RESEARCH UNIT
FOR GENERAL PRACTICE
Aalborg

Study protocol

The POCUS IN PRACTICE study Implementation of point-of-care ultrasonography in general practice

A stepped wedge cluster randomized trial

Center for General Practice at Aalborg University
13-12-2022

Study protocol according to the SPIRIT 2013 Checklist

Administrative information

1 **Title**

POCUS in Practice: Implementation of point-of-care ultrasonography in general practice: A stepped wedge cluster randomized trial

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: NCT05696821
Date of registration in primary registry	The study protocol will be uploaded to clinical trials
Secondary identifying numbers	AAU study registration: 2022-068-03601
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	Camilla Aakjær Andersen caakjaer@dcm.aau.dk
Contact for scientific queries	Camilla Aakjær Andersen caakjaer@dcm.aau.dk
Public title	The POCUS IN PRACTICE study
Scientific title	Implementation of point-of-care ultrasonography in general practice: A stepped wedge cluster randomized trial
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	**Inclusion criteria:** 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 **Exclusion criteria:** 1. GPs with a possible conflict of interest 2. No signed informed consent to participate.
Study type	A stepped wedge cluster randomized trial
Date of first enrolment	Expected: January 2023
Target sample size	Two hundred general practitioners
Recruitment status	Has started
Primary outcome(s)	(P1) To estimate the effect of a POCUS intervention for primary care clinics on the number of registered reimbursement codes. (P2) To estimate the effects of a POCUS intervention for primary care clinics on the number of referrals send to secondary care specialists.

Key secondary outcomes	We will estimate if POCUS leads to change in: S1. Number of consultations in primary care (e-mail, telephone, video, visits) S2. GPs' perceived stress (Cohen's 10-item Perceived Stress Scale) S3. GPs' job satisfaction (Warr-Cook-Wall Job satisfaction Scale) S4. GPs burnout symptoms (Maslach Burnout inventory) S5. Healthcare costs And in addition, we will evaluate: S6. Patients experiences following POCUS use S7. Adverse events reported by the participating GPs following the intervention S8. The patient pathway and the quality of selected POCUS applications used in general practice

3 Protocol version

Version 5.0 December 27th 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. Professor, GP, Janus Laust Thomsen (JLT) will provide support in the health economic evaluation and senior researcher Annette Fischer Pedersen (AFP) will provide support regarding the evaluation of GPs' work environment. Senior researcher Søren Lundbye-Christensen (SLC) will provide statistical support. Allan Riis (AR) will draft the data handling and statistical analysis plan (SAP), clean, and analyze the dataset.
CAA and MBJ wrote the first draft of the protocol.
Ulrike Mehnert (UM), Thomas Løkkegaard (TL), Troels Mengel-Jørgensen (TMJ), Liv Dyre (LD), Nicolai Soll (NS), Bo Stork (BS), Kasper Lorentzen (KL), MBJ, Louise Pihl (LP), Christian Sjernebjerg (CS) and Søren Kæseler Andersen (SKA), Christian Valentiner-Brandt (CVB), Torsten Rudbæk Rahbek (TRR), Uwe Lorenzten (UL), Lukasz Damien Kamionka (LDK), Morten Sparholt (MS), Rasmus Rottmann Johansen (RRJ), Jens Tilma (JT) and Jesper Wamberg (JW) will participate as teachers in the training program
All participating researchers areexpected to make valuable scientific additions to the draft and will be invited to be co-authors on subsequent manuscripts based on these data.
The expected author list when reporting the overall results 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)
Contact name: Camilla Aakjær Andersen
Address: Center for General Practice in Aalborg, Fyrkildevej 7, 1., 9220 Aalborg East, Denmark
E-mail: caakjaer@dcm.aau.dk

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

Increased complexity and demands

Increased longevity results in more patients with a higher burden of disease and disability. These patients are complex to handle which increases the future need of healthcare services[1 2] Simultaneously, hospitals are becoming increasingly specialized and centralized with patients' length of stay shortened[3 4] leading to a shift in healthcare services from hospitals to primary care. The general practitioner (GP) must therefore handle more complex patients, finalize the examination and treatment of more patients, and need the capabilities to refer to the correct sub-specialized department. This renders the diagnostic capacity and precision in the GP's office increasingly important. Point-of-care ultrasonography (POCUS) may be of benefit in this regard[5].

The potential of point-of-care ultrasonography

In a cohort study of patients being scanned by 20 GPs, we found that POCUS changed their diagnosis in 49% of consultations, increased the diagnostic confidence in 89% of patients, and changed the intended referral plan in 51% of consultations[6]. POCUS is widely used by GPs in some countries[7], but only about 12% of Danish GPs currently use the POCUS (unpublished data[8]). Hence, there is a great potential for further disseminating this technology. Still, we do not know if the positive results obtained in a smaller group of GPs are valid in a broader GP population and to what extend GPs will adapt this technology if offered training in a supportive setting. Several studies have demonstrated that POCUS competences can be achieved in short training courses, but to maintain skills and develop skills is a process over time[9 10 11]. To fully profit from GPs using POCUS, it has to be integrated in clinical pathways and this requires sufficient competences and a widespread plan for implementation.

Enticing general practitioner to scan

Motivation, competence, and opportunity are important aspects to consider in relation to changing the behaviour of health care professionals[12]. In interviews with POCUS users who were early adopters of the

technology, they reported that POCUS can increase their job satisfaction, professional contentment, and sense of performance[13]. It is not known if this also applies if POCUS is implemented broadly to GPs. From a national survey[8], we found that Danish GPs see the potential in using POCUS, but have concerns about capability (lack of guidelines and education in the use of POCUS) and opportunity (economical aspects, time pressure and workload). Furthermore, half of Danish GPs report at least one burnout symptom[14]. Hence, if POCUS is implemented on a larger scale in general practice, it will be important to evaluate how it affects the GP population.

Patients' perspectives and safety

Danish patients scanned in the GPs' office described that POCUS improved the service and quality in care[15]. However, there are no reported safety data regarding a broad implementation of POCUS in general practice and problems relating to the initial phase. Therefore, a surveillance of adverse events during the implementation could contribute with new knowledge about patient safety by identifying scanning types and procedures that potential carry a risk, when GPs begin using POCUS.

Health economics

Despite the fact that POCUS has been broadly implemented in primary care in some countries[7] there are very few studies describing the cost-effectiveness of this[5]. In addition, transferring cost-effectiveness evaluations from one health care system to another can be challenging[16]. In a Danish health economic evaluation of women consulting their GP due to vaginal bleeding early in their pregnancy, we found that it was cost-effective to have the GP scanning compared to usual practice (referral to specialist in private gynaecology practices or hospital departments)[17]. However, there is a need for a broader health economic evaluation of implementing this technology in general practice.

Organizational aspects

In recent years, an overarching program theory implementation plan has directed the research and implementation of use of POCUS in general practice in Denmark. The plan was developed in a collaboration between Center for General Practice at Aalborg University (CAM AAU)[18] and the Danish Society for Ultrasonography in General Practice (DAUS)[19] to ensure the quality and safety of the implementation of POCUS in general practice.

