RESEARCH UNIT
FOR GENERAL PRACTICE
Aalborg

## Study protocol

# The clinical impact of POCUS use:

## A hybrid type 2 effectiveness-implementation trial from Danish general practice

Center for General Practice at Aalborg University
19-02-2025

# Study protocol according to the SPIRIT 2013 Checklist

## Administrative information

1 **Title**

The clinical impact of POCUS use: A hybrid type 2 effectiveness-implementation trial from Danish general practice

**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: NCT05523882 |
| **Date of registration in primary registry** | Uploaded to clinical trials on August 29 2022 |
| **Secondary identifying numbers** | Red-CAP registration number Record ID 242-3 |
| **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<br>The General Practice Foundation in Denmark |
| **Contact for public queries** | mbj@dcm.aau.dk |
| **Contact for scientific queries** | caakjaer@dcm.aau.dk |
| **Public title** | *The clinical impact of POCUS use in General Practice*<br>In Danish**:** *Den kliniske betydning af brugen af ultralyd – et forskningsprojekt fra dansk almen praksis* |
| **Scientific title** | The clinical impact of POCUS use: A hybrid type 2 effectiveness-implementation trial from Danish general practice |
| **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:**<br>1. postgraduate medical doctor with a specialization in general practice.<br>2. work in office-based general practice in Denmark<br>3. access to an ultrasound device in the practice during the study period<br>**Exclusion criteria:**<br>1. possible conflict of interest<br>2. no signed informed consent to participate. |
| **Study type** | A hybrid type 2 effectiveness-implementation trial |
| **Date of first enrolment** | Expected: August 2022 |
| **Target sample size** | Twenty general practitioners |
| **Recruitment status** | Not yet recruiting |
| **Primary outcome(s)** | This study aims to simultaneous assess the clinical effectiveness of the intervention and to measure the impact of the implementation strategy as co-primary aims. |

## 3 Protocol version

Version 8 August 28th 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, Martin Bach Jensen (MBJ), Julie Jepsen Strøm (JJS) 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)
Søren Lundbye-Christensen (SLC) will help draft the SAP.
Thomas Løkkegaard (TL) and Christian Stjernebjerg (CS) will participate as course directors in the educational intervention.
CAA, MBJ, JJS, SLC, AR, TL, and CS 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 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.

The expected author list is: Andersen CA, ……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
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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, Ulrike Mehnert (UM), Troels Mengel-Jørgensen (TMJ), Søren Kæseler Andersen (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.

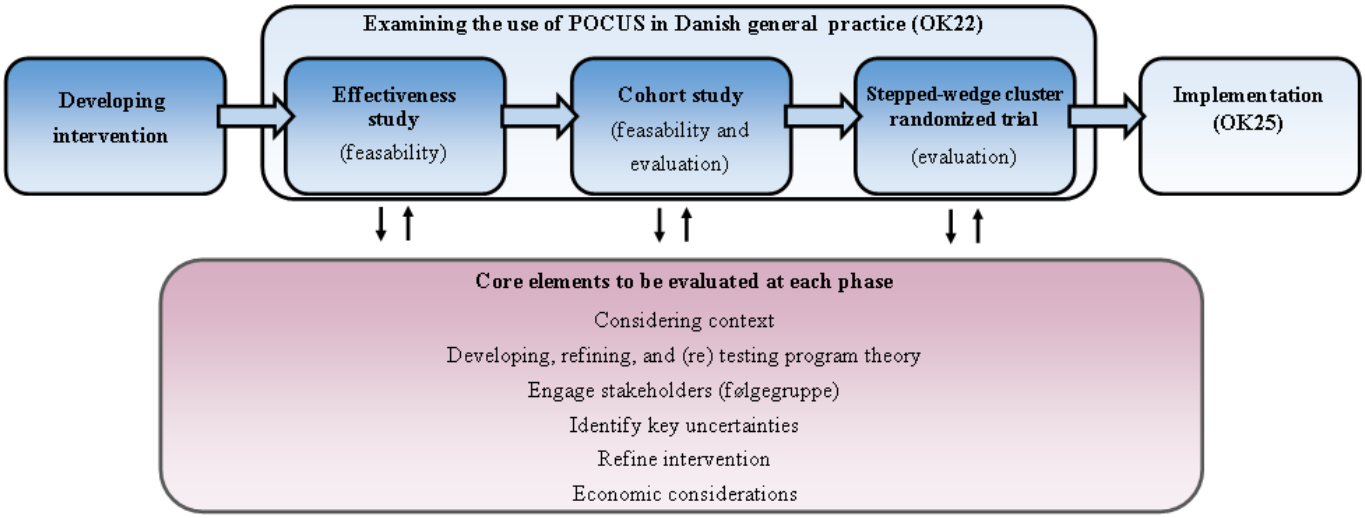
A safety committee will be set up to handle all reports of adverse and suspected adverse events (AEs) and serious adverse events (SAEs). MBJ will head the committee.

# Introduction

## 6 Background and rationale

In 2023/2024 the POCUS IN PRACTICE (PIP) study, a large stepped wedged cluster randomized clinical trial (SW-CRT) will be conducted in general practice in Denmark. The overarching aim of this study is to evaluate the implementation of point-of-care ultrasound (POCUS) in Danish general practice. An educational intervention for this study has been developed and tested in a previous study (Evaluating scanning competence following a structured POCUS training program for general practitioners: A hybrid effectiveness-implementation study: Clinical trials registration: NCT05274581). Since then, the intervention has been further developed and in line with the medical research council's framework for developing and evaluating complex interventions[2], the intervention is ready for the next stage of evaluation (figure 1).

