Training thoracic ultrasound skills: a multicentre, blinded, randomized controlled trial of simulation-based training versus training on healthy figurants - study protocol.

- A randomized trial in gaining competences in thoracic ultrasound

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Background

Thoracic ultrasound (TUS) differs from ultrasound examinations in other organ systems, because it is not possible in the healthy, ventilated lung to visualize structures or anatomical parts of the lung, like it is when examining abdomen or performing an echocardiography [1,2]. It is therefore not possible to transfer results directly from educational studies using simulation-based training in other areas of medicine, to thoracic ultrasound.

TUS examinations are considered safe, and without pain, exposure to radiation or delay of patients' course, but ultrasound in general is highly operator dependent [1] and lack of theoretical knowledge or practical skills could potentially lead to incorrect diagnosis and thus treatment. Therefor simulation-based training, theoretical and practical tests could be the key to a "pre-trained novice" with a level of competency higher than a complete novice when performing the first TUS examination on a patient in a clinical setting.

The objective of this trial is to examine whether TUS training on a simulator is superior to training on healthy figurants, which today is a commonly used method for gaining skills and competencies in TUS. Secondly, to examine whether the choice of hands-on training has an effect on the number of examinations performed by the trainees from baseline to 4 months follow-up.

Methods

The design is a three-armed, multicentre, blinded randomized controlled trial.

Setting

The trial takes place at three simulation centres at university hospitals in Denmark; Odense University Hospital, Rigshospitalet, and Aarhus University Hospital. The intervention period is scheduled to run from August 2018 to May 2019.

Participants

All physicians employed at public hospitals in Region of Southern Denmark, Capital Region of Denmark, Region Zealand, and Central Denmark Region, are eligible for inclusion in the trial. Because physicians from a wide range of specialities can benefit from TUS examinations, no exclusion criteria are established based on the specialities from the physicians.

The promotion of the educational program and trial is done through posters at the respective departments, social media, and educational groups. Trainees sign up for participation, and inclusion

by mail, and will receive a reply including information about the trial. Exclusion criteria are; lack of informed consent, physicians with connection to the trial, or involvement in the design or conduction.

Prior to intervention

Prior to the randomization all participants will complete an online educational programme in TUS in order to reach sufficient theoretical knowledge, and must pass a theoretical test and answer a questionnaire regarding previous experience with ultrasound in general and TUS, current position and employment. All included participants will receive a study identification number that makes it possible to pair the results from the questionnaire to the intervention and performances.

All materials needed prior to the theoretical test, including online educational material, log-in to questionnaire and test will be send to the participants by mail as well. The online educational material comprises access to Munksgaards' online portal in basic ultrasound, which includes theoretical sonographic sessions, instruction videos in TUS, practical hands-on demonstrations, ultrasound clips, and vodcasts. The preparation is estimated to 2-3 hours. The theoretical test is administered in Research Electronic Data Capture (REDCap) provided by Odense Patient data Explorative Network (OPEN). Participants will be excluded if they do not complete the test.

When participants have completed the test, they will move on to part two, which is the practical hands-on training. Part two of the trial will take place in one of the simulation centres. All participants will receive an introduction to the ultrasound machine. A medical student working on the project will do the introduction, which comprises following general information about ultrasound but no information about TUS:

- Turn on/off
- Select and change transducer
- Select preset
- Adjust depth, gain and focus
- Store images/clips

Subsequently, the randomization will take place.

Randomization

Randomization is done in REDCap, which allows an online, computer-generated allocation sequence concealed to the project leaders. Participants are randomized for hands-on training on simulator, healthy figurants, or no intervention, last mentioned serve as controls. The ratio for each category is 1:1:1. There is no stratification for site (location).

Trial intervention

The trial intervention includes a new experimental educational approach; in vitro simulation-based TUS training. The TUS module for the US Mentor Simulator is made in collaboration with 3D Systems (3D Systems Healthcare, Littleton, USA, formerly known as Simbionix). A TUS expert developed nine cases, and the cases cover the most common causes of respiratory failure, dyspnoea and cough. The content and curriculum of the educational programme are based on the guidelines and recommendations from the Royal College of Radiologists [3], European Federation of Societies for Ultrasound in Medicine and Biology [4], International evidence-based recommendations by Volpicelli et al. [1], and Lung ultrasound in the critically ill by Lichtenstein et al [5].

This simulation model will serve as first intervention arm, and after the introduction to the ultrasound machine, the group randomized for simulation training is allowed to practice for 2.5 hours before assessment.