The services provided by Danish general practice are regulated by an agreement between the Organisation of General Practitioners in Denmark (Praktiserende Lægers Organisation - PLO) and the Danish Regions, who are responsible for providing public health care services to all citizens. In their 2022 agreement (OK22) it was decided to establish a research project to evaluate the use of POCUS in Danish general practice and CAM AAU was commissioned to do this. In OK22 it was stated that the research project should prioritize participants in rural areas, deliver the intervention across the country, ultrasound courses should be delivered by the General Practitioners in Denmark Continuous Education Organization (PLO-e), and current POCUS-users should be allowed to participate in the study. CAM AAU has conducted two smaller preparatory studies that will be followed by a large stepped-wegde cluster randomized trial (SW-CRT) to fulfil this task.

Using a stepped wedge cluster randomised trail design

A SW-CRT design[20] was chosen to facilitate roll out of the intervention, as the delivery of the educational intervention was logistically challenging and resource demanding. Furthermore, we aimed to prevent contamination and disappointment effects from GPs or general practice clinics, who were not randomised to the intervention. As the stepped-wedge designs are adequately analyzed with random cluster effect models, a large intra-cluster variation is taken into account by applying this design.

7 Specific objectives

The overarching aim in this SW-CRT is to investigate the effects of implementing POCUS in general practice compared to usual practice prior to the intervention.

Primary objectives:

(P1) To estimate the effect of a POCUS intervention for primary care clinics on the number of registered reimbursement codes.

Hypothesis P1: For general practice clinics that receive a POCUS intervention the use of POCUS will increase after the intervention evaluated by comparing the number of registered reimbursement codes before the intervention to the number of reimbursement codes registered after the intervention.

(P2) To estimate the effects of a POCUS intervention for primary care clinics on the number of referrals send to secondary care specialists.

Hypothesis P2: For general practice clinics that receive a POCUS intervention the referral rate (number of referrals to hospital or specialist clinics/number of consultations) will decrease evaluated by comparing the referral rate from before the intervention to the referral rate after the intervention.

Secondary objectives:

We will estimate if POCUS leads to change in:
S1. Number of consultations (e-mail, telephone, video, GP office, visits)
S2. GPs' perceived stress (Cohen's 10-item Perceived Stress Scale)
S3. GPs' job satisfaction (Warr-Cook-Wall Job satisfaction Scale)
S4. GPs' burnout symptoms (Maslach Burnout inventory)
S5. Healthcare costs

And in addition, we will evaluate:
S6. Patients experiences following POCUS use
S7. Adverse events reported by the participating GPs following the intervention
S8. The patient pathway and the quality of selected POCUS applications used in general practice

Tertiary objectives:

T1. GPs' experiences of job contentment before and after the intervention
T2. GPs' experiences of POCUS use in their practice after the intervention
T3. GPs' experiences of POCUS' influence on perceived stress, job satisfaction and burnout symptoms after the intervention.

8 Trial design

This is a stepped-wedge cluster randomized trial

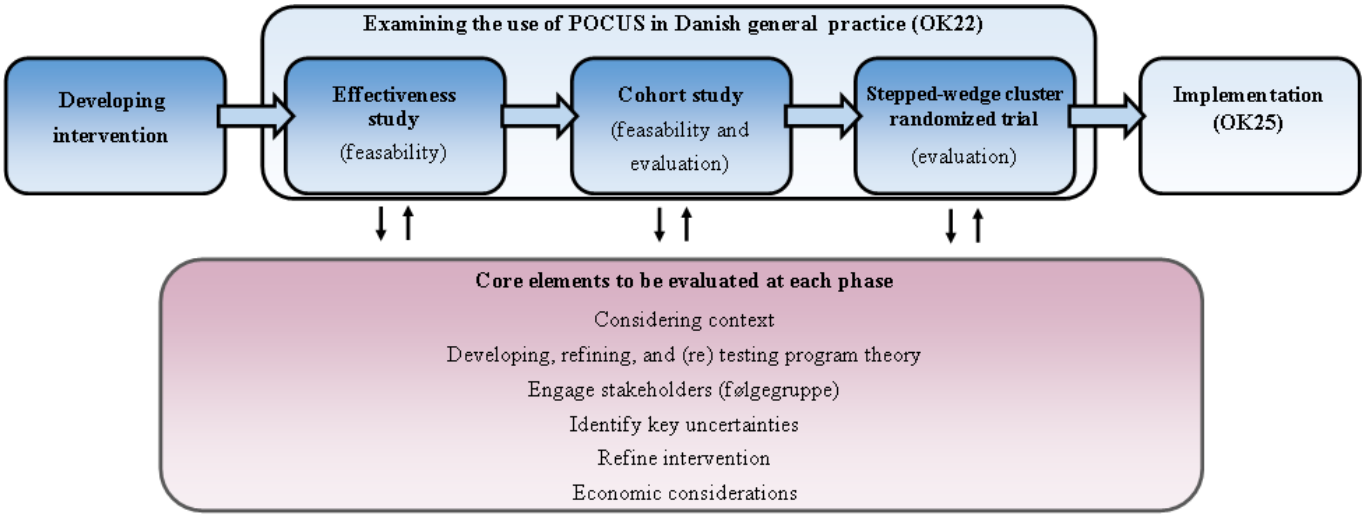
Study process

This research project has been developed following the Medical Research Council's model for developing and evaluating complex interventions[21] (Figure 1).

Reporting of this trial will follow international guidelines for reporting[22] and protocols will follow the SPIRIT statement[23] . Before the inclusion of the first participant, the trial protocols will be registered on clinicaltrials.gov.

Prior to the present study, we have developed and pilot tested an educational intervention in two preparatory studies. In an effectiveness study (ClinicalTrials.gov Identifier: NCT05274581), we tested if the educational intervention could lead to scanning competence and if scanning competence could be maintained over time. In a cohort study (ClinicalTrials.gov Identifier: NCT05523882), we tested the data collection tools and the implementation of the educational intervention.