**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.

## 7 Specific objectives

Being a hybrid type 2 effectiveness-implementation study[3], this study aims to simultaneous assess the clinical effectiveness of the intervention and to measure the impact of the implementation strategy as co-primary aims. The implementation-related outcomes have been developed based on recommendations for implementation strategy measures for use in feasibility and pilot implementation studies[4].

**Outcomes to assess the effectiveness of the intervention:**

For GPs attending a 3-months basic POCUS course, we aim to determine:

(E1) how the frequency of use of different POCUS examinations develops in the first two years after introducing POCUS use in general practice including the variation over time and between GPs.

(E2) how the frequency of referrals for secondary care develops in the first two years after introducing POCUS use in general practice and including the variation in referrals over time and between GPs.
(E3) how the number of consultations delivered in primary care develops in the first two years after introducing POCUS use in general practice including the variation over time and between GPs.
(E4) how the GPs' reported effect of POCUS on their clinical decision and patient management in general practice develops in the first year after introducing POCUS use in general practice.
(E5) the number of unwanted cases associated with the use of POCUS reported by the participating GPs in the first two years after introducing POCUS use in general practice.

**Outcomes to assess implementation strategy effects:**

(I1) Adoption: the proportion of participating GPs that adopt the intervention and start using POCUS in their daily practice during the educational interventions (months 1-3).
(I2) Fidelity (adherence): the proportion of participating GPs that complete the educational elements in the intervention (pre-post tests, webinars, assignments, attendance on seminar days, logbook registrations).
(I3) Reach (penetration): The proportion of teachers who actively support participants by engaging in the online part of the educational interventions
(I4) Sustainability (maintenance): the proportion of participating GPs that adopt the intervention and continue to use POCUS in their daily practice following the educational interventions (months 5-6).

**Outcomes to inform further development of the implementation strategy**

(D1) Adaptability: the extent to which the teachers and participants find that the implementation of the educational intervention meets local needs
(D2) Acceptability: the extent to which the teachers and participants find the implementation of the educational interventions is agreeable in terms of content and delivery
(D3) Feasibility: the extent to which the teachers and participants find the educational intervention to be suitable for implementation
(D4) Compatibility (appropriateness): the extent to which the teachers and participants perceive the implementation of the educational intervention is in line with the organisation's values, mission, priorities
(D5) Dose (satisfaction): the extent to which the teachers and participants are satisfied with the amount of support and resources received as part of implementation strategy
(D6) Complexity: the extent to which the teachers and participants perceive the implementation of the educational intervention as being difficult or complex
(D7) Context: the extent to which the teachers and participants find that organisational political, economic or social factors influenced the implementation of the educational intervention
(D8) Culture: the extent to which the teachers and participants find that the setting, organisational values or norms influenced the implementation of the educational intervention

(D9) Self-efficacy: the extent to which the teachers and participants find that they had the capacity (e.g. knowledge and skills) to implement the educational intervention
(D10) Cost: measures of the cost of implementation the educational intervention
(D11) Resources: measures of the resources and managing required for the implementation the educational intervention

**Outcomes to assess the feasibility of trial methods**

(F1) the extent to which recruitment of participants was possible
(F2) the extent to which participants retention was possible
(F3) the extent to which retention of teachers was possible
(F4) the extent to which teachers delivered the intervention by protocol
(F5) the extent to which participants received the intervention by protocol
(F6) the extent to which data collection through registers was obtainable and valid
(F7) the extent to which data collection through GP questionnaires was obtainable and valid
(F8) the extent to which data collection through GP questionnaires was obtainable in a questionnaire measuring GPs' sense of burnout, stress and job satisfaction estimated 3 months after introducing POCUS in general practice.

8 Trial design

We use the effectiveness-implementation hybrid trial design typology proposed by Curran et al[3] which has been found suitable for preparatory studies in relation to implementing complex interventions[4]. This is a hybrid type 2 effectiveness-implementation trial[3], with simultaneous testing of both the effectiveness of an intervention and the feasibility of the implementation strategy as co-primary aims. This hybrid type is a blending of clinical effectiveness and implementation research that aims in support of more rapid translation. As the implementation strategy is being tested alongside and in support of a clinical intervention, it is possible to create and study a "medium case"/pragmatic set of delivery/implementation conditions versus "best" or "worst" case conditions. Therefore, while speeding translation, it is possible with Hybrid Type 2 designs to provide more valid estimates of potential clinical effectiveness[3].

We previously tested other effectiveness related outcomes (the educational intervention's ability to give participating GPs' scanning competence) in a hybrid type 1 effectiveness-implementation trial[5] and the present study builds on the evaluation of implementation-related outcomes from the previous study.

Reporting of this trial will follow the guidelines for reporting implementation studies: The StaRI standard[6]. Reporting of the protocol will follow the SPIRIT statement[7]. Before data collection starts, the trial will be registered on ***clinicaltrials.gov***.

## Methods

### 9 Study settings

This study will be conducted in office-based general practice in Denmark with the educational sessions taking place at two different ultrasound educational facilities.

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 Organisation of General Practitioners in Denmark (Praktiserende Lægers Organisation PLO) that has an educational branch (PLO-e). PLO-e is the practical organizer of the ultrasound course delivered in this educational intervention. 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.

