



Study protocol

Evaluating scanning competence following a structured POCUS training program for general practitioners

A hybrid effectiveness-implementation study

Study protocol according to the SPIRIT 2013 Checklist

Administrative information.....	3
1 Title.....	3
2a Trial registration.....	3
2b The World Health Organization Trial Registration Data Set.....	3
3 Protocol version	4
4 Funding	4
5 Roles and responsibilities	5
5a Names, affiliations, and roles of protocol contributors.....	5
5b Name and contact information for the trial sponsor.....	5
5c Role of study sponsor and funders	5
5d Composition, roles, and responsibilities of the steering committee and safety committee ...	5
Introduction.....	7
6 Background and rationale	7
7 Specific objectives	8
8 Trial design	9
Methods - Participants, interventions, and outcomes	10
9 Study settings.....	10
10 Participants.....	10
11a Description of the intervention.....	11
11b Criteria for discontinuing or modifying allocated interventions for a given trial participant	22
11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence.....	22
11d Relevant concomitant care and interventions that are permitted or prohibited during the trial.....	23
12 Outcome measures	23
13 Time schedule	24
14 Sample size.....	25
15 Recruitment	25
16a Allocation Sequence generation.....	25
16b Allocation concealment mechanism.....	25
16c Implementation.....	25
17 Blinding.....	25
Data collection, management, and analysis	26

18a	Data collection - Plans for assessment and collection of outcome, baseline, and other trial data	26
18b	Data collection - Plans to promote participant retention and complete follow-up.....	28
19	Data management.....	28
20a	Statistical methods for analysing primary and secondary outcomes.....	29
20c	Missing data	29
	Data monitoring	29
21a	Data monitoring committee (DMC).....	29
21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	29
22	Harms	29
23	Auditing.....	29
	Ethics and dissemination.....	30
24	Research ethics approval.....	30
25	Protocol amendments	30
26a	Consent or assent.....	30
26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable.....	30
27	Confidentiality.....	30
28	Declaration of interests.....	30
29	Access to data.....	30
30	Ancillary and post-trial care.....	30
31a	Dissemination policy.....	30
31b	Authorship eligibility guidelines.....	31
31c	Plans for granting public access to the full protocol, participant-level dataset, and statistical code.....	31
32	Informed consent materials	31
	References.....	31

Administrative information

1 Title

Evaluating scanning competence following a structured POCUS training program for general practitioners - A hybrid effectiveness-implementation study.

2a Trial registration

The trial will be registered on clinicaltrials.org

2b The World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	Clinicaltrials.gov number:
Date of registration in primary registry	Uploaded to clinical trials Marts 2nd 2022
Secondary identifying numbers	Red-CAP registration number ID-242-2. Center for General Practice at Aalborg University (CAM AAU)
Source(s) of monetary or material support	n/a
Primary sponsor	Center for General Practice at Aalborg University (CAM AAU)
Secondary sponsor(s)	Novo Nordisk Foundation The General Practice Foundation in Denmark
Contact for public queries	mbj@dcm.aau.dk
Contact for scientific queries	caakjaer@dcm.aau.dk
Public title	<i>General practitioners' POCUS competence following structured training</i>
Scientific title	Evaluating scanning competence following a structured POCUS training program for general practitioners – A hybrid effectiveness-implementation study
Countries of recruitment	Denmark
Health condition(s) or problem(s) studied	The use of point-of-care ultrasonography (POCUS) in general practice
Intervention(s)	An educational intervention consisting of three teaching seminars over three months, a curriculum of 10 point-of-care ultrasound (POCUS) applications, an online learning platform providing educational support before, during and after the teaching sessions.
Key inclusion and exclusion criteria	<p><u>Inclusion criteria:</u></p> <ol style="list-style-type: none"> 1. GP, i.e. postgraduate medical doctor with a specialization in general practice. 2. Work in office-based general practice in Denmark 3. Access to an ultrasound device in the practice during the study period <p><u>Exclusion criteria:</u></p> <ol style="list-style-type: none"> 1. GPs with a possible conflict of interest 2. No signed informed consent to participate.
Study type	A hybrid effectiveness-implementation study
Date of first enrolment	Expected: March 2022
Target sample size	Twenty general practitioners
Recruitment status	Not yet recruiting
Primary outcome(s)	Primary outcome 1 (P1): For GPs, participating in a POCUS training program with online support and three teaching sessions, the ultrasound competence score (summarized OSAUS score across ten scanning modalities) after the educational period (three months after baseline).

	<p>Primary outcome 2 (P2): For GPs, participating in a POCUS training program with online support and three teaching sessions, the ultrasound competence score (summarized OSAUS score across ten scanning modalities) six months after baseline.</p>
Key secondary outcomes	<p>Secondary outcome 1 (S1): For GPs, participating in a POCUS training program with online support and three teaching sessions, the OSAUS scores and the item scores, after the educational period (three months after baseline), for each of the ten scanning modalities included in the curriculum.</p> <p>Secondary outcome 2 (S2): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who have an ultrasound competence score (OSAUS score) of three or above after the educational period (three months after baseline), for all of the seven OSAUS items of each of the ten scanning modalities included in the curriculum.</p> <p>Secondary outcome 3 (S3): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who have an ultrasound competence score (OSAUS score) of three or above six months after baseline, for each of the ten scanning modalities included in the curriculum.</p> <p>Secondary outcome 4 (S4): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who rate themselves to be competent to perform un-supervised POCUS in general practice, after the educational period (three months after baseline), for each of the ten scanning modalities included in the curriculum.</p> <p>Secondary outcome 5 (S5): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who rate themselves to be competent to perform un-supervised POCUS in general practice, six months after baseline, for each of the ten scanning modalities included in the curriculum.</p> <p>Process-related outcome 1 (PR1): The number of performed POCUS examinations by each GP in the first six months after introducing POCUS use in general practice (months 1-6 after baseline).</p> <p>Process-related outcome 2 (PR2): The number of adverse events and near-miss cases associated with the use of POCUS reported by the participating GPs in the first six months after introducing POCUS use in general practice (months 1-6 after baseline).</p> <p>Process-related outcome 3 (PR3): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who have completed the different educational elements in the educational intervention three months after baseline.</p>

3 Protocol version

Version 9. Marts 2nd 2022

4 Funding

This study will be conducted as independent research at Center for General Practice at Aalborg University and is financially supported by The Novo Nordisk Foundation (grant number 0061821) and The General Practice Foundation in Denmark (grant number A3495).

5 Roles and responsibilities

5a Names, affiliations, and roles of protocol contributors

Camilla Aakjær Andersen (CAA) will be the principal investigator.

CAA and Martin Bach Jensen (MBJ) will oversee the choice of and collection of outcome measures

CAA and MBJ wrote the first draft of the protocol.

Allan Riis (AR) will draft the data handling and statistical analysis plan (SAP)

Ulrike Mehnert (UM), Thomas Løkkegaard (TL), Troels Mengel-Jørgensen (TMJ), Liv Dyre (LD), Nicolai Soll (NS), Bo Stork (BS) will participate as teachers in the training program

Ole Graumann (OG), MBJ, Louise Pihl (LP), Christian Sjernebjerg (CS) and Søren Kæseler Andersen (SKA) will perform the OSAUS evaluations of scanning competence

CAA, MBJ, AR, UM, TL, TMJ, LD, NS, BS, OG, LP, CS and SKA are all expected to make valuable scientific additions to the draft and will be co-authors on subsequent manuscripts based on these data. The definition of author is defined on ICMJE's four criteria¹:

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

Drafting the work or revising it critically for important intellectual content; AND

Final approval of the version to be published; AND

Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The expected author list is: Andersen CA, Riis A,Jensen MB.

5b Name and contact information for the trial sponsor

Trial sponsor: Center for General Practice at Aalborg University (CAM AAU)

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5c Role of study sponsor and funders

Sponsor (CAM AAU) is part of the study design, data analyses and writing of the manuscript.

Sponsor will ensure that the results will be submitted for publication. Sponsor is non-commercial and declares no conflict of interest.

Other sponsors have no part in the study design, data analyses or writing of the manuscript.

The authors declare no conflict of interest.

5d Composition, roles, and responsibilities of the steering committee and safety committee (see Item 21a for data monitoring committee)

A steering committee affiliated with CAM AAU (TL, UM, TMJ, SKA, MBJ and CAA) will handle and oversee the development of the intervention, the coordination and organisation of the ultrasound courses, and the data collection and data management.

A safety committee will be set up to handle all reports of adverse and suspected adverse events (AEs) and serious adverse events (SAEs). MBJ will head the committee.

Introduction

6 Background and rationale

The interest in performing point-of-care ultrasound (POCUS) in general practice is increasing, advanced due to the development of affordable, mobile ultrasound scanners. Furthermore, primary care residents are commonly exposed to POCUS during their hospital-based training laying the foundation for its later use in an office-based setting.