Figure 1. Flowchart of the study process

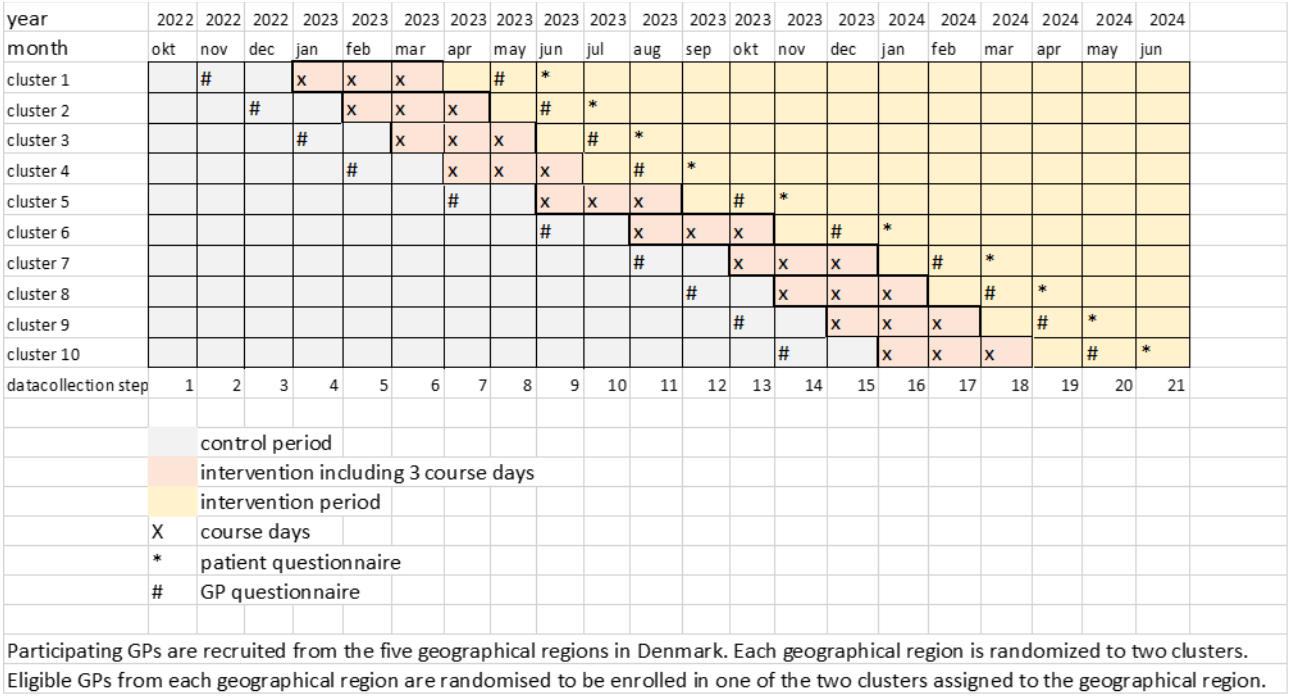


OK 22: Projects included in the 2022 collective agreement between Danish Regions and The Danish Association of General Practitioners.
OK 25: The 2025 collective agreement between Danish Regions and The Danish Association of General Practitioners, will possibly include a larger scale implementation of POCUS in general practice depending on the results of the OK22 projects.

In this SW-CRT we aim to determine the effects of our intervention by estimating the uptake of the technology by the GPs (outcome P1), change in referral rate (outcome P2), change in number of consultations delivered in primary care (outcome S1), GPs job satisfaction, level of stress, and burn-out (outcomes S2-4), as well as a health economic evaluation (outcome S5). We will also evaluate patient experiences (Outcome S6), advance events and the patient pathway following POCUS use after the introduction of the intervention.

Two-hundred GPs will participate in the study. All participants will be offered the educational intervention (Figure 2). Participants will be randomized to participate in clusters. Each cluster consists of a group of 20 GPs from the same geographical area (the five Danish regions), who receive the educational intervention at a training facility (location) at a given time. The ten clusters will receive the intervention at different timepoints (Figure 2). Hence, the study will include two clusters from each of the five Danish regions, who will receive the educational intervention at a location in the specific region: North Denmark Region (Aalborg or Sæby), Central Denmark Region (Aarhus or Herning), Region of Southern Denmark (Vejle or Odense), Region Zealand (Roskilde or Næstved) and Capital Region of Denmark (København V or Lyngby).

Figure 2. Time schedule for the SW-CRT data collection



year	2022	2022	2022	2023	2023	2023	2023	2023	2023	2023	2023	2023	2023	2023	2023	2024	2024	2024	2024	2024	2024
month	okt	nov	dec	jan	feb	mar	apr	may	jun	jul	aug	sep	okt	nov	dec	jan	feb	mar	apr	may	jun
cluster 1		#		x	x	x		#	*												
cluster 2			#		x	x	x		#	*											
cluster 3				#		x	x	x		#	*										
cluster 4					#		x	x	x		#	*									
cluster 5							#		x	x	x		#	*							
cluster 6									#		x	x	x		#	*					
cluster 7											#		x	x	x		#	*			
cluster 8												#		x	x	x		#	*		
cluster 9													#		x	x	x		#	*	
cluster 10														#		x	x	x		#	*
datacollection step	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21

	control period
	intervention including 3 course days
	intervention period
X	course days
*	patient questionnaire
#	GP questionnaire

Participating GPs are recruited from the five geographical regions in Denmark. Each geographical region is randomized to two clusters.
Eligible GPs from each geographical region are randomised to be enrolled in one of the two clusters assigned to the geographical region.

Methods - Participants, interventions, and outcomes

9 Study settings

This study will be conducted in office-based general practice in Denmark

Denmark has a public health care system. However, GPs are self-employed and work in office-based general practice clinics. 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[24]. There is no fee for performing POCUS in primary care and GPs must cover expenses for the ultrasound device and their ultrasound education themselves. However, during this study GPs will have the opportunity to participate in a free-of-costs ultrasound course and following course attendance they will be able to claim a fee for performing POCUS in general practice (262,37 DKK).

Continuous medical education for GPs is centrally organized under the wings of PLO-e. PLO-e is the practical organizer of the ultrasound course delivered in this educational intervention in collaboration with the research team. Hence, PLO-e will handle the financial and practical aspects of organizing and executing the course. PLO-e has 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

All GPs in Denmark received a newsletter from PLO describing the study and inviting eligible GPs to participate. This include a link to a questionnaire where GPs interested in participating would provide the researchers with information relating to the inclusion and exclusion criteria as well as information in regard to the prioritization criteria described in OK22. Two-hundred GPs working in office-based general practice in Denmark will be selected from a list of GPs responding to the link questionnaire. 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.