Some of the GPs participating in this study may later on be eligible to have the course fee reimbursed and receive payment for the scans (approximately DKR 262 per scan). A decision regarding this lies not with the research team, but will depend on matters relating to the general practice agreement between PLO and the Danish Regions. A decision regarding this is expected in September 2022.

## 10 Participants

All GPs participating in two ultrasound courses organized by PLO-e (course number 9018822 and 9017222) are eligible to participate in this study. Independent of previous use of ultrasound in general practice, participants had to meet the following criteria:

Inclusion criteria:

1. Postgraduate medical doctor with a specialization in general practice
2. Working in office-based Danish general practice
3. Access to an ultrasound device in the practice during the study period

Exclusion criteria:

1. Not willing to participate in the data collection or share data for this study
2. No signed informed consent to participate

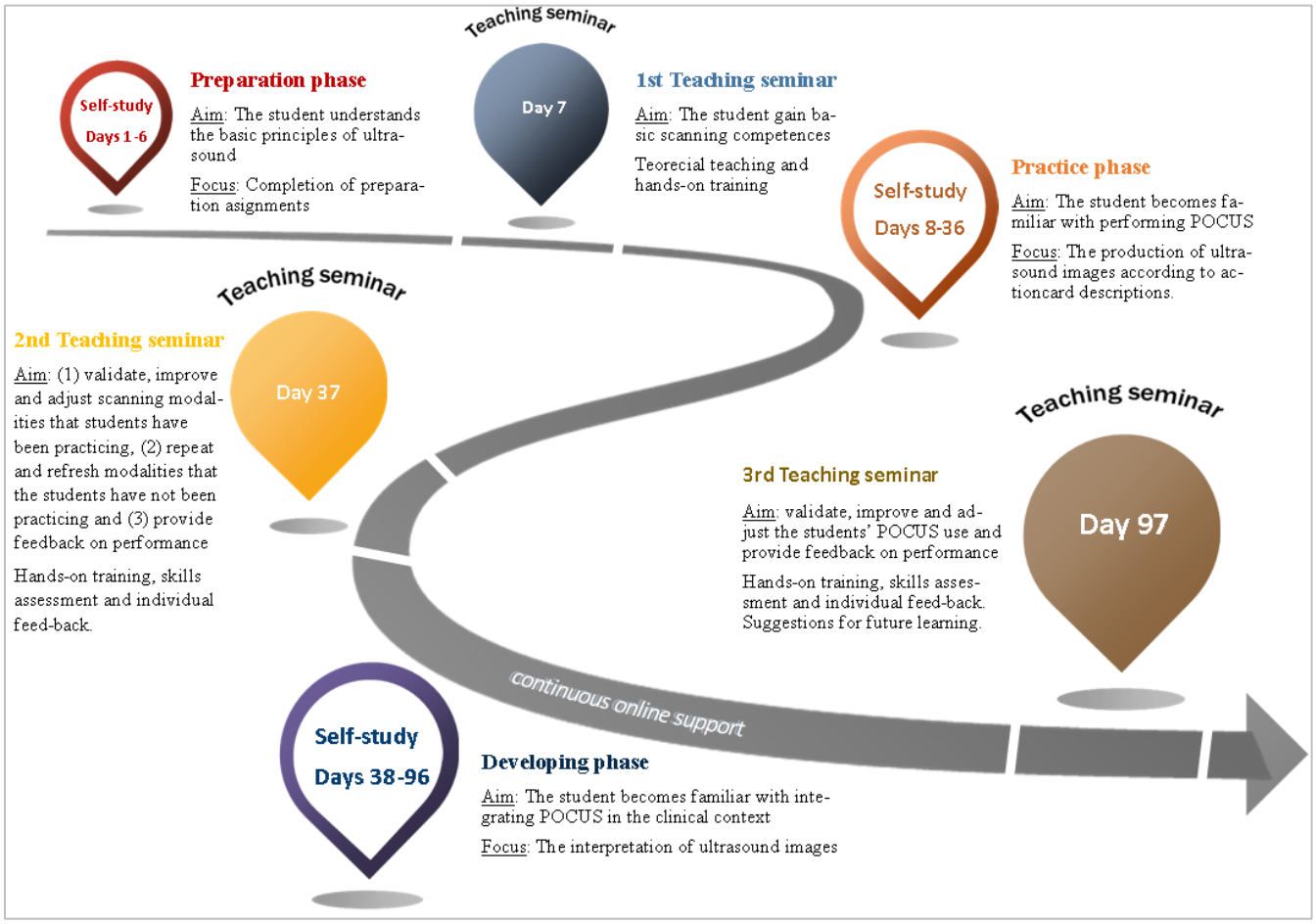
All patients seen in general practice, that the GPs find relevant to examine with POCUS can be used in the data collection. For this study, we will not collect identifiable personal or health-related data on patients. However, we will receive aggregated data on patients' age and gender. These data are 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 2).