Ultrasound is a highly user-dependent image modality which requires the ability to integrate anatomy, image acquisition, and clinical knowledge². A robust training program in the use of POCUS is mandatory to minimize adverse effects in the form of false positive and false negative results^{3 4}.

An increasing body of evidence shows that GPs can perform POCUS in a safe manner^{5 6}.

However, GPs are faced with unique educational challenges⁷. While hospital-based physicians have the advantage of consulting with their peers if they experience problems with interpreting difficult cases, GPs work alone without easy access to more experienced colleagues.

Furthermore, GPs face a wide variety of clinical conditions which require the GP to be able to perform multiple scanning modalities some of which may be infrequently used⁸. This may lead to a decay in competency. Therefore, measures must be put in place to maintain the retention of POCUS skills after initial POCUS training. While there are multiple studies showing that GPs can learn different scanning modalities, evidence is more limited as to their ability to keep competencies over time³.

An educational intervention for GPs' POCUS education has been developed by this research group based on a systematic literature review of educational ultrasound programs for general practitioners³, a previous educational intervention⁸, previous studies exploring the educational needs of general practitioners^{7 9}, previous studies exploring skills assessments of POCUS performing GPs^{10 11} and the research groups extensive experience in planning ultrasound courses. This educational intervention was built to meet the basic educational needs of GPs by combining focused hands-on practical training with an online educational platform that provides continuous support in a longitudinal learning process. Prior to this study, the educational intervention was pilot tested on six GPs and six GP trainees (unpublished data). Adaptions followed based on feedback from participants, to increase feasibility and acceptance of the intervention.

Traditionally, ultrasound learning has focused on the number of examinations needed for competence¹², but this may be an unreliable measure of competence because of the large individual variations in learning curves. The Objective Structured Assessment of Ultrasound Skills (OSAUS) assessment tool has been developed and validated as a generic tool for assessing scanning competence¹³. The OSAUS scale consists of seven items: 'indication for the examination', 'applied knowledge of ultrasound equipment', 'image optimization', 'systematic examination', 'interpretation of images', 'documentation of the examination' and 'medical decision-making' and each item is rated using a provided five-point Likert-scale with descriptions of performance ranging from very poor (score = 1) to excellent (score = 5). In a setting of a university department of obstetrics and fertility clinic it was shown that a cut-off OSAUS score of 3.0 for trans abdominal fetal biometric scans and 2.5 for a systematic pelvic scan would effectively discriminate between novices and intermediate/expert users¹⁴. Hence, a

mean score of three or more may be anticipated for users with some experience though even consultants at a university department may score below three in some items.

7 Specific objectives

The overarching aim of this study is to investigate whether a new educational intervention tailored for GPs can lead to scanning competence at the end of the training program (three months after baseline) and if scanning competence can be maintained after additional three months (six months after baseline).

Effectiveness related primary outcomes

Primary outcome 1 (P1): For GPs, participating in a POCUS training program with online support and three teaching sessions, the ultrasound competence score (summarized OSAUS score across ten scanning modalities) after the educational period (three months after baseline).

Primary outcome 2 (P2): For GPs, participating in a POCUS training program with online support and three teaching sessions, the ultrasound competence score (summarized OSAUS score across ten scanning modalities) six months after baseline.

Effectiveness related secondary outcomes

Secondary outcome 1 (S1): For GPs, participating in a POCUS training program with online support and three teaching sessions, the OSAUS scores and the item scores, after the educational period (three months after baseline), for each of the ten scanning modalities included in the curriculum.

Secondary outcome 2 (S2): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who have an ultrasound competence score (OSAUS score) of three or more, after the educational period (three months after baseline), in all of the seven OSAUS items, for each of the ten scanning modalities included in the curriculum.

Secondary outcome 3 (S3): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who have an ultrasound competence score (OSAUS score) of three or more, six months after baseline, in all of the seven OSAUS items, for each of the ten scanning modalities included in the curriculum.

Secondary outcome 4 (S4): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who rate themselves to be competent to perform un-supervised POCUS in general practice, after the educational period (three months after baseline), for each of the ten scanning modalities included in the curriculum.

Secondary outcome 5 (S5): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who rate themselves to be competent to perform un-supervised POCUS in general practice, six months after baseline, for each of the ten scanning modalities included in the curriculum.

Implementation process related outcomes

Process-related outcome 1 (PR1): The number of performed POCUS examinations by each GP in the first six months after introducing POCUS use in general practice (months 1-6 after baseline).

Process-related outcome 2 (PR2): The number of adverse events and near-miss cases associated with the use of POCUS reported by the participating GPs in the first six months after introducing POCUS use in general practice (months 1-6 after baseline).

Process-related outcome 3 (PR3): The proportion of GPs, participating in a POCUS training program with online support and three teaching sessions, who have completed the different educational elements in the educational intervention three months after baseline.

8 Trial design

This is a hybrid effectiveness-implementation study¹⁵. We will test the effectiveness of an educational intervention in a real-world setting while gathering information on its delivery and the implementation of the intervention.

Reporting of this trial will follow STROBE guideline for reporting cohort studies¹⁶. Reporting of the protocol will follow the SPIRIT statement¹⁷. Before data collection starts, the trial will be registered on *clinicaltrials.gov*¹⁸.

Methods - Participants, interventions, and outcomes

9 Study settings

This study will be conducted in office-based general practice in Denmark with the educational sessions taking place at an ultrasound educational facility (MedSim, Central Denmark Region).

GPs in Denmark are self-employed and work in office-based general practice clinics. Denmark has a public health care system where almost all patients are listed with a GP for primary health care. Consultations and treatments are free-of-charge for patients. GPs act as gatekeepers for other primary care healthcare providers and secondary care specialists. GPs are paid through a combination of remuneration and fee-for-service financed through taxes. There is no fee for performing POCUS in primary care and GPs must cover expenses for the ultrasound device and their ultrasound education themselves.

Continuous medical education for GPs is centrally organized under the wings of the Danish Medical Association for General Practitioners (Praktiserende Lægers Organisation PLO-e). PLO-e is the practical organizer of the ultrasound course delivered in this educational intervention. The ultrasound course has been included in PLO-e's course catalogue for 2022 and as such all GPs working in Danish general practice has had the opportunity to sign-up for the course. Hence, PLO-e has handled the participant recruitment and registration as well as the financial and practical aspects of organizing and executing the course. PLO-e had no influence on the scientific content or data collection in the study.

The study will be coordinated from CAM AAU and data will be collected by the research team at the training sessions and by the participating general practitioners in their clinics. All study data will be stored at a secure server at Aalborg University.

10 Participants

Twenty GPs working in office-based general practice in Denmark, who have signed up for a PLO-e ultrasound course, will be invited to participate in the study. To participate a GPs must fulfill the inclusion criteria and not the exclusion criteria

Inclusion criteria:

1. GP, i.e., be a postgraduate medical doctor with a specialization in general practice.
2. Work in office-based general practice in Denmark
3. Have access to an ultrasound device in the practice during the study period

Exclusion criteria:

1. GPs with a possible conflict of interest (e.g., industry affiliation related to the use of ultrasound)
2. No signed informed consent to participate.