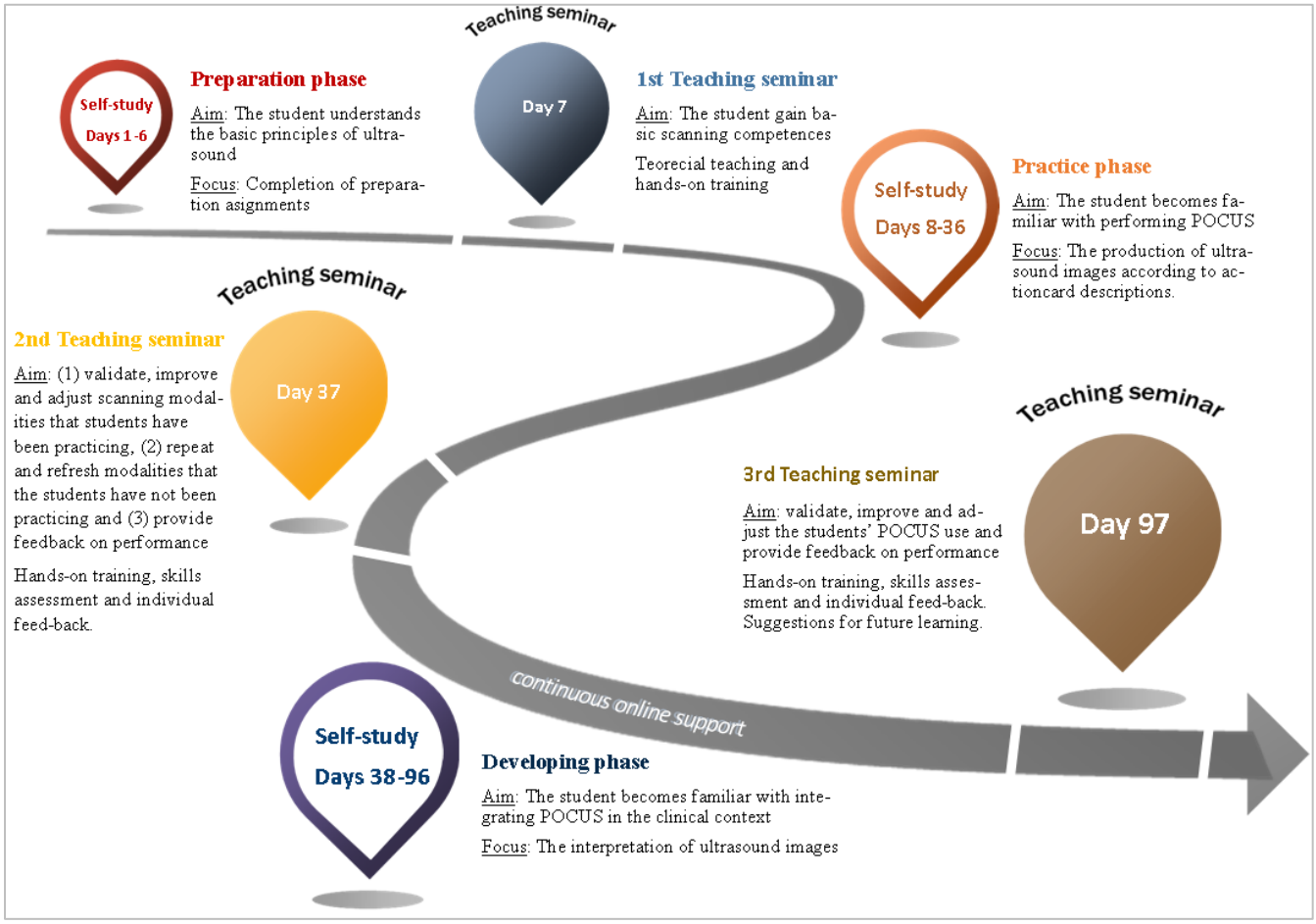
All patients seen in general practice, that the GPs find relevant to examine with POCUS can be used in the data collection. For this study, we will not collect identifiable personal or health-related data on patients. However, we will receive aggregated data on patients' age and gender. These data are used to describe the patient population but will neither be stored with the other study data nor used in analysis with other data (see section 12).

11a Description of the intervention

All participants will receive the educational intervention through attendance of the ultrasound course arranged by PLO-e. The educations intervention consists of three teaching seminars delivered 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 3).
The online platform includes videos demonstrating the performance of POCUS, suggestions for additional literature, 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 provides participants access to webinars and communication with other participants and teachers.

Figure 3 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 send in a motivational description 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 their background information.

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 either in the motivational description or by hand in order to 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 contend 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 perform[13]. For this education intervention 10 POCUS scanning modalities have been selected.
This selection is based on: (1) a previous systematic needs assessment[25] assessing the relevance of different scanning modalities, (2) previous studies measuring the frequency of different POCUS modalities used in general practice[6 26], (3) a national survey in Denmark exploring which POCUS examinations were performed by GP[8], 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[27 28] and because previous studies have shown that GPs often start scanning just a few applications[26 29], 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)[30]	69.0	99.0	72%	100%
Hydronephrosis (kidney)[31]	70.2	75.4	46%	95%
Viable intrauterine pregnancy (uterus)[32]	97.0	98.0	87%	93%
Joint effusion (knee)[33]	84.0	93.0	46%	73%
Gallstone (Gall bladder)[34]	89.8	88.0	64%	98%
Second teaching seminar				
Ascites (abdominal FAST)[35]	100.0	100.0	37%	85%
Intrauterine device location (uterus)**			86%	95%
Constipation (Rectum diameter)*** [36]	95.5	94.1	19%	46%
Subcutaneous abscess (skin)[37]	96.2	82.9	42%	98%
Pleural effusion (lung)[38]	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

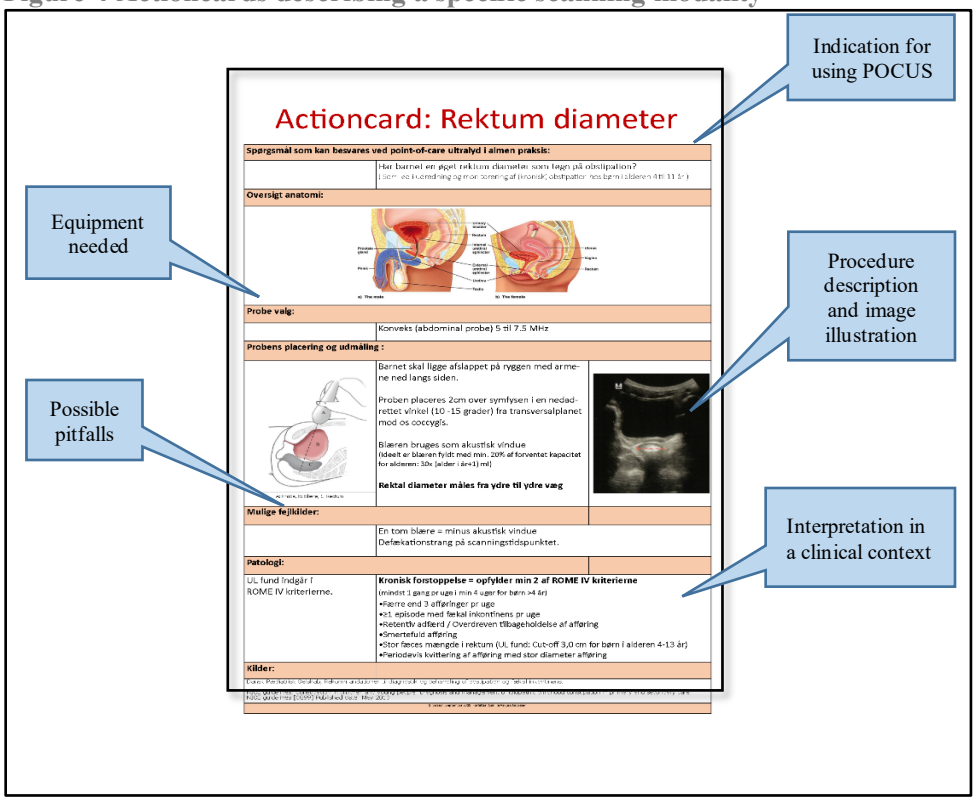
A basis of the educational intervention are *actioncards* designed for each POCUS scanning modality (figure 4). The *actioncards* are 1-page instructions specifying the indication for performing the POCUS examinations, the transducer and specific equipment settings needed to perform the examination, 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[39].
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.

Instruction videos

An instruction video is developed for each scanning modality 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.