The second intervention arm in the trial is a commonly used hands-on training method; examination of healthy volunteers (figurants), in this case medical students who signed up for the job, and who is a part of the research group. Trainees are as well allowed to train for up to 2.5 hours, but the medical students are not allowed to help or guide the trainee during the examinations.

Last group will not receive any hands-on training other than the general information, and will serve as controls. Figure 1 present a flowchart of the trial.

When trainees have finished the hands-on training, they will continue to assessment of competencies, done by an instructor blinded to the intervention. The medical student will inform the instructor, and the assessment will take place in the emergency department examining real patients suspected to have thoracic pathology/pathologies. As assessment tool the LUS-OSAUS score sheet is used [6]. The assessment will be repeated twice.

Blinding

It is not possible to blind the participants to the educational intervention, but the instructor assessing the participants is blinded to the intervention. The data-managers providing the statistical analysis are going to be blinded when performing the analyses and when drawing conclusions of the results.

Measurements and assessment of outcomes

Appendix 1 covers the present codebook (version 1.0, July 2018) of variables, including type of variables, legal values and labels. Table 1 provides an overview of the outcomes, and statistical analyses, and Table 2 a timeline for obtaining data and registration in the database.

Outcomes

The primary outcome is difference in LUS-OSAUS score between the three groups [6]. The LUS-OSAUS score is calculated as the sum of all 17 items in the tool (min. 17, max. 85 point), evaluated by instructor and first author, PP. The participant is evaluated two consecutive times.

The LUS-OSAUS tool is, to our knowledge, the first assessment tool with established evidence of validity. The publication shows that LUS-OSAUS can differentiate between different levels of competencies.

Secondary outcome is difference in number of scans performed from baseline to follow-up (4 months) between the two intervention arms.

Sample size

Significance 5%, Power 90%, mean difference wanted between the two interventional groups is 8.5 point. Standard Deviation 8.67. Sample size per group is 22 (total; 66 participants).

Statistical analyses

Data will be accessed using OPEN analyse, and analysed using STATA and SPSS. OPEN Analyse is an analyse environment that complies with the current regulations on data privacy. OPEN Analyse acts as terminal server solution from the researcher's private PC with logging if files, but data are stored and processed on a server at the Regional IT.

A two-sided significance level of 0.05 will be used. Statistical methods for the primary and secondary outcomes are presented in Table 1, and include Post Hoc ANOVA with Bonferroni correction, hands-on training facility as independent variable (SIM, FIG, controls), and LUS-OSAUS scores as dependent variable.

All data will be analysed as intention to treat, therefor missing data will be handled by multiple imputation technique, even though missing data are expected to be minimal because instructors are registering a great amount of the data to the database.

Ethical considerations

Participants are physicians, and even though patients are used for assessment, no patient data are going to be used. Neither participants nor instructor will look in the electronic patient database, or at previous radiological examinations. The patient will be given oral information about the trial including aim, running and assessment of participants, and that ultrasound is a non-invasive and radiation-free radiological examination with no risk of complications or side effects. Subsequent, orally informed consent will be given from the patient. If the ultrasound examination provides further information to the patient inquiry, which is suspected as new information, the physician in charge of the patient will be informed orally.

The trial complies with the Declaration of Helsinki on biomedical research and with the act on processing personal data. The Regional Committees on Health Research Ethics for Southern Denmark has been given the project description and protocol, and found that in accordance to Danish regulations, ethical approval is not required for carrying out the trial (S-20172000-44).

The trial is notified to the Danish Data Protection Agency under the in Region of Southern Denmark, and, as prescribed, a data management contract is going to be signed with authors and supervisors outside the region. The trial is going to be registered at www.clinicaltrials.gov when the account access is available.

The educational programme is planned to include two parts, the web-based theoretical session which participants can access at all time, and the hands-on session planned to take place during normally working hours. Participants are not going to receive salary or compensation for the participation in the educational programme. The educational programme is offered by the Simulations Centres in the Regions, and is therefor free of charge for physicians employed at the public hospitals. Participants can at any time withdraw from the trial.

Participants are assured written and orally, that personal data (including questionnaire and assessment scores) are anonymized, and will remain this way during data management, storage, analyses and reporting or publication.

Discussion

The presented trial is set to investigate whether a TUS simulator as hands-on training facility, can provide a higher level of competencies after 2.5 hour training, than training on healthy figurants, which is a commonly used model today [7-9].