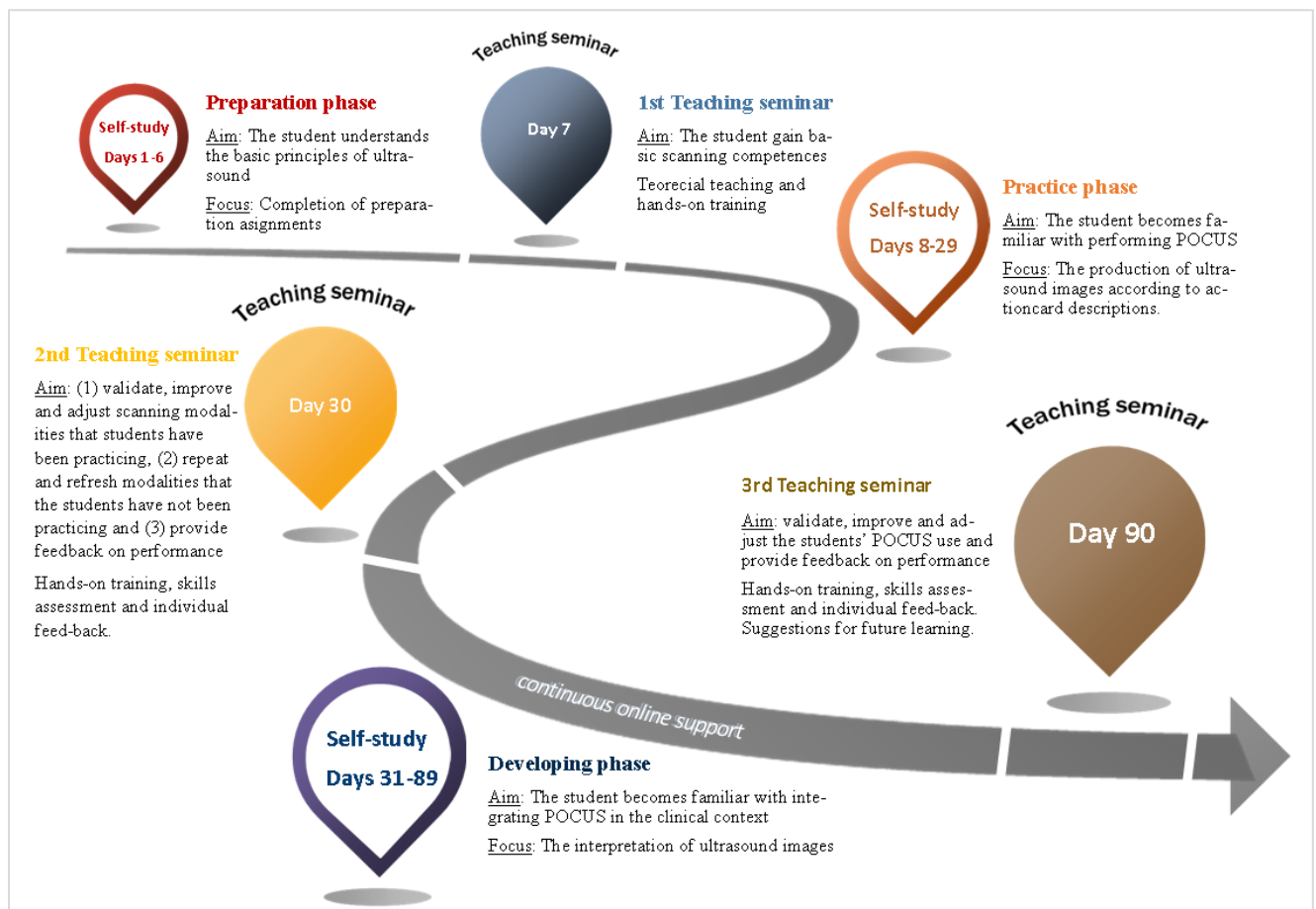
The educational intervention will be delivered by an educational team (UM, TL, BS, TMJ, NS, CS), who is an experienced GPs, POCUS users and teachers. The competence assessment (OSAUS score) will be delivered by a team of POCUS experts (SKA, OG, MBJ, CS and LP), who have extensive POCUS experience.

11a Description of the intervention

All participants will receive the educational intervention. The educational intervention consists of three teaching seminars over three months, a curriculum of 10 POCUS applications, an online learning platform providing educational support before, during and after the teaching sessions (see Figure 1).

The online platform includes instruction videos demonstrating the performance of POCUS, suggestions for additional literature, flashcards training the recognition of pathology, participant assignments to support the development of skills, self-quizzes to focus attention of learning outcomes and specific *actioncards* for each of the 10 POCUS applications framing the examinations in the clinical context. In addition, the online platform gives participants access to webinars and communication with other participants and teachers.

Figure 1 Point-of-care ultrasonography educational intervention for general practitioners



Individual preparation (Days 1-7)

Prior to the first seminar day, the participants are invited to access and complete the preparatory material on the digital platform (Microsoft Teams), which includes suggested literature and videos about the basics of ultrasonography, how to perform POCUS, how to use POCUS in the

examination of patients, and how to integrate POCUS in the general practice consultation. To prime the participant prior to the first seminar the preparation includes a pre-self-quiz outlining the specific learning outcomes of the first seminar day.

The participants also have to respond to an individual assignment where they in words will declare their motivation for participating in the course, their expectations for the course, their individual learning goals, their previous experiences with POCUS and other prerequisites. They will also be asked to identify possible barriers towards their learning process and pose three questions that they want answered during the first teaching seminar. This allows for the participants to reflect on their own motivation and capability and any difficulties and questions they may have. The participants are encouraged to enter the first training session with a focus on their individual learning goals and to make sure that difficulties and questions are addressed during the seminar. The POCUS teachers will comment on the participants' assignments. The assignment and comments will be saved in the online platform.

The teachers will address and integrate topics from the assignments during the first teaching seminar.

The pre-course assignment will also include a baseline questionnaire for participants, where they will be asked to declare the following information: Age (years), gender (M, F, other), previous use of ultrasound (number of months with regular use), previous ultrasound courses of minimum 1 day duration (yes/no), scanner type (low range, mid-range, high end) and type of transducers on the device (categories).

The participants must require an ultrasound device prior to the first teaching seminar and become familiar with basic functions. The participants are asked to register questions and difficulties related to the use of their ultrasound device and bring these to the first teaching seminar.

Introductory webinar

Early in the preparation phase, the participants will be invited to attend an introduction webinar, where the course leader will introduce the online platform and the course content to the participants. The purpose of the introduction webinar is to stimulate commitment, create awareness about course content and requirements, and introduce and facilitate use of the online platform. The participants will also be encouraged to plan for the implementation of POCUS training during daily routines, to allocate time for practice each week, and to discuss possible barriers for this with colleagues.

Curriculum

From a previous qualitative study, we know that GPs select and perform POCUS examinations that are focused on a specific clinical problem, relevant in the clinical context, within the GPs area of interest, not too time consuming, and not too difficult to perform¹⁹. For this education intervention 10 POCUS scanning modalities have been selected.

This selection is based on: (1) a previous systematic needs assessment⁹ assessing the relevance of different scanning modalities, (2) previous studies measuring the frequency of different POCUS modalities used in general practice^{8 10}, (3) a national survey in Denmark exploring which POCUS examinations were performed by GP²⁰, and (4) evidence of the diagnostic accuracy of different scanning modalities performed in the hands of non-imaging specialists (Table 1).

Hence, the selected curriculum for this study include ten POCUS scanning modalities that are frequently encountered in general practice, relevant in the clinical setting in terms of POCUS

examinations with an impact on diagnostic security or clinical pathway and manageable in terms of performance and competence.

To prevent cognitive overload^{21 22} and because previous studies have shown that GPs often start scanning just a few application^{7 19}, the ten scanning modalities in the curriculum will be introduced stepwise. Five scanning modalities will be introduced on the first teaching seminar, while the remaining five applications will be introduced on the second teaching seminar.

Table 1 Diagnostic accuracy of curriculum for the educational intervention

Curriculum	Diagnostic accuracy*		% of current users who perform the examination (National survey) ²⁰	% of users who found the examination relevant (Delphi study) ⁹
	sensitivity	specificity		
First teaching seminar				
Residual urine (bladder) ²³	69.0	99.0	72%	100%
Hydronephrosis (kidney) ²⁴	70.2	75.4	46%	95%
Viable intrauterine pregnancy (uterus) ²⁵	97.0	98.0	87%	93%
Joint effusion (knee) ²⁶	0.84	0.93	46%	73%
Gallstone (Gall bladder) ²⁷	89.8	88.0	64%	98%
Second teaching seminar				
Ascites (abdominal FAST) ²⁸	100.0	100.0	37%	85%
Intrauterine device location (uterus)**			86%	95%
Constipation (Rectum diameter)*** ²⁹	95.5	94.1	19%	46%
Subcutaneous abscess (skin) ³⁰	96.2	82.9	42%	98%
Pleural effusion (lung) ³¹	88.0	90.0	28%	76%

*Diagnostic accuracy of POCUS reported in studies using the same scanning protocol as we intend to use in this intervention.

** No studies have been identified, where ultrasound is compared to a gold standard e.g. MRI or CT scan

*** Using POCUS for measuring rectal diameters as part of the ROM-IV criteria for diagnosing constipation in children is a relative new scanning modality and as such the GPs participating in the above-mentioned studies, have not been trained to perform the examination. However, the examination has been included in the NICE guidelines and the patient category is common in general practice.

Actioncards

A basis of the educational intervention are *actioncards* designed for each POCUS scanning modality. The *actioncards* are 1-page instructions specifying the indication for performing the POCUS examinations, the transducer and specific equipment settings needed to perform the examination, the POCUS procedure including transducer placement, image acquisition and optimization, the interpretation of the examination, possible pitfalls to be aware off and integration of findings into a clinical context.

The *actioncards* are used as résumés of the preparation literature, to structure the examination during the teaching seminars and as supporting guidelines that can be used or consulted during the examination if needed.