Figure 4 Actioncards describing a specific scanning modality



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

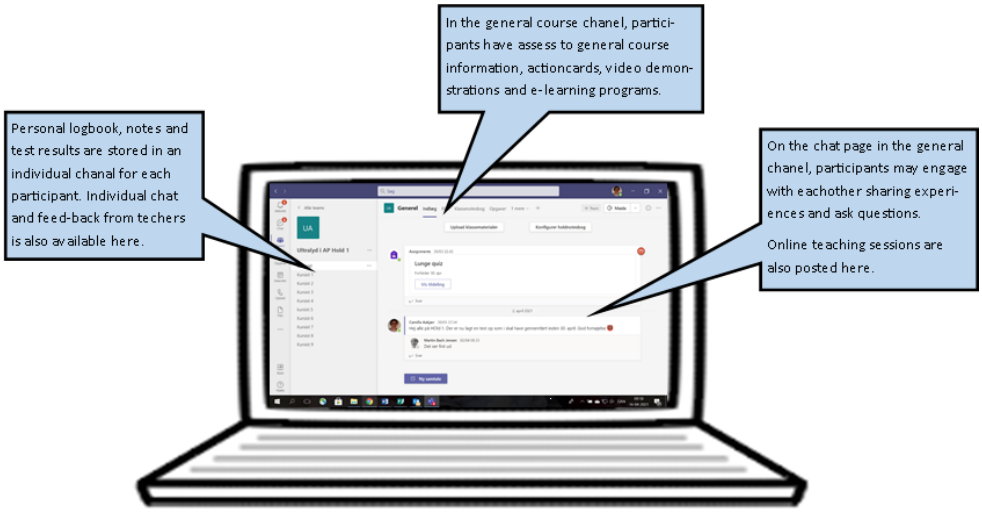
Throughout the learning process, participants will be invited to complete online assignments. The first assignment (Motivational description 1) will be a questionnaire concerning the individual participants' capability, opportunity and motivation for using POCUS. These factors are known key-elements driving the behavior of healthcare providers[40]. 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 (Motivational description 2 and 3) 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 brings 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 uses the online groupware platform (figure 5) Microsoft Teams (Microsoft Corporation, Redmond, Washington, United States) which all participants in the course and the teachers have access to.

Figure 5 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 link to an online 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, 37 and 97)

The educational intervention includes three teaching seminars on days 7, 37 and 97. 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.

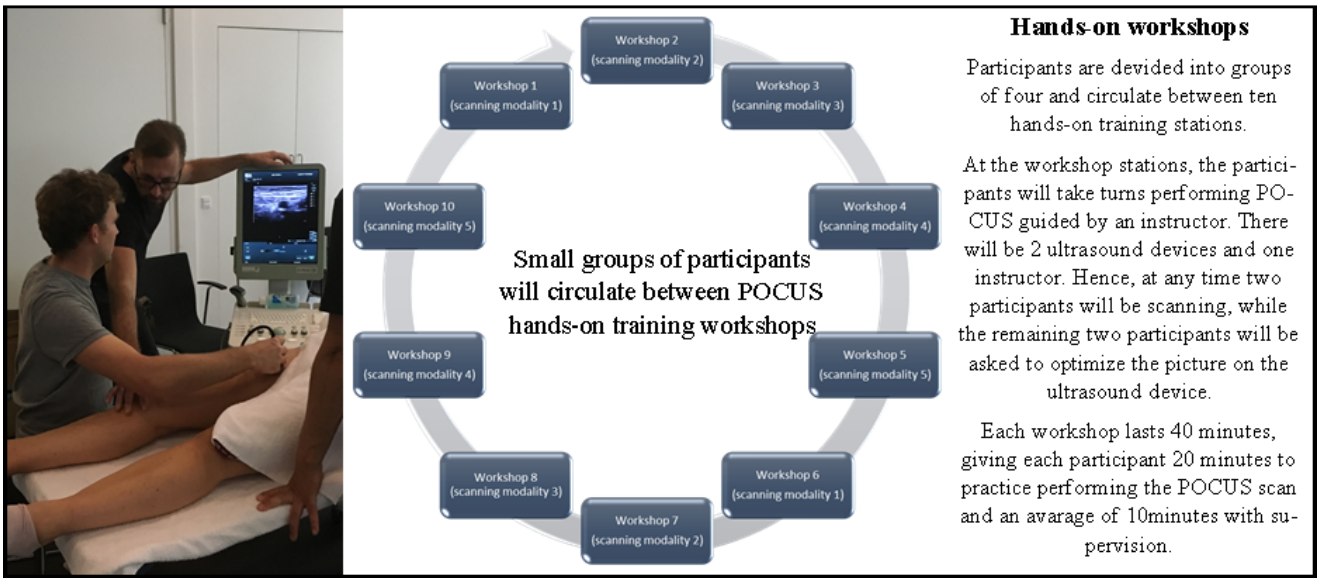
Teaching seminar 1

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 motivational descriptions 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 6). 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 scan[41]. The overall aim with the workshops is to enable participants to perform the five POCUS examination with assistance.

Figure 6. Structure of hands-on workshops on the first teaching seminar



The participants will have the opportunity 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 participant 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 though 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, *motivational description 2* is send 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, motivational descriptions 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 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 Objective Structured Assessment of Ultrasound Skills (OSAUS) generic assessment including only items 2-5 which focus solely on the technical and practical ability to produce ultrasound images[42]. 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.

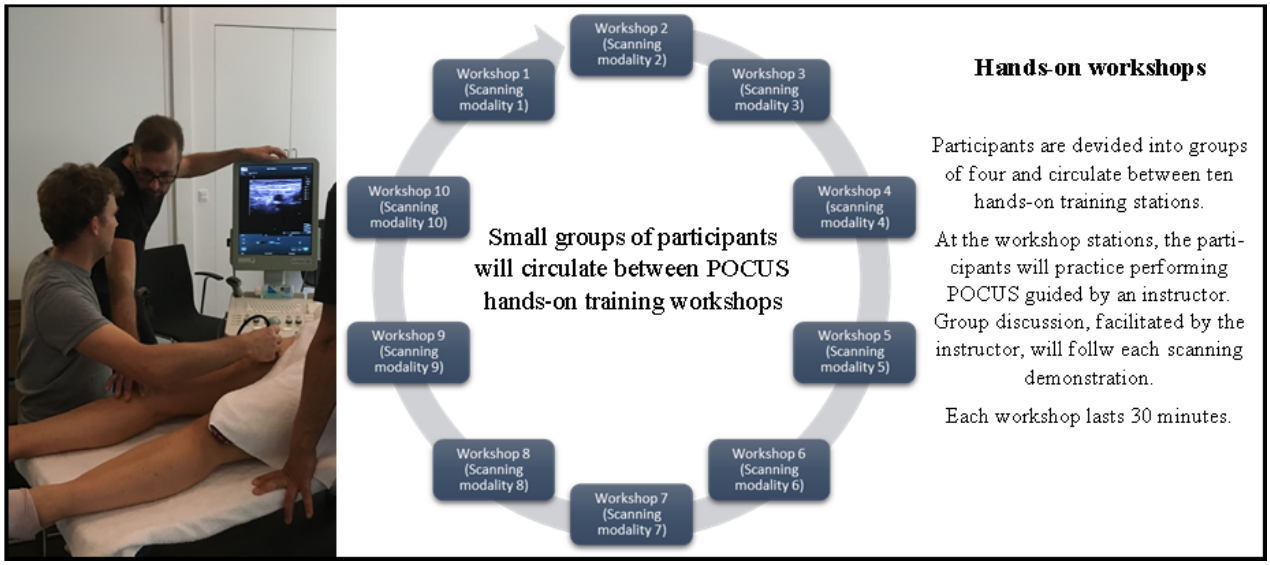
After the second teaching seminar a post-self-quiz is available (a replication of the pre-self-quiz for teaching seminar 2) for the participants to create awareness about learning process and to illustrate to which extend the learning objectives of the first teaching seminar made been reached. The teachers 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 logbooks 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 though 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 7). 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 7. 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 in a questionnaire and 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 extend 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.

