BMJ Open

Medical device education: study protocol for a randomised controlled trial comparing self-directed learning with traditional instructor-led learning on an anaesthesia workstation

Caterina Gutersohn ,[1] Sandra Schweingruber,[1] Maximilian Haudenschild,[1] Markus Huber,[1] Robert Greif ,[2,3] Alexander Fuchs [1,4]

To cite: Gutersohn C, Schweingruber S, Haudenschild M, *et al*. Medical device education: study protocol for a randomised controlled trial comparing self-directed learning with traditional instructor-led learning on an anaesthesia workstation. *BMJ Open* 2023;**13**:e070261. doi:10.1136/bmjopen-2022-070261

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-070261).

Received 17 November 2022
Accepted 02 August 2023

For numbered affiliations see end of article.

Correspondence to
Caterina Gutersohn;
caterina.gutersohn@insel.ch

ABSTRACT

Introduction Continuous professional development is essential for maintaining competencies in healthcare. This applies to medical device knowledge and safe handling, which are fundamental for patient safety. Little is known about the efficiency of self-directed learning with an integrated video in medical device education. This study investigates whether anaesthesia providers acquire their medical device competencies on an anaesthesia workstation differently via self-directed learning than traditional teacher-led workshops.

Methods and analysis This single-centre, non-inferiority, randomised, controlled trial aims to enrol at least 224 anaesthesia providers (ie, certified nurses and physicians). Participants will be randomised to (1) self-directed learning with an integrated learning video (intervention) or (2) a traditional teacher-led workshop (control), for a 1-hour session on a new anaesthesia workstation. The two educational approaches and their effect on medical device competence will be assessed concerning 12 competencies in the same 10 min, objective, structured, clinical examination-like station for both groups. The primary endpoint will be an assessment score of ≥60%. Non-inferiority will be declared if the upper limit of a 90% two-sided CI excludes a difference of more than 10% in favour of the control group. Secondary endpoints will be: (1) the score achieved in the study assessment, (2) the number of open questions after the training, (3) training time in minutes, (4) use of resources and (5) costs, all of which are compared between both groups.

Ethics and dissemination Study participants will provide written informed consent. All recorded data will be stored on a password-protected research server at the study site accessible only to the investigators. The Bern Cantonal Ethics Committee waived the need for ethical approval (Req-2021–00837; 25 July 2021). There are no ethical, legal or security issues regarding data collection, processing, storage or dissemination.

Trial registration number NCT05530382, 7 September 2022; ClinicalTrials.gov

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The controlled, randomised study design for an educational intervention with a large number of participants.
⇒ The interprofessional learning approach targeting certified experts in anaesthesia care and physicians using the same educational methods, since the same skills and competencies need to be acquired.
⇒ The two teaching techniques cannot be blinded to the participants.
⇒ The outcome-oriented rather than process-oriented assessment of this single-centre study might limit its generalisation to other healthcare institutions.

INTRODUCTION

Continuous professional development is essential for learning and maintaining professional competence in healthcare.[1] This also applies to knowledge of medical devices as well as skills and competencies in specialised in-hospital disciplines. The proper and safe handling of medical devices is fundamental for improving patient safety.[2] Traditionally, training to use medical devices was done in instructor-led face-to-face workshops offering hands-on practice combined with didactic lectures, which is both time-consuming and resource-intensive. Current working conditions and shift work, especially in anaesthesia, critical care and emergency hospital services, pose challenges for both educators and learners, making it difficult for them to provide and attend timely and comprehensive training and learning opportunities. Adult learners desire more self-directed, efficient and effective training.[3] Studies on learning and retaining complex psychomotor skills have revealed that supplemental videos are more effective than didactic classroom teaching on its own,[4] especially for procedural processes in everyday contexts.[5] Self-controlled practice seems to

be more effective than externally controlled practice,[3] while simulated learning situations enable performance training of specific cognitive or psychomotor skills.[6] The dual-coding learning theory[7] describes how video activates the human brain by simultaneously conveying visual and auditory information, making it easier to understand the information and to better integrate it into long-term memory.[8] High-quality instructional videos involving different sensory channels result in better learning when learners are not forced to divide their attention between several incompatible sources.[9] This means that videos should be produced as professionally as possible and use easy-to-understand language as well as sound.[9] Such educational videos should be short (preferably less than 10 min), as learners' attention gradually wanes over time.[10] According to cognitive load theory, the structure of the learning video is also important for enabling new pieces of information to be linked with existing knowledge, while complexity should be minimised and unnecessary and distracting information should be avoided.[11]

Medical device education must cover two areas: first, the medical field and underlying physiology; second, the technical field of the device's use. In an instructional video, both of these must be linked to understandable and logical actions, to enable the proper and safe handling of the medical device by the learner.