Figure 2 Actioncards describing a specific scanning modality

Actioncard: Rektum diameter

Spørgsmål som kan besvares ved point-of-care ultralyd i almen praksis:
Har barnet en øget rektum diameter som tegn på obstruktion?
(som en kontrol og ikke som en diagnostisk obstruktion) (se også tabellen side 11-13)

Overblik anatomi:
[Anatomical diagrams of the rectum and sigmoid colon]

Probe valg:
Korveks (abdominal probe) 5 til 7,5 MHz

Probens placering og udmåling:
Barnet skal ligge afslappet på ryggen med arme ned langs siden.
Proben placeres 2cm over symfyse i en nedadrettet vinkel (10-15 grader) fra transversalplanet mod os coccygis.
Blæren bruges som akustisk vindue (ideelt er blæren fyldt med min. 20% af forventet kapacitet for alderen: 30% (veder 4-13 år))
Rektal diameter måles fra ydre til ydre væg

Mulige fejlkloder:
En tom blære = minus akustisk vindue
Defekationstræng på scanningspunktet.

Patologi:
UL fund indgår i ROME IV kriterierne.
Kronisk forstoppelse = opfylder min 2 af ROME IV kriterierne (mindst 3 gange pr uge mindst 4 uger for børn > 4 år)
•Færre end 3 afføringer pr uge
•1 episode med fekal inkontinens pr uge
•Akutretent afføring / Overdreven tilbageholdelse af afføring
•Smertefuld afføring
•Stor feces mængde i rektum (UL fund: Cut-off 3,0 cm for børn i alderen 4-13 år)
•Rektocelex kvælling af afføring med stor diameter afføring

Kilder:
[References and sources]

Instruction videos

An instruction video is developed for each of scanning modalities included in the curriculum. All instruction videos are built with a structure similar to the structure of the *actioncards*: (1) Description of the indication for the examination, (2) Description of the needed equipment and equipment settings, and (3) demonstration of the conduction of the POCUS examination including tips and tricks regarding transducer placement, patient cooperation, image optimization etc.

The video demonstration of the performance of the POCUS scan will be divided into three pictures that are displayed simultaneously. One picture illustrating the ultrasound image on the monitor, one picture illustrating the hand on the transducer and thereby the transducer manipulation and one picture illustrating the anatomy.

Self-tests

Participants have access to self-tests before (pre-self-test) and after (post-self-test) each teaching seminar. These self-tests include 10-15 questions covering the learning outcomes of each teaching seminar and the pre- and post-tests for each seminar are largely similar. Some questions will concern ultrasound physics and basic scanning knowledge, others will be more application specific. Hence, the pre-self-test is designed to prime participants and create awareness about the learning outcomes of the following teaching seminar, whereas the post-self-test is designed as individual feed-back for participants and to create awareness about certain difficulties or missed information. The POCUS-teachers will monitor the results of these tests as part of their assessment of the participants learning progress.

Assignments

Throughout the learning process, participants will be invited to complete online assignments. The first assignment will be a questionnaire concerning the individual participants' capability, opportunity and motivation for using POCUS. These factors are known key-elements driving the behavior of healthcare providers³². Hence, we aim to identify previous experience with POCUS in order to assemble groups of participants with similar background for the hands-on sessions, identify possible barriers for the learning process in order to remove these or minimize the influence of these in the learning process and identify motivational factors to create awareness about these among participants and to use these in the learning process and mentoring. In between teaching seminars, a number of assignments will include uploading of POCUS scans for review and feed-back from the POCUS teachers. Before the second and third seminar day, an assignment will be sent to participants including a questionnaire where participants are asked to specify learning goals and questions for the coming teaching seminar in order to create awareness about these. Participants are encouraged to bring these to the teaching seminar to ensure that questions are covered or addressed during the seminar.

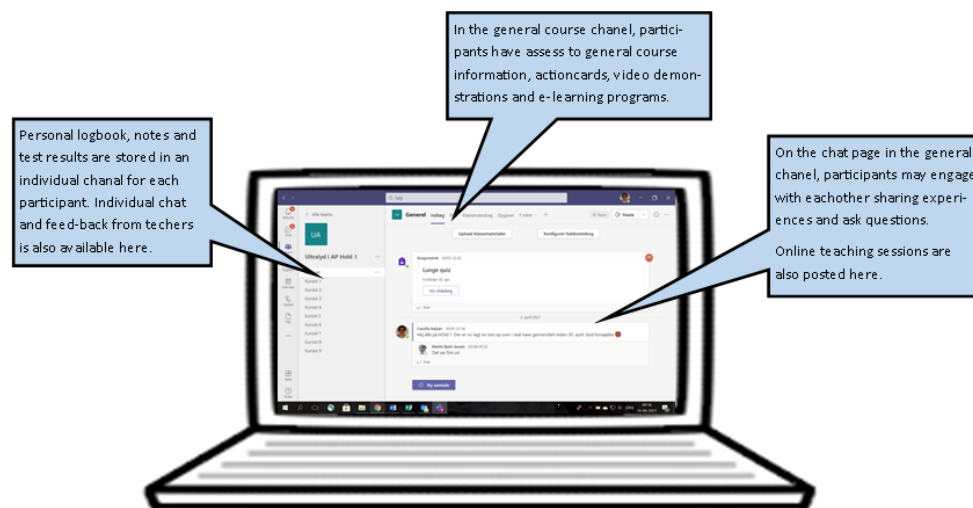
Webinars

In between teaching seminars, participants will be invited to participate in short webinars addressing obstacles and difficulties encountered in the learning process. The course director and the teachers will have gathered topics for the webinar from monitoring the individual participants' learning processes registered in logbooks, self-tests results, uploaded assignments or questions posed in the chat forum. Webinars will be approximately 30 minutes and participants will have the opportunity to ask questions during the sessions.

Online groupware platform (from day 1)

The educational intervention includes an online groupware platform, which all participants in the course and the teachers have access to.

Figure 3 Online platform to support the longitudinal learning process



Through the online platform participants will have access to:

1. Course information including timelines, course material, general and practical information.
2. Folders where *actioncards*, documents, instruction videos and other education material are uploaded.
3. A wall for sharing information between all participants. Here there is a group chat function, where participants may share experiences and reflections with each other the learning process. The teachers may also engage in this ongoing debate. Videos, documents, links etc. may be uploaded or posted and shared here and all participants will have the opportunity to comment on uploads and posts. Notifications for the participants are also posted here.
4. Invitations to webinars with the teachers, where tips and tricks are shared based on the participants uploaded or returned comments, feed-back, uploads and logbook registrations.
5. A document where notes can be shared between the participants during webinars or teaching seminars.
6. Link to the individual assignments to be completed by participants during the learning process. The teachers on the course have the opportunity to comment and respond in the assignment.
7. A logbook where the individual participant can note conducted POCUS examination during the learning process (date, type of POCUS, focus during the examination, reflections afterwards). A template specifies the number of examinations recommended at each phase in the educational intervention.
8. A direct chat opportunity with the teachers, where participants can have access to guidance and support from the course teachers. It is also possible to upload scanning images or videos for review by the teachers.
9. The individual structured feedback for all scanning modalities collected at teaching seminar 2 and 3.
10. Access to Pre/post self-quizzes before and after each training seminar and access to the results.

Participants will receive a notification by email or on their phones, when there is activity on the online platform. The overall purpose of this online platform is to support the participant in the continuous learning process. We aim to create awareness about the learning process, individual focus points and goals, the importance of training and gaining experience, and to make guidance available when difficulties/problems are encountered.

Teaching seminars (day 7, 30 and 90)

The educational intervention includes three teaching seminars on days 7, 30 and 90. All seminar days have a similar overall structure with a focus on hands-on training and the individual participant's development of scanning competences. However, the teaching aims are different on each seminar which means different focus in the teaching and different activities between seminar days.