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 2 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[8]. For this education intervention 10 POCUS scanning modalities have been selected.
This selection is based on: (1) a previous systematic needs assessment[9] 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 GP[9], 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[10 11] and because previous studies have shown that GPs often start scanning just a few applications[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)[12] | 69.0 | 99.0 | 72% | 100% |
| Hydronephrosis (kidney)[13] | 70.2 | 75.4 | 46% | 95% |
| Viable intrauterine pregnancy (uterus)[14] | 97.0 | 98.0 | 87% | 93% |
| Joint effusion (knee)[15] | 0.84 | 0.93 | 46% | 73% |
| Gallstone (Gall bladder)[16] | 89.8 | 88.0 | 64% | 98% |
| **Second teaching seminar** | | | | |
| Ascites (abdominal FAST)[17] | 100.0 | 100.0 | 37% | 85% |
| Intrauterine device location (uterus)** | | | 86% | 95% |
| Constipation (Rectum diameter)*** [18] | 95.5 | 94.1 | 19% | 46% |
| Subcutaneous abscess (skin)[19] | 96.2 | 82.9 | 42% | 98% |
| Pleural effusion (lung)[20] | 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

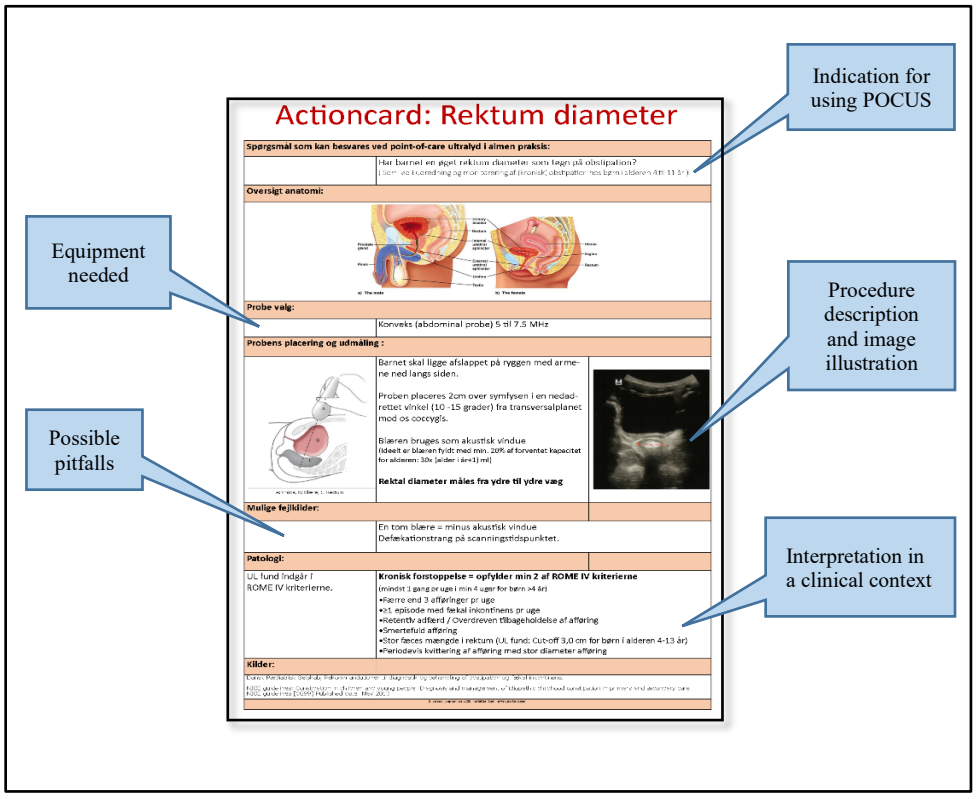
A basis of the educational intervention are *actioncards* designed for each POCUS scanning modality (figure 3). The *actioncards* are 1-page instructions specifying the indication for performing the POCUS examinations, the transducer and specific equipment settings needed to perform the examination, 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[21].
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 3 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

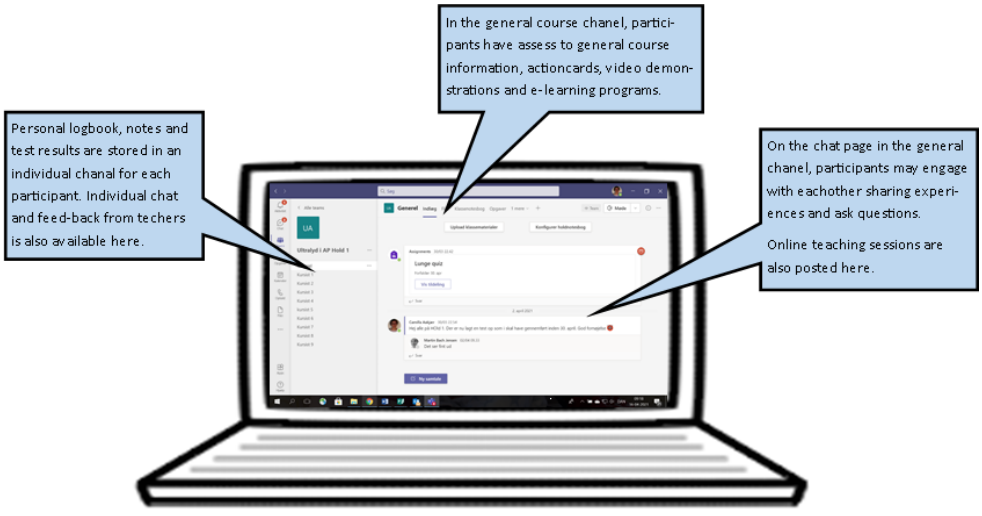
Throughout the learning process, participants will be invited to complete online assignments. The first assignment (Motivational description 1) will be a questionnaire concerning the

individual participants' capability, opportunity and motivation for using POCUS. These factors are known key-elements driving the behavior of healthcare providers[22]. 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 includes an online groupware platform (figure 4), which all participants in the course and the teachers have access to.