In a PubMed literature search from inception to 26 October 2022 using the search terms 'self-directed' AND 'medical device' OR 'anaesthesia workstation', no publication was found that addresses self-directed education based on video instruction in the field of medical device training. The goal of this study was, therefore, to answer the research question if the scores of anaesthesia staff on a practical test are non-inferior, whether they participated in a self-directed learning curriculum with an integrated learning video compared with traditional instructor-led teaching curriculum to train a new anaesthesia workstation.

METHODS AND ANALYSIS

Study design

We will conduct a single-centre, randomised, control, non-inferiority trial, involving education in the use of a new type of anaesthesia workstation (Atlan, Dräger, Lübeck, Germany) at the Department of Anaesthesiology and Pain Medicine of the Bern University Hospital in Bern, Switzerland. As the department's entire clinical working anaesthesia staff needs to be trained, all these staff members will be invited to participate in the study (giving a potential maximum of 260 participants: 103 certified experts in anaesthesia care and 157 physicians). A stratified two-staged block randomisation, with the type of provider as stratum (ie, certified experts in anaesthesia care vs physicians) and a block size of 4, will be used to allocate the participants into two groups: (A) traditional, instructor-led, face-to-face workshop (control group) versus (B) self-directed learning with an integrated learning video (intervention group) as shown in figure 1. The study's statistician (MHu), who is not involved in the teaching and assessment process, will generate the block-stratified randomisation. A study nurse not otherwise involved in the teaching process will randomise the study participants.

Data collection

Data will be collected from all participants, including their characteristics (ie, age, sex, profession (certified expert in anaesthesia care, resident or board-certified anaesthetist), years of professional experience and self-reported learning method preferences), and the study outcome parameters, like time spent on learning and final-exam results, will be defined under measurements. All data related to the investigation will be stored in coded form in REDCap (REDCap Consortium, Vanderbilt University, Nashville, Tennesse), a dedicated, password-protected research database on a departmental research server. The data will be password protected and only accessible to the investigators.

Participant inclusion and exclusion criteria

Participants will be recruited before their mandatory training sessions on how to use a new anaesthesia workstation. We will include the clinical working anaesthesia staff of the anaesthesia department (ie, certified experts in anaesthesia care, anaesthesia residents, registrars and consultants) over 18 years of age who voluntarily agree to participate. We will exclude participants with training in or practical experience with the new anaesthesia workstation from the previous year.

Measurements

The participants' learning results in relation to the two teaching formats under investigation will be assessed via an objective, structured, clinical examination-like station. This 10 min station is adapted from the medical-device testing station for the objective, structured, clinical examination for anaesthesia care trainees at the Department of Anaesthesia and Pain Medicine, Bern University Hospital, which is based on the exam regulations of the Bern Nursing School. The assessed study participants will be given a case vignette and must configure and operate the anaesthesia workstation correctly in relation to a fictitious ventilated and anaesthetised patient. Twelve predefined competencies (box 1) are marked either as achieved or not as achieved, including predefined oral questions used to assess knowledge acquisition.

To pass the assessment, participants must achieve a competence level that is based on the framework curriculum for certified experts in anaesthesia care in Switzerland,[12] with the following three criteria:

(1) principle of function, (2) safety aspects and (3) handling and operating of the anaesthesia workstation and theory–practice transfer. Each criterion is assessed by means of four questions using a four-point rating scale (0=does not apply, 1=rather does not

