**Study Synopsis**

**Title:** Refreshing iv cannulation skills using mental imagery in medical students: Rater-blinded three-arm intervention

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**Abstract**

**Hypotheses and endpoints / goals:** The use of mental images in psychomotor procedural skill learning has long been used successfully to improve the performance of top athletes, for example, during the Olympics. More recently, this learning strategy has also been used to learn basic surgical skills. There are few studies describing the use of mental imagery in anesthesia and no reports on the use of mental imagery in undergraduate medical education. The hypothesis to be tested is whether mental imagery is more effective than physical simulation or standard of teaching in maintaining simple medical skills (IV cannulation) in medical students.

**Study type / methods:** We will carry out a single-center, rater-blinded RCT. Medical students will be randomly assigned to 3 groups, 6 months after their compulsory IV cannulation course:

1) 5 min. Standard refresher course,

2) 5 min. Self-learning tutorial,

3) 5 min. Tutorial with mental picture session.

The performance will be assessed in an OSCE station for IV cannulas at the University of Bern (optional OSCE in the1st year of studies).

**Sample size:** Assuming an alpha error of 0.01, and an effect size of a Cohen’s f of 0.305 (medium effect) with an aimed power of 0.80, the total sample size neede resulted in 156 students. To compensate for 20% of non-responders, we will aim for 180 participants.

**Expected benefits and advantages:** To maintain competence, modern and simple educational approaches enable resource-efficient teaching while maintaining patient safety. This study will evaluate the use of mental imagery or self-study modules in the classroom and may lead to a paradigm shift in teaching psychomotor procedural skills of medical students.

**Status of the project (protocol, KEK, registration, recruitment):**

First version of the protocol is completed, the KEK waived the need for ethical approval and the preparatory planning with collaboration partners is nealy finished. The study will take place in the summer semester 2021 after the introductory course in autumn 2020. All students are invited to participate in the study following a mail form the Dean's Office.

**Introduction:**

Patients participating in healthcare education remain an important part of the student-patient interaction and learning but increasingly question the process of their care in such educational events and want to take part in the decisions made about teaching during their healthcare management1. It is expected that learners and healthcare practitioners would be prepared for clinical practice before caring for patients2. The defined outcomes of competency-based curricula lend themselves to using a simulation approach. Additionally, not only in Anaesthesiology but in most medical specialties, the current highly legislated workload and amount of patients scheduled further restrict opportunities for the traditional “apprenticeship” learning of medical skills3. Simulation offers a feasible alternative to learning procedural skills, and the opportunity to rehearse performance in complex integrated scenarios in a safe, protected, learner-centred simulated clinical setting4.

Skills labs and simulation are now a requirement of some Boards for Graduate Medical Education. Simulation education for technical skill acquisition aims to reproduce reality with varying levels of *physical* fidelity.

Recently, a method to teach and maintain skills called mental imagery has been introduced in medical education. Mental imagery is a structured process of mental rehearsal prior to the procedure5 and is used for the eliciting of representations with accompanying experience of sensory information without a direct external stimulus. Such visualizations are elicited through the use of the senses and recall, leading to a re-experience of the initial stimulus at the moment of first exposure. MI is therefore seen as a form of *non-physical* simulation – also known as mental practice, mental rehearsal, motor imagery, or mental visualization, and can be defined as “the cognitive rehearsal of a task in the absence of overt physical movement”6. It is widely used and recognized effective in the realms of stroke rehabilitation, cognitive behavioural therapy, high-performance athletics, and professional musicianship7-9 as a means to improve performance and reduce procedural error.

There are several studies that have researched this procedure in postgraduate settings6,10-12, but only one underpowered study on the use of MI in undergraduate students13. Mental imagery, due to its simplicity, could facilitate learning and skill maintenance in the undergraduate medical srtudent setting and relieve educators from the physical, temporal, and financial burdens associated with low-fidelity simulator model design, construction, transportation, and maintenance.

The aim of the present study is to test whether mental imagery is superior than low-fidelity simulations or traditional refresher courses in maintaining a simple medical psychomotor procedural skills (IV cannulation) in medical students.

**Methods:**

*Participants and setting:*

All 1st year medical students from the Medical Faculty of the University of Bern are eligible for recruitment to this study. Students will provide voluntary, informed consent to participate.

Cooperation will be provided with the Bernese Interdisciplinary Skills and Simulation Center (BiSS) and the Bernese Institute of Primary Health Care (BIHAM).

All regular first-year medical students at the University of Bern can enroll in the study. Students who refuse to participate will be excluded from the study. Refusal to participate will not affect their formative assessment or any grades arising thereof.

