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Effectiveness of 2x2-hour traditional lectures and case methods in Swedish general practitioners' continuing medical education about COPD: a cluster randomized controlled trial

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ABSTRACT

Objectives: To study the effects of CME about COPD for GPs by comparing two commonly used CME methods with each other and no CME (reference group).

Design: A pragmatic cluster randomized controlled trial with primary health care centers (PHCCs) as units of randomization.

Setting, participants and interventions: 24 PHCCs in Stockholm County, Sweden, were randomized into two CME intervention arms: case method learning (CM) (n=12) and traditional lectures (TL) (n=12). A reference group without CME (n=11) was recruited separately. GPs (n=255) participated in the study arm to which their PHCC was allocated: CM, n=87; TL, n=93; and reference, n=75. Two 2-hour CME seminars were given in a period of 3 months.

Primary outcome measures: Changes in scores between baseline and 12 months on a 13-item questionnaire about evidence-based COPD management (0-2 points/question, maximum total score 26 points).

Results: 133 (52%) GPs completed the questionnaire both at baseline and 12 months. Both CM and TL resulted in small yet significantly higher total scores at 12 months than at baseline (CM, 10.34 vs 11.44; TL, 10.21 vs 10.91; $p<0.05$); there were few significant differences between these CME methods. At both baseline and 12 months, all three groups' scores were generally high on questions about smoking cessation support and low on those that measured spirometry interpretation skills, interprofessional care, and management of multimorbidity.

Conclusions: Neither short CM nor short TL CME sessions substantially improve GPs' skills in managing COPD. It is justified to challenge the use of these common CME methods as a strategy for improving GPs' level of knowledge about

management of COPD and other complex chronic diseases characterized by multimorbidity.

Trial registration: ClinicalTrials.com, Protocol Record 2013/232-31/5.

Funding: Stockholm and Dalarna County Councils.

Keywords: continuing medical education, professional training, case method learning, traditional lectures, primary care physicians, COPD, chronic diseases, primary care, cluster randomized controlled trial.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The educational interventions (2x2-hour traditional lectures and case-based seminars) studied in this cluster randomized controlled trial are frequently used in real-life Swedish primary care, which strengthens the relevance of this study.
- The cluster design of study was a strength, since it decreased potential bias from contamination across individuals at each primary health care center.
- The follow-up investigation 12 months after the intervention was a strength, as it permitted us to observe the effects of the educational interventions beyond the immediate post-study period.
- The main limitation of the study was the large percentage of non-responders at the end, which significantly impaired the ability to draw conclusions.
- Using a written test of knowledge (the GP questionnaire) to assess the effects of the educational interventions was not optimal because it did not assess change in GPs' behaviors and because the scaling was narrow, decreasing the chances of clear distribution of the scores, which in turn led to few statistically significant changes in the scores.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is often comorbid with other conditions and is generally underdiagnosed and insufficiently managed in primary care (1). Despite improvements in recent years, primary care personnel can still contribute to delays in COPD diagnosis and care through insufficient actions to prevent, detect, and manage the disease (1-4).

In Sweden, the majority of patients with COPD are managed in primary care by general practitioners (GPs), who typically work together with other GPs in group practices and often in co-operation with specialized asthma/COPD nurses and pulmonary rehabilitation personnel (4, 5). As GPs are usually the patient's first professional health care contact, their knowledge about and skills in COPD management need to be up-to-date (6). However, there is a considerable gap between current COPD guidelines and what is actually done at GPs' practices. To help transfer theory into practice, more studies on the implementation of COPD guidelines are needed (7).

Continuing medical education (CME) is a necessary step in implementing optimal care. Although modern research stresses the effectiveness of multiple educational methods in CME (8-10), Swedish GPs still often sign up for 1-2 hour lectures, possibly because of their busy schedules. Traditional lectures (TL) are carried out mainly in didactic style with a CME leader as an academic expert. CME that uses case method learning (CM) can be carried out in similar settings and in a similar amounts of time as TL, but the CME leader uses an interactive teaching approach. The professional's perspective on the case described is a central feature in the discussions (11). When used in CME in primary care settings, CM has a positive

impact on learning (12, 13). In a typical CM seminar, a CME leader facilitates the discussion of one to two patient cases. CM stimulates creative thinking, communication, tolerance for different views, the ability to defend one's own point of view with logic, analysis, and decision making (14). It is a learning method that requires previous knowledge and clinical experience in the subject and maturity in the participants.

The current study is part of the PRIMAIR study, a cluster-randomized controlled trial (CRCT) at primary health care centers (PHCC) in Stockholm County in 2014-2017. PRIMAIR aimed to assess the effects of CME on professional COPD practice (GP-related outcomes) and healthcare outcomes (patient-related outcomes). This paper presents the GP-related outcomes.

The aim of the current study was to compare the effects of CME on the topic of COPD, delivered in the form of praxis-typical, short (1-2 hour) sessions of either CM or TL, tailored for and targeted to GPs. The hypothesis was that CME based on CM leads to greater improvements in GPs' level of knowledge about and skills in COPD management than TL or no CME.

METHODS

This paper was written in line with the 2010 Consolidated Standards of Reporting Trials (CONSORT) statement: extension to cluster randomized trials (15). The CONSORT checklist and flow chart (Figure 1) were used.

Using a computer randomization program, the authors randomized 24 PHCCs in Stockholm, Sweden, into two intervention arms: a CM arm and a TL arm. A reference group of 11 PHCCs (no CME) was recruited separately and was not randomized, as

the PHCCs in this group would not receive CME. The GPs participated in the study arm to which their PHCC was allocated.

The pharmaceutical industry did not participate in any part of the study, and we did not offer financial incentives to the participants. As there are no formal requirements for CME for GPs in Sweden, educational credits were not offered.

The CME sessions took place at the PHCCs. Five CME leaders, all GPs competent and experienced in COPD management, ran two 2-hour sessions at each PHCC. The two sessions took place a maximum of 3 months apart. Each PHCC was assigned the same CME leader and CME method (either CM or TL). Thus, four TL leaders taught at two to four PHCCs each, and one CM leader taught at all 12 PHCCs that received CM. John Biggs' educational theory of constructive alignment (16) was used to align the intended learning outcomes, learning activities, and assessments. The intended learning outcomes of the CME were derived from the pre-2015 COPD guidelines (2, 17, 18) and from a 2013 qualitative study of GPs in Stockholm that described barriers to and facilitators of the COPD guideline implementation process (19). Each leader adhered to the intended learning outcomes, but the learning activities differed in the CM and LT intervention groups. The leaders were also allowed to use their own presentation materials, such as slide shows and handouts. Apart from a short didactic introduction, participant activating methods (discussions) were the main method of used in the CM sessions, whereas the TL sessions followed a traditional didactic style.

A GP questionnaire, constructed by the authors and improved after a "think-aloud" discussion with a group of non-participating GPs, was used to assess GPs' level of knowledge. The paper format questionnaire consisted of five short patient case vignettes and two to three questions per vignette (13 in total). The questions were

about “knowledge/skills” and “practical management” and consisted of a mixture of multiple choice and open questions. The participants could score 0, 1, or 2 points per question. Responses were scored with a premade scoring template. GPs completed the questionnaires immediately prior to and 12 months after the CME sessions, taking 20 to 30 minutes each time. At baseline, the GPs replied to the questionnaire on their own without consulting each other. The GPs in the intervention arms did so at the first CME session, and the GPs in the reference group did so at a staff meeting. At 12 months, most GPs, regardless of study arm, filled in the questionnaire at an ordinary staff meeting. All did so individually. The few GPs who were not present at the staff meeting were contacted by telephone or email and reminded twice. They were allowed to complete the questionnaire on their own.

The GP questionnaire with a summary of the intended learning outcomes and the scoring template is found in Supplementary data file 1.