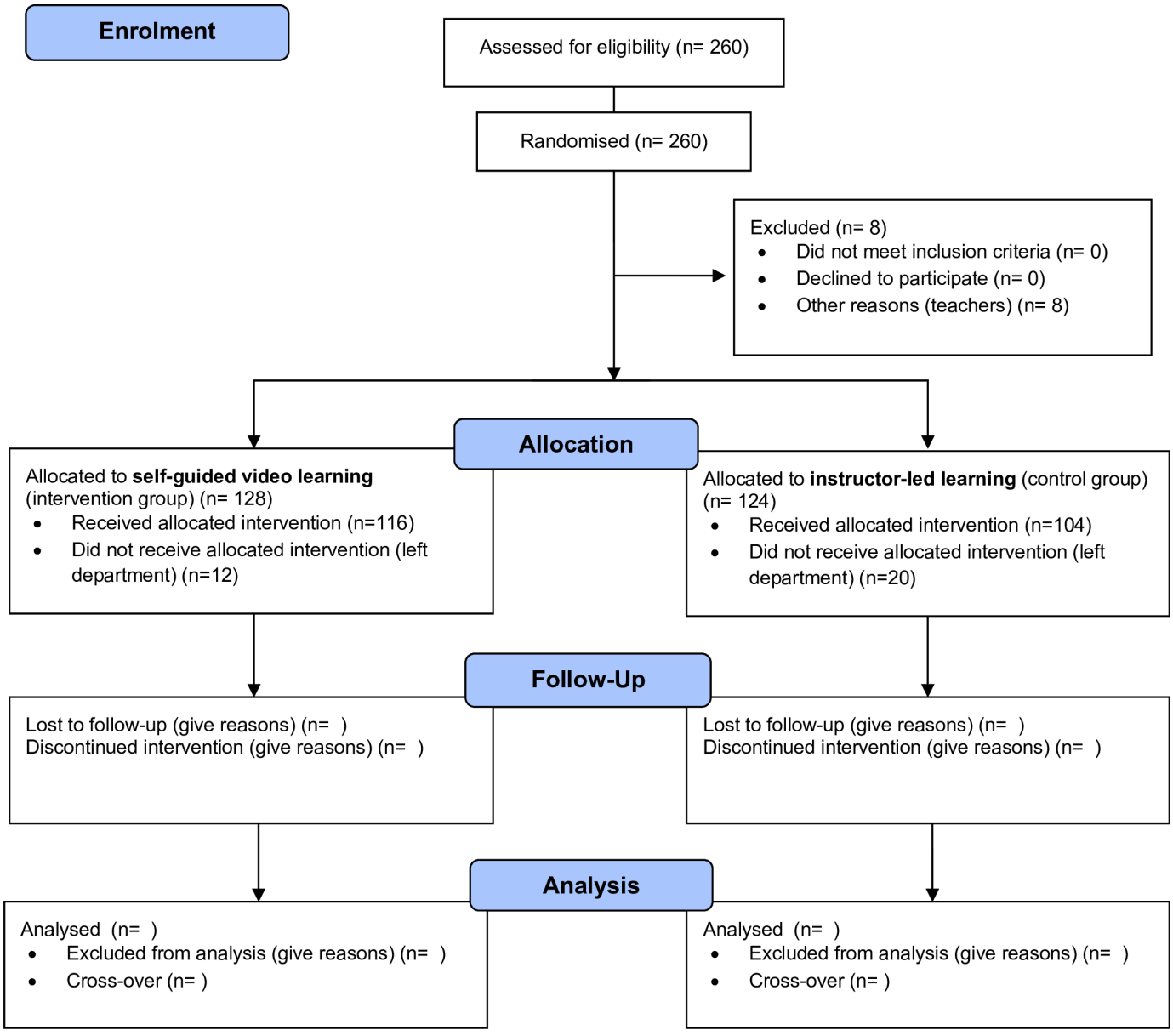

Figure 1 CONSORT flow diagram. CONSORT, Consolidated Standards of Reporting Trials.

apply, 2=applies, 3=applies very well), meaning that a maximum of 36 points can be earned. The anaesthesia-workstation assessment is graded as follows: 'excellent': 100% score=36 points (A); 'very good': 90%–99%=33–35 points (B); 'good': 80%–89%=29–32 points (C); 'satisfactory': 70%–79%=26–28 points (D); 'sufficient': 60%–69%=22–25 points (E); 'failed': less than 60% ≤ 22 points (F), in which case the exam is not passed.

The assessors will be certified experts in anaesthesia care who are trained as educators and as key users of the new anaesthesia workstation. The 1-day key users' training takes place beforehand and involves both theoretical and practical components.

In the instructor-led teaching group, the number of open questions asked at the end of the session will be recorded manually by the session's educator. In the self-directed learning with an integrated learning video group, the educator available to the trainees will record contact data (ie, phone calls, emails and direct open questions) at the end of the training period.

Each participant will be asked directly by the examiners about the total time spent learning before the test starts. Resources and expenses will be compared between the two groups in relation to materials, room costs and personnel spending.

Outcomes

The primary endpoint will be the rate of passed assessment in the objective, structured, clinical examination-like station. Secondary endpoints will include: (1) the overall score achieved in the objective, structured, clinical examination-like station assessment, (2) the number of open questions after the training, (3) learning time in minutes, (4) use of resources (ie, personnel, venue and

Box 1 The twelve competencies assessed

Principle of function
1. Can properly prepare an anaesthesia workstation for preoxygenation.
2. Can set the anaesthesia workstation correctly for facemask ventilation.
3. Is able to programme mandatory ventilation settings on the anaesthesia workstation and justifies the choice of the ventilation mode correctly.
4. Demonstrates a correct recruitment manoeuvre of the lungs.