**Figure 4 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, 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.

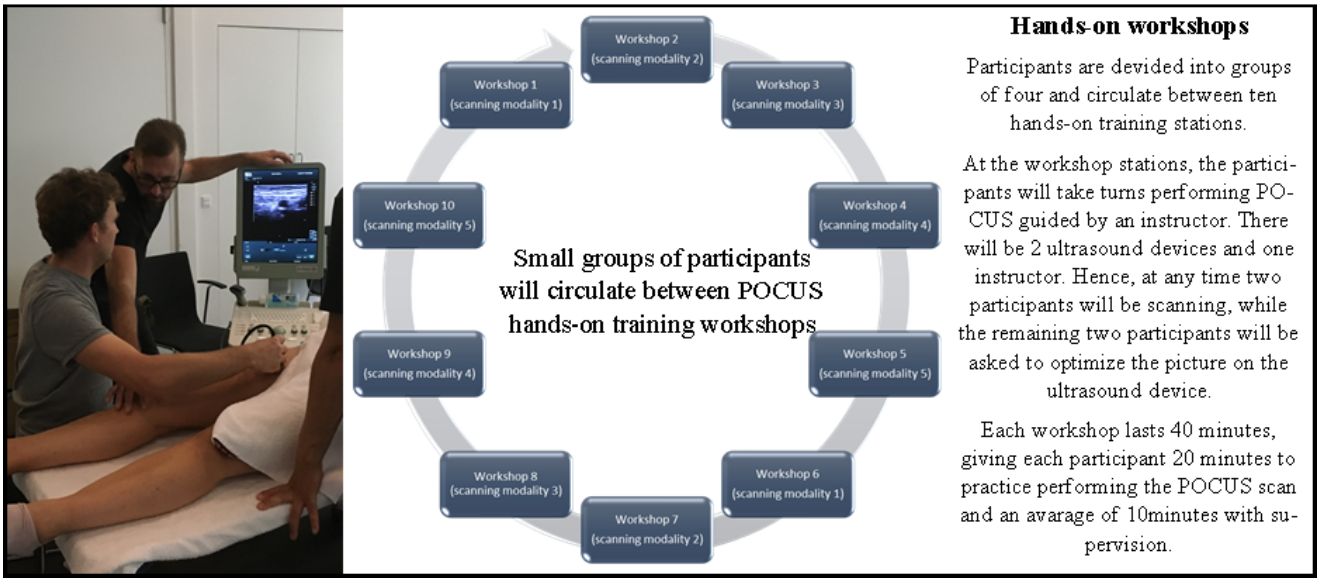
**Teaching seminar 1**

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 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 5). 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[23]. The overall aim with the workshops is to enable participants to perform the five POCUS examination with assistance.

**Figure 5. 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 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 applicable[13]. 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).

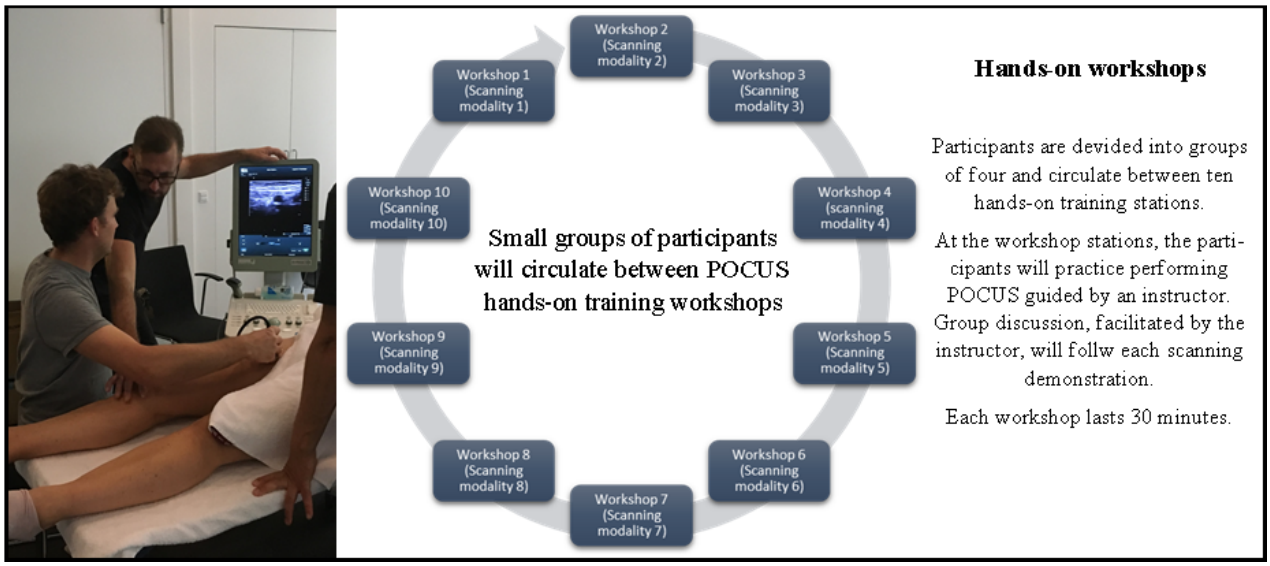
**Teaching seminar 3**

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 6). 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 6. 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 (Figure 7). 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.
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 and we will include this in the process evaluation (outcomes I1, I2, I4 and F5).

