Center for General Practice at Aalborg University

Statistical analysis plan

Can a tailored quality assurance program help general practitioners maintain POCUS scanning competence?

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Content

1. Overview of analysis

This document contains the statistical analysis plan for “Can a tailored quality assurance program help general practitioners maintain POCUS scanning competence?: A cohort study from Denmark”. The study protocol (ClinicalTrials.gov ID NCT05625646) specified the intended analyses *prior to collection of the primary outcome*. This document elaborates on these intended analyses to be performed in the main study paper.

This study is a follow-up of a prior study (ClinicalTrials.gov ID NCT05274581) in which 18 general practitioners completed a tailored ultrasound educational program and had their ultrasound scanning competences assessed immediately after the program and at follow-up after three months. The three-month follow-up in the previous study is baseline for the present study.

Hence, data for the present study were gathered between September 7th 2022 and January 22nd 2024. Scanning competence scores were collected at baseline (September 7th and November 3rd 2022) and after 14 months (November 30th 2023 and January 22nd 2024). Quarterly quizzes were collected in: December 2022/January 2023(Quiz 1), March/April 2023(Quiz 2), August/September 2023(Quiz 3) and October/November 2023(Quiz 4). Remuneration fess for performed ultrasound scans were collected between November 2022 and November 2023. Background characteristic on participating general practitioners were collected on March 3rd 2022 when participants enrolled in the previous study and updated for the present study.

2. Setting

The study is conducted in Danish general practice where office-based general practitioners practice family medicine and use ultrasound to examine patients with relevant conditions. Prior to the study, all participating general practitioners have completed an ultrasound educational program at a training facility and the data collection for the primary outcomes will be collected at the training facility.

2.1 Eligibility

2.1.1 inclusion criteria

To be eligible for the study, subjects must fulfil the following criteria:

1. 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
4. Have completed the ultrasound educational program in the previous study

2.1.2 exclusion criteria

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

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

3. Adherence

During the study, CAA monitored participants' scanning activity and responses to the quizzes and reached out to participants failing to be active or failing to complete the quizzes.

4. Background characteristics

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

Variable	Unit	Description
Age	Years	Mean (SD) or median (IQR)
Sex	Male, female, other	Frequency (%)
Previous use of ultrasound	Number of months with regular use	Mean (SD) or median (IQR)
Previous ultrasound courses of minimum 1 day duration	Yes, no	Frequency (%)
Scanner type	Low range, mid range, high end	Frequency (%)
Type of practice	Collaboration, partnership, solo	Frequency (%)
Location of practice	Urban, rural, mixed	Frequency (%)
Number of patients assigned to the practice,	1000-20000	Mean (SD) or median (IQR)
Number of GPs working in the practice.	1-20	Mean (SD) or median (IQR)

5. Outcomes

5.1 Primary outcomes

For the primary outcomes P1 and P2 and the secondary outcomes S1 and S2, we will use the Objective Structured Assessment of Ultrasound Skills (OSAUS) score collected at baseline and at follow-up.

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'. Each item is rated using a 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.

Primary outcome 1 (P1): The summarized OSAUS score at follow-up for all ten modalities will be calculated as percentage of maximum score. To summarize normal and non-normal distributed data similarly mean (SD) as well as median (IQR) will be presented together with minimum and maximum scores.

Primary outcome 2 (P2): The summarized OSAUS score at follow-up for each participating GP will be compared to the OSAUS sum score at baseline. The mean difference will be reported along with the proportion of GPs, with an OSAUS sum score at follow-up larger than or equal to the ultrasound competence score at baseline.

5.2 Secondary outcomes

(S1): For GPs, participating in a POCUS quality assurance program, the OSAUS item scores at follow-up, for each of the ten scanning modalities included in the curriculum will be calculated and presented as median, IQR, minimum and maximum score.

(S2): For GPs, participating in a POCUS quality assurance program, the proportion of GPs, who achieve a minimum OSAUS item score of three for all seven items for each of the ten scanning modalities at follow-up will we reported.

For the secondary outcome **S3**, we will use the GPs assessment of their own scanning competence. The GPs will declare to which degree they have POCUS scanning competence within a specific scanning modality to perform the scan un-supervised in

general practice (To a very high degree, to a high degree, to some degree, to a lesser degree, not at all, unsure).

(S3): For GPs, participating in a POCUS quality assurance program, the proportion of GPs, who rate themselves as competent to perform POCUS un-supervised in general practice at follow-up , within each of the ten scanning modalities.

For the secondary outcome **S4**, we will use fee-specific codes registered by the GP during consultation in general practice. 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 and fee-specific codes for using POCUS in the medical record system. Prior to this study, 10 fee-specific codes for the 10 different POCUS examinations in the curriculum 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 and (2) number of consultations. PLSP will deliver monthly aggregated data for each participating GP from baseline to 12 months after baseline.

(S4): The number of monthly performed POCUS examinations by each GP from baseline to follow-up will be summarized to demonstrate monthly variation over time.

For the secondary outcome **S5** and **S6**, we will use the results of distributed online quizzes to the participants. During the study, four online quizzes will be sent to participants by email (Months 3, 6, 9, and 12). A reminder will follow after two weeks to participants who fail to respond the quiz.

(S5): For GPs, participating in a POCUS quality assurance program, the absolute number and proportion of GPs, who complete the online quiz at months 3, 6, 9 and 12 will be reported.

(S6): The results of the online quizzes at months 3, 6, 9 and 12 after baseline will be summarized and reported as tests scores for GPs, participating in a POCUS quality assurance program will be reported.