Information about GPs’ gender, age, years in the profession, and degree (specialist in family medicine or in training to become one) was gathered at baseline. Other information gathered at baseline included data on the PHCC where they worked, such as ownership (county council or private), whether there was a nurse-led asthma/COPD clinic at the PHCC, and sociodemographic characteristics of the PHCC’s catchment area (Care Need Index [CNI]) (20). The CNI is a deprivation index based on sociodemographic factors, including percentage of older adults living alone, children under age 5, unemployed people, people with low educational status, single parents, high mobility, and foreign-born people. A high CNI score indicates high sociodemographic burden. The mean CNI score PHCC catchment areas in Stockholm County is 2.49.

GP sample size was determined by the power calculation of the patient sample size in the PRIMAIR Study, which was determined to be 230 patients with COPD in GOLD stages 2 to 3 (2) in each arm. To keep the number of clusters reasonable, we chose to invite only PHCCs with more than 10,000 registered patients (n=80). We estimated that 10 to 12 PHCCs were needed per arm to achieve sufficient statistical power for the patient sample. Accordingly, the number of GPs was determined by the number of PHCCs we included. Unequal cluster sizes (5 to 10 GPs) were expected because of variations in staff numbers at baseline and dropouts at 12 months. The intraclass correlation coefficient (ICC) was set at 0.01 based on earlier studies on cluster randomizations in primary care (21-23).

Statistics

We performed the statistical analysis with STATA, version 14 (Stata Corp. 2015. Stata Statistical Software: Release 14. College Station, TX: Stata Corp. LP) and SPSS, version 23 (PSPP (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.). We computed summary statistics such as means, proportions, and measures with standard parametric methods. We used a McNemar test to compare matched pairs of scores per question at baseline and 12 months for proportions of GPs who scored “0 points” vs “1 or 2 points.” We used clttest and xtreg (adjusting for cluster) to analyze differences in total scores within the study arms and for adjusting for “total scores at baseline,” “CNI,” and “years in profession.” A transition model, adjusted for clusters, was applied to analyze associations between items (“0 points” or “1 or 2 points”) and study arms at baseline and 12 months, which also provided odds ratios (ORs) and their 95% confidence intervals (CIs). In a transition model the outcome variable at a previous time point is included as a fixed effect covariate. We condition the response at time j on the

response at time j-1. ICC was estimated by xtlogit. P-values <0.05 were considered indicative of statistical significance.

A detailed description of the methodology and interventions is found in the study protocol (24).

Ethics

The present CRCT, including a model consent form and other related documentation given to participants, was approved by the Regional Ethical Review Board of Stockholm (ref 2013/232-31/5). Prior to enrollment, all PHCC managers and all participants provided written informed consent to be involved in the study. The study is registered at www.clinicaltrials.com, Protocol Record NCT02213809, 10 August 2014.

RESULTS

Description of the participants

At baseline, 207 GPs attended the CME sessions. In the CM arm, 87 of 100 GPs (87%), in the TL arm, 93 of 107 GPs (87%) agreed to participate in the study. The reference group consisted of 75 GPs. The majority (90%) of the GPs who did not agree to participate (n=27) worked at a PHCC without a nurse-led asthma/COPD clinic (p<0.005). They did not differ from the participants regarding age, gender, years in profession, educational degree, or PHCC's CNI scores or ownership form.

Of the 255 participants who responded to the questionnaire at baseline, 122 (48%) did not respond again at 12 months ("non-responders"). The remaining 133 GPs were the final participants ("responders"). There were no significant differences

between any of the groups studied (the two intervention arms and the reference group) in the proportions of responders and non-responders. A higher percentage of the non-responders than responders were employed at PHCCs in socially deprived areas of Stockholm ($p<0.05$). The characteristics of the responders and non-responders are seen in Table 1.

A higher percentage of GPs in the CM arm than the TL arm and the reference group worked at a PHCC with a nurse-led asthma/COPD clinic (64% vs 36%-38%, $p=0.012$). A higher percentage of GPs in the reference group than the CM and TL arms worked at privately run PHCCs (72% vs 32%-42%, $p=0.001$). The means for gender, age, years in profession, and CNI scores did not differ significantly between the GPs in the groups studied (the two intervention arms and the reference group), and the participants were generally representative for Swedish GPs with regard to these characteristics (25).

Scores

Total scores – within and between the arms

After adjustment for the clusters (i.e. PHCCs) and mean scores at baseline, the mean scores in both intervention arms were significantly higher at 12 months than at baseline (CM: 10.34 vs 11.44; TL: 10.21 vs 10.91; $p<0.05$) (Figure 2). There was no statistically significant difference between the improvement in the CM and TL arms. No significant changes in scoring over time were observed in the reference group. All the non-responders had significantly lower mean baseline scores than the responders (9.11 vs 10.47, $p=0.003$). At baseline, the GPs who worked at PHCCs in the most socially deprived areas (CNI 2.29-5.05, 21% of all GPs) had lower mean scores than the others (8.50 vs 10.32, $p=0.000$), and the non-responders in the deprived areas scored lowest of all non-responders (7.98 vs 9.71, $p=0.007$).

Scores on individual questions – comparison of the arms

Table 2 compares the results for each of the 13 questions in the two intervention arms and the reference group by providing ORs of "scoring 1 or 2 points at 12 months." The TL arm had a statistically significantly higher OR of "scoring 1 or 2 points at 12 months" than the reference group on two of the questions: the question about the follow-up of stable patients (question 9) and the question about multimorbidity in a patient with airway symptoms (question 13). On the question about smoking cessation support for patients who were motivated to quit smoking (question 6), the TL arm had a higher OR of "scoring 1 or 2 points at 12 months" than the CM arm. The CM arm's ORs were not significantly higher for any of the questions than the TL arm or reference group's ORs. Regarding the effects of intracluster conditions, we found three significant ICCs (questions 1, 10, and 12), all of them were approximately 0.10 (CIs could not be estimated because no standard error was available).

Scores on individual questions – within the arms

For 10 of 13 questions, there was no significant difference between baseline and 12 months in the proportion of participants who scored 1 or 2 points and who scored 0 points (Figure 3). Scores on two questions improved significantly (CM arm, question 2, spirometry interpretation; TL arm, question 9, follow-up of stable patients), and scores on one question dropped significantly (reference group, question 13, multimorbidity in a patient with airway symptoms) (Figure 4a-c).

DISCUSSION

Main findings

The results of our study do not bear out the hypothesis that CM leads to greater improvements in GPs' level of COPD-related knowledge and skills than TL. However, the hypothesis that CM would be superior to no intervention was confirmed. Both CM and TL led to small, yet significant, improvements in Swedish GPs' levels of knowledge of COPD and COPD management skills. Neither of the CME methods was more effective than the other. GPs' baseline level of knowledge was low, and improvements at 12 months were generally modest.

Over time, strong areas of knowledge remained strong, and weak areas weak

For the most part, the differences between strong and weak areas of knowledge about COPD were maintained over time. We were not surprised by the high level of knowledge about smoking cessation support, as most GPs are well aware of and do not question the importance of quitting smoking. However, there is a gap between what GPs know and what they do: earlier research has shown that doctors rarely take active measures to help patients quit smoking (26). The preliminary results of a questionnaire to randomly selected COPD patients at the PHCCs participating in this study indicate that approximately 60% of the patients who are current smokers or have quit smoking in the last five years (n=382) state they have *not been offered* smoking cessation support, and 80% state they have *not been given* such support by their GPs or nurses (Sandelowsky, in manuscript). As the benefits of smoking cessation far outweigh the benefits of diagnosing new cases or providing pharmacological treatments for COPD (27), the GP's role as a motivator and authority in patient education should not be overlooked and needs continuous attention in CME situations.