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

The teachers 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.

### 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 (day 1-372). Still, information seeking e.g. through internet sources or books are allowed throughout 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.

**Outcomes to assess the effectiveness of the intervention:**

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 11 different POCUS examinations 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, and (3) number of consultations (outcomes E1-3). PLSP will deliver monthly aggregated data for each participating GP from baseline to 24 months after baseline. These continues data will be summarized to demonstrate variation over time.

For the registration of the clinical effect of POCUS use in the consultation (outcome E4), we will use an adapted version of a questionnaire used in a previous cohort study[24]. The GPs will be asked to specify the following for each POCUS examination: (1) organs/structures examined with POCUS (drop down menu or free text), (2) whether POCUS use entailed a change in diagnosis (yes/no), (3) whether POCUS use entailed a change in referral (yes/no), (4) whether POCUS use entailed a change in treatment (yes/no), (5) whether POCUS use entailed a change in diagnostic certainty for the GP (yes/no), (6) whether POCUS use was helpful for the GP in terms of making a decision for patient management (5-point Likert scale), (7) whether POCUS use was helpful for the GP in terms of arriving at a diagnosis (5-point Likert scale). GP will assess the questionnaire immediately after performing POCUS during consultations in clinical practice. These categorical data will be collected for each participating GP from day 7 to day 372.

For the registration of unwanted cases (outcome E5), 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. Data will be collected from baseline to 24 months after baseline. 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 assessment of unwanted cases 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/).

**Outcomes to assess implementation strategy effects:**
For the assessment of implementation strategy effects (outcomes I1-4), we will use the register data (fee specific codes) collected by PLSP on the monthly use of POCUS for each participating GP (outcomes I1 and I4) and the activities logged (pre-post tests, webinars, assignments, attendance on seminar days, logbook registrations) in the online platform used in the educational intervention (outcomes I2-3) to estimate the frequency of use and the percentage of adherence, respectively. The continues data (outcomes I1and I4) will be collected prospectively from day 7 to day 372, while the binary data (outcomes I2 and I3) are collected retrospectively at the end of the educational intervention including registration made in the online platform from day 1 to day 97 (at the end of the educational intervention).

**Outcomes to inform further development of the implementation strategy**
For outcomes related to the development of the implementation strategy (outcomes D1-D11), we will use a questionnaire distributed to participants three months after introducing POCUS in

general practice and teachers following the final teaching seminar (day 97). A reminder will follow after 2 weeks. The questionnaire will include the following questions with a 5-point Likert scale:

(D1) Did the educational intervention meets local needs?
(D2) Was the educational interventions agreeable in terms of content and delivery?
(D3) Was the educational intervention suitable for implementation?
(D4) Was the educational intervention in line with your values, mission, priorities?
(D5) Are you satisfied with the amount of support and resources allocated to you?
(D6) Was the educational intervention too difficult or complex to implement?
(D7) Did any organisational political, economic or social factors influence the implementation of the educational intervention?
(D8) Did the setting, including organisational values or norms influence the implementation of the educational intervention?
(D9) Did you have the capacity (e.g. knowledge and skills) to implement the educational intervention?

And the following questions with a free-text answer category:

(D10) How must did you have to invest financially to implement the educational intervention?
(D11) How much time and resources did you have to invest to implement the educational intervention?

**Outcomes to assess the feasibility of trial methods**

For the assessment of the feasibility of trial methods (outcomes F1-F8), we will evaluate the data quality by calculating the proportion of missing or incomplete registrations, recruited participants in relation to possible number of participants as well as participant retention and adherence. The steering committee will discuss the results and perform a qualitative evaluation based on predefined progression criteria (see section 16c).

Regarding the GP questionnaire (outcome F8), we will pilot test 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 $\geq 18$ to be a high level of stress[25]. 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 $\leq 3$ 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. The GP questionnaire will be distributed to participating GPs prior to the third teaching seminar (day 37, at the end of the educational intervention).

**Participants characteristics**
On the first teaching seminar (day 7) the following participant characteristics will be collected: 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), type of practice (collaboration, partnership, solo), location of practice (urban, rural, mixed), number of patients assigned to the practice, number of GPs working in the practice.

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.

## 13 Time schedule

We will invite participants from two PLO-e ultrasound course to participate:
Teaching seminars course 1: August 31st and September 28th and November 30th 2022
Teaching seminars course 2: September 6th and October 10th and November 29th 2022

Data collection participants in course 1: August 24th 2022 to November 30th 2024.
Data collection participants in course 2: August 30th 2022 to November 30th 2024.

## 14 Sample size

This is accompanying research and as such no formal sample size calculations are made. Our potential study population is 36 GPs, who have signed up to participate in an ultrasound course organized by PLO-e. We expect a participation rate of 66% corresponding to 21 GPs. Previous cohort studies from Danish general practice have shown that GPs' average use of POCUS corresponds to once a day. With a data collection period of 24 months for participants corresponding to 200 working days, we expect approximately 8400 POCUS registrations in this study.

## 15 Recruitment

Two ultrasound courses delivering the educational intervention have 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 courses. PLO-e has handled the participant recruitment and registration based on a first-come-first-served principle as well as the financial and practical aspects of organizing and executing the courses. The two ultrasound courses have a total of 36 available spots and all 36 participants are offered the opportunity to participate in the data collection for this study. However, not all participants will be offered financial compensation for participating in the study, as a collective agreement between the Danish regions and the association of GPs only allows for those GPs with in longest distance to a radiology department to have a free course attendance and a fee for performing POCUS during the data collection.