Simulation-based medical education (SBME) has several advantages, and is a complex educational intervention that enables both immersive and experimental learning, and makes it possible to acquire and maintain skills in a calm and safe environment without putting patients at risk if a wrong decision or interpretation is made [10]. The use of this approach has increased within the last decade, and in various specialities using technical procedures [11-13].

Furthermore, all pathologies considered mandatory to the content or course are possible to explore, and a trainee is able to practice a particular case or high-risk cases, over and over again, if doubt arises or if the trainee does not provide a satisfying result. Seen in a research perspective, SBME makes it possible to compare results of different trainees for research purpose, because of a standardized set-up. On the other hand, disadvantages in simulation training appear; e.g. if the fidelity drops for a short moment, the trainee may use a lot of effort to move back into the simulation setting, the technical models require updates, maintenance, and an instructor is often necessary in the beginning for introduction, and for emphasizing trainee reflection and peer review elements [10]. Last, but not least simulation training cannot replace traditional apprenticeship or stand alone, but must be seen as and add-on approach prior to supervised training in a clinical setting [10,14].

Today in TUS, it is often a fixed number of examinations on patients that determines whether a physician can do a sufficient ultrasound examination sufficiently [3,4,15]. Otherwise a supervisor, subjectively, accepts and approves a trainee's skills, but none of those methods ensure the professional level of competencies, and can be affected by external factors and cause feasibility problems [16]. There will be situations where a patient is seriously ill, and rapid start of treatment is basis for a good outcome. In these situations education is not first priority, and is easily put in line.

Secondly, due to the varying incidence of various pulmonary diseases and pathologies, hands-on training on patients in a clinical setting does not ensure examination of all important sonographic findings [17].

To our knowledge no previous studies have been published, comparing the effects of different hands-on training facilities in TUS. Several studies have shown a positive effect of one particular modality, e.g. laboratory animals [7,18], cadavers [19], phantoms [20], or like in this trial, healthy figurants [21] or simulators [22], but did not compare the effects.
Previous studies that have investigated simulation training in ultrasound of other organ systems than lungs or thorax, or ultrasound guided procedures, have showed large and significant effect when compared to no training [23,24], but in order to provide realistic and transferable comparison the control group should not be no training, but training as is the case today; training on healthy figurants. In order to implement simulation training for gaining TUS competencies, and rethink the educational tasks for physicians, the results for the simulator group are expected to be better than the group of comparison and controls.

Limitations
The study will suffer from a number of limitations. Given the nature of the trial it is not possible to blind the participants, but the instructor assessing the participant is blinded to the intervention. During the analyses and reporting, the allocation will be blinded to the data-managers.

TUS is a quit new modality, and the clinical training during follow-up can be influenced by several factors as; accessibility of an ultrasound machine in the departments of the participants, accessibility of supervision and sparring with other clinicians using lung ultrasound, and attendance on courses teaching TUS from baseline to follow-up. To take this into account, participants will fill out a questionnaire regarding some of the potential co-factors and confounders, to make it possible to stratify for these. Because the trial is randomized we expect these systematic errors and confounders to be randomly and equally allocated in the three groups.
The most optimal primary outcome in educational studies, is a patient-related, clinical outcome, but unfortunately this is not possible.

Trial status

Planning of the trial was initiated in March 2017, but validation studies of a written and practical test were needed before initiating this trial. The intervention is scheduled to begin in August 2018 and will continue until April 2019, and follow-up assessments continue until August 2019.

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Figure 1. Participant flowchart in accordance with the CONSORT statement.