*Procedure:*

The interprofessional IV cannulation course took place between late October and mid December 2020 in the Bernese Interdisciplinary Skills and Simulation Center (BiSS). The course is compulsory for all 1st year students and is carried out in partnership with the nursing training centre (BZ Pflege Bern). All first year medical students from the Faculty of Medicine, University of Bern, took part in a 2x2 hours teaching session in small groups (first afternoon practice on a part-task trainer arm model, second afternoon live IV puncture on colleague medical students or model). A complete description of the course can be found in Table 1. The physical practice was carried out in a Simulation Centre with individual supervision. Tutors were all medical students in the final years of training, supervised by experienced ICU nurses.

Table 1: Interprofessional IV Cannulation Course Outline

|  |  |
| --- | --- |
| **Flipped Classroom** (student effort: 1h)**:**   1. Preparation withE-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.(<https://www.nanoo.tv/link/v/fuzPhkqU>) * **Module 3:** IV cannulation: where and how, contraindications, pitfalls, complications, with tutorial video, 9min.(<https://www.nanoo.tv/link/v/vnfRZMCs>) | |
| **Course Part 1** (Duration: 2h) | **Course Part 2 (**Duration: 2h) |
| **Theory**  15 minutes IV-cannulation  15 minutes taking blood samples | **Practice (2h)**  Practice on model Practice on peers (voluntary) |
| **Practice (90 min)**  Practice on model  Practice on peers |
| Available materials: Positioning aids for the patient's arm, gauze, alcohol swab, tourniquet, IV cannulas (18G, 20G), cannula dressing, disposal container, gloves | |
| Tutor concurrent feedback | Tutor concurrent feedback |
| **Further practice:** Room and practice model provided for further practice | |

Table 2: Interprofessional IV Cannulation Course Learning Outcomes

|  |  |
| --- | --- |
| Learning Outcomes  At the end of the teaching, students will be able to: | |
| Knowledge | * List the indication, 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 indication, risks and procedure of the intervention; * Prepare for the procedure (including providing the necessary materials, labeling tubes, checking the patient's identity, positioning, etc.); * Determine a puncture site for the procedure; * Correctly perform the intervention, in accordance with the hygiene guidelines; * Assess own abilities and determine when to call for help in case of problems; * Constructively exchange ideas with other participants of the task. |
| Attitudes | * Perceive 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 own´s function and task within an interprofessional team |

The IV cannulation basic clinical skill will be assessed 6 months later, during a general 1st year OSCE. This OSCE assessment comprises of three different stations: 1) that assess IV cannulation skills, 2) the basic life support algorithm, and 3) a problem-oriented anamnesis. During the OSCE, three groups of three students participate in a cross-over fashion, each student in one group starting with a different exam. As each station accommodates three students per round, three students will be at the PVK position at the same time. This distribution will occur randomly. Students will be assessed with an itemized checklist and will get rater feedback at the end of their performance. The duration of each task is 8 minutes (6 min performance and 2 min feedback), and students are allowed 2 minutes to change to the following station. At the end of the round, each student has completed all three items.

*Study Design:*

We will carry out a three-armed, rater-blinded RCT. Six months after their initial standard IV cannulation teaching, medical students will be randomly assigned to 3 groups, using a block randomization software (www.sealedenvelope.com):

1) Group A: ***8 min. standard refresher*** (kinesthetic group, with Part-task trainer only): Students will have the allotted time to practice in the model, similarly to what occurred in the course sessions. A supervising tutor will be present in the room and will offer concurrent feedback. All materials used during the course sessions will be available.

2) Group B: ***8 min. self-learning tutorial***. Students randomized to this intervention will have all materials used during the course session at their disposal. They will work alone and will have a laminated instruction sheet (Appendix 1) to guide them through the procedure.

3) Group C: ***8 min. Tutorial with guided*** *Mental Imagery* ***rehearsal of the competence*** (audio-guide only). Students will listen to a *Mental Imagery* audio script of the procedure while lying down on a lounger. No iv cannulation materials are available.

*Construction of the Mental Imagery (MI) audio Script*

RB, MB and CCG, considered specialists in IV cannulation, will join a 45-min online focus group, facilitated by JBE, to develop the mental practice script. Participants will be asked to describe, in the first person, the visual and kinesthetic clues at each step of IV cannulation. Participants will also be asked to describe common pitfalls during IV cannulation. This technique was adopted from the performance psychology literature14,15. The focus group will be recorded, transcribed and analysed using iterative content analysis. Its findings will be merged to create the mental practice script. This script will subsequently be audio-recorded by FL, a specialist in hypnosis.

The guided *Mental Imagery* rehearsal will consist first of a 2-minute audio relaxation with breathing exercises, followed by verbal instructions in IV cannulation (disinfection, puncture, advancement of the cannula and securing the cannula in place), while the students imagine the technique as if they were performing them themselves. Instruction will be delivered at a slow pace and emphasing the correct technique. The audio-script will be available for listening.