Insufficient skills in spirometry interpretation may be one of the major causes of problems with implementing evidence-based COPD practice (28). CM involved active

participation in training spirometry interpretation and discussing spirometry results, which may explain the improvements in responses to the question that measured spirometry interpretation skills. However, this was the only question on spirometry interpretation, and conclusions based on the responses to one question may not be reliable. TL positively affected replies to the questions on smoking cessation support to motivated patients, follow-up of patients with stable COPD, and management of airway symptoms in multimorbid patients. We did not investigate whether this finding was due to factors related to the CME leaders (i.e. uneven focus on the different intended learning outcomes) or to the didactic lecturing style.

Neither CME method led to significant improvements in managing COPD in patients with multi- and comorbidities, managing acute exacerbation under time pressure, managing patients who lack motivation to quit smoking, or handling patients whose focus during the consultation is something other than COPD. Thus, these typical real-life conditions and problems in Swedish primary care, which represent important obstacles to implementing guidelines (19), remain difficult to overcome with two short sessions of CME, regardless of whether lectures or case methods are used.

Comparison with previous studies

Kiessling et al found that using CM to implement evidence-based practice in primary care was associated with decreased mortality in patients with coronary heart disease in Sweden 10 years after the training had taken place (12). The educational meetings in Kiessling's study were carried out similarly to those in our study; i.e., as short CM seminars for GPs at their workplaces, led by an external facilitator. COPD may be a more complex health issue than cardiovascular diseases, and evidence-based management may thus be more complex to implement. The complexity of COPD

typically includes disabling comorbidities (1), confronting lifestyle choices (mainly smoking), low patient motivation to adhere to treatment (19, 29), GPs' negative views of COPD (19), consequences of COPD in patients' family lives (30), and the crucial role of interprofessional care (31).

We are not alone in finding that CM sessions brief enough for busy GPs to attend are of limited effectiveness. A 2016 Swedish study about the effectiveness of CM in CME for GPs on the topic of childhood asthma used CM similar to those in our study. That intervention had no effects on prescriptions of anti-asthmatic drugs for children (32).

In line with theories of adult learning, the American College of Chest Physicians recommends multiple teaching techniques, such as CM, audience response system, lectures, hands-on demonstrations, discussion groups, and role playing to effectively change physician knowledge, performance, and clinical outcomes (8). In fact, two previous CME studies from the United States, by Drexel et al and Adams et al, found that CME had positive effects on GPs' management of COPD when used as one of multiple educational methods, including a combination of short didactic lectures, case discussions, spirometry workshops, and inhaler demonstrations (13, 33). Moreover, Adams et al observed positive outcomes following interactive and collaborative CME for multidisciplinary participants, which is particularly relevant, as the current Swedish guidelines strongly recommend interprofessional COPD care (31). However, the follow-up measurements in both the Adams et al and Drexel et al studies were made shortly after the CME intervention and thus do not provide information about the sustainability of results. Additionally, in the Drexel et al study, no pre-intervention measurements were performed, which limits the researcher's ability to evaluate of the effects of the CME.

Methodological considerations

Strengths and weaknesses

One strength of this study was the cluster randomization of the PHCCs, which reduced the likelihood of possible contamination across individuals at each PHCC (cluster). Including a reference group enabled us to compare knowledge gained through our interventions with information gained through other sources during the study period. Using a transition model in the analysis of data was a strength because of its simplicity. The statistically significant ICCs we found for the questions were higher than expected, indicating that intracluster conditions may have affected the GPs' results in some of the individual questions more than assumed prior to the intervention. This information may assist researchers conducting CRCTs in similar environments in the future. Our assessment indicated that there were practically no interactions between the clusters that could have biased the results.

Swedish GPs report they have little time for CME because of heavy workloads due to time constraints, staffing problems, and financial incentives at the PHCC that encourage multiple short visits (25). A previous study in a similar setting found that primary health care professionals appreciate CME outreach visits (34). The CME outreach visits in the current study were thus another strength, as they enabled the GPs to attend the CME sessions despite their busy schedules. Another strength was the choice to conduct the follow-up measurement 12 months after the intervention, which enabled us to describe the sustained effects of the interventions.

The recruitment of the reference group deviated from optimal CRCT design. Thus, some caution should be used when interpreting the results for the reference group.

Another limitation of our study was the potential for reporting bias at 12 months due to non-response. High non-response impaired the statistical power of the 12-month analysis and decreased our ability to generalize the results. A high drop-out percentage was also observed in the Adams et al CME study. The high drop-out rates in the two studies may reflect the strenuous working conditions GPs often experience: reminders had practically no effect on response rate. Non-responders may also have been uncomfortable reporting their potential lack of knowledge gain after the CME. Moreover, it was alarming to find that many of the non-responders worked in deprived urban areas where smoking and COPD are common (35, 36).

A source of bias may have been the minor overlapping of the two pedagogical methods. Although we focused on providing didactic lectures in the TL sessions, some natural interplay may have taken place. On the other hand, CM consists of a mixture of didactic and participatory learning methods. The TL sessions were taught by four different CME leaders and the CM sessions were facilitated by one, which may have further biased the results, as the TL leaders may have stressed different content.

We found GPs' baseline level of knowledge about COPD surprisingly low. Either a pilot survey prior to the intervention or designing the teaching activities after the baseline data were collected and analyzed could have improved the teaching activities.

The GP questionnaire had strengths and limitations. A “think-aloud” discussion with a group of non-participating GPs helped us improve the five case vignettes' understandability and relatability, increasing the chances of valid replies to the questions. However, written descriptions, such as in case vignettes and multiple-choice answers, always involve a risk of misinterpretation, and thus of biased replies.

We suspect this could have happened in question 8, as it was expressed in inverted (negative) wording. Another limitation of the study was that the questionnaire was the only assessment method we used, so we were unable to assess whether the GPs' behaviors changed in practice. The use of mixed methods would have helped ensure the best possible assessment validity (37). The narrow, 0-2 point scale, together with strict scoring requirements, may have contributed to difficulties in differentiating the participants' results. We tried to minimize the testing bias that can occur when the same questionnaire is administered twice by not revealing the answers and by using paper questionnaires to disable digital distribution of the questionnaire. Finally, participants may have received information about COPD through other channels during the study period.

Implications and future research

The findings of this study can be useful in developing CME interventions that are feasible to implement in a busy primary care practice and that target the management of complex, chronic health issues (25, 38). The particularly low competence in the subject of COPD among GPs in socially deprived areas sends an important message to policymakers, as smoking and COPD are particularly prevalent in these areas (35, 36).

An evaluation of patient-related outcomes before and after the CME intervention is underway as a part of the PRIMAIR study. Future research could evaluate the effects of a sequel to our CME intervention that incorporates other educational methods and/or angles the focus towards interprofessional learning activities to support team-based COPD care in primary care. However, such interventions would likely need to be longer than two short sessions, which would make them challenging to implement in primary care. As many people now acquire knowledge via digital media, future

research could also investigate the effects of easy-to-access online handbooks and guides as support for GPs in clinical decision-making.

CONCLUSION

GPs' levels of knowledge of and skills for COPD were low at baseline, and the effects of both case methods and traditional lectures were equally modest. Thus, these common educational methods alone may not be sufficient to substantially improve GPs' level of knowledge and management of COPD. Critics are justified in challenging the use of a single CME method in short sessions as a strategy for improving management of patients with COPD or other complex chronic diseases characterized by multimorbidity.

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AUTHORS' CONTRIBUTIONS

Hanna Sandelowsky (HS), Ingvar Krakau (IK), Sonja Modin (SM), Björn Ställberg (BS), and Anna Nager (AN) conceived and designed the study. HS and BS were two of the five CME leaders. HS collected the data. HS, BS, Sven-Erik Johansson (SEJ), and AN analyzed the data. HS wrote the paper. All authors edited, revised, and approved the final manuscript.