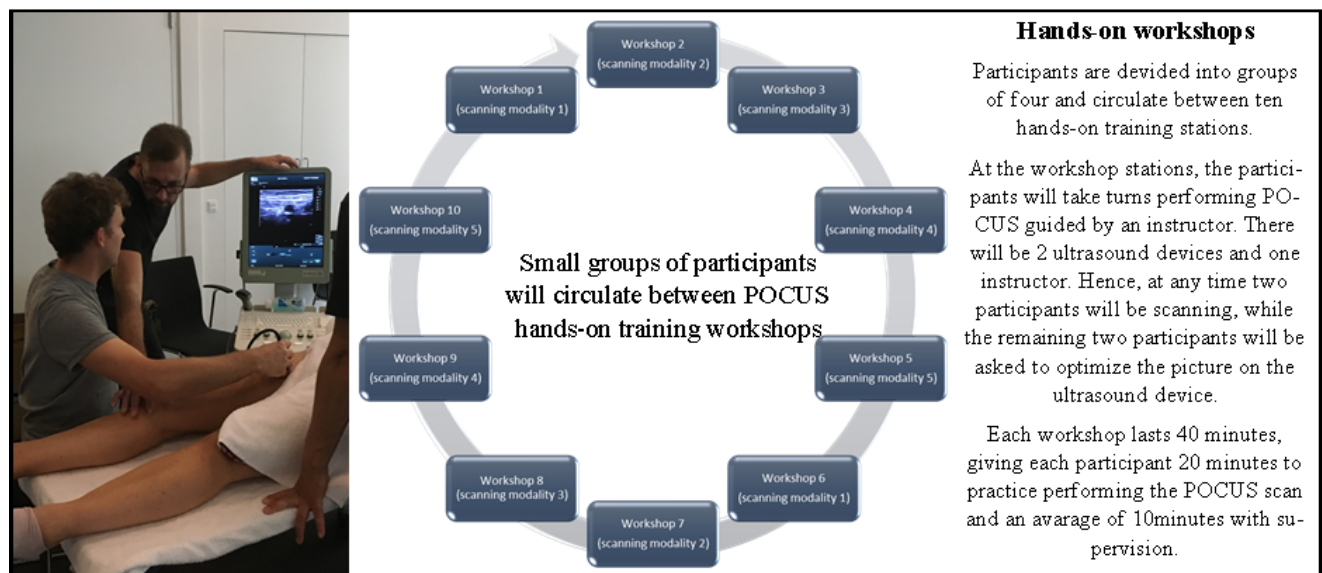
Teaching seminar 1

The aim of the first teaching seminar is to give participants first-hand experiences with performing POCUS scans and to create a foundation of knowledge and experience which is to be further developed in the coming months. Furthermore, the participants will learn to perform five of the POCUS scans in the selected curriculum.

The teaching seminar will start off with a short lecture summarizing the theoretical foundation for using POCUS and the participants preparation. The teachers will summarize the results of the first assignment and address questions, barriers and concerns raised by participants. Afterwards, a short lecture will follow introducing basic transducer manipulation and image optimization. The participants are then introduced to the five selected POCUS modalities in a short lecture summarizing the fundamentals of the five scans. The participants are then divided into small groups of four participants based on their POCUS experience as declared in the prior assignment. Participants working in the same practice, will be separated into different group to ensure a good

group dynamic. The small groups will now circulate between hands-on workshops (Figure 4). Each hands-on workshop will focus on one scanning modality. At the workshop, a teacher demonstrates the scanning modality according to the specific *actioncard*. The participants then take turns explaining the performance of the scan and practice performing the POCUS examination on healthy volunteers (or phantoms for pelvic ultrasound). The teacher will assist and provide guidance. During this first teaching seminar, the participants attend five workshops and thereby get their first experiences with conducting five of the POCUS examinations according to the actioncards. The participants attend the five workshops twice – first with a focus of getting the view and optimizing the view and second with a focus on optimizing the image. Hence, the workshops are constructed in order to (1) conceptualize the POCUS scan, (2) visualize the POCUS scan, (3) verbalize the POCUS scan and finally (4) practice the POCUS scan³³. The overall aim with the workshops is to enable participants to perform the five POCUS examination with assistance.

Figure 4. Structure of hands-on workshops on the first teaching seminar



The participants will be asked to bring their own ultrasound device for the teaching seminar in order to learn to master their own device. The small groups are composed to match members with similar equipment, prior knowledge and similar competence. At the beginning of the day, the participants will be asked to share their learning goals and specific challenges with their small group and at the end of the day, they will have time to discuss the learning outcomes of the day and consult the teachers with unanswered questions. After the teaching seminar a post-self-quiz is available (a replication of the pre-self-quiz) for the participants to create awareness about learning process and to illustrate to which extend the learning objectives of the first teaching seminar made been reached. The teachers will reach-out and offer extra support to participants where the test scores or performance during the hands-on workshops reveal problems or difficulties.

In-between teaching seminar 1 and 2 (practice phase)

After the first teaching seminar participants are encouraged to start practicing POCUS examinations. This phase in the learning process is considered and articulated as a training phase, where participants are to conduct as many POCUS examinations as possible with a primary aim of training without having to draw conclusions based on their scans. As such, participants are in this phase encouraged to treat patients as usual without taking scan results into account.

Participants are also encouraged to train examinations on volunteers e.g. family members, as the goal in this phase is to perform as many examinations as possible.

During the three weeks between the two teaching seminars, participants are encouraged to register all POCUS examinations in their individual logbook and note reflections and questions that occur during this process. It is recommended that participants aim to perform a minimum of three POCUS examinations of each scanning modality in the curriculum and upload one POCUS examination of each scanning modality for review by the teachers (assignments 2, 3, 4, 5, and 6). Midway in the practice phase (day 20), participants will be invited to participate in a half-an-hour webinar. In this webinar, one of the teachers will go through some of the encountered problems and difficulties uploaded or posted on the online platform. Participants will also have the opportunity to ask questions.

Prior to the second teaching seminar, assignment 7 is sent to the participants. In this assignment participants have to register their specific focus points and individual learning goals for the second seminar as well as any questions they may have to the teachers.

A specific pre-self-quiz will be available before teaching seminar 2. This self-test will access basic knowledge of the five POCUS scans introduced at the first teaching seminar and prime the participants for the learning objective of the second teaching seminar.

Teaching seminar 2

From evaluation of previous POCUS training sessions, we know that GPs usually start off practicing their scanning skills by selecting a few scanning modalities in the curriculum. Thereby they develop a comfort zone of scanning modalities before they move on to include more scanning modalities in their portfolio. Therefore, the aim of the second training seminar is to (1) validate the scanning modalities that the participating GPs have been practicing in order to adjust and improve their performance, (2) to repeat and refresh the scanning modalities in the curriculum, that the participants have not been practicing in-between the teaching seminars to make the participant comfortable to move on to train these or even include these in their portfolio, (3) to provide feedback on performance and allow for guidance and support on encountered problems or difficulties and (4) to introduce five new POCUS modalities.

The teaching seminar starts off with a plenum session where encountered experiences, problems or difficulties are shared and discussed. The teachers will address registrations and reflections from the logbooks, assignment 7 and common difficulties identified in the uploaded scans. The participants are invited to openly share and discuss. Afterwards, the participants are divided into small groups of four participants and they then circulate between hands-on workshop stations, as they did in teaching seminar 1. The first five workshop stations will include the five scanning modalities taught at the first teaching seminar. Here, the teacher will not demonstrate the scan or lecture, instead the participants will take turns demonstrating the scan for the teacher. The teacher will then assess the participants' individual scanning competences using an adapted version of the OSAUS score including only items 2-5 which focus solely on the technical and practical ability to produce ultrasound images. It has been the intention from the beginning, that

items 1 and 6 should only be used if applicable¹³. The teachers will give feedback on ways to improve performance and help the participants to set new learning goals and focus points for the continuous learning process. The feedback and teacher suggestions are uploaded to the participants individual channels on the online platform, allowing participants to consult these at a later stage in the learning process. While one participant is demonstrating the scan for the teacher using one of the scanners at the workshop, the remaining three participants will practice performing the scan and give each other feedback using the other ultrasound device. Following the first five workshops, there will be a short lecture for all participants, where the five new scanning modalities are explained and elaborated. After this the participants return to the workshops.

The next five workshop stations will introduce five new scanning modalities from the selected curriculum. At the workshop, a teacher will demonstrate the scanning modality according to the specific *actioncard*. The participants will then take turns explaining the performance of the scan and practice performing the POCUS examination on healthy volunteers (or phantoms for pelvic ultrasound). The teacher will assist and provide guidance.

After the second teaching seminar a post-self-quiz is available (a replication of the pre-self-quiz for teaching seminar 2) for the participants to create awareness about learning process and to illustrate to which extend the learning objectives of the first teaching seminar made been reached. The teachers will reach-out to participants, where the test scores reveal problems or difficulties, as well as participants, where the OSAUS score revealed specific difficulties. These participants will be offered additional support if needed.

In-between teaching seminar 2 and 3 (developing phase)

This phase in the learning process is considered and articulated as a developing phase, where participants continue to develop their scanning skills and routines. The participants are encouraged to use POCUS examinations on all patients with relevant clinical conditions suited for POCUS and to work with the integration of POCUS into their clinical practice and medical decision making. It is important in this phase that the participants develop routines and become comfortable performing POCUS examinations. During the eight weeks between the teaching seminars 2 and 3, participants are encouraged to register all POCUS examinations in their individual logbook in the online platform and note reflections and questions that occur during this process. The participants will still have the opportunity to consult the teachers during this phase by uploading questions, images or videos to the online platform. It is again recommended that participants perform a minimum of three POCUS examinations on patients within each scanning modalities during the eight weeks and that participants upload at least one POCUS examination of each of the five new scanning modalities for review and feed-back (assignments 8-12).

During the eight weeks, participants will be invited to participate in two half-an-hour webinars (on day 50 and 75). At these webinars, one of the teachers will go through some of the encountered problems and difficulties uploaded or posted on the online platform and present images and videos of common pathologies with the 10 selected POCUS modalities. Participants will also have the opportunity to ask questions and the teacher will have an ultrasound device and a volunteer available for live POCUS demonstration.

