attempts at i.v. cannulation using part-task trainer simulation" served as predictors. A stepwise method was used to determine the influence of the predictors one by one. An a priori probability of less than 0.05 was considered to be statistically significant.

Patient and Public Involvement

No patient involved.

Results

Three hundred and sixteen students were invited to participate in the study. After excluding students who did not attend the OSCE or arrived late, 309 students were enrolled (participation rate of 97.8%). The participants' characteristics did not differ between the three groups (Table 2). Overall, the items in the checklist showed an internal consistency of α= 0.691, which is considered acceptable[27].

Table 2: Participants' characteristics

	Total (n=309)	**Mental Imagery (n=104)**	**Part-Task Trainer (n=100)**	**Written Instructions (n=105)**	**p-value**
Age, years (mean±SD)	21.3±1.9	21.1±1.9	21.2±1.7	21.6±2.2	0.500
Female sex, n (%)	189 (61.2)	64 (62.1)	69 (68.3)	56 (53.3)	0.085*
German mother tongue, n (%)	282 (91.0)	92 (89.3)	92 (91.1)	98 (92.5)	0.545*
No previous experience in healthcare, n (%)	301 (97.4)	101 (98.1)	96 (95.0)	104 (98.1)	0.563*
Individual sum of previous attempts at i.v.-cannulation in part-	3.0±1.9	3.1±1.9	2.9±1.9	3.0±1.9	0.693

task trainer simulation, n (mean±SD)					
Individual sum of previous attempts at human i.v.cannulation, n (mean±SD)	3.2±8.0	2.3±1.9	3.8±9.0	3.6±10.4	0.372

*Chi-square

Figure 2 shows a histogram of the students' overall performance (in percentage). There was no statistically significant difference between groups in the one-way ANOVA on our primary outcome total score in percentage of the OSCE assessment: mental imagery scored 72.0±17.9%, part-task trainer simulation scored 74.4±15.6%, and written instructions scored 69.9±16.6% ($F_{2,306} = 1.856, p = 0.158$).

Stepwise multiple linear regression showed that i.v.-cannulation experience during part-task trainer simulation had a significant but small effect on the OSCE performance ($R^2 = 0.015, p = 0.031$). We performed diagnostics on the regression model and verified that the checked assumptions were met. Students reported the number of previous attempts at cannulation as 6.5±8.5, without differences between the three groups (p=0.224). The human i.v.-cannulation experience showed no additional contribution to the OSCE performance ($Beta\ In = 0.072, t = 1.245, p = 0.214$) and the simple correlation between these two variables is not significant ($r = 0.091, p = 0.113$).

Discussion

Our study shows that the performance of i.v. cannulation, assessed at an objective, structured skills exam, did not differ after three different refresher tutorials (mental imagery, part-task trainer simulation, and written instructions).

Our results differ from those of several randomised controlled trials on mental imagery in postgraduate education. Studies that involved surgical trainees' "warming up" with mental imagery [16, 17] described significantly improved performance with a warm-up before laparoscopic surgery. However, when considering the effects of warm-up on the different aspects of psychomotor performance, Paschold et al. [28] found that these were affected by the nature of the warm-up, the type of surgery, and the expertise of the surgeon. This suggests that optimal warm-up strategies are task- and procedure-specific and may change with varying expertise [19], consequently yielding conflicting results.

Use of mental imagery in anaesthesia studies also showed conflicting findings. A 2016 study reported improved fiberoptic intubation skills after a 5-minute mental imagery warm-up on a virtual reality bronchoscopy simulator when compared with a control group [29]. In contrast, anaesthetists practicing mental imagery did not manage crises better during simulation [30]. The reasons proposed by the study authors for the negative results were the nature of the task, the limited "dose" effect (20 min vs. the 30–90 min reported in successful interventions), and the number reduced of cues in the mental script.

More recently, comparable effects of mental imagery and low-fidelity simulation were described in anaesthesiology residents learning to administer epidural anaesthesia [31]. Our study results align with the latter, as all three "warm-up" methods resulted in similar student performance in an objective, structured skills exam.

It is of more interest to compare our results with the study by Sanders et al. [20].They also did not find a significant difference in medical students' venipuncture performance with or without mental imagery. But they did find a significant difference in student performance between part-task trainer simulation and a control. Those authors assessed their students immediately after their training session, while our assessment occurred following the refresher, at 6 months after the initial training. Thus, the two studies might not be readily comparable.

