Center for General Practice at Aalborg University

Statistical analysis plan

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

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Version number and date

Version 9. 30-09-2024

Content

1. Overview of analyses

This document contains the statistical analysis plan for 'Evaluating scanning competence following a structured POCUS training program for general practitioners: A hybrid effectiveness-implementation study'. The aim is to clarify the intended analyses prior to collection of the primary outcome. This document describes the analyses to be performed in the main study paper.

The main time points for analyses are at baseline, after three months (at the end of the educational intervention) and after six months.

Participants will be recruited on the first teaching seminar on the 3rd of March 2022 (baseline). Effectiveness related outcomes will be collected on the third teaching seminar on the 9th of June 2022 (three months after baseline) and on the 7th and 8th of September 2022 (six months after baseline). Implementation related outcomes will be collected from baseline until the end of the trial on the 8th of September 2022 (six months after baseline).

2. Background of the trial

The trial is designed as a hybrid effectiveness-implementation study allowing for simultaneously evaluating the effect of a training program in real world settings and evaluating the implementation strategy (1). The trial is categorized as a type 1 hybrid design (2) with the purpose to rigorously test participants' competences when finishing an ultrasound course and again after three months evaluate if participants maintain their competences. Secondarily, we gather implementation data about the uptake of scanning procedures in practice and adherence to the training program (2).

The principal research aim is to evaluate ultrasound competences after an educational intervention by use of the OSAUS score. The study is conducted in Danish general practice and the study is registered at ClinicalTrials.gov (registration number: NCT05274581).

2.1. Eligibility

2.1.1. Inclusion criteria

To be eligible for the study, subjects must fulfill the following 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

2.1.2. Exclusion criteria

To be eligible for this study, subjects must not meet any of the following 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.

3. Adherence

Teachers at the educational intervention will support adherence to research protocols. The teacher will act as mentors for the participants and monitor participants' activity on the online platform. The teachers will reach out to participants who fail to register data and reminders are sent to the participants to remind about registering of all performed POCUS examinations during clinical work.

4. Baseline characteristics

Tables of summary statistics will be produced in one group. The table will include:

Variable	**Unit**	**Description**
Age	years	mean(SD) and median(IQR)
Sex	male, female, other	frequency (%)
Experience as a medical doctor	years	mean(SD) and median(IQR)
Experience as a GP	years	mean(SD) and median(IQR)
Experience with POCUS	years	mean(SD) and median(IQR)
Previous POCUS training	course participation, training during residency, experience from employment within another medical specialty, ad hoc training by colleague, other, no previous training	frequency (%)
Type of practice	solo-practice, partnership practice, solo-practice in collaboration, partnership practice in collaboration, other	frequency (%)
Location of practice	rural, city, mixed	frequency (%)
Distance to radiology department	km	mean(SD) and median(IQR)
Region	North Denmark Region, Central Denmark Region, Region of Southern Denmark, Region Zealand, Capital Region of Denmark	frequency (%)

Number of full-time equivalent GPs working in the clinic	1-20	mean(SD) and median(IQR)
Number of patients listed with the clinic	1000-20000	mean(SD) and median(IQR)

Note: The number of missing for each variable will be reported.

5. Effectiveness outcomes

5.1. The primary effectiveness outcome

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

The OSAUS assessment tool has been developed and validated as a generic tool for assessing scanning competence (3). The OSAUS scale consists of seven items: 'indication for the examination', 'applied knowledge of ultrasound equipment', 'image optimization', 'systematic examination', 'interpretation of images', 'documentation of the examination' and 'medical decision-making' and each item is rated using a provided five-point Likert-scale with descriptions of performance ranging from very poor (score = 1) to excellent (score = 5). Hence, for each scanning modality a total score from 7 to 35 points may be achieved.

(P1): The summarized OSAUS score after the educational period (three months after baseline) for all ten modalities will be calculated as percentage of maximum score. To summarize normal and non-normal data similarly mean(SD) as well as median(IQR) will be presented. Minimum and maximum score will also be presented.

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

5.2 Secondary effectiveness outcome measurements

(S1). The total OSAUS score and the total items scores for each of the ten scanning modalities included in the curriculum after the educational period (three months after baseline) will be calculated and presented as mean(sd) and median(IQR). Minimum and maximum score will also be presented.

(S2). A OSAUS score between 2.5 and 3.0 has previously been found valid and reliable to distinguish between novice POCUS users and experts(4). To apply a conservative cut-off (3.0 for each item) yields a combined pass/fail score for a scanning modality of 21.0 points of a maximum of 35.0 points. We calculate the proportion of GPs, who achieve a minimum OSAUS score of three for all seven domains for each of the ten scanning modalities after the educational period (three months after baseline). As variation in scores can occur between the five expert assessors. We will normalize the scores by multiplying a given accessors score

with (0.2 x sum of scores of all five accessors/the given accessors score) prior to calculating the proportion of successful GPs.