COMPETING INTERESTS

HS has received honoraria for educational activities from Boehringer Ingelheim, Novartis, AstraZeneca, and TEVA and an unrestricted research grant from AstraZeneca. AN has received compensation for educational activities from AstraZeneca and SM from Novartis. BS has received honoraria for educational activities and lectures from AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Meda, , Novartis, and TEVA and has served on advisory boards arranged by AstraZeneca, Novartis, Meda, TEVA, GlaxoSmithKline, and Boehringer Ingelheim. IK and SEJ report no competing interests.

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References

1. Stallberg B, Janson C, Johansson G, Larsson K, Stratelis G, Telg G, et al. Management, morbidity and mortality of COPD during an 11-year period: an observational retrospective epidemiological register study in Sweden (PATHOS). Prim Care Respir J. 2014;23(1):38-45.

2. Global Initiative for Chronic Obstructive Lungdisease. 2013 [cited 17 Jan 2018]. Available from: ttp://www.goldcopd.com/

3. Lindberg A, Bjerg A, Ronmark E, Larsson LG, Lundback B. Prevalence and underdiagnosis of COPD by disease severity and the attributable fraction of

smoking Report from the Obstructive Lung Disease in Northern Sweden Studies. Respir Med. 2006;100(2):264-72.

4. Lisspers K, Johansson G, Jansson C, Larsson K, Stratelis G, Hedegaard M, et al. Improvement in COPD management by access to asthma/COPD clinics in primary care: Data from the observational PATHOS study. Respir Med. 2014 Sep;108(9):1345-54.

5. Arne M, Emtner M, Lisspers K, Wadell K, Stallberg B. Availability of pulmonary rehabilitation in primary care for patients with COPD: a cross-sectional study in Sweden. Eur Clin Respir J. 2016;3:31601.

6. Lisspers K, Stallberg B, Hasselgren M, Johansson G, Svardsudd K. Primary health care centres with asthma clinics: effects on patients knowledge and asthma control. Prim Care Respir J. 2009;19(1):37-44.

7. Pinnock H, Thomas M, Tsiligianni I, Lisspers K, Ostrem A, Stallberg B, et al. The International Primary Care Respiratory Group (IPCRG) Research Needs Statement 2010. Prim Care Respir J.19 Suppl 1:S1-20.

8. Davis D, Galbraith R, American College of Chest Physicians H, Science Policy C. Continuing medical education effect on practice performance: effectiveness of continuing medical education: American College of Chest Physicians Evidence-Based Educational Guidelines. Chest. 2009;135(3 Suppl):42S-8S.

9. Forsetlund L, Bjorndal A, Rashidian A, Jamtvedt G, O'Brien MA, Wolf F, et al. Continuing education meetings and workshops: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2009(2):CD003030.

10. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implement Sci. 2012;7:50.

11. Nordquist J. Att undervisa med case i utbildningar inom hälso- och sjukvården. Stockholm: Karolinska Institutet, Mecical Care Centre 2009.

12. Kiessling A, Lewitt M, Henriksson P. Case-based training of evidence-based clinical practice in primary care and decreased mortality in patients with coronary heart disease. Ann Fam Med. 2011;9(3):211-8.

13. Drexel C, Jacobson A, Hanania NA, Whitfield B, Katz J, Sullivan T. Measuring the impact of a live, case-based, multiformat, interactive continuing medical education program on improving clinician knowledge and competency in evidence-based COPD care. Int J Chron Obstruct Pulmon Dis. 2011;6:297-307.

14. Mauffette-Leenders LA, Erskine JA, Leenders MR. Learning with cases. London [Ont.]: Richard Ivey School of Business, The University of Western Ontario; 1997.

15. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661.

16. Biggs John CT, editor. Teaching for Quality Learning at University: The McGraw-Hill Companies; 2011.

17. National Board of Health and Welfare. Socialstyrelsens riktlinjer för vård av astma och kroniskt obstruktiv lungsjukdom (KOL). Faktadokument och beslutsstöd för prioriteringar. 2004.

18. Swedish Medical Products Agency. Läkemedelsverkets riktlinjer för behandling av kroniskt obstruktiv lungsjukdom. 2009 [cited 17 Jan 2018]. Available from: https://lakemedelsverket.se/upload/halso-ochsjukvard/behandlingsrekommendationer/KOL_rek_webb.pdf

19. Sandelowsky H, Hylander I, Krakau I, Modin S, Stallberg B, Nager A. Time pressured deprioritization of COPD in primary care: a qualitative study. Scand J Prim Health Care. 2016:1-11.

20. Sundquist K, Malmstrom M, Johansson SE, Sundquist J. Care Need Index, a useful tool for the distribution of primary health care resources. Journal of epidemiology and community health. 2003;57(5):347-52.

21. Adams G, Gulliford MC, Ukoumunne OC, Eldridge S, Chinn S, Campbell MJ. Patterns of intra-cluster correlation from primary care research to inform study design and analysis. J Clin Epidemiol. 2004;57(8):785-94.

22. Killip S, Mahfoud Z, Pearce K. What is an intracluster correlation coefficient? Crucial concepts for primary care researchers. Ann Fam Med. 2004;2(3):204-8.

23. Hayes RJ MH. Cluster Randomised Trials. Boca Baton, FL: Chapman & Hall/CRC, Taylor & Francis Group; 2009.

24. Sandelowsky H, Krakau I, Modin S, Stallberg B, Nager A. Case Method in COPD education for primary care physicians: study protocol for a cluster randomised controlled trial. Trials. 2017;18(1):197.

25. Pettersson S. [Swedish Medical Association's Primary Care Survey] In Swedish. Stockholm. Swedish Medical Association. 2015. p. 16-59.

26. Stead M, Angus K, Holme I, Cohen D, Tait G, Team PER. Factors influencing European GPs' engagement in smoking cessation: a multi-country literature review. Br J Gen Pract. 2009;59(566):682-90.

27. Black WC, Gareen IF, Soneji SS, Sicks JD, Keeler EB, Aberle DR, et al. Cost-effectiveness of CT screening in the National Lung Screening Trial. N Engl J Med. 2014;371(19):1793-802.

28. Foster JA, Yawn BP, Maziar A, Jenkins T, Rennard SI, Casebeer L. Enhancing COPD management in primary care settings. MedGenMed. 2007;9(3):24.

29. Roddy E, Antoniak M, Britton J, Molyneux A, Lewis S. Barriers and motivators to gaining access to smoking cessation services amongst deprived smokers--a qualitative study. BMC Health Serv Res. 2006;6:147.

30. Zakrisson AB, Theander K, Anderzen-Carlsson A. The experience of a multidisciplinary programme of pulmonary rehabilitation in primary health care from the next of kin's perspective: a qualitative study. Prim Care Respir J. 2013;22(4):459-65.

31. National Board of Health and Welfare. Nationella riktlinjer vid vård av astma och KOL. 2015 [cited Jan 24 2018]. Available from: http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19949/2015-11-3.pdf

32. Ingemansson M. Evidence-based practice for children with asthma in primary care – quality of management and effects of learning Stockholm: Karolinska Institutet, Stockholm, Sweden; 2016.

33. Adams SG, Pitts J, Wynne J, Yawn BP, Diamond EJ, Lee S, et al. Effect of a primary care continuing education program on clinical practice of chronic obstructive pulmonary disease: translating theory into practice. Mayo Clin Proc. 2012;87(9):862-70.

34. Berggren E, Odlund Olin A, Orrevall Y, Strang P, Johansson SE, Tornkvist L. Early palliative home care: Evaluation of an interprofessional educational intervention for district nurses and general practitioners about nutritional care. SAGE open medicine. 2017;5:2050312117726465.

35. Engstrom K, Magnusson C, Galanti MR. Socio-demographic, lifestyle and health characteristics among snus users and dual tobacco users in Stockholm County, Sweden. BMC Public Health. 2010;10:619.

36. Nacul LC, Soljak M, Meade T. Model for estimating the population prevalence of chronic obstructive pulmonary disease: cross sectional data from the Health Survey for England. Popul Health Metr. 2007;5:8.