Participant commitment
The educational intervention requires considerable commitments from the participants. 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.

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 be active on the online platform or complete assignments.

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

The GPs are asked to declare any other POCUS education or courses that they may participate in during the study.

12 Outcome measures

Following the educational interventions GPs will return to work in their clinics and use POCUS during clinical encounters. GPs can freely choose which patients are relevant and suited for POCUS examinations.

Register data: (Primary outcome P1 and P2 and secondary outcome S2 and S5)
Following the use of POCUS in the general practice consultations the GPs will follow normal procedures for registration of activities in general practice using remuneration codes, fee-specific codes for using POCUS, and referrals in the medical record system. Prior to this study 11 fee-specific codes for 10 different POCUS examinations and one code for 'any other' POCUS examination will be installed in the medical record system. The Primary Sector Data Provider Platform (PLSP) will develop an algorithm that allows for the following data extraction on each participating GP in a given time frame: (1) number of POCUS examinations performed, (2) number of referrals send for secondary care, and (3) number of consultations performed in

primary care. PLSP will deliver monthly aggregated data for each participating GP during the study (October 2023 to June 2024 both months included).

GP questionnaire: (Secondary outcome S2-S4 and Tertiary outcomes T1-T3)

For the GP questionnaire, we will use validated scales to determine GPs' perceived stress (Cohen's 10-item Perceived Stress Scale), GPs' job satisfaction (Warr-Cook-Wall Job satisfaction Scale) and GPs burnout symptoms (Maslach Burnout inventory). Prior to the study, these questionnaires were tested for face validity in four focus groups with 18 POCUS using GPs (unpublished materiel). The Cohen's 10-item Perceived Stress Scale includes ten items about the frequency of stress-related feelings and thoughts. Each item is rated from 0 (never) to 4 (very often). Previous research has reported a sum score of ≥ 18 to be a high level of stress[43]. The Warr-Cook-Wall Job satisfaction Scale includes 9 sub-items measuring facets of job satisfaction and one overall item rated on a scale from 1 (extreme dissatisfaction) to 7 (extreme satisfaction). In previous research[25] a cut-off on the overall item of ≤ 3 has been used to identify low job satisfaction. The Maslach Burnout inventory consists of 22 items exploring the following three burnout dimensions: (1) emotional exhaustion (9 items) characterised by depletion of emotional resources, (2) depersonalisation (5 items) characterised by emotional detachment from people related to work including patients and (3) personal accomplishment (8 items) including perceived value of work and self-efficacy. All dimensions are rated on a scale from 0 (never) to 6 (every day). A sum score is calculated for each dimension. For each scale, we will calculate a mean sum score with SD and a median sum score with IQR.

For the tertiary outcomes, we will use items previously developed and validated in Danish general practice measuring aspects of GP's job contentment (outcome T1):

- To which degree do you feel you have the job satisfaction du desire? (to a very high degree, to a high degree, to some degree, to a low degree, not at all, I do not know)
- Do you feel that you are respected by to medical colleagues at the hospital? (to a very high degree, to a high degree, to some degree, to a low degree, not at all, I do not know)
- Do you feel appreciated as a general practitioner in the health care system? (to a very high degree, to a high degree, to some degree, to a low degree, not at all, I do not know)
- Do you feel that you are burdened by a need to keep yourself professional up-to-date (to a very high degree, to a high degree, to some degree, to a low degree, not at all, I do not know)
- Do you feel that you are burdened by the risk of making errors and overlooking something serious? (to a very high degree, to a high degree, to some degree, to a low degree, not at all, I do not know)
- In your daily work, do you think about the risk of getting involved in legal patient complaint? (never, rarely, sometimes, often, very often)

And questions regrading the GPs' experience of POCUS use in general practice (outcome T2). Here participants will be asked to declare on a 5-point-likert scale if they agree or disagree with the following:

- I have experienced that POCUS use can:
    - Qualify my diagnosis
    - Qualify my referrals
    - Lead to faster diagnosis for the patient
    - Enable me to finalize more treatments

        - Make it easier to me to manage patient problems
        - Give me more energy in my daily work
        - Give me a professional contentment
        - Give me more variation in my daily work
        - Increase patient satisfaction
- I have experienced that my use of POCUS is limited by
        - My general workload
        - The time consumption for using POCUS
        - Lack of POCUS education
        - Insufficient POCUS equipment
        - Lack of access to the device
        - My colleagues opposition towards POCUS
        - The fact that I already have easy access to ultrasound examinations in secondary care
- I have experienced that my use of POCUS can
        - be at the expence of other assignmets
        - continuously call for more education
        - increase the patients' demand for more advanced procedures
        - make it difficult to keep focus on the patients' thoughts and feelings
        - increase my hours in the clinic
        - make me more exhausted after work
        - make my work more frustrating
- I am concerned whether
        - the quality of my scans are sufficient
        - I am able to maintain scanning compentence over time
        - POCUS will give a diagnostic insecurity
        - I will overtreat patients
        - I will overlook serious disease
        - I will be able to know the limits of my own abilities
        - I will misdiagnose
        - I will have a legal responsibility if I make a mistake
        - My POCUS will lead to unnecessary extra examinations
        - My POCUS will lead to incidental findings
        - I will be taken on a specialist task that I am not equipped to do
        - I will remove focus from the patient history
        - I will increase the distance between the doctor and the patient
        - Patients will put too mush emphasis on the POCUS results
        - Patients' concerns will be increased

And finally, the GPs will be asked to declare on a 5-point-likerts scale if they agree or disagree that POCUS use had influenced their sense of perceived stress, job satisfaction or burnout symptoms (outcone T3).

The GP questionnaire will be distributed to participating GPs prior to the educational intervention and after the educational intervention (see Figure 2).

Patient questionnaire (secondary outcome S6)

A patient questionnaire will be delivered to all patients (≥ 18 years old) examined with POCUS, who will be able to provide an informed consent, in month 5-6 after the educational intervention (See Figure 2). The participating GPs will deliver the questionnaire to the patient after the consultation. Patients will fill out the questionnaires themselves on their own mobile devices using a QR code (or alternatively a paper questionnaire). We will use items previously developed and validated[44]. The patients will be asked to declare on a 5-point-likert scale:

- If they felt informed about the purpose of the POCUS examination
- If they felt informed about the results of the POCUS examination
- If they were informed about the difference between POCUS and traditional ultrasound examinations
- If they thought the POCUS examination was a natural part of the consultation?
- If they thought the POCUS examination was disturbing in the consultation with the doctor?
- If they thought the contact between the doctor and themselves was improved or worsened?
- If they thought the ultrasound examination gave them a better or poorer understanding of their health problem?
- If they felt more thoroughly or less thoroughly examined after the ultrasound examination?
- If they felt more or less taken seriously.
- If they felt more or less secure?
- If they thought the ultrasound examination had a large or small impact on the treatment they received?
- If their confidence in the GPs assessment of their health problem had increased or decreased?
- If they thought the ultrasound examination makes the level of service at the GP's office increase or decrease?
- If they thought the ultrasound examination makes the quality in care at the GP's office increase or decrease?
- Their overall experience with the ultrasound examination performed by the physician?