Before the third and final teaching seminar, the participants will be asked to complete a pre-self-quiz and to send in a list of questions or topics that they want included in the final teaching seminar (assignment 13).

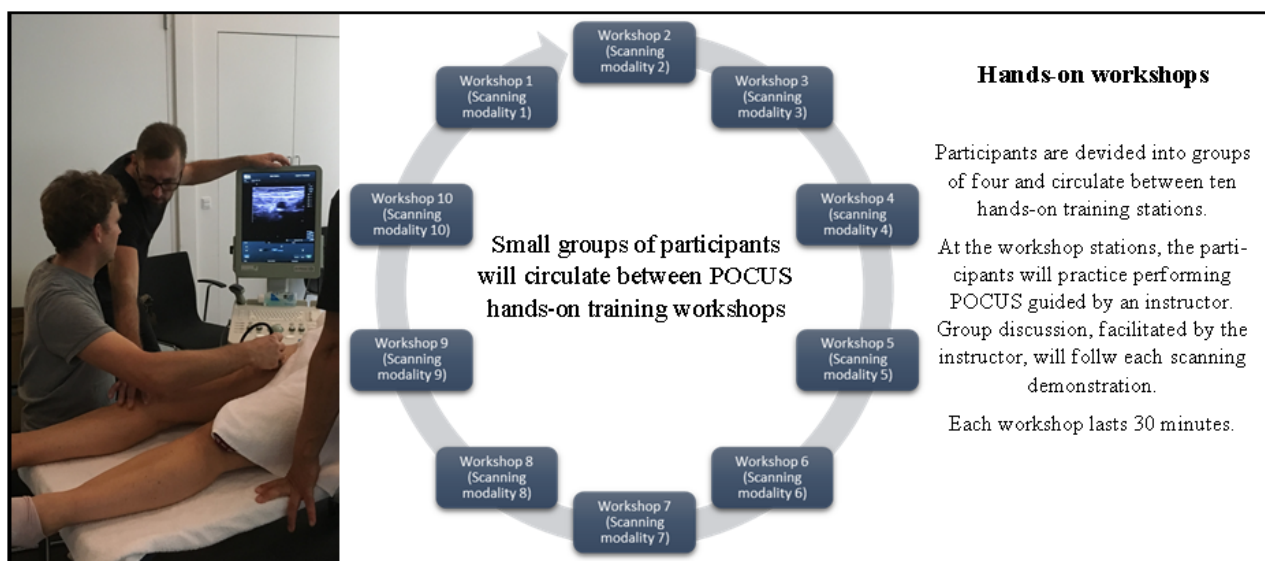
Teaching seminar 3

Before the final teaching seminar, the teachers will prepare feedback for each participant based on the information gathered about each participant, i.e., from notes in the logbook, the uploaded scans, impressions from teaching seminars, the correspondence in the chat function, etc.

The structure of this final teaching seminar is similar to previous seminars. However, besides validating, adjusting and improving the participants' POCUS examinations, the goal is also to evaluate the participants' learning process, scanning competence and to offer guidance for future development.

Like the second seminar, this teaching seminar starts off with a plenum session where encountered experiences, problems or difficulties are shared and discussed. The teachers will address questions raised on the online platform and common difficulties identifies in the uploaded scans. The participants are invited to openly share and discuss. Afterwards, the participants are divided into small groups of 4 participants and they then circulate between hands-on workshop stations, as they did on the previous seminars. At the workshop stations, the participants will take turns demonstrating the POCUS scan for the teacher (figure 5). The teacher will then assess the participants' individual scanning competences using item 2-5 on the OSAUS score, give feedback on ways to improve performance and help the participants to set new learning goals and focus points for the continuous learning process. The participants will also receive suggestions for improvement from fellow participants, as the instructor invites to a discussion about the use of the scanning modality in general practice. The feedbacks and teacher suggestions are uploaded to the online platform, so participants may consult these at a later stage.

Figure 5. Structure of hands-on workshops on the third teaching seminar



At the end of the teaching seminar, participants will be asked to evaluate the educational intervention, their own learning outcome and to identify unanswered questions in the small groups. Afterwards, these are discussed in a final plenary session for all participants and teachers.

If needed, the teachers will upload additional information to the online platform to support the participants' further learning.

After the teaching seminar a final post-self-test is available (a replication of the pre-self-test for teaching seminar 3) for the participants to create awareness about continuous learning process and to illustrate to what extent the learning objectives of the teaching seminar have been reached. The teachers will reach out to participants, where the test scores reveal problems or difficulties, as well as participants, where the demonstration of the scan revealed specific difficulties. These participants will be offered additional support.

Competence assessment by experts

On the third teaching seminar, participants will have their scanning competence assessed by external experts. These experts are blinded to the participants previous experience and learning process. During the workshop rotation, each participant will step-a-side to have their competence assessed by a POCUS expert. This assessment will be staggered from the scanning modality being the topic of the workshop. Hence, the participants will first have the workshop with a specific scanning modality and then immediately after, during the next workshop, they will take turns, stepping-a-side for 10 minutes to have their scanning competence for the modality assessed.

The experts will assess the participants by asking the following questions:

- In which clinical scenarios would you perform this POCUS examination (Item 1 in the OSAUS)

The experts will ask participants to demonstrate the POCUS examination (for maximum five minutes) to assess the following:

- Applied knowledge of the ultrasound equipment (Item 2 in the OSAUS)
- Image optimisation (Item 3 in the OSAUS)
- Systematic examination (Item 4 in the OSAUS)
- Interpretation of images (Item 5 in the OSAUS)

The experts will present the participants with two picture of common pathology and ask the participants the following questions:

- How would you interpret these ultrasound findings? (Item 5 in the OSAUS)
- If you were to describe this examination in the medical record, what would you write? (Item 6 in the OSAUS)
- What would you do if you found it? (Item 7 in the OSAUS)

Immediately before each competence assessment by experts, participants will be asked to fill out a questionnaire where they declare whether or not they have POCUS scanning competence within this scanning modality to perform the scan un-supervised in general practice. The expert assessor are blinded to this declaration.

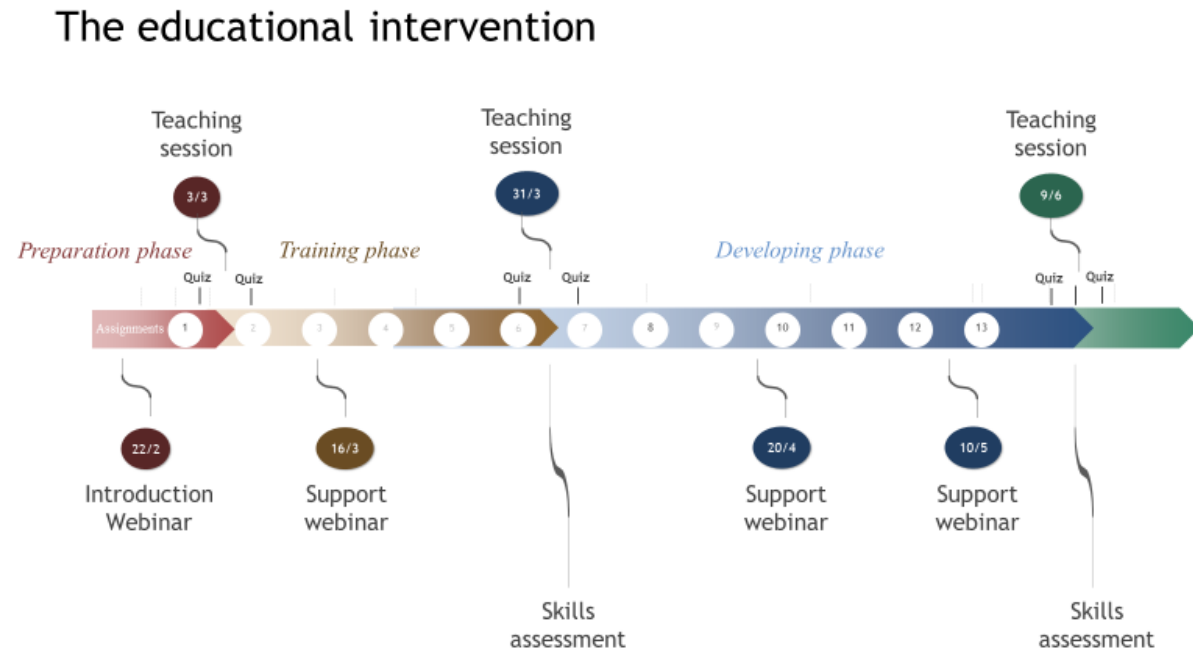
Participant commitment

The educational intervention requires considerable commitments from the participants (Figure 6). This will be outlined in both the course description, the introduction webinar and on the first teaching seminar. Participants will have to allocate three whole days for the teaching seminar and considerable time to practice scanning skills especially during the training phase (days 8-29). Furthermore, time will be allocated to perform assignments and follow the discussion on the online platform.