37. Wass V, Van der Vleuten C, Shatzer J, Jones R. Assessment of clinical competence. Lancet. 2001;357(9260):945-9.

38. Baron RJ. What's keeping us so busy in primary care? A snapshot from one practice. N Engl J Med. 2010;362(17):1632-6.

Table 1. The main characteristics of the participants in the two intervention arms and reference group.

Main characteristics	Baseline	12 months	
Participants	**All**	**Responders**	**Non-responders**
n (%)	255 (100)	133 (52)	126 (48)
Number of participants per PHCC, mean (range)	7.5 (2-15)	4.3 (1-10)	
Gender, n (%)			
Women	149 (58)	81 (61)	68 (56)
Age, mean (range)	47 (27-69)	47 (27-68)	47 (27-69)
Degree in family medicine, n (%)			
Specialist in family medicine	184 (72)	102 (77)	82 (67)
Training to be a specialist in family medicine	71 (28)	31 (23)	40 (33)
Years worked in primary care, mean (range)	14 (0-41)	15 (0-37)	14 (0-41)
Asthma/COPD clinic at PHCC, n (%)			
Yes	114 (45)	70 (53)	51 (42)
Ownership of PHCC			
Stockholm County Council	132 (52)	71 (53)	61 (50)
Private	123 (48)	62 (47)	61 (50)
CNI of PHCC's location, mean (SD)	2.17 (0.78)	2.03[1](0.67)	2.32[1](0.86)
range	0.92-5.05	0.92-5.05	0.92-5.05

CNI, Care Need Index; COPD, chronic obstructive pulmonary disease; PHCC, primary health care center. The CNI is based on sociodemographic factors, including percentage of older adults living alone, children under age 5, unemployed people, people with low educational status, single parents, high mobility, and foreign-born people. High CNI = high sociodemographic burden; mean CNI in Stockholm County = 2.49.

[1]p of the difference between responders and non-responders <0.05

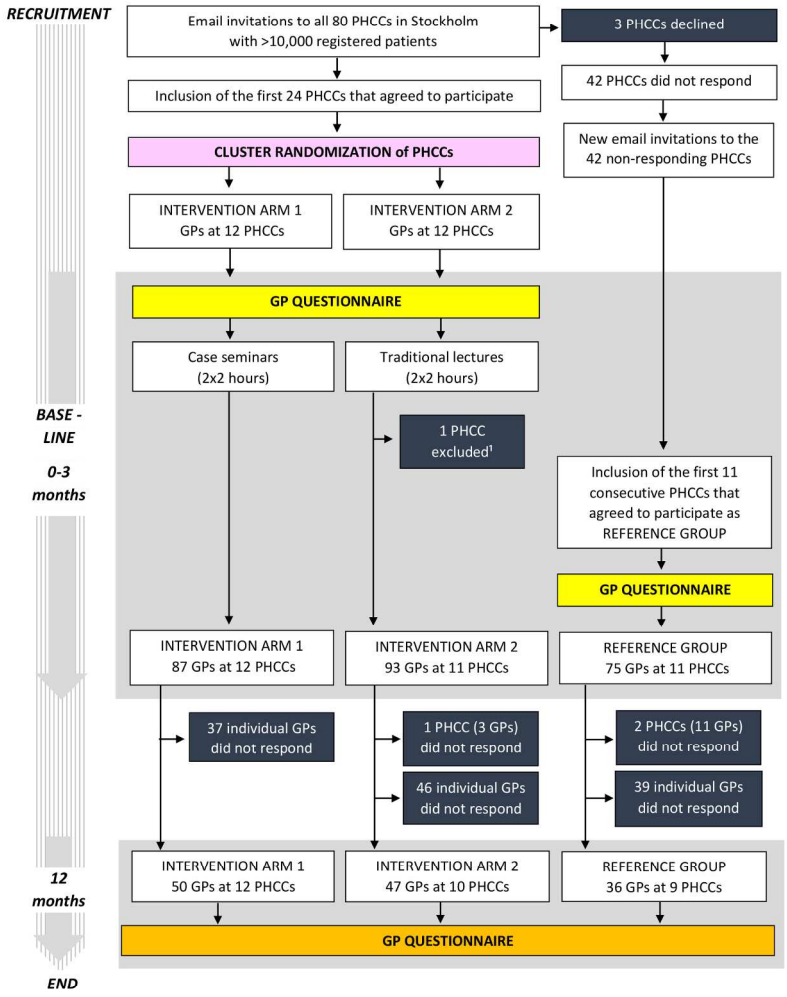
Table 2. Comparison of the odds ratios and 95% confidence intervals of scoring 1 or 2 rather than 0 points in the two intervention arms (case methods, CM; traditional lectures, TL) and the reference group (no continuing medical education) 12 months after the intervention. All measures are adjusted for clusters (primary health care centers) and total scores at baseline.

Question	Odds Ratio				
	CM and TL vs. Reference group [95% CI]			CM vs.TL [95% CI]	
	CM	TL	Reference group	CM	TL
1. Diagnostic procedures	0.55 [0.22 – 1.40]	0.55 [0.21 – 1.42]	1	1.00 [0.43 – 2.31]	1
2. Spirometry interpretation	1.29 [0.53 - 3.10]	0.61 [0.24 - 1.55]	1	2.10 [0.90– 4.95]	1
3. Smoking cessation (unmotivated patients)	N.A.[1]				
4. Acute exacerbation (treatment)	1.40 [0.57 – 3.45]	0.77 [0.31 – 1.96]	1	1.81 [0.77– 4.24]	1
5. Acute exacerbation (follow-up)	N.A.[2]				
6. Smoking cessation (motivated patients)	0.41 [0.14 - 1.24]	1.35 [0.39 – 4.69]	1	0.30 [0.10 – 0.88]	1
7. Maintenance treatement	1.04 [0.42 – 2.54]	0.72 [0.30 - 1.74]	1	1.44 [0.63 – 3.29]	1
8. Comorbidity: heart failure	2.46 [0.79 – 7.66]	1.70 [0.61 - 4.95]	1	1.45 [0.57 – 3.67]	1
9. Follow-up (stable patients)	2.37 [0.96 - 5.86]	4.48 [1.51 – 13.3]	1	0.53 [0.20 - 1.40]	1
10. Inter-professional interventions	1.82 [0.59 – 5.61]	1.42 [0.45 – 4.49]	1	1.29 [0.50 – 3.31]	1
11. Suspected respiratory failure	1.51 [0.62 - 3.72]	0.97 [0.39 - 2.41]	1	1.57 [0.68 - 3.62]	1
12. Multi-morbidity, no airway symptoms	1.36 [0.54 - 3.40]	0.97 [0.39 – 2.43]	1	1.39 [0.60 – 3.24]	1
13. Multi-morbidity, airway symptoms	1.34 [0.53 - 3.37]	2.64 [1.06 - 6.60]	1	0.51 [0.22 - 1.15]	1

[1]Odds ratios not applicable because there was no convergence in the model.

[2]Odds ratios not applicable because the model was questionable.

Figure 1. Study enrollment, general practitioner part of the PRIMAIR study.



GP, general practitioner; PHCC, primary health care center.

¹The main author started working as a GP at this particular PHCC.

Figure 1. Study enrollment, general practitioner part of the PRIMAIR study.

165x233mm (300 x 300 DPI)

Figure 2. Development of total scores in the two intervention arms and reference group over time. Total score minimum = 0 points, maximum = 26 points.