The were also asked to declare on a scale from 1-10:

- How likely they were to recommend the ultrasound examination to other patients having the same health problem and the same physician? (NPT score)

As these patient questionnaires cannot be linked to other study data, the patients will be asked to provide the following background information about themselves: age, gender, level of education, employment, location of practice (region in Denmark) and area examine with POCUS during the consultation (abdomen, heart, lung, musculoskeletal, gynaecological).

GP registration of possible adverse events: (outcome S7)

For the registration of possible adverse events, we will use a questionnaire giving the GPs the possibility to explain in free text using their own words to explain (1) what was scanned, (2) circumstances surrounding the scan, (3) what happened, and (4) reflections after the scan. This reporting of cases will be anonymous. Data will be collected from the educational intervention to the end of the study. We will report the aggregated total number of monthly registrations for each participating GP. The free text elaborations will not be reported, but passed on to the safety committee (see section 5d). The registration of adverse events for the study does not substitute the GP's registration of untoward incidents required by Danish law (https://stps.dk/da/ansvar-og-retningslinjer/vejledning/rapporteringspligt/).

Evaluation of the patient pathway and quality of selected POCUS examinations: (outcome S8)

After the study (July 2024), participating GPs will be instructed to make an evaluation of the patient pathway following selected POCUS examinations. A separate protocol will be developed for this part. The GPs will be asked to make a registration for each patient, who has been examined with a specific POCUS examination. Based on information found in the medical record the GP is asked to register the following information for each patient: (1) If the patient had subsequent imagining following the index consultation where POCUS was used by the GP, (2) if the patient was later re-examined for the same health complaint by the same GP, (3) if the patient was later re-examined for the same health complaint by another physician, (4) if the diagnosis at the index consultation was used was later confirmed og dismissed, (5) if the ultrasound findings in the index consultation was later confirmed og dismissed, (6) if there were any adverse events identified that where related to the POCUS examinations or the following course for the patient.

Background characteristics of participating GPs

At baseline the following participant characteristics will be collected in a baseline questionnaire: Age (years), gender (M, F, other), seniority (year of graduation from medical school), experience (years working as a GP), previous use of ultrasound (number of years with regular use), previous ultrasound training (yes,no), scanner type (low range, mid range, high end), practice owner (yes, no), type of practice (collaboration, partnership, solo), location of practice (urban, rural, mixed), distance to the nearest imaging facility, number of patients assigned to the practice, and number of GPs working in the practice. In addition, we will register GP's participation in educational activities during the educational intervention.

Characteristics of scanned patients

From PLSP, we will receive the aggregated data (age, gender) on patients, who have had a POCUS fee-specific code registered in their medical record during the study. Age and gender are calculated based on patient ID in the medical records in the clinics (CPR numbers). These data are extracted and transferred to CAM AAU anonymously.

The collected characteristics of participating GPs and scanned patients will be used to describe the population and to do sensitivity analyses.

13 Time schedule

Approval of the study by Danish Regions and PLO: June 2022
Allocation of clusters: June 2022
Recruitment: June – September 2022
Registration of the study in Clinical Trials: October 2022
Participant allocation: October 2022
Ethical approval: November 2022
Data collection: (Time of data collection for each cluster is illustrated in Figure 2).

- Retrospective data collection using register data (Primary outcome P1 and P2 and secondary outcome S2 and S5): January 2023 – June 2024.
- Prospective data collection using GP questionnaires (Secondary outcome S2-S4): November 2022 – May 2024.
- Prospective data collection using patient questionnaires (Secondary outcome S6 and S7): June 2023 – June 2024
- Prospective data collection using GPs' registration of unwanted cases (outcome S8): January 2023 – June 2024.

- Background characteristics on participating GPs are collected at the first teaching seminar: January 2023 – January 2024.
- Retrospective evaluation of medical records are collected in July – October 2024.

Cleansing of data and data analysis: July 2024 – December 2024
Reporting of the study: 2025

14 Sample size

This is a pragmatic trial where size of the sample is given by the collective agreement between PLO and the Danish Regions. We plan to make post-hoc power calculations to support the reliability of our analytic findings.

15 Recruitment

All GPs working in Danish general practice will be invited to participate in the study by newsletter invitation circulated by PLO to all PLO members. The newsletter will contain a link to a questionnaire in which the GPs will be asked to specify their name, practice, location of practice (region in Denmark), distance to nearest ultrasound scanning service, whether or not they are already using POCUS, whether or not they will have access to an ultrasound device during the educational intervention, and whether or not they are willing to share data. There will be a deadline (September 1st 2022) for responding to the invitation.

Following the deadline for signing up to participate in the study, the GPs reply to the questionnaires will be screened according to the inclusion and exclusion criteria to make a list of eligible participants fulfilling all inclusion and none of the exclusion criteria:

Selection of participants

The selection of participants follows the below prioritizing.

1. The list of eligible participants will be sorted based on geography (based on regions) and according to the GPs distance to the nearest ultrasound scanning service. In each region, the 40 GPs with the longest distance to an ultrasound scanning service, will be offered to participate in the study.
2. In case a GP, offered to participate in the study, does not wish to participate, the offer will be given to the next on the list.
3. In case there are less than 40 participants in a region, eligible GPs from the neighbouring region with the longest distance to an ultrasound scanning service, will be allocated to the region with less than 40 participants.
4. GPs, who have signed-up to participate in the PLO-courses held in 2022 will be excluded from participating in this study, as they will have participated in the preparatory studies.
5. POCUS-users account for approximately 12% of all PLO members (unpublished data). Therefore, only approximately 12% (five GPs per region) of eligible participants can be POCUS-users. If the prioritized list includes more than five POCUS-users, we will consider the first five POCUS-users on the list and exclude the remaining POCUS-users giving way for non-users further down the list to be considered.

Hence, the final list of eligible GPs, who will be offered participation in the studies, will include 200 GPs, with a maximum of 25 POCUS-users, working in the general practice clinics with the longest distance to ultrasound scanning services.

Assignment of interventions

16a Allocation Sequence generation

When the GPs sign up to participate in the study, they will be able to see the dates for the teaching seminars at each location, but they will not be able to choose between these (their assignment to a specific cluster will be determined by randomization).
Once 200 GP have been allocated to the five regions used in the SW-CRT, the 40 participants allocated to each region will be randomized to participate in one of the two clusters: North Denmark Region (Aalborg or Sæby), Central Denmark Region (Aarhus or Herning), Region of Southern Denmark (Vejle or Odense), Region Zealand (Roskilde or Næstved) and Capital Region of Denmark (København V or Lyngby).