Safety aspects
5. Can adapt profile settings to a patient and explain why this is important.
6. Can set up the pause mode on the anaesthesia workstation and names possible applications in clinical practice.
7. Adapts alarms on the anaesthesia workstation based on patient data and explains why this is important.
8. Shows the necessary rescue procedure in the event of an oxygen failure.

Handling and operating the anaesthesia workstation and theory–practice transfer
9. Shows how to initiate a correct self-test of the anaesthesia workstation.
10. Shows the necessary actions on the anaesthesia workstation when changing from mechanical to spontaneous ventilation.
11. Knows where to connect a nasal oxygen cannula to the anaesthesia workstation.
12. Shows how to prepare the anaesthesia workstation for the next patient after usage.

logistics) and (5) costs (ie, personnel costs for teachers, production of the video, room costs and costs of materials). All of these will be compared between the intervention group and the control group.

Didactic development of the teaching and assessment formats: the creation of the self-directed learning practice station and the assessment station

The didactic development, as well as the similarities and differences between the two teaching formats, is summarised in table 1 .

The following considerations guided the development of the teaching formats and the assessment:
1. What operational skills related to the anaesthesia workstation are essential during an anaesthesia procedure?
2. What specific knowledge related to the anaesthesia workstation is needed for an anaesthesia procedure?
3. What medical and technical knowledge is required to correctly manage ventilation and set alarms for safe patient care?

Based on these considerations, the study team agreed on the relevant competencies that need to be learnt to safely handle an anaesthesia workstation. This consensus was based on a simulated anaesthesia procedure using an anaesthesia workstation, which was then checked to assess whether the needed skills were present in these competencies. This guided the further development of the two 60 min teaching programmes in different formats:

The self-directed learning with an integrated learning video (intervention group) contains three parts:
1. Theory is taught through the learning video.
2. The practical component involves a worksheet for solving practical exercises on the anaesthesia workstation.
3. Competencies self-check with theoretical questions, hands-on application tasks and an answer key is used as a self-administered competence check.

The teacher-led workshop (control group) likewise contains three parts:
1. The theoretical content taught by the teacher is identical to the content in the video, as the same case study is used.
2. The same practical tasks are proposed as in the self-directed learning group.
3. The same application questions are used in the self-directed learning station.

A cross-comparison of the two teaching formats (by SS, MHa) asked whether the content was congruent and whether the defined competencies were mapped out in both formats. Certified experts in anaesthesia care trained as educators who were not involved in the research project piloted the feasibility of the two learning formats.

Production of the learning video

The following specifications were defined in a script for the video production: (1) visualising the anaesthesia workstation to reduce abstractness as compared with the device manual; (2) providing cognitive support for the translation from theory into practice by recording the anaesthesia workstation operating in a real-world environment involving a scenario where a patient is treated with anaesthesia and (3) showing problem-solving strategies for troubleshooting for technical incidents, safety aspects and hygiene standards.

A professional external team (https://www.timonrupp.ch/, Timon Rupp Filmproduktion, Steffisburg, Switzerland) produced the video in a surgical setting with a simulated patient and voice recordings made separately by a professional voice artist. The video presents a case study of anaesthesia induction, maintenance and recovery from anaesthesia. It guides study participants from theory to hands-on problem-solving using the anaesthesia workstation. Important learning points are highlighted by superimposing written text over short, still images. The rough cut was evaluated by the study team, and their feedback was integrated into the final version.

Organisation of the study

Study participants will be informed by email about their randomised group allocation 2 months before their training and assessment. All participants will receive as preliminary reading a summary of the anaesthesia workstation manual, condensed from the original manual by the staff of vocational anaesthesia care trainers.

The self-directed learning station will be available for 8 weeks and accessible to learners 24×7, meaning that

Table 1 Development of teacher-led learning and self-directed learning

	Teacher-led learning	Self-directed learning
Preliminary considerations	1) What operational skills related to the anaesthesia workstation are essential in an anaesthesia process? 2) What specific knowledge related to the anaesthesia workstation is needed for an anaesthesia procedure? 3) What knowledge is required to correctly manage ventilation and set alarms for safe patient care?	
Application competencies	1) The patient's condition must drive the use of the anaesthesia workstation. 2) Independently run the anaesthesia workstation self-test according to the producer's checklist and troubleshoot simple machine errors. 3) Select the appropriate ventilation mode, adapted to the patient's condition in every phase of anaesthesia. 4) Adapt the settings of the anaesthesia workstation and its alarm configuration to the patient's condition. 5) Differentiate between anaesthesia workstation alarms and environment-specific alarms and initiate appropriate measures to ensure patient safety.	
Learning points	1. Anaesthesia workstation check 2. Principles of operation function 3. Practical application (ventilation modes, settings) 4. Handling and operation	5. Security issues 6. Sources of error 7. Cross-comparison 8. Theory-practice transfer 9. Hygiene/maintenance
Teaching plan	Preliminary reading assignment: device summary	
The two teaching formats	On-site teacher-led session: ► Theoretical input taught face-to-face ► Guided practical exercises on the anaesthesia workstation with the teacher ► Teacher-led competence check involving theoretical questions, hands-on application tasks and correct answers	Self-learning session: ► Theoretical input through learning video ► Practice via an assigned worksheet with exercises on the anaesthesia workstation without teacher present ► Competencies self-check with theoretical questions, hands-on applications tasks and answer key as self-check of learned competencies
Duration	60 min	
Piloting	The feasibility of the two learning formats was piloted by certified experts in anaesthesia care trained as educators who were not involved in the research project.	