*Measurements:*

After the intervention, all participants will complete a questionnaire to ascertain previous experience and demographics. Students will be identified using their first and last name . Students will then be submitted to the general first-year assessment OSCE. Concerning the IV cannulation assessment, it will take place in an eight-minute OSCE station. The patient is played by a simulated patient (SP), the actual iv-puncture is performed on a model strapped to the arm of the SP (make and model similar to practice models). This setting ensures that psychomotor skills, hygiene as well as communicative aspects of the students can be assessed. The assessment is conducted by trained experts using an adapted version of a validated OSCE checklist in use at the University of Bern (Appendix 2). The instrument will be tested for validity, reliability and internal consistency. Raters are blinded to of the student group assignment.

*Statistical analysis*

The statistical analysis will be performed by DS, the statistician of the Institute for Medical Education of the University of Bern. DS has also performed the sample size calculation.

A descriptive analysis of the data will be conducted. We intend to perform a one-way analysis of variance test (ANOVA) and covariance (ANCOVA) test. Post hoc testing will be via Tukey’s HSD. In case of non-normally distributed data, we will use the Kruskal-Wallis test. Multivariate analysis will be attempted to control for variations in previous experience. An a priori probability of less than 0,05 will be considered to be statistically significant. All data will be analysed using suitable software (e.g. SPSS, STATA, or R).

Sample size calculation:

The required sample size was calculated using an a priori power analysis with G\*Power V.3.1.16 Assuming an effect size (f2=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 will aim for 180 participants.

**Practical aspects:**

Ethical approval has been submitted. Registration of the study on ISRCTN after ethical approval.

The Formative Assessment OSCE takes place on 2 full and 2 half days at the Uni Ziegler, Morillonstrasse 79:

**28.04.21 (07:15 – 18:15)**

**29.04.21 (07:15 – 12:50)**

**05.05.21 (07:15 – 16:50)**

**06.05.21 (07:15 – 12:50)**

The course is organized by Nick Lüthi (AUM) and a new employee in the Dean's Office (Ms. Roes) on the medical side. Nick Lüthi is ready to support us logistically in the project, but has no ambitions to collaborate scientifically. Three SPs will need to be summoned –eventually 6th year medical students. Two study nurses will be requested for the abovementioned dates.

Incentive for study participants

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**Appendix 1: Self-Learning tutorial contents (in laminated paper format)**

|  |  |
| --- | --- |
| Ablauf | Vorgehensweise |
| Vorbereitung | |
| Händehygiene beachten | Desinfizieren Sie sich die Hände unter Beachtung der 5 Indikationen:  - VOR Patient\*innenkontakt  - VOR sauberen/aseptischen/ invasiven Tätigkeiten  - NACH Kontakt mit potentiell infektiösem Material  - NACH Patient\*innenkontakt  - NACH Kontakt mit der unmittelbaren Patient\*innenumgebung. |
| Material bereitstellen | Richten Sie folgendes Material:  Lagerungshilfen für den Arm des Patienten; geeignete saugfähige Unterlagen; Tupfer; Desinfektionsmittel; Staubinde; pVK, pVK Fixationsverband; Pflaster, Verband; Entsorgungsbehälter; Handschuhe |
| Begrüssen und Identität des Patienten überprüfen | Nehmen Sie Kontakt mit dem Patienten und stellen Sie sich vor.  Überprüfen Sie die Identität, falls Ihnen der Patient nicht persönlich bekannt ist: Name, Vorname, Geburtsdatum |
| Indikation und Kontraindikationen überprüfen | Stellen Sie sicher, dass Sie die Indikation zur Einlage eines pVKs mit oder ohne Blutentnahme nachvollziehen können.  Stellen Sie sicher, dass keine Kontraindikationen vorliegen  Klären Sie ab, ob Allergien oder eine Blutgerinnungsstörung vorliegen. |
| Patient/in aufklären und Einverständnis einholen | Klären Sie den Patienten/die Klientin über den Zweck des pVKs und ggf. der Blutentnahme und über mögliche Risiken/Komplikationen auf. |
| Durchführung | |
| Patienten stabil lagern | Achten Sie darauf, dass der Patient/die Klientin sicher und bequem sitzt oder liegt.  Achten Sie darauf, dass der Arm stabil und bequem gelagert ist |
| Stabile und bequeme Arbeitsposition wählen | Setzen Sie sich hin und versuchen Sie eine stabile Auflage des Armes, mit dem Sie punktieren, herzustellen.  Achten Sie dabei auch auf eine rückenschonende Arbeitshaltung. |
| Stauung anlegen | Legen Sie die Staubinde am Oberarm mindestens eine Handbreite oberhalb der Punktionsstelle an. |
| Material vorbereiten und zusammenstellen | Öffnen Sie sterile Verpackungen und bereiten Sie das Material funktionstüchtig vor. |
| Punktionsstelle desinfizieren | Verteilen bzw. reiben Sie das Desinfektionsmittel auf der Haut ein, in dem Sie einmal von oben nach unten über die zu punktierende Stelle wischen.  Lassen Sie die Haut vor der Punktion ungefähr 15 Sekunden trocknen. |
| Handschuhe anziehen | Ziehen Sie in der Zwischenzeit die Handschuhe an. |
| Punktieren | Nehmen Sie den pVK und entfernen Sie die Schutzkappe. Halten Sie den Katheter mit Daumen, Zeige- und Mittelfinger.  Spannen Sie die Haut distal der Punktionsstelle. Achten Sie auf den Verlauf der Vene und richten Sie vor der Punktion den Katheter in diese Führungslinie.  Achten Sie darauf, dass der Schliff der Kanüle nach oben gerichtet ist.  - Direkte Punktion: Durchstechen Sie die Haut mit der Kanüle in einem möglichst flachen Winkel.  Achten Sie darauf, ob sich die Kontrollkammer mit Blut füllt.  Schieben Sie die Kanüle ungefähr 5 mm vor. Erst dann ziehen Sie den Mandrin zurück und schieben den Katheter mit zurückgezogenem Mandrin weiter vor.  Keinesfalls dürfen Sie den Metallmandrin vorher hin- und her schieben. |
| Stauung lösen | Lösen Sie die Stauung. |
| pVK sichern | Sichern Sie den pVK unmittelbar mit einem Klebestreifen. |
| Mandrin entfernen | Legen Sie zwei Tupfer unter den Anschluss des Katheters, bevor Sie den Metallmandrin vollständig herausziehen; drücken Sie mit der anderen Hand proximal die Vene ab.  Ziehen Sie erst dann den Mandrin vollständig heraus. Entsorgen Sie ihn sofort im Abfallbehälter. |
| pVK verschliessen oder anschliessen | Stöpseln Sie den pVK mit einem Verschlussdeckel ab. |
| Abfall entsorgen | Entsorgen oder desinfizieren Sie das Material.  Ziehen Sie die Handschuhe so aus, dass die Innenseite nach aussen gewendet wird.  Desinfizieren Sie sich danach die Hände. |