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

(S4): Before the OSAUS assessment the GPs will be asked to assess whether or not they have scanning competence within the specific scanning modality to perform the scan un-supervised in general practice (yes to a very high degree, yes to a high degree, yes to some degree, yes to a lesser degree, no, unsure). We calculate the proportion of GPs, who rate themselves as competent to perform POCUS un-supervised in general practice, after the educational period (three months after baseline), within each of the ten scanning modalities.

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

5.3 Additional outcomes (not predefined in study protocol)

(S6): Change in OSAUS scores between 3 and 6 months are calculated using linear regression. Scores after 3 and 6 month will be compared by a paired t-test.

(S7) we will use a linear regression model to test associations between OSAUS score at 3 and 6 months and the following variables: experience as a GP (years), experience using POCUS (years), participation in the planned course activities (number of completed webinars and course days), number of completed pre-post quizzes, number of completed assignments, number of performed POCUS examinations.

6. Implementation outcomes

(PR1): The GPs keep a log-book of all scans they perform. The number of scans of the 10 modalities performed during months 1 to 3 and month 4 to 6 are summarized. Results are presented as mean(sd) or median(IQR) number of performed POCUS examinations by each GP during months 1 to 3 and during months 4 to 6. Minimum and maximum score will also be presented.

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

(PR3): We will graphically evaluate the mean OSAUS score (y-axis) at the end of the educational intervention (3 months after baseline) as a function of each of the following educational aspects (x-axis): participation in the planned course activities (number of completed webinars and course days), number of completed pre-post quizzes, number of completed assignments, number of performed POCUS examinations.

7. Data collection

The OSAUS score

The participants will step-a-side to have their scanning competence assessed by a POCUS-expert assessor, who is blinded to the participants prior experience with POCUS, the number of performed POCUS examinations, and any other elements in the participants' learning process. Each POCUS-expert assessor will rate four participants twice: three months after baseline and six months after baseline. The POCUS-expert assessor will rate the individual participants screening competences by asking the below questions (blinded to the participants prior experience with POCUS, the number of performed POCUS examinations, and any other elements in the participants' learning process):

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

The POCUS-expert assessor will then ask participants to demonstrate the POCUS examination (for maximum five minutes) to rate the following:

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

Following the demonstration of the scan, the POCUS-expert assessor will present the participants with one picture of common pathology and ask the participants the following questions:

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

Self-rated scanning competence

Before the competence assessment by POCUS-expert assessor, the participants are asked to answer an online questionnaire and self-report if they have the scanning competence to perform the given POCUS examination un-supervised in general practice ((yes to a very high degree, yes to a high degree, yes to some degree, yes to a lesser degree, no, unsure).

Registration of performed POCUS examinations

Participants register their POCUS use during the educational intervention (months 1-3 after baseline) and in the months following the intervention (months 4-6 after baseline) using a paper registration sheet. Participants will bring these paper-registrations to the teaching seminars and the final OSAUS assessment, where the principal investigator will collect the data from each participant.

Adverse events and near-miss cases

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

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

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

Educational activities

The participants' adherence and activity in the educational elements will be registered during the educational period (months 1-3) on the online platform. The principal investigator will collect these data by monitoring the online platform activities.

8. Sample size

All 20 GPs taking part as participants in a specific training program are invited. It is expected that at least 16 (80%) will provide OSAUS data for the study. With 16 participants the total number of completed OSAUS questionnaires will be 160.

9. Safety committee

A safety committee will be set up to handle all reports of adverse and suspected adverse events (AEs) and serious adverse events (SAEs). Martin Bach Jensen will head the committee. The safety committee has the mandate to end the trial.

10. Statistical analysis

Data are presented as mean (sd) and median [IQR] or n (%). Results with p-values < 0.05 will be considered statistically significant. Comparisons and adjustments will all be done using appropriate linear regression models. These analyses will also be performed using bootstrap calculation of standard error to accommodate potential violations of normality and variance homogeneity assumptions. Statistical analyses will be performed in Stata (IC version 17).

A predictive mean matching (pmm) imputation method will be used to fill in missing values by the command "mi impute pmm" in Stata , for all OSAUS scores after 3 and 6 months. Predictive mean matching (PMM) is a partially parametric method that matches the missing value to the observed value with the closest predicted

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

10.1. Flow chart

A detailed flow chart with number of invited, reasons for exclusions and reasons for dropouts will be reported for the participating GPs in a Figure.

10.2. Handling of missing data

We analyse only full sample GP's. We supply with sensitivity analyses (worst case/best case) to assess robustness towards missingness.

11. Handling of data and blinding

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

The researcher cleaning the data set and responsible for analyzing the primary outcome will have no knowledge of participants. He has a physiotherapy background and have never diagnosed or treated patients in general practice.

12. Ethics

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

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

Written and signed informed consent is taken from all participants prior to participation in an educational intervention. Consent is not a requirement for participation in the data collection. 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. The GPs are asked to refrain from seeking other POCUS education prior to and during the study. Following the training sessions, information seeking e.g., through internet sources or books are permitted.

13. SAP Amendment

During the data analysis it was decided to drop the additional outcome S7, as this analysis did not add information to the results of the study beyond what was reported for the predefined outcome PR3.

14. References

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