The number of previous i.v.-cannulation part-task trainer simulation attempts had a small but significant effect on the OSCE performance. Students in our study performed, on average, more than six attempts at i.v. cannulation in the 6 months before their first-year OSCE. This number is considered as the number of attempts necessary to achieve a plateau level of the learning curve for this procedure [6, 32]. Additionally, our results may simply reflect that the part-task trainer was effective in teaching the canulation skills. That might partly explain why the three different refresher strategies resulted in comparable results. As our study participants reached the critical mass of medical students who had already acquired the necessary skills in i.v.-cannulation before the study took place, an improvement might be hard to detect, and our students probably did not necessarily profit from these refreshers. That might explain the puzzling finding in our study that the written instructions group was just as effective as the other two interventions, and questions the need for such a refresher shortly before an OSCE at all.

Although we did not formally assess the cost of our three interventions, it seems obvious that written instructions and mental imagery are far more economical than the purchase and maintenance of a low-fidelity part-task arm, including the instructor's salary and time spent teaching). This cost-effectiveness argument needs to be further investigated in a properly performed cost-effectiveness analysis.

Our study has several other limitations. It assessed the effectiveness of different refresher techniques for i.v.-cannulation skills, but its successful transfer to clinical practice could not be ascertained. We assume that our results can be applied to related techniques which require venipuncture, like taking blood samples, but despite our robust design, our results may not be generalizable to other cohorts. Additionally, due to the post-test methodology of the study, no conclusion can be taken regarding the student's performance of i.v. cannulation before the intervention. Finally, it is possible that the 6-minute intervention was simply too short to detect a difference in the teaching strategy and its effect on the performance of the skill.

In summary, these results suggest that all interventions were successful at refreshing i.v.-cannulation procedures in undergraduate medical students.

Conclusions:

Medical schools currently seek to offer more efficient, cost-effective and innovative methods to enhance learning. Our study comparing three 6-minute refresher strategies, indicates that part-task trainer simulation is not superior to mental imagery and written instructions for refreshing i.v.-cannulation skills in first-year medical students. Both mental imagery and written instructions have a far better effort-return ratio than resource-intensive hands-on training with part-task trainer simulation. Mental imagery and written instructions cannot completely replace physical clinical skills training in i.v. cannulation, but may effectively supplement it, similar to other fields involving complex psychomotor skill learning.

Declarations

Ethics approval and consent to participate: All participants provided written informed consent to participate and the Bern Cantonal Ethics Committee (Req-2021-00096, 26.01.2021) waived the need for ethical approval as no patients were involved.

Consent for publication: Not applicable

Availability of data and materials: All data relevant to the study are included in the article or uploaded as supplementary information. Datasets containing student information are available after anonymisation from the corresponding author on reasonable request. The remaining data are available in a public, open access repository information at https://doi.org/10.1257/rct.8043-1.0 [24].

Competing interests: RG is the Director of Training and Education of the European Resuscitation Council, the Task Force Chair Education, Implementation, and Team of ILCOR, and a member of the Direction of the MME Program of the University of Bern. The remaining authors report no declarations of interest.

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Author contributions:

JBE wrote the outline and performed the data collection, demographic statistical analysis and interpretation of the data.

RB and MB contributed to the outline, performed the data collection, and helped in data interpretation and the writing process.

DS performed the bivariate statistical analysis and helped interpret the data.

RG initiated the study, supervised the creation and adaptation of the outline, and critically reviewed the manuscript.

CB supervised the creation and adaptation of the outline, performed data collection and helped in data interpretation and the writing process.

All of the authors have read and approved the final version of the manuscript.