they are free to choose when to attend, provided that the station is not occupied. Participants randomised to the teacher-led format must book a class online (https://terminplaner4.dfn.de/, Deutsches Forschungsnetz, Berlin, Germany). All instructors in the teacher-led training are certified experts in anaesthesia care with a subspecialisation in education. They will be informed and briefed in advance by the study team to ensure the standardisation of the learning content, the procedure and the precise lesson plan to which they must adhere.

After study participants have completed their training, they must attend an assessment station between 4 and 8 weeks after the initial training.

Validation of the assessment station

The problems-to-solve hands-on assignment was designed in the same way as the validated exam in device usage for anaesthesia-care students. Two certified experts in anaesthesia care with a subspecialisation in education checked the validity of the assessment station using Messick's framework[13] (in brief: survey method, checking content, response process, internal structure, relationship to other variables and consequences). The congruence between the learning level of the questions and the competencies was discussed, and they were revised to reach a consensus among four of the teachers. Two certified experts in anaesthesia care trained as educators not involved in the research project piloted the workshops and tested their temporal feasibility.

Sample size calculation

Assuming a significance level of α=0.05, a final-exam success rate ('passed') in both groups (ie, traditional instructor-led learning and self-directed learning) of 90% and a non-inferiority margin of Δ=10%, a sample size of 224 participants was calculated as necessary to establish the non-inferiority of the self-directed learning with an integrated learning video group with a power of 80%. This sample size is similar to previous studies.[14–16] Due to high levels of personnel fluctuation in the department, block randomisation was performed in two stages. First, all clinical staff members able to participate in the study (n=260)

were randomised. Then, to ensure block size consistency, new employees replaced the previously randomised drop-outs with the same profession to maintain an appropriate sample size. Due to organisational issues, the teachers were recruited after their initial randomisation and thus were excluded.

Statistical analysis plan

Participants' characteristics will be displayed as descriptive statistics by counts and percentages for categorical variables, by mean and SD for normally distributed quantitative variables and by the median and IQR in the case of skewed quantitative variables. The distribution of the participant characteristics in both groups will be compared with standardised mean differences.

Non-inferiority of the primary outcome will be assessed both via the crude difference in success rates in both groups and via the Mantel-Haenszel method to account for the stratified randomisation in terms of the provider as sensitivity analysis. The Mantel-Haenszel analysis will provide separate crude group comparisons of certified experts in anaesthesia care and physicians. Given the significance level of α=0.05, a 90% two-sided CI of the difference in success rates will be compared with the non-inferiority margin of Δ=10%.

To account for the individual distribution of secondary endpoints, the score achieved in the adapted device exam will be transformed to the (0,1) interval to account for the bounded value range of the scores, and the transformed scores in the two groups will be compared via a generalised linear model with a beta distribution. The number of open questions after the training in both groups is compared via an unpaired two-sample Wilcoxon test. The training time spent in minutes, the use of resources and the cost will be compared using either a Student's t-test, if the outcomes are normally distributed, or, if not, an unpaired two-sample Wilcoxon test. As the secondary outcomes are exploratory in nature, no p value adjustment for multiple comparisons is performed. Primary and secondary outcomes will be further stratified into certified experts in anaesthesia care and physicians. The main analysis will be performed as a modified intention to treat analysis. A sensitivity analysis will be performed per protocol.

No imputation methods will be used if data are missing, and the final analysis will be a complete case analysis. The statistical software used for all analyses will be R Statistical Language.[17]

TRIAL STATUS

This trial was registered on ClinicalTrials.gov on 7 September 2022. Participants were randomised into the two groups based on learning method on 19 September 2022 by a study team member (SS). The teaching phase started on 4 October 2022. The assessment of the participants will start on 1 December 2022.

ETHICS AND DISSEMINATION

The Bern Cantonal Ethics Committee waived the need for ethical approval on 25 July 2021, according to the Swiss Act for Human Research (BASEC Nr. Req-2021–00837). The conduct of the study will follow the Helsinki Declaration.[18] All participants will receive detailed study information to enable written informed consent (online supplemental material 1) before the start of the assessment. Study participation is voluntary and no incentives will be offered to study participants.