The offer to participate in the study is made upon registration to the course and repeated at the first webinar (day 1). At the webinar participants are informed about the research project and written information about the project including a consent form is distributed to participants. The signed consent forms are collected from participants on the first training seminar (day 7).

## Assignment of interventions

**16a Allocation Sequence generation**

n/a

**16b Allocation concealment mechanism**

n/a

**16c Implementation**

After the educational intervention, we will perform a process evaluation by collecting and assessing a number of implementation-related outcomes. We will use predefined progression criteria for all outcomes to make an interim analyses and evaluate whether adaptions to the intervention is needed prior to the large stepped wedged cluster randomized clinical trial (SW-CRT). The steering committee will perform this evaluation.

**We will consider changing the intervention and/or implementation strategy if:**

**Implementation strategy effects:**

(I1) Adoption: less than 80% percent of participating GPs adopt the intervention and start using POCUS in their daily practice during the educational interventions (months 1-3).
(I2) Fidelity (adherence): less than 75% of participating GPs complete the educational elements in the intervention (pre-post tests, webinars, assignments, attendance on seminar days, logbook registrations).
(I3) Reach (penetration): less than 90% of teachers will actively support participants by engaging in the online part of the educational interventions
(I4) Sustainability (maintenance): less than 75% of participating GPs adopt the intervention and continue to use POCUS in their daily practice following the educational interventions (months 5-6).

**Development of the implementation strategy**

(D1) Adaptability: Less than 90% of teachers or participants find that the implementation of the educational intervention meets local needs
(D2) Acceptability: Less than 90% of teachers or participants find the implementation of the educational interventions is agreeable in terms of content and delivery
(D3) Feasibility: Less than 90% of teachers or participants find the educational intervention to be suitable for implementation
(D4) Compatibility (appropriateness): Less than 90% of teachers or participants perceive the implementation of the educational intervention to be in line with the organisation's values, mission, priorities
(D5) Dose (satisfaction): Less than 90% of teachers or participants are satisfied with the amount of support and resources received as part of implementation strategy

(D6) Complexity: More than 90% of teachers or participants perceive the implementation of the educational intervention as being difficult or complex
(D7) Context: More than 90% of teachers or participants find that organisational political, economic or social factors influenced the implementation of the educational intervention
(D8) Culture: More than 90% of teachers or participants find that the setting, organisational values or norms influenced the implementation of the educational intervention
(D9) Self-efficacy: Less than 90% of teachers or participants find that they had the capacity (e.g. knowledge and skills) to implement the educational intervention
(D10) Cost: if costs of implementation the educational intervention exceeds the budget for the research project
(D11) Resources: if measures of the resources and managing required for the implementation the educational intervention exceeds the budget for the research project

**Feasibility of trial methods**

(F1) if we are not able to recruit 66% of the eligible participants
(F2) if we are not able to retain 66% of participants
(F3) if we are not able to retain 90% of teachers
(F4) if less than 90% of teachers delivered the intervention by protocol
(F5) if less than 90% of participants received the intervention by protocol
(F6) if less than 90% of data from registers was obtainable and valid
(F7) if less than 90% of data collection through GP questionnaires was obtainable and valid
(F8) if less than 90% of data collection through GP questionnaires was obtainable and valid

**17 Blinding**

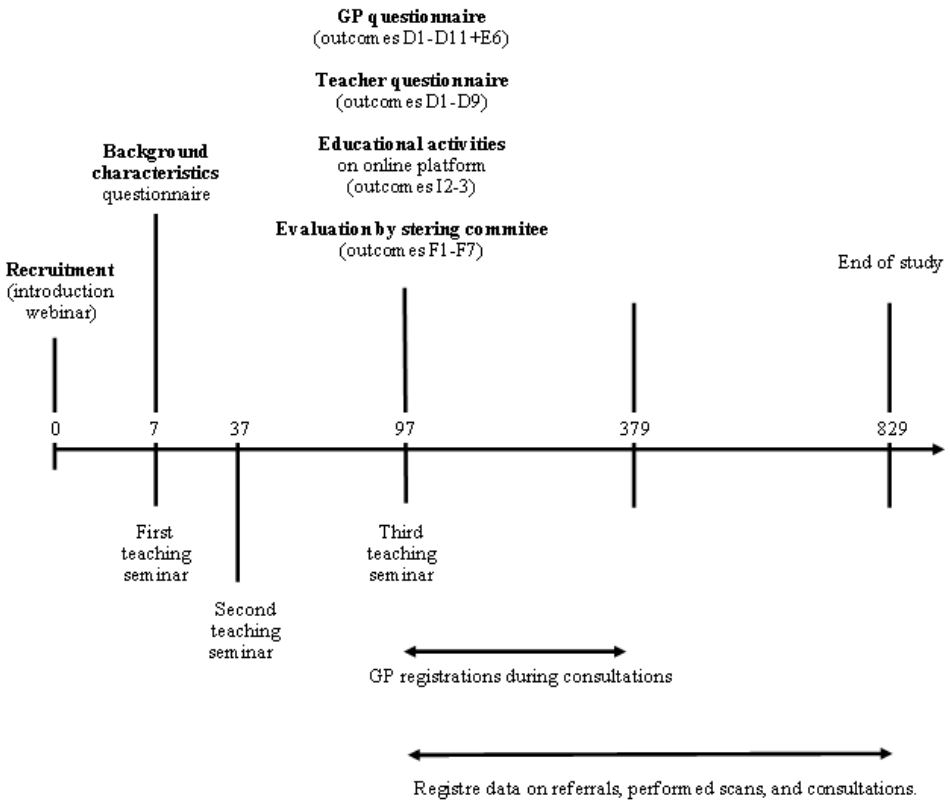
The researcher cleaning the data set and responsible for analyzing the primary outcome will have no knowledge of participants. He is a researcher with a physiotherapy background.