To ensure this commitment, time will be spent on building group relations on the first teaching seminar. In addition, a teacher will be allocated each participant as a mentor during the learning process. The mentor will monitor individual progress in the online platform and correspond with

the individual participant in the chat functions, provide feed-back on assignments and reach out to participants, who fail to be active on the online platform.

Figure 6. Overview of participant activities in the educational intervention



11b Criteria for discontinuing or modifying allocated interventions for a given trial participant

The trial may be discontinued for a GP in case of withdrawal of an informed consent. Hence, data collection will stop for that person at the time of withdrawal of the informed consent. Otherwise, this is an intention-to-treat study hence participants will not be excluded because of low adherence to the educational elements. However, we will collect data of the degree of participation for each participant.

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence

The teacher will act as mentors for the participants and monitor participants' activity on the online platform. The teachers will monitor the activity of the participants, they are mentoring and reach out to participants, who fail to be active on the online platform or complete assignments. Reminders are sent to the GPs during the six months to remind them to register all POCUS examinations performed during clinical work.

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

The GPs are asked to refrain from seeking other POCUS education or courses during the study (months 1- 6). Still, information seeking e.g. through internet sources or books are allowed throughout the study.

12 Outcome measures

Primary outcomes:

The primary outcome is the Objective Structured Assessment of Ultrasound Skills (OSAUS) score scored after three (P1) and six months (P2).

The OSAUS assessment tool has been developed and validated as a generic tool for assessing scanning competence¹³. The OSAUS scale consists of seven items: ‘indication for the examination’, ‘applied knowledge of ultrasound equipment’, ‘image optimization’, ‘systematic examination’, ‘interpretation of images’, ‘documentation of the examination’ and ‘medical decision-making’ and each item is rated using a provided five-point Likert-scale with descriptions of performance ranging from very poor (score = 1) to excellent (score = 5). All items are weighted equally, as high inter-item correlation have been found previously¹⁴. Hence, for each scanning modality a total score from 7 to 35 points may be achieved.

(P1): The summarized OSAUS score after the educational period (three months after baseline) for all ten modalities will be calculated as percentage of maximum score and presented as median, IQR, minimum and maximum score.

(P2): The summarized OSAUS score after six months for all ten modalities will be calculated as percentage of maximum score and presented as median, IQR, minimum and maximum score.

Secondary outcomes

(S1). The total OSAUS score and the total items scores for each scanning modality included in the curriculum after the educational period (three months after baseline) will be calculated and presented as median, IQR, minimum and maximum score.

(S2). We calculate the proportion of GPs, who achieve a minimum OSAUS score of three for all seven domains for each of the ten scanning modalities after the educational period (three months after baseline). As variation in scores can occur between the four expert assessors. We will normalize the scores by multiplying a given assessors score with $(0.2 \times \text{sum of scores of all five assessors} / \text{the given assessors mean score})$ prior to calculating the proportion of successful GPs.

(S3): We calculate the proportion of GPs, who achieve a minimum OSAUS score of three for all seven domains for each of the ten scanning modalities after six months.

(S4): We calculate the proportion of GPs, who rate themselves as competent to perform POCUS un-supervised in general practice, after the educational period (three months after baseline), within each of the ten scanning modalities.

(S5): We calculate the proportion of GPs, who rate themselves as competent to perform POCUS un-supervised in general practice, after six months, within each of the ten scanning modalities.

Implementation process-related outcomes

(PR1): The GPs keep a log book of all scans they perform. The number of scans of the 10 modalities performed during months 1 to 3 and month 4 to 6 are summarized. Results are presented as the mean number of performed POCUS examinations by each GP during months 1 to 3 and during months 4 to 6.

(PR2): The number of adverse events and near-miss cases associated with the use of POCUS during months 1 to 6 will be summarized for each of the ten scanning modalities. Results will be presented as total numbers and frequencies.

(PR3): We will graphically evaluate the mean OSAUS score (y-axis) at the end of the educational intervention (3 months after baseline) as a function of each of the following educational aspects (x-axis).

- a. course days
- b. webinars,
- c. pre-and post-self-quizzes
- d. assignments (upload and feed-back)
- e. scans performed during the educational intervention

Background characteristics of participating GPs

At baseline the following participant characteristics will be collected: Age (years), gender (M, F, other), year of graduation from medical school, experience as a GP working in general practice (years), previous experience with ultrasound use (yes/no), previous training in ultrasound use (yes/no), scanner type (low range, mid range, high end), type of employment (practice owner/ employed/other), type of practice (collaboration, partnership, solo), location of practice (urban, rural, mixed), distance to nearest radiology department (km), number of patients assigned to the practice, number of GPs working in the practice will be presented.

13 Time schedule

Figure 7 Study timeline

Week	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
webinar																												
Teaching seminar																												
Skills assessment																												
Educational period																												
Transition period																												

Teaching seminars: Marts 3rd and 30th and June 9th 2022

Skills assessment: June 9th and September 1st 2022

Data collection educational period (months 1-3): Marts 3rd – June 9th 2022

Data collection after educational intervention (months 4-6): June 10th – September 1st 2022

14 Sample size

Our potential study population is 20 GPs who have signed up to participate in an ultrasound course organized by PLO-e. We expect a participation rate of 80% corresponding to 16 GP.

With 16 participants the total number of possible completed 7-item OSAUS questionnaires will be 16 for each modality and 160 for the combined estimate after 3 months and after 6 months. This is considered sufficient to estimate mean estimates and provide confidence intervals with acceptable spread.

15 Recruitment

Generally, to successfully change health care professionals' behaviours an intervention has to address motivation, capability, and opportunity³². From interviews with GPs not using POCUS (unpublished data) and a national survey²⁰, we have identified the following specific barriers to implementation of POCUS in general practice:

- cost of the ultrasound equipment
- lack of remuneration for performing POCOS,
- lack of education in the use of POCUS,
- lack of guidelines,
- high workload and time pressure in general practice.

This intervention was designed to take these potential barriers into account. From cohort studies conducted in Danish general practice we know that the time consumption for performing POCUS is below 10 minutes for the majority of novice POCUS users⁸ and with a median of 5 [IQR 3-8] minutes among experienced POCUS users¹⁰. However, we do not know if implementing POCUS in general practice overall increase or decrease work load.

Assignment of interventions

16a Allocation Sequence generation

n/a

16b Allocation concealment mechanism

n/a

16c Implementation

n/a

17 Blinding

Expert assessors performing the competence assessment (primary outcomes) have a medical background and are considered experts in the field. They will not be teaching participants in the training program. They will be blinded to the participants prior experience with POCUS, the number of performed POCUS examinations, and any other elements in the participants' learning process.

The researcher cleaning the data set and responsible for analyzing the primary outcome will have no knowledge of participants. He is a researcher with a physiotherapy background.

Data collection, management, and analysis

18a Data collection - Plans for assessment and collection of outcome, baseline, and other trial data

The OSAUS ultrasound competence assessment tool have been developed as a genetic tool to assess ultrasound competence across medical specialities. The assessment tool was developed through a Delphi study¹³ and it has been used to assess clinicians' ability to transfer learning from an ultrasonography course into diagnostic performance on patients¹¹. Furthermore, the tool has been found valid and reliable to distinguish between novice POCUS users and experts³⁴.

The OSAUS assessment tool measures competency according to seven key domains: 1) Indication for the examination 2) Applied knowledge of ultrasound equipment 3) Image optimization 4) Systematic examination 5) Interpretation of images 6) Documentation of examination and 7) Medical decision making. Each domain is rated using a five-point Likert scale with descriptions of performance ranging from very poor (score=1) to excellent (score=5).