All researchers involved in the study will comply with the Data Protection Act and the Swiss Human Research Act. All data will be stored for up to 10 years after the end of the project, in line with the Swiss Human Research Act.

The anonymised data set generated during the present study will be made available by the primary investigator on reasonable request from researchers with suitable and answerable research questions and local ethics committee approval in line with the Swiss Human Research Act. The primary investigator will ensure that electronic file permissions are correctly assigned and advise on other aspects of data storage and security.

The study results will be published in a peer-reviewed international medical journal without any limitations concerning the investigated results.

PATIENT AND PUBLIC INVOLVEMENT STATEMENT

We were unable to find an anaesthesia-related patient group willing to review this protocol, since the study will be carried out without patient involvement, as patients are not the study subjects. However, we were able to include the legally mandatory patient representative of the Bern Cantonal Ethics Committee, who reviewed the final manuscript after the ethics submission, providing suggestions with final endorsement.

IMPORTANCE OF THE STUDY

Safe handling of medical devices is of fundamental importance for patient safety, especially in unconscious anaesthetised patients. Traditional practical training in the use of medical devices through teacher-led face-to-face workshops is time-consuming and resource-intensive. With our study, we aim to fill a gap in the research with regard to whether self-directed learning (ie, video combined with hands-on simulation) is as effective as a traditional teacher-led workshop providing training in the use of a complex medical device. In addition to the comparison of achieved competencies in both groups, we will investigate how the individual approach to self-directed learning helps today's requirements of professional time and resource-optimised learning. This teaching method might change future practices in relation to medical-device training, as it allows self-directed, time-tailored learning for individual learners. By means of the theoretical considerations articulated during the development of the two teaching formats, we ultimately identified

individual actions that were transferred into 12 competencies to be assessed as displayed in box 1. The study participants must make use of these during the assessment, but they must also subsequently implement these competencies in their use of the device, in our case, the anaesthesia workstation. These competencies map out an anaesthesia process starting from testing the anaesthesia workstation to making it ready and available again for the next patient. Both investigated formats teach these competencies and there is, thus, no difference when it comes to the content to be learnt, ensuring that both groups acquire the same level of competencies. Learning videos aim to attain a higher cognitive level than a pure study of literature. The video enables the integration of potential technical sources of error and their problem-solving strategies into the learning content. This corresponds to the second level of the Miller pyramid 'know-how' and to Kirkpatrick's second level of evaluation: learning.[19] The integration of explanations into the video—in addition to pure step-by-step instructions—has shown positive effects on cognitive storage.[20] Titles should be as meaningful as possible and refer to the learning content.[21] To promote cognitive activation and support the learning process, so that the learning content is retained for as long as possible, it is important to build on existing knowledge.[22] In doing so, the learning content should be adapted to pre-existing grids and be generalisable for other medical devices.[9] This offers the learner the possibility of establishing mental chunks, separating what is important from what is unimportant. 'Text with picture' has a greater effect on learning and its subsequent implementation in clinical practice than the exclusive study of literature or video without text.[23] Pauses in learning videos give time to think, reducing cognitive overload, especially when teaching complex topics, such as the use of an anaesthesia workstation. Instructional videos are limited when it comes to transferring theoretical visual knowledge into practical manual action, as the hands-on part is missing. According to the Miller,[20] self-guided video learning combined with a practical test station might better train behavioural competencies, as it combines the theoretical and cognitive levels with practical exercises. Furthermore, the problem-solving behaviour involved is an important part of cognitive activation, as that has a high level of personal relevance for the learner and, later, user, which is crucial for their future work with the device and for increasing patient safety. All of this offer significant didactic potential in a self-learning context, as topics that seem important to the learner are better anchored mentally. Considering the complex learning requirements described in the area of medical device training, a self-directed blended learning programme could probably contribute to solving the difficulties mentioned above. If such learning strategies are able to be translated into users' clinical practice, Kirkpatrick level 3, it will truly bring about behavioural changes at the workplace, including the acceptance of such changes by the organisation's processes and culture.[19] Investigating this last step lies beyond the scope of the present study, but it may be the object of future studies. However, the results of the proposed study investigate two learning methods that might stimulate a broad discussion about sustainability and adaptive learning methods for ongoing professional development.