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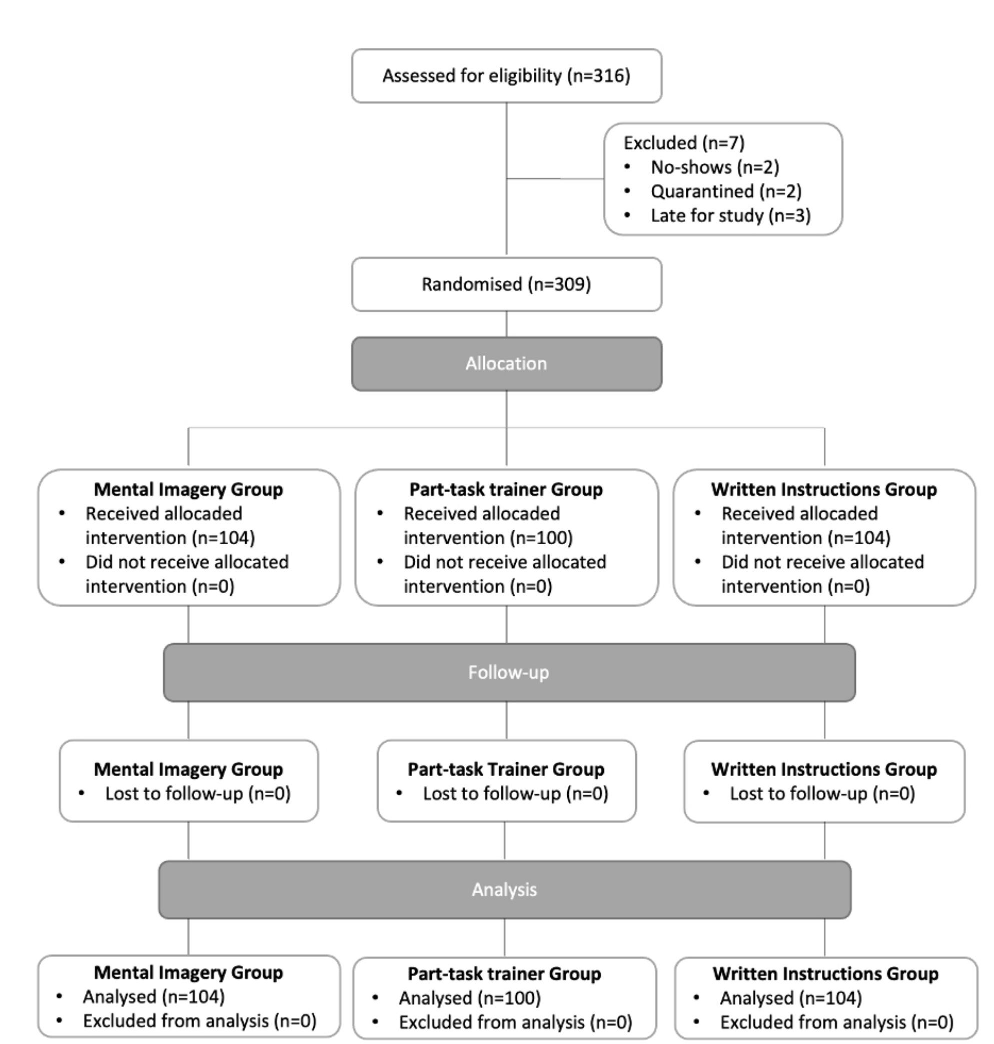
Figures:

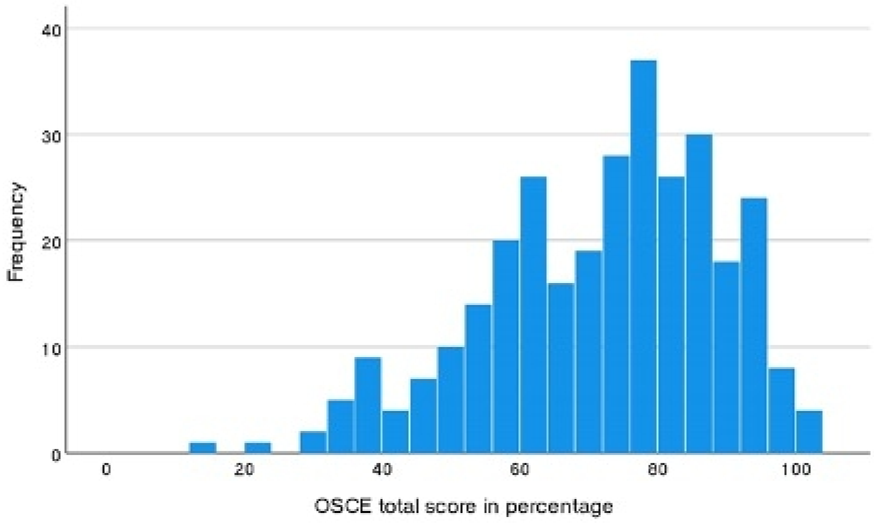
Figure 1: Study Flowchart

Figure 2: Histogram of OSCE total performance (in percentage)



Study Flowchart

159x167mm (150 x 150 DPI)



Histogram of OSCE total performance (in percentage)

159x93mm (72 x 72 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5-6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	13
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.