Figure 8. The OSAUS competence assessment tool

	1	2	3	4	5
1. Indication for the examination					
If applicable. Reviewing patient history and knowing why the examination is indicated.	Displays poor knowledge of the indication for the examination		Displays some knowledge of the indication for the examination		Displays ample knowledge of the indication for the examination
2. Applied knowledge of ultrasound equipment					
Familiarity with the equipment and its functions, i.e. selecting probe, using buttons and application of gel.	Unable to operate equipment		Operates the equipment with some experience		Familiar with operating the equipment
3. Image optimization					
Consistently ensuring optimal image quality by adjusting gain, depth, focus, frequency etc.	Fails to optimize images		Competent image optimization but not done consistently		Consistent optimization of images
4. Systematic examination					
Consistently displaying systematic approach to the examination and presentation of relevant structures according to guidelines.	Unsystematic approach		Displays some systematic approach		Consistently displays systematic approach
5. Interpretation of images					
Recognition of image pattern and interpretation of findings.	Unable to interpret any findings		Does not consistently interpret findings correctly		Consistently interprets findings correctly
6. Documentation of examination					
Image recording and focused verbal/written documentation.	Does not document any images		Documents most relevant images		Consistently documents relevant images
7. Medical decision making					
If applicable. Ability to integrate scan results into the care of the patient and medical decision making.	Unable to integrate findings into medical decision making		Able to integrate findings into a clinical context		Consistent integration of findings into medical decision making

doi:10.1371/journal.pone.0057687.t003

From: Tolsgaard MG, Todsén T, Sørensen JL, Ringsted C, Lorentzen T, Ottesen B, et al. (2013) International Multispecialty Consensus on How to Evaluate Ultrasound Competence: A Delphi Consensus Survey. PLoS ONE 8(2): e57687. <https://doi.org/10.1371/journal.pone.0057687> (reference 13)

Education of POCUS expert assessors

The POCUS expert assessors all have prior experience using the OSAUS score. Still, prior to the assessment of the participants' performance in this study, the POCUS experts participate in a 90-minutes online training session with the principal investigator (CAA). During this training session, the POCUS experts are presented to the OSAUS score and the procedure for assessing the participants in this study. The POCUS experts are instructed to rate according to the standard expected from a GP, who is capable of performing POCUS unsupervised in general practice. During the training session, the POCUS experts will rate five POCUS videos individually and afterwards compare and discuss the results until agreement is reached. A similar training of POCUS raters has been reported in previous studies^{14,34}.

Self-rated scanning competence

Before the competence assessment by experts, the participants are asked to fill out a questionnaire, where they will declare whether or not they have the scanning competence to perform the given POCUS examination un-supervised in general practice.

Registration of performed POCUS examinations

The paper registration of clinical practice during patient consultations in general practice using APO registration sheets is a well-known and established method in Danish general practice³⁵. A paper logbook for participants will be developed as registration sheets for the participating GPs registration of POCUS use during the educational intervention (months 1-3 after baseline) and in the months following the intervention (months 4-6 after baseline). The registration sheets will be adapted versions of the sheets used in a previous APO studies⁸ (figure 9). This registration sheet has been used in a pilot study of the educational intervention (unpublished material).

Fig.9. Adapted version of a registration sheet used in a previous cohort study

Læge:

Vælgst lav registreringer på en linje for hver patient, som du har undersøgt med ultralyd													
		Skannings modalitet						Konsekvens af skanning - uddyb					
		1	2	3	4	5	6	7	8	9	10	11	12
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													

1 M-linier - Rektusdiaphragma
 2 M-linier - Rektus abdominis
 3 M-linier - Hydrocefalus
 4 M-linier - Aorten (FAST)
 5 M-linier - Galdeblære
 6 Graviditets - Spinalstræng
 7 Øvre og nedre Skjoldbruskkirtel
 8 AASG - Udenrigs Læred
 9 Hæm - Polytrauma / Abdomen
 10 Lunge CT - Pleuralblødning
 11 Lunge CT - Pleuralblødning
 12 Lunge CT - Pleuralblødning
 Åben konsekvens

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Adverse events and near-miss cases

Adverse events (AE) and serious adverse events (SAE) related to or possibly related to the use of POCUS will be registered during all time after the training sessions.

At the teaching sessions, participating GPs will be taught how to report AE and SAE related or possibly related to the use of POCUS as well as near-miss cases. These events will be reported to the study adverse event committee in an online questionnaire specifically designed for this purpose. The participants will have a link for an online questionnaire in SurveyXact (Rambøll, Aarhus Denmark) where they will register: (1) Type of POCUS, (2) indication for the examination, (3) description of the event, (4) participant's reflections after the events and (5) questions for the adverse events committee.

The reporting of AE/SAEs to the study adverse event committee does not substitute or have any influence on the GPs responsibility to report adverse events to the Danish authorities (UTH anmeldelse).

Educational activities

The participants' participation and activity in the educational elements will be registered during the educational period (months 1-3) on the online platform and by the principal investigator using Excel.

18b Data collection - Plans to promote participant retention and complete follow-up

During the study, the principal investigator is available for consultation for the participating GPs in order to resolve any problems or obstacles. Monthly reminders will be sent to the participating GPs remaining them to include patients and contact the research team in case of problems.

19 Data management

The OSAUS assessment will be filled out by the expert assessors in questionnaires using tablets. The expert assessors will access the SurveyXact app (Rambøll, Aarhus, Denmark) on the tablets using unique access links. The Raters will then insert the GP ID number and fill out the questionnaire. After filling out the questionnaire, the access will close. As internet access may be unstable at the training facilities, the questionnaire can be filled out on both offline and online tablets. If the tablet is online, the questionnaire is stored directly on SurveyXact's server. If the tablet is offline, the questionnaire is stored safely in the app for direct upload when internet access is achieved. Questionnaires stored in the app cannot be accessed. The questionnaires stored on SurveyXact's server can only be accessed by the research team. Backup copies from the SurveyXact server are weekly collected and stored at a secure server at Aalborg University during the data collection period.

The participating GPs will be asked to bring paper versions of the registration sheets (Logbook) at the third training day and the final day of skills assessment, where the principal investigator will collect these and bring them to CAM AAU, where the questionnaires will be imputed into the database by a research assistant.

All study data registered on the online platform will be transferred and imputed in an excel sheet at the end of the educational intervention. All digital study related data are stored on secure server on Aalborg University and handled according to the General Data Protection Regulation.

20a Statistical methods for analysing primary and secondary outcomes.

All statistical analyses will be performed using STATA version 17 (StataCorp, Texas, USA) and analyzed according to a predefined statistical analysis plan, which will be uploaded prior to the data collection for the primary outcome (three months after baseline).

20b Methods for any additional analyses (e.g. subgroup and adjusted analyses).

Sensitivity analyses will be performed without imputation of missing values by only including complete OSAUS scores.

Sub-analyses will be performed to explore the importance of different educational elements in the intervention. These sub-analyses will be defined in the statistical analysis plan.

20c Missing data

A predictive mean matching (pmm) imputation method will be used to fill in missing values by the command “mi impute pmm” in Stata³⁶, for all OSAUS scores after 3 and 6 months.

Predictive mean matching (PMM) is a partially parametric method that matches the missing value to the observed value with the closest predicted mean³⁷.

Data monitoring

21a Data monitoring committee (DMC).

The principal investigator (CAA) will monitor the data collection and contact the project steering committee in case of problems related to data collection or the validity of the collected data. The principal investigator (CAA) will also contact the steering committee in care of participant drop-out.

21b Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial

n/a

22 Harms

The participating GPs will be obliged to report any Suspected Unexpected Serious Adverse Reactions (SUSARs), Serious Adverse Events (SAEs) and Adverse Events (AEs) related or possibly related to the use of POCUS to the adverse event committee.

23 Auditing

n/a

Ethics and dissemination

24 Research ethics approval

The study will be performed in accordance with the Declaration of Helsinki. The project was notified to the regional ethical committee (Den Videnskabsetiske Komité for Region Nordjylland, reference number 2022-000764) who responded that according to Danish Law (komitélovens § 14, stk. 2), no ethical approval is needed for this project.

The project has been registered and conducted according to the regulations of the Danish Data Protection Agency (registration number ID-242-2).

25 Protocol amendments

Any modifications to the protocol that will impact the conduct of the study such as study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects will be communicated to the Ethics Committee of North Denmark Region for approval. The registration on clinicaltrials.gov will be updated if any of the above-mentioned modifications are made.

26a Consent or assent

Informed consent form the participating GPs will be collected by the principal investigator prior to the study.

26b Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

n/a

27 Confidentiality

Personal information about participants consenting to participate will be stored on a secure server at Aalborg University. All data will be kept for 10 years after completion of the study which in accordance with The European Code of Conduct for Research Integrity.

28 Declaration of interests

The authors declare that they have no competing interests.

29 Access to data

During the educational intervention the following authors will have access to data on the online platform (UM, TMJ, TL, NS, LD, BS, CAA). Participants will during the educational intervention have access to their own data shared on the online platform. The following authors will have access to collected data stored at the secure server at Aalborg University (AR, MBJ and CAA).

30 Ancillary and post-trial care

Any participants who suffer harm from trial participation will be eligible to seek compensation by The Patient Compensation Association.

31a Dissemination policy

We aim to publish positive, negative or inconclusive results of the study in a peer-reviewed journal. The project group will also present results at conferences.

31b Authorship eligibility guidelines

We aim to follow the definition of authors defined on ICMJE's four criteria¹:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

31c Plans for granting public access to the full protocol, participant-level dataset, and statistical code

It is unsure if data can be anonymized sufficiently to be made publicly available.

32 Informed consent materials

The Danish informed consent form will be attached as an appendix

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