(S7): For GPs, participating in a POCUS quality assurance program, we will graphically illustrate the relationship between total number of performed POCUS examinations for each of the ten scanning modalities included in the curriculum and OSAUS sum score at follow-up.

(S8): For GPs, participating in a POCUS quality assurance program, we will graphically illustrate the relationship between the number of completes quizzes in the quality assurance program and OSAUS sum score at follow-up.

(S9): For GPs, participating in a POCUS quality assurance program, we will graphically illustrate the relationship between the test score in the quizzes in the quality assurance program and OSAUS sum score at follow-up.

(S10): For GPs, participating in a POCUS quality assurance program, we will graphically illustrate the relationship between the OSAUS sum score at baseline and OSAUS sum score at follow-up.

(S11): the evaluation made by GPs, participating in a POCUS quality assurance program, will include:

- The absolute number and proportion of participants, who think the online quizzes helped them maintain scanning skills over the past year.

- The absolute number and proportion of participants, who think the online quizzes helped maintain focus on ultrasound over the past year.

- The absolute number and proportion of participants, who think the online quizzes developed their scanning skills over the past year.

- The absolute number and proportion of participants, who think the online quizzes were manageable in terms of time.

- The absolute number and proportion of participants, who think the online quizzes were manageable in terms of content.

- The absolute number and proportion of participants, who were overall satisfied with the online quizzes.

- The absolute number and proportion of participants, who think the OSAUS assessments have helped them maintain scanning skills over the past year?

- The absolute number and proportion of participants, who think the OSAUS assessments have developed their scanning skills over the past year.

- The absolute number and proportion of participants, who were overall satisfied with the OSAUS assessments.

6. Data collection

Multiple Choice Questionnaire (MCQ)

MCQ's will be distributed by email to participating GPs at 3, 6, 9, and 12 months. The email includes a link to an online questionnaire prepared and collected using Forms (Microsoft Office, Redmond, USA). A reminder will follow after two weeks to participants failing to complete the MCQ after the initial invitation. Data will be transferred and saved on a secure server at Aalborg University.

Assessment of scanning competence

The assessment of participants scanning competence using the OSAUS score will be performed in the same manner using the same expert assessors at baseline and after 14 months.

During the assessment, only the participant and the assessor are present. Each assessment will follow the same structure, where experts will assess the participants by asking the following questions:

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

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

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

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

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

Following the assessment, the participant will receive feedback on the level of performance and educational advice. The total duration of the assessment is expected to last 90 minutes for each participant. The assessor completes an OSAUS score for each of the ten examinations performed by the participant.

The OSAUS assessment tool measures competency according to seven key domains: 1) Indication for the examination 2) Applied knowledge of ultrasound equipment 3)

Image optimization 4) Systematic examination 5) Interpretation of images 6) Documentation of examination and 7) Medical decision making. Each domain is rated using a five-point Likert scale with descriptions of performance ranging from very poor (score=1) to excellent (score=5).

Education of POCUS expert assessors

The POCUS expert assessors all have prior experience using the OSAUS score. Still, prior to the assessment of the participants' performance in this study, the POCUS experts participate in a 90-minutes online training session with CAA who has prior experience with the education of a team of assessors. During this training session, the POCUS experts are presented to the OSAUS score and the procedure for assessing the participants in this study. The POCUS experts are instructed to rate according to the standard expected from a GP, who is capable of performing POCUS unsupervised in general practice.

Self-rated scanning competence

In relation to the expert assessment of scanning competence, participants were asked to fill out a questionnaire where they declare whether or not they have POCUS scanning competence within this scanning modality to perform the scan un-supervised in general practice. The expert assessors were blinded to this declaration.

Evaluation questionnaire

After 12 months following the final MCQ-quiz and the final evaluation of scanning competence, we will circulate an evaluation questionnaire for participants. This questionnaire will be developed based on collected experiences during the study.

7. Sample size

Our potential study population is the 18 GPs who participated in the ultrasound course organized by PLO-e. We expect a participation rate of 80% corresponding to 15 GP.

With 15 participants the total number of possible completed 7-item OSAUS questionnaires will be 15 for each modality and 150 for the combined estimate at follow-up.

8. Safety committee

A steering committee affiliated with CAM AAU (TL, UM, TMJ, SKA, MBJ and CAA) will handle and oversee the development of the quality assurance tool.

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

9. Statistical analysis

The analysis of OSAUS sum scores and item scores will be performed using linear regression or repeated measures ANOVA, with participants being the random effect. Cohen's d will be used to estimate effect size. To account for interrater variation, we will calculate an average score for each expert and adjusted results so that experts have the same average score. Sensitivity analyses will be performed and the results of both complete case and adjusted analyses will be reported. Distributions of baseline values will be presented as mean (SD) and median [IQR] for continuous or n (%) for categorical variables. Fisher's exact test will be used to compare out sample to the general population of GPs in Denmark. OSAUS scores will be presented in tables as summarized complete case (raw data) and statistical optimal data (including imputation and adjustment for expert variation). Results with p-values < 0.05 will be considered statistically significant. All statistical analyses will be performed using STATA version 18 (StataCorp, Texas, USA).

9.1 Handling of missing data

Missing will be reported for each complete case analysis. A predictive mean matching (mm) imputation method will be used to account for missing values in the OSAUS item scores.

10. 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.

11. Ethics and dissemination

11.1 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.
Prior to the collection of register data, we will seek permission from the Danish Regions 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.

12. References

(1) Schenker, N., and J. M. G. Taylor. 1996. Partially parametric techniques for multiple imputation. Computational Statistics & Data Analysis 22: 425–446. https://doi.org/10.1016/0167-9473(95)00057-7

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(3) International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors. Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html