Appendix 2: **Assessment Criteria**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **ja** | **+/-** | **nein** |
| 1. Klärt Identität des Patienten | 1 | 0 | 0 |
| 1. Erkundigt sich nach Vorfällen bei früheren pVVK, spez. Angst vor Schmerz/Blut, holt explizit Einverständnis zur pVVK. 3=ja, 2=+/- | 1 | 0.5 | 0 |
| 1. Allergien: Pflaster, Desinfektionsmittel. 2=ja, 1=+/- | 1 | 0.5 | 0 |
| 1. Erklärt die einzelnen Schritte der pVVK Einlage vk | 2 | 1 | 0 |
| 1. Einrichtung der Arbeitsbedingungen: Armschiene, Molton, Material in Reichweite, gute Arbeitshaltung im Sitzen. 3-4=ja, 2=+/- | 1 | 0.5 | 0 |
| 1. Händedesinfektion. vk | 1 | 0.5 | 0 |
| 1. Blutstauung: Oberarm *2=ja, 1=+/-* | 1 | 0.5 | 0 |
| 1. Desinfektion: mit getränktem Tupfer, mind. 15 Sekunden trocknen lassen, desinfizierte Stelle nicht mehr berühren. *3=ja, 2=+/-* | 1 | 0.5 | 0 |
| 1. Handschuhe anziehen *j/n* | 1 | - | 0 |
| 1. Punktion: Spannen der Haut vor dem Stechen, richtiger Winkel zum Gefäss, kurzes Nachstechen, nachdem Blut in der Kontrollkammer erscheint. *vk* | 2 | 1 | 0 |
| 1. Vorschieben *gelingt beim 1. Mal = ja; beim 2. Mal = +/-* | 1 | 0.5 | 0 |
| 1. Lösen des Stauschlauches nach gelungenem Vorschieben. *j/n* | 1 | - | 0 |
| 1. Sicherung der pVVK nach gelungenem Vorschieben. *j/n* | 0.5 | - | 0 |
| 1. Abstöpseln der pVVK. *j/n* | 0.5 | - | 0 |
| 1. Sofortige und fachgerechte Entsorgung des Materials *vk* | 1 | 0.5 | 0 |
| 1. Erkundigt sich bei Pat. nach Befinden während und nach der Punktion vk | 1 | 0.5 | 0 |
| 1. **Durchführung insgesamt:** technisch korrekt, flüssig, professionell (gut-genügend-ungenügend) | 20% | 6.66% | 0 |