Author affiliations
[1]Department of Anaesthesiology and Pain Medicine, Inselspital, University Hospital Bern, University of Bern, Bern, Switzerland
[2]University of Bern, Bern, Switzerland
[3]School of Medicine, Sigmund Freud Private University Vienna, Wien, Austria
[4]Unit for Research & Innovation in Anaesthesia, Department of Paediatric Anaesthesia, Istituto Giannina Gaslini, Genoa, Italy

Twitter Alexander Fuchs @alexffuchs

Acknowledgements We would like to thank N. Heinemann, the patient representative of the Bern Cantonal Ethics Committee, for his critical review of the manuscript and for endorsing this research project from the patient's perspective.

Contributors CG and RG conceptualised this study, wrote the protocol and the draft of the manuscript and its final version for submission. Literature search was done by CG, RG and AF. Ethical application and trial registration were made by AF. MHa and CG conceived and produced the learning video. SS and MHa developed the teaching and test station. MHu computed sample size calculation and made the statistical analysis plan. The concept for data acquisition and randomisation was made by MHu, CG and SS. Logistic and organisational plan was created by CG. All the authors discussed the manuscript draft and contributed to the final version of the manuscript. All authors agreed on the final version.

Funding This investigator-initiated research project received funding from the Department of Anaesthesiology and Pain Medicine, Inselspital, Bern University Hospital (Grant Number N/A).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Caterina Gutersohn http://orcid.org/0000-0001-9539-1873
Robert Greif http://orcid.org/0000-0003-0160-2073
Alexander Fuchs http://orcid.org/0000-0001-7188-1683

REFERENCES

1 Ziv A, Small SD, Wolpe PR. Patient safety and simulation-based medical education. *Med Teach* 2000;22:489–95.
2 Mattox E. Medical devices and patient safety. *Crit Care Nurse* 2012;32:60–8.
3 Brydges R, Carnahan H, Safir O, *et al*. How effective is self-guided learning of clinical technical skills? it's all about process. *Med Educ* 2009;43:507–15.

4 Höffler TN, Leutner D. Instructional animation versus static pictures: a meta-analysis. *Learning and Instruction* 2007;17:722–38.
5 Wulf G, Shea C, Lewthwaite R. Motor skill learning and performance: a review of influential factors. *Med Educ* 2010;44:75–84.
6 Motola I, Devine LA, Chung HS, *et al*. Simulation in Healthcare education: a best evidence practical guide. *Medical Teacher* 2013;35:e1511–30.
7 Paivio A. Dual coding theory and education. In Draft paper for the conference on "Pathways to Literacy Achievement for High Poverty Children; The University of Michigan School of Education, 2006 Available: https://asset-pdf.scinapse.io/prod/1963996086/1963996086.pdf [accessed 27 Jun 2023].
8 Thomas NJT. Dual coding and common coding theories of memory. 2020. Available: https://stanford.library.sydney.edu.au/archives/fall2017/entries/mental-imagery/theories-memory.html [Accessed 27 Jun 2023].
9 Moreno R, Mayer RE. Cognitive principles of multimedia learning: the role of modality and contiguity. *Journal of Educational Psychology* 1999;91:358–68.
10 Norman MK. Twelve tips for reducing production time and increasing long-term usability of instructional Video. *Med Teach* 2017;39:808–12.
11 Sweller J, van Merrienboer JJG, Paas FGWC. Cognitive architecture and instructional design. *Educ Psychol Rev* 1998;10:251–96.
12 Santé O. *Rahmenlehrplan für Nachdiplomstudien der höheren Fachschulen*. Anästhesiepflege, Intensivpflege, Notfallpflege, 2015.
13 Kinnear B, Kelleher M, May B, *et al*. Constructing a validity map for a workplace-based assessment system: cross-walking Messick and Kane. *Acad Med* 2021;96:S64–9.
14 Szyld EG, Aguilar A, Lloret SP, *et al*. Self-directed Video versus instructor-based neonatal resuscitation training: a randomized controlled blinded non-inferiority multicenter international study. *J Perinatol* 2021;41:1583–9.
15 Klasen M, Sopka S. Demonstrating equivalence and Non-Inferiority of medical education concepts. *Med Educ* 2021;55:455–61.
16 Mpotos N, Lemoyne S, Calle PA, *et al*. Combining Video instruction followed by voice feedback in a self-learning station for acquisition of basic life support skills: a randomised non-inferiority trial. *Resuscitation* 2011;82:896–901.
17 Team RC. R: A language and environment for statistical computing Vienna,Austria. 2013 Available: www.R-project.org
18 World Medical Association. World Medical Association declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;310:2191–4.
19 Kirkpatrick JD, Kirkpatrick WK. Association for talent development. In: *Kirkpatrick's four levels of training evaluation*. 2016.
20 Miller GE. The assessment of clinical skills/competence/performance. *Acad Med* 1990;65(9 Suppl):S63–7.
21 Niegemann H, Weinberger A. Handbuch Bildungstechnologie. In: *S.Lernen mit Bewegtbildern: Videos und Animationen*. Berlin, Heidelberg: Springer, 2020.
22 Fauth BL. T.Kognitive Aktivierung Im Unterricht. 2018. Available: https://www.kts-buchen.de/assets/downloads/Wirksamer%20Unterricht%20-%20Band%202_Kognitive%20Aktivierung.pdf [Accessed 27 Jun 2023].
23 Schmitz FM, Schnabel KP, Bauer D, *et al*. The learning effects of different presentations of worked examples on medical students' breaking-bad-news skills: a randomized and blinded field trial. *Patient Educ Couns* 2018;101:1439–51.

INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HÔPITAL UNIVERSITAIRE DE BERNE
Universitätsklinik für Anästhesiologie und Schmerztherapie

Klinikdirektor und Chefarzt
Prof. Dr. med. Frank Stüber

Information für Teilnehmende an einer Studie des Bildungssektors:

Interne KAS-Schulung des neuen Respirators Atlan: Eine randomisierte Vergleichsstudie von Lernen im traditionellen Unterricht vs. Selbstlernen mit Video.

Liebe Kolleginnen und Kollegen

Im Rahmen der Schulung des neuen Respirators Atlan haben wir zwei Lernformate per Zufall allen Mitarbeiter der KAS zugeordnet (Präsenzschulung und Selbstlernen mit Video). Um entsprechende Kompetenz mit dem Gerät nachzuweisen wird ein kurzer Anwendungstest durchgeführt. Anhand dieser Resultate wollen wir den Effekt der beiden Unterrichtmethoden auswerten.

Wir laden Euch ein, die Resultate des Anwendungstests und ein paar persönliche Daten in codierter Form freiwillig für diese Begleitstudie dem Forschungsteam zur Verfügung zu stellen. Damit wird es möglich, die beiden Lernformate zu vergleichen und Erkenntnisse für zukünftige Geräteschulungen zu gewinnen.

Die zu Eurer Person erfassten Daten werden im KAS Forschungsserver (RedCap Inselspital Anästhesiologie) codiert gespeichert und in anonymisierter Form ausgewertet. Der Zugang zu diesen Daten ist nur dem Forschungsteam mit registriertem Zugang möglich. Diese Studie folgt der Schweizer Gesetzgebung zur Forschung und internationaler Richtlinien zur Forschung in der Medizin.

Die Studienteilnahme ist freiwillig und kann jederzeit und ohne Angabe von Gründen widerrufen werden. Dies hat keine Auswirkungen auf das Anstellungsverhältnis an der KAS. Daten, welche bis zu einem allfälligen Widerruf erhoben wurden, werden zur Verhinderung fälschlicher Datenauswertung mitanalysiert.

Das Studienteam bedankt sich herzlich für eure freiwillige Teilnahme und Unterstützung. Wir stehen bei Fragen gerne jederzeit zur Verfügung.

Für das Studienteam: Caterina Gutersohn

Medizinbereich Querschnittsfächer MBQU, Universitätsklinik für Anästhesiologie und Schmerztherapie KAS, 3010 Bern
Caterina Gutersohn, Berufsbildungsverantwortliche Anästhesie-, Intensiv-, Notfallpflege AIN, OPO D 215,
Telefon +41 (0)31 632 16 74, caterina.gutersohn@insel.ch

Einwilligungserklärung für Teilnehmende der Studie:

Interne KAS-Schulung des neuen Respirators Atlan: Eine randomisierte Vergleichsstudie von Lernen im traditionellen Unterricht vs. Selbstlernen mit Video.

_____

Name und Vorname der Teilnehmenden

_____

E-Mail

Geburtsdatum: _____

Ich gebe hiermit meine Einwilligung zur codierten Speicherung und anonymisierten Auswertung der von mir erhobenen Daten und Angaben aus dem Anwendungstest zur Schulung des neuen Respirators Atlan für Forschungszwecken (elektronische Verarbeitung, anonymisierte Analyse und Publikation).

Ich bestätige, dass ich

- das zu dieser Einwilligungserklärung gehörende Aufklärungsdokument gelesen und verstanden habe.
- darüber informiert wurde, dass meine Einwilligung freiwillig ist.
- weiss, dass ich diese Einwilligung jederzeit - ohne Angaben von Gründen - widerrufen kann und dies keine Auswirkungen auf mein Anstellungsverhältnis an der KAS haben wird.
- weiss, dass die Daten geschützt und verschlüsselt auf einem sicheren Forschungsserver gespeichert werden.

_____

Ort, Datum, rechtsgültige Unterschrift der Teilnehmenden

Bern, 27.11.2022