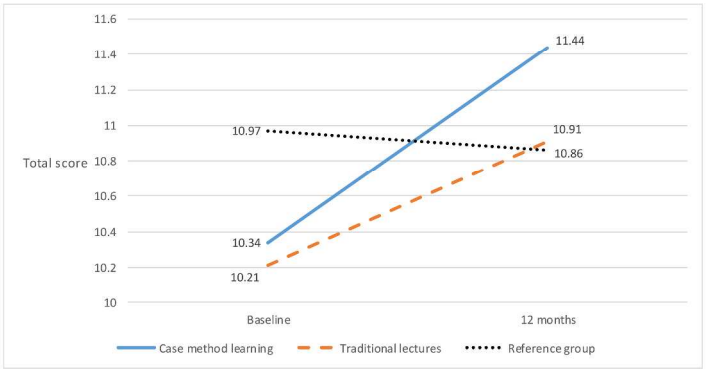
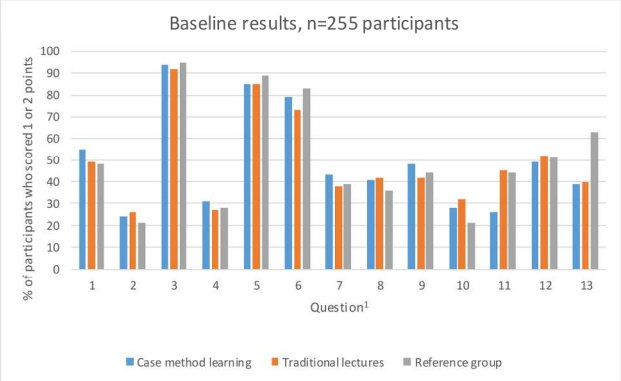


Figure 2. Development of total scores in the two intervention arms and reference group over time. Total score minimum = 0 points, maximum = 26 points.

233x330mm (600 x 600 DPI)

Figure 3. Baseline results per question in the two intervention arms and reference group, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

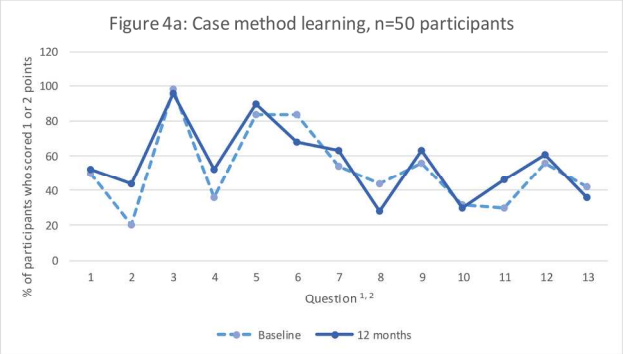


[1]Questions: 1) Diagnostic procedures; 2) Spirometry interpretation; 3) Smoking cessation (unmotivated patients); 4) Treatment of acute exacerbation; 5) Follow-up of acute exacerbation; 6) Smoking cessation (motivated patients); 7) Maintenance treatment of COPD (GOLD B patients); 8) Heart failure medication for patients with COPD; 9) Follow-up of patients with stable COPD; 10) Inter-professional interventions; 11) Managing a suspected respiratory failure; 12) Multi-morbidity in COPD patients without obvious symptoms from airways or COPD comorbidities (an annual check-up); 13) Multi-morbidity in COPD patients with symptoms from airways and/or COPD comorbidities (an annual check-up)

Figure 3. Baseline results per question in the two intervention arms and reference group, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

165x233mm (300 x 300 DPI)

Figure 4a-c. Changes over time in the scores per question in each group studied, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.



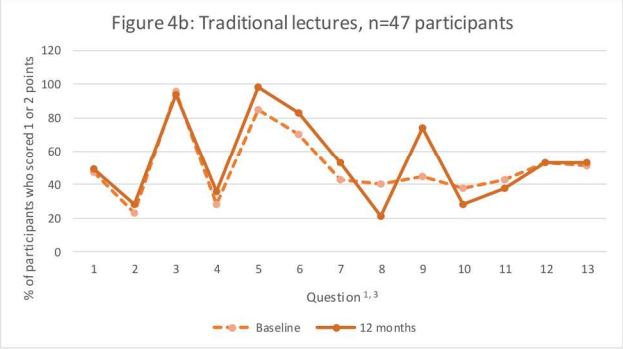


Figure 4a-c. Changes over time in the scores per question in each group studied, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

165x233mm (300 x 300 DPI)

Supplementary file 1. The GP questionnaire, with the addition of the intended learning outcomes (light green arrows) and the scoring templates[1] (dark green arrows). The questionnaire and the scoring were based on the guidelines that were available prior to 2015[1].

Case I

Your patient, a 59-year old male computer technician, comes to see you complaining of severe breathlessness in the past year, especially when exerting himself. He has attributed it to being unfit, since he doesn't like exercising. He has smoked for all his adult life. He also has a phlegmy morning cough. He has no known allergies and no pets. His children are worried about him, hence his appointment with you. He says his family go on at him about his smoking, but he has no intention of quitting.

Question 1	After a clinical examination, you suspect him of having COPD. Which of the following options (you may choose more than one answer) form part of your initial investigation of this patient?	
	a	PEF measurement
	b	Spirometry
	c	Lung X-ray
	d	PEF curve
	e	NT-ProBNP
	f	BMI
⇨	**ILOs[2]**	Diagnostic procedures
⇨	**Scoring template**	b+c+e = 2 points b+c = 1 points b+c+e+a = 1 points b+c+a = 1 points

His spirometry reading:

		Before bronchial dilation		After bronchial dilation		
Variable	Normal value	Recorded value	% of normal	Recorded value	% of normal	% change
VC	5.2	3.5	67	3.6	69	+3
FVC	5.2	3.0	58	3.0	58	+3
FEV1	3.9	1.7	44	2.0	56	+18
FEV1/VC	0.75	0.49	65	0.55	73	+12
FEV1/FVC	0.75	0.57	76	0.67	89	+18

Question 2	Going by his spirometry values, the most probable diagnosis is:	
	a	Asthma

	b	COPD, stage 2
	c	Asthma and COPD, stage 2
	d	COPD, stage 1
	e	Asthma and COPD, stage 3
	f	COPD, stage 3
	g	Neither asthma nor COPD
	ILOs	Spirometry interpretation
	Scoring template	b = 2 points
Question 3	How do you deal with his reluctance to quit smoking?	
	Write your answer here	
	ILOs	Smoking cessation, unmotivated patients
	Scoring template	Explain/inform about smoking and COPD = 1 point Provide correct information about alternatives for supporting smoking cessation (e.g. motivational interviewing, medications) = 1 point

Case II

You are the emergency doctor on duty today at your medical centre. A 59-year old female smoker arrives complaining of an increase in breathlessness, phlegm and expectoration over the past few days.
You see from her records that she has been registered to your colleague, who ordered a spirometric examination four years ago on account of the patient being a smoker and having a cough for which she sought medical attention. Spirometry revealed COPD with an FEV1 reading at 60% of the expected value.
You also see that she had been prescribed an expectorant, a fast-acting beta-2 stimulant in dry powder inhaler form (with some repeat prescriptions) and antibiotics for a urinary infection.
You can hear that she is breathless and obstructive and that she has a cold. She has a temperature of 37.1 degrees, a CRP of 26 and an oxygen saturation of 91%.
You send her for bronchial dilatory inhalations. She subsequently feels better and her saturation rises to 95%.