## 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.

Figure 7. Data collection




Register data: Data regarding different POCUS examinations, number of referrals, number of consultations will be delivered by PLSP (outcomes E1-3, I1 and 4). The data are registered prospectively by GPs in the medical records during the consultations from the first teaching seminar (day 7) until 24 months after the first teaching seminar (day 829). We will receive these data retrospectively from PLSP, who will use an algorithm to collect monthly aggregated data for each participating GP.
PLSP will also deliver aggregated data on patients age and gender independent from other study data.

GP registrations: For the GPs' registration of POCUS effect in the consultation (outcome E4), GPs will use paper registrations in logbooks during the educational intervention (day 7 to 96). Here the registrations are made for the GPs own purpose as part of the learning process. Following the educational intervention, we will ask the GPs to continue making these registrations with the purpose of research, using a QR code to access an online questionnaire. The paper registrations will be collected by the research team at the third teaching seminar (day 97) while the online-questionnaire data are collected continuously from day 97 to 372.
For the reporting of anonymously unwanted cases, GPs will have a QR code and a link for an online questionnaire (outcome E5). These data are collected prospectively continuously during consultations from the day 7 – day 829.

GP questionnaire: For the pilottest of a cross-sectional questionnaire exploring burnout, stress and job satisfaction at 3 months (outcome F8), an online questionnaire will be distributed to participants following the third seminar day and a possible reminder will follow after two weeks. The questionnaire collecting background characteristics on participating GPs will be distributed on the first teaching seminar (day 7).

Online platform: For the evaluation of participant adherence (outcome I2) and reach (outcome I3) we will use the registrations on the online platform (Microsoft Teams) supporting the educational intervention. These are collected retrospectively at the end of the educational intervention (day 97).

Process evaluation questionnaire: For the evaluation of implementation of the educational intervention (outcomes D1-11) a questionnaire will be distributed to teachers and participants following the educational intervention (day 97).

**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. Reminders will be sent to the participating GPs reminding them to scan patients and contact the research team in case of problems.

**19 Data management**

The data management will follow the rules of the General Data Protection Regulation (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 CAM AAU 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.

All patient-related data will remain in the GPs clinics until the end of the educational intervention (day 97). No data will be transferred to CAM AAU before legal approval by the health authorities has been obtained.

**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 to clinical Trials.org prior to the analysis of data (24 months after baseline). Data will be summarized and reported using descriptive statistics.

For effectiveness related outcomes E1-E5, frequencies and variance are reported as mean and 95% CI or median and IQR depending on the distribution of data. We will use graphic illustrations to demonstrate change over time. To test if changes over time are significant, we will use repeated measures ANOVA analysis.

For outcomes related to the implementation strategy effects (I1-I4) and feasibility of trial methods (F1-F7), we will report proportions as frequencies, while outcomes related to the implementation strategy (D1-D9) will be reported with an average score and outcomes D10-D11 with a summarized estimate on costs. For fesability related outcome F8, we will report the questionnaire response rate and the corresponding 95% CI.

**20b Methods for any additional analyses (e.g. subgroup and adjusted analyses).**
We will perform subgroup analysis to explore the effects of participants' background characteristics and type of POCUS examinations performed. This will be elaborated in the SAP.

**20c Missing data**
Missing values, owing to e.g. premature termination of the questionnaire, are considered completely random and will be declared for each outcome. 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 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 undesirable effects including 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 safety 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 North Denmark Region Committee on Health Research Ethics.
(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.
As we are collecting patient-related data for the purpose of research, we will seek permission by the health authorities (Application sent October 13th 2022). All patient-related data will be collected retrospectively after this approval is obtained. We will honor our information obligations to patients about the project by making project information available in the GP's clinic as hand-outs and posters.

The project has been registered and conducted according to the regulations of the Danish Data Protection Agency (registration number ID 242-3).

## 25 Protocol amendments

This is the second version of the study protocol. An amantment has been made prolonging the study follow-up for the primary outcomes to 24 months instead of 12 months. This was done, as register-based data was not made available until November 2024. Consentforms and permissions did allow for this extension.

## 26a Consent or assent

Informed consent form the participating GPs will be collected by the principal investigator prior to the study. We will not seek consent from patients, as no collected study data are directly linked to the specific patient. This decision was made to enable us to collect data on all patients examined with POCUS in general practice during the study, including patients who are unable to provide informed consent (children, elderly, and patients with mentally handicap).

## 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

The following authors will have access to collected data stored at the secure server at Aalborg University (AR, MBJ, JJS, SLC 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.
We aim for two scientific publications: Article 1 will include effectiveness-related outcomes (E1-E6), while Article 2 will report the development of the intervention and implementation-related outcomes (I1-4, D1-11 and F1-7).

**31b Authorship eligibility guidelines**

We 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**

Danish informed consent form will be developed and used in the study.

## References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