Randomisation will be performed on two levels – cluster order and individual participation at a specific time.

Order of clusters

First, the overall order of all clusters will be randomized. I.e. the order of the clusters defined by each location are decided based on simple randomization -drawing an anonymous paper slip at random order with one of the following texts: Aalborg, Sæby, Aarhus, Herning, Vejle, Odense, Roskilde, Næstved, København V and Lyngby. From this an order for the delivery of courses is established (Figure 2). This randomisation and the fixed timeline for the delivery of these courses will be done on June 17th 2022 in order to plan and prepare the delivery of the intervention.

Participants' time of intervention

The randomisation of participants at a given location to receive the intervention at one of two time points of will take place after the deadline for signing up for the course prior to the start of the data collection (October 2022). The randomisations will be done by a research assistant not involved in assessment or delivery of the intervention (the randomisation process will be video documented). Following this randomization process, the GPs will be offered participation in the SW-CRT by e-mail including a link for the PLO-e course allocated to the specific cluster.

16b Allocation concealment mechanism

n/a

16c Implementation

n/a

17 Blinding

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

Data will be collected at different timepoints (see Figure 2).

Register data: Data regarding different POCUS examinations, number of referrals, number of consultations will be delivered by PLSP (outcomes P1-P2, S1 and S5). The data are registered prospectively by participating GPs in the medical records during from October 2023 to June 2024. We will receive these data retrospectively from PLSP, who will use an algorithm to collect monthly aggregated data for each participating GP. Due to availability of reimbursement codes in the medical record system, primary outcome P1 is collected in months 3-21, while primary outcome P2 and S1 is collected in months 1-21.
From PLSP, we will receive the following aggregated data on patients (age, gender) calculated based on patient ID in the medical records in the clinics (CPR numbers). These data are extracted and transferred to CAM AAU anonymously.

GP questionnaire: For the cross-sectional questionnaire exploring burnout, stress and job satisfaction before and after the educational intervention, an online questionnaire will be distributed by email to participants and a possible reminder will follow after two weeks. The questionnaire will be collected through SurveyXact (Rambøll, Aarhus, Denmark).

The questionnaire collecting background characteristics on participating GPs will be collected on the first teaching seminar using a QR code to an online questionnaire SurveyXact (Rambøll, Aarhus, Denmark).

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 as anonymous cases 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.

Patient questionnaire: Following the consultation in general practice all patients who are (1) ≥18 years of age, (2) able to provide informed consent and (3) who have been examined with POCUS are offered the opportunity to participate in a questionnaire study exploring their experience of being examined with POCUS in general practice. The patients are given information about the study by their GP. If the patient agree to participate, the GP will deliver a QR code to an online questionnaire (SurveyXact, Rambøll, Aarhus, Denmark) or a paper questionnaire in a sealed envelope to the patient. The patient will then fill-out the questionnaire in the waiting area before they leave the clinic. Online questionnaires are directly transferred to the SurveyXact database and from there transferred to the secure AAU server, while paper questionnaires are kept in the sealed envelopes in the clinic until they are collected by a research assistant from CAM AAU.

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 remainders will be sent to the participating GPs remaining them to include patients and contact the research team in case of problems.

19 Data management

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 collected by PLSP or SurveyXact are stored on secure server on Aalborg University and handled according to the General Data Protection Regulation (GDPR).

The data management will follow the rules of GDPR and the Danish Data Protection Agency. All study data will be stored on a secure server at Aalborg University. Questionnaire data will be collected using the online platform SurveyXact (Rambøll, Aarhus, Denmark). A data management agreement has been made between Rambøll and Aalborg University. At the end of the data collection, data will be moved from SurveyXact to Aalborg University's server. Register data will be collected by PLSP. Data management agreements between PLSP and Aalborg University will be made prior to the collection of data. PLSP will receive data from the different IT suppliers for the general practice clinics. Data management agreements between the IT suppliers and PLSP as well as the GP clinics and the IT suppliers already exists. For this specific study, we will develop an instruction for the GPs to incorporate in the existing data management agreement prior to the collection of data.

20a Statistical methods for analysing primary and secondary outcomes.

All statistical analyses will be performed using STATA version 17 (StataCorp, Texas, USA).

The principles of Intention-to-treat is followed in the analysis. If a GP e.g. misses one teaching seminar, we will still consider the GP has having completed the educational intervention. Data will be analyzed according to a pre-established Statistical Analysis Plan (SAP) in consultation with a statistician. For the primary outcomes (continuous data), we plan to use linear regression models adjusting for the fixed effect of time and the random effects of clusters.
Due to the nature of the study the intervention cannot be blinded to the participants, but for statistical assessment, data will be blinded as regard to time of collection and location.

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

Sensitivity analyses and sub-analyses will be performed to explore the importance of different educational elements in the intervention and background characteristics of participating GPs. These sub-analyses will be defined in the statistical analysis plan.

20c Missing data

A sensitivity analysis will be performed in cases, where missing values are not considered random.

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 case 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

Ultrasound examinations are safe to perform on patients and radiation-free procedures[45]. Previous studies have found high diagnostic accuracies of POCUS examinations in the hands of generalists such as GPs[46]. Still, introducing a diagnostic test may lead to an increased number of incidental findings and possible over-detection and overdiagnosis. A previous review of 564 medical records from patients examined with POCUS in Danish general practice did not reveal any adverse events related to POCUS use (unpublished data). However, patients generally put a lot of emphasis on diagnostic tests. Hence, the GPs are taught how to communicate the limits of their POCUS examination to patients to avoid false expectations and false reassurance.

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. This reporting does not substitute the GP's registration of untoward incidents required by Danish law (https://stps.dk/da/ansvar-og-retningslinjer/vejledning/rapporteringspligt/).

23 Auditing

n/a

Ethics and dissemination

A minority of Danish GPs (12%) are already using POCUS in general practice. They have assembled their POCUS education individually and they are using POCUS very differently[1 2]. This study aims to explore the effects of a tailored educational program for GP, framing specific evidence-based POCUS examinations to the general practice context. All scanning modalities included in the curriculum have previously been tested and evaluated in Danish general practice. Focused POCUS use in general practice has the potential to lead to faster and more precise diagnosis for patients seen in general practice.

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 (The North Denmark Region Committee on Health Research Ethics, registration number 96036), who responded that do ethical approval was necessary. The project is registered and conducted according to the regulations of the Danish Data Protection Agency (registration number 2022-068-03601).

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 registered on clinicaltrials.gov.

26a Consent or assent

Informed consent form the participating GPs will be collected by the principal investigator prior to the study. Patients, who participate in the patient questionnaire are asked to provide consent to the collection and analysis of these data.

During the study (January 2023-June 2024) participating GPs will inform patients about the study by making a written description of the study available in the clinic (see attached patient information).

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

Prior to the collection of retrospective register data by PLSP, we will seek The North Denmark Region for permission to use of data from patients' medical records without patient consent based on Danish Law (*Sundhedsloven)*.

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 educational teachers will have access to data on the online platform. 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 patients who suffer harm from a GPs' 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 criteria[1]:

- 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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