Question 4	With which of the following drugs do you choose to treat her current symptoms following the emergency bronchial dilation? (You may choose more than one answer.)	
	a	One dose of Betapred, 16 tablets
	b	One dose Betapred, 8 tablets
	c	Doxycyklin (oral)
	d	Amoxicillin (oral)
	e	Phenoxymethylpenicillin (penicillin V)
	f	Steroids, e.g. prednisolon 20-30 mg per day, orally for 5-10 days
	g	Steroids, e.g. prednisolon 5-10 mg per day, orally for 5-10 days
	h	Inhaled steroids, high dose for 14 days
	ILOs	Pharmacological treatment of acute exacerbation

	Scoring template	(c or d) + f = 2 points
Question 5	Do you feel this patient needs monitoring? If yes, how? If no, why not?	
	Write your answer here	
⇨	**ILOs**	Follow-up of acute exacerbation *(Managing issues with time pressure)*
➡	**Scoring template**	Propose a clinical follow-up carried out by a GP (not by a nurse) some weeks after an emergency visit = 1 point Propose concrete actions at the follow-up (e.g. medication, investigations, symptom evaluations) = 1 point Propose a follow-up time obviously too far in the future or 'over-investigating' with irrelevant methods = reduction of 1 point
Question 6	She wants to quit smoking and asks for your help. What smoking cessation method do you recommend?	
	Write your answer here	
⇨	**ILOs**	Smoking cessation, motivated patients *(Local routines and practices in supporting smoking cessation)*
➡	**Scoring template**	Propose smoking cessation strategies that employ counseling and medications = 2 points Nicotine replacement therapy only = 1 point Counseling only = 1 point Varenicline/bupropion without counseling = 0 points

Case III

You meet a 60-year old male patient with previously untreated COPD. Spirometry shows FEV1 at 71% of the expected value. The man quit smoking a couple of years ago and he has no medical history of acute exacerbation periods. He now experiences increasing breathlessness while out walking, gardening and doing other effortful activities.

Question 7	Which of the following treatment options would you recommend for this patient if you wish to start maintenance therapy? (You may choose more than one answer.)	
	a	Only short-acting beta 2 stimulants as needed
	b	Long-acting beta-2 stimulants
	c	Short-acting anticholinergics
	d	Long-acting anticholinergics
	e	A combination of long-acting beta-2 stimulants and long-acting anticholinergics
	f	Inhaled steroids
	g	A combination preparation of long-acting beta-2 stimulants and inhaled steroids (e.g. Symbicort Forte® or Seretide Forte®)
	h	Roflumilast (Daxas®)
	I	Acetylcysteine effervescent tablets
⇨	**ILOs**	Maintenance treatment of COPD (GOLD B patients)
➡	**Scoring template**	b = 2 points alternatively d = 2 points alternatively b+d = 2 points alternatively e = 2 points
Question 8	The patient also has heart failure, which is common in patients with COPD. When it comes to treating heart failure with beta blockers in a “normal case”, which of the following actions are **wrong**? (You may choose more than one answer.)	
	a	To opt for a beta-1 selective beta blocker, such as karvedidol (Kredex®)
	b	To opt for a beta blocker as per the heart failure recommendations, e.g. metoprolol
	c	To opt for no beta blockers
	d	To opt for a beta blocker as in (b) and to increase the beta agonist (beta-2 stimulant) in inhaled form
⇨	**ILOs**	Heart failure medication for patients with COPD
➡	**Scoring template**	c+d = 2 points c = 1 point
Question 9	When and how do you monitor the patient after your administration of maintenance therapy for COPD?	
	Write your answer here	
⇨	**ILOs**	Follow-up of patients with stable COPD (*Recognizing and prioritizing COPD patients without or with few airway symptoms)*
➡	**Scoring template**	Mention a clinical follow-up with symptom evaluation = 1 point Follow-up occurs 1–4 months after initiation of maintenance treatment for COPD = 1 point

		Pulmonary X-ray and spirometry are not recommended as routine monitoring of treatment = reduction of 1 point

Case IV

Your patient is a 65-year old female ex-smoker with stage 3 COPD. She has had a difficult year with three long exacerbation periods with obsructivity and has repeatedly received treatment from a hospital emergency unit and her local medical centre. In the past few years, she has met the centre's COPD nurse every six months or so. During a follow-up appointment, you find that she feels fine but has lost weight and loses her breath a little during conversation, especially directly after having walked some way down the corridor. Her saturation value is currently 93% and she has a BMI of 21.

Question 10	What do you do? (You may choose more than one answer.)	
	a	Refer her to the lung clinic
	b	Refer her to the physiotherapist
	c	Advise her to eat an extra energy-rich diet
	d	Refer her to a district nurse/dietician for a dietary consultation and prescribe a liquid nutritional supplement
	e	Prescribe Physical Activity in the Prevention and Treatment of Disease (FYSS)
	f	Send her for an arterial blood gas test
	g	Check that she is on optimal medication
⇨	**ILOs**	Interprofessional interventions (*Local routines for interprofessional management of COPD)*
➡	**Scoring template**	b+c+d+g = 2 points b+d+g = 2 points
Question 11	In which of the following situations would it be most appropriate for you to suspect respiratory insufficiency and send the patient for an arterial blood gas test?	
	a	The patient has started to experience exacerbations
	b	The patient's FEV1 is < 40% of the expected value
	c	The patient's saturation at rest is < 92%
	d	The patient's saturation drops to < 90 % on exertion
	e	The patient's saturation drops to < 92% on exertion
	f	The patient's saturation at rest is < 94%
	g	The patient feels the drugs are not helping
⇨	**ILOs**	Managing suspected respiratory failure
➡	**Scoring template**	c = 2 points

Case V

A 70-year old male smoker with heart failure, hypertension, COPD, mild depression and chronic back pain came to see you a year ago. He is taking Spiriva®, Enalapril, Lasix Retard®, Metoprolol, Citalopram and Alvedon®, and has now come for his annual checkup. He seems to be in good health. You open the conversation by asking how he is.

Two possible scenarios now present themselves (A and B):

A) The patient says he's fine. He mainly wants to have a PSA test, renew his prescriptions and get help with his bad back.

Question 12	How do you deal with the patient?	
	Write your answer here	
⇨	**ILOs**	Multimorbidity in COPD patients without obvious symptoms from airways or COPD comorbidities (an annual check-up) (*Patient or GP not becoming concerned about COPD because patient's agenda does not include airway symptoms.* *Managing multimorbidity and discussing COPD during limited consultation time.)*
⇨	**Scoring template**	Actively assess smoking status = 1 point Actively assess any symptoms from airways and/or COPD comorbidities = 1 point

B) The patient says he has no energy and gets easily out of breath.

Question 13	How do you deal with the patient?	
	Write your answer here	
⇨	**ILOs**	Multimorbidity in COPD patients with symptoms from airways and/or COPD comorbidities (an annual check-up) (*Connected to question 12, managing even more complicated multimorbidity during limited consultation time. Prioritizing COPD with comorbidities in the consultation.)*
⇨	**Scoring template**	All three of the following required for 2 points: Testing for anemia, evaluating heart function (NT-pro-BNP or echocardiography), and taking a chest X-ray. One of the above missing = reduction of 1 point (minimum score, 0 points).

BMI, body mass index; COPD, chronic obstructive pulmonary disease; CRP, C - reactive protein; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; GP, general practitioner; ILOs, intended learning outcomes; PEF, peak expiratory flow; PSA, prostate specific antigen; VC, vital capacity.

[1] The scoring templates were based on the pre-2015 Swedish COPD guidelines (reference 14) and the results of a qualitative study exploring the barriers to and facilitators of the COPD guideline implementation process (reference 15).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N.A.
Participants	4a	Eligibility criteria for participants	6-7 + Figure 1
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-9 + (Reference 24: protocol article)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-8 + Suppl file 1
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N.A.
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N.A.
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	6 +

		interventions	(Reference 24: protocol article)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N.A.
	11b	If relevant, description of the similarity of interventions	N.A.
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10-11 + Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	10-11 + Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6 + Figure 1
	14b	Why the trial ended or was stopped	N.A.
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	28 (Table 1)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10-11 + Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11-12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N.A.
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N.A.
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16-18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	Reference 24
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19, 7

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Effectiveness of traditional lectures and case methods in Swedish general practitioners' continuing medical education about COPD: a cluster randomized controlled trial

Journal:	*BMJ Open*
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Effectiveness of traditional lectures and case methods in Swedish general practitioners' continuing medical education about COPD: a cluster randomized controlled trial

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ABSTRACT

Objectives: To study the effects of continuing medical education (CME) about chronic obstructive pulmonary disease (COPD) for GPs by comparing two commonly used CME methods with each other and no CME (reference group).