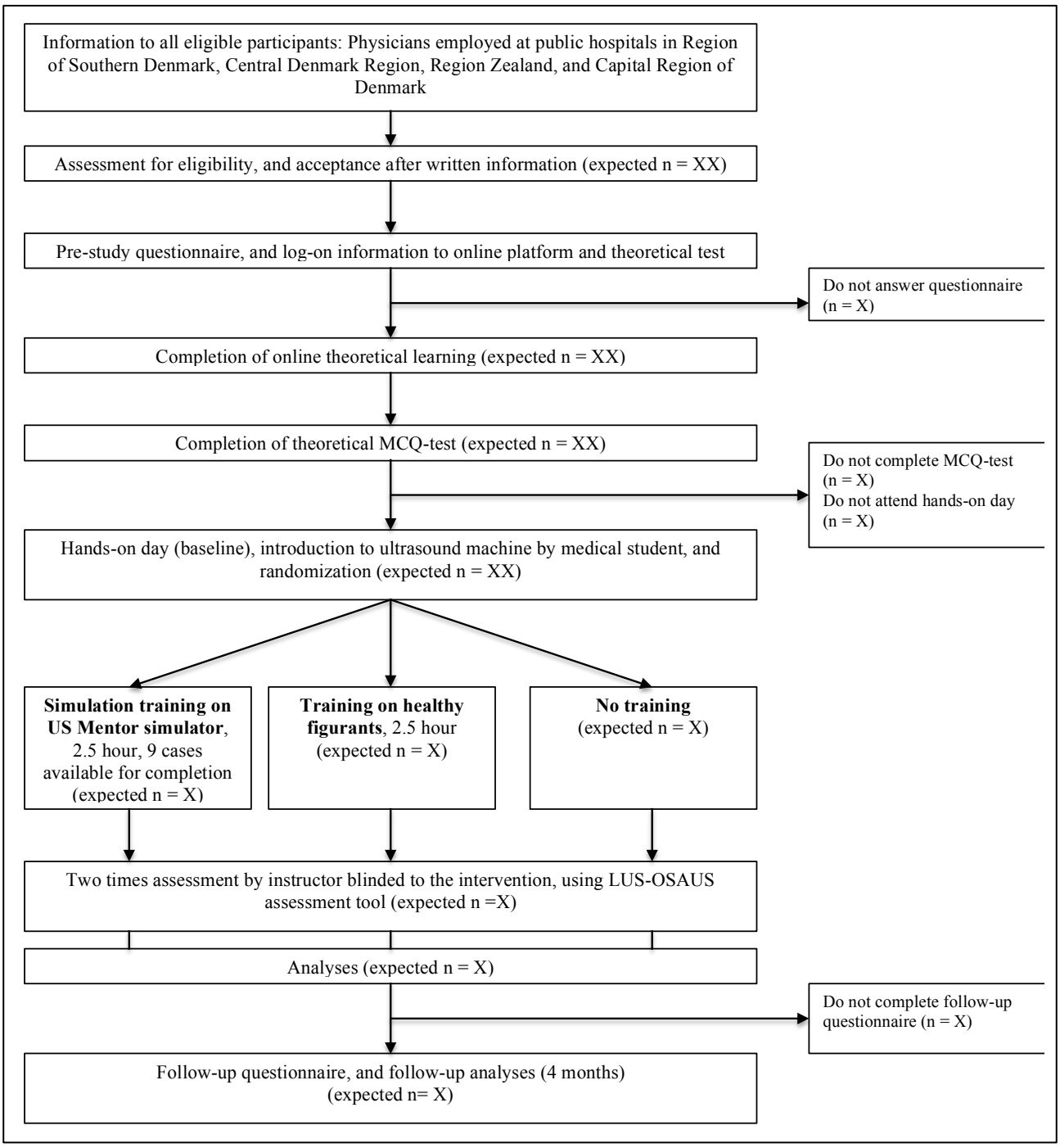

Table 1. Variables, hypothesis, outcome measures and method of statistical analysis

	Hypothesis	Outcone measures	Type of variable	Methods of statistical analysis
Primary outcome				
Difference in LUS-OSAUS between the groups	Training on simulator provides a better result than training on healthy figurants and no hands-on training	Sum and percentage of maximal number of points	Gaussian distribution expected, continous interval data	Parametric analysis, and ANOVA with Bonferroni correction for multiplicity
Secondary outcome				
Number of examination performed from baseline among the three groups to follow up (4 months)	Training on simulator gives the trainee a better starting point for doing examinations in the clinical daily work	Participant reported number of examinations performed	Gaussian distribution expected, continous interval data	Parametric analysis, and ANOVA with Bonferroni correction for multiplicity

Table 2. Timeline of measurements

	Pre study (registration and theoretic session)	**Baseline (course day)**	**4 months**
Participant information	X		
Theoretical Test	X		
LUS-OSAUS		XX	
Follow-up questionaire			X

Centre Number:

Study Number:

Participant Identification Number for the trial:

CONSENT FORM

Title of Project: **Training thoracic ultrasound skills: a multicentre, blinded, randomized controlled trial of simulation-based training versus training on healthy figurants**

Name of Researcher: **Pia Iben Pietersen**

Please initial all boxes

1. I confirm that I have been informed of the study . I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of the data may be looked at by individuals from the study group, or from regulatory authorities where it is relevant to my taking part in this research. I am informed that my data is being kept and handled according to the European Data Protection rules, and I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Name of Participant _____

Date _____ Signature _____

Name of Person taking consent _____

Date _____ Signature _____