Design: A pragmatic cluster randomized controlled trial with primary health care centers (PHCCs) as units of randomization.

Setting, participants and interventions: 24 PHCCs in Stockholm County, Sweden, were randomized into two CME intervention arms: case method learning (CM) (n=12) and traditional lectures (TL) (n=12). A reference group without CME (n=11) was recruited separately. GPs (n=255) participated in the study arm to which their PHCC was allocated: CM, n=87; TL, n=93; and reference, n=75. Two 2-hour CME seminars were given in a period of 3 months.

Primary outcome measures: Changes in scores between baseline and 12 months on a 13-item questionnaire about evidence-based COPD management (0-2 points/question, maximum total score 26 points).

Results: 133 (52%) GPs completed the questionnaire both at baseline and 12 months. Both CM and TL resulted in small yet significantly higher total scores at 12 months than at baseline (CM, 10.34 vs 11.44; TL, 10.21 vs 10.91; $p<0.05$); there were few significant differences between these CME methods. At both baseline and 12 months, all three groups' scores were generally high on questions about smoking cessation support and low on those that measured spirometry interpretation skills, interprofessional care, and management of multimorbidity.

Conclusions: Neither short CM nor short TL CME sessions substantially improve GPs' skills in managing COPD. It is justified to challenge the use of these common CME methods as a strategy for improving GPs' level of knowledge about

management of COPD and other complex chronic diseases characterized by multimorbidity.

Trial registration: Clinicaltrials.gov, 10 August 2014, Identifier NCT02213809.

Funding: Stockholm and Dalarna County Councils.

Keywords: continuing medical education, professional training, case method learning, traditional lectures, primary care physicians, COPD, chronic diseases, primary care, cluster randomized controlled trial.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The educational interventions (2x2-hour traditional lectures and case-based seminars) studied in this cluster randomized controlled trial are frequently used in real-life Swedish primary care, which strengthens the relevance of this study.
- The cluster design of study was a strength, since it decreased potential bias from contamination across individuals at each primary health care center.
- The follow-up investigation 12 months after the intervention was a strength, as it permitted us to observe the effects of the educational interventions beyond the immediate post-study period.
- The main limitation of the study was the large percentage of non-responders at the end, which significantly impaired the ability to draw conclusions.
- Using a written test of knowledge (the GP questionnaire) to assess the effects of the educational interventions was not optimal because it did not assess change in GPs' behaviors and because the scaling was narrow, decreasing the chances of clear distribution of the scores, which in turn led to few statistically significant changes in the scores.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is often comorbid with other conditions and is generally underdiagnosed and insufficiently managed in primary care (1). Despite improvements in recent years, primary care personnel can still contribute to delays in COPD diagnosis and care through insufficient actions to prevent, detect, and manage the disease (1-4).

In Sweden, the majority of patients with COPD are managed in primary care by general practitioners (GPs), who typically work together with other GPs in group practices and often in co-operation with specialized asthma/COPD nurses and pulmonary rehabilitation personnel (4, 5). As GPs are usually the patient's first professional health care contact, their knowledge about and skills in COPD management need to be up-to-date (6). However, there is a considerable gap between current COPD guidelines and what is actually done at GPs' practices. To help transfer theory into practice, more studies on the implementation of COPD guidelines are needed (7).

Continuing medical education (CME) is a necessary step in implementing optimal care. Although modern research stresses the effectiveness of multiple educational methods in CME (8-10), Swedish GPs still often sign up for 1-2 hour lectures, possibly because of their busy schedules. Traditional lectures (TL) are carried out mainly in didactic style with a CME leader as an academic expert. CME that uses case method learning (CM) can be carried out in similar settings and in a similar amounts of time as TL, but the CME leader uses an interactive teaching approach. The professional's perspective on the case described is a central feature in the discussions (11). When used in CME in primary care settings, CM has a positive impact on learning (12, 13). In a typical CM seminar, a CME leader facilitates the

discussion of one to two patient cases. CM stimulates creative thinking, communication, tolerance for different views, the ability to defend one's own point of view with logic, analysis, and decision making (14). It is a learning method that requires previous knowledge and clinical experience in the subject and maturity in the participants.

The current study is part of the PRIMAIR study, a cluster-randomized controlled trial (CRCT) at primary health care centers (PHCC) in Stockholm County in 2014-2017. The overall objective of PRIMAIR pertained to the effects of CME on professional COPD practice of individual GPs (GP-related outcomes) and the effects of CME on individual patients (patient-related outcomes). This paper presents only the GP-related outcomes. A detailed description of the GPs' baseline results has been published previously (15).

The aim of the current study was to compare the effects of CME on the topic of COPD, delivered in the form of praxis-typical, short (1-2 hour) sessions of either CM or TL, tailored for and targeted to GPs. The hypothesis was that CME based on CM leads to greater improvements in GPs' level of knowledge about and skills in COPD management than TL or no CME.

METHODS

This paper was written in line with the 2010 Consolidated Standards of Reporting Trials (CONSORT) statement: extension to cluster randomized trials (16). The CONSORT checklist (Supplementary file 1) and flow chart (Figure 1) were used.

Using a computer randomization program, the authors randomized 24 PHCCs (clusters) in Stockholm, Sweden, into two intervention arms: a CM arm and a TL arm.

A reference group of 11 PHCCs (no CME) was recruited separately and was not randomized, as the PHCCs in this group would not receive CME. The GPs participated in the study arm to which their PHCC was allocated.

The pharmaceutical industry did not participate in any part of the study, and we did not offer financial incentives to the participants. As there are no formal requirements for CME for GPs in Sweden, educational credits were not offered.

The CME sessions took place at the PHCCs. Five CME leaders, all GPs competent and experienced in COPD management, ran two 2-hour sessions at each PHCC. The two sessions took place a maximum of 3 months apart. Each PHCC was assigned the same CME leader and CME method (either CM or TL). Thus, four TL leaders taught at two to four PHCCs each, and one CM leader taught at all 12 PHCCs that received CM. John Biggs' educational theory of constructive alignment (17) was used to align the intended learning outcomes, learning activities, and assessments. The intended learning outcomes of the CME were derived from the pre-2015 COPD guidelines (2, 18, 19) and from a 2013 qualitative study of GPs in Stockholm that described barriers to and facilitators of the COPD guideline implementation process (20). Each leader adhered to the intended learning outcomes, but the learning activities differed in the CM and LT intervention groups. The leaders were also allowed to use their own presentation materials, such as slide shows and handouts. Apart from a short didactic introduction, participant activating methods (discussions) were the main method of used in the CM sessions, whereas the TL sessions followed a traditional didactic style.

The outcome measures for the GPs pertained to individual participants. A GP questionnaire, constructed by the authors and improved after a "think-aloud" discussion with a group of non-participating GPs, was used to assess GPs' level of

knowledge. The paper format questionnaire consisted of five short patient case vignettes and two to three questions per vignette (13 in total). The questions were about “knowledge/skills” and “practical management” and consisted of a mixture of multiple choice and open questions. The participants could score 0, 1, or 2 points per question. Responses were scored with a premade scoring template. GPs completed the questionnaires immediately prior to and 12 months after the CME sessions, taking 20 to 30 minutes each time. At baseline, the GPs replied to the questionnaire on their own without consulting each other. The GPs in the intervention arms did so at the first CME session, and the GPs in the reference group did so at a staff meeting. At 12 months, most GPs, regardless of study arm, filled in the questionnaire at an ordinary staff meeting. All did so individually. The few GPs who were not present at the staff meeting were contacted by telephone or email and reminded twice. They were allowed to complete the questionnaire on their own. The completed GP questionnaires did not include any information that could identify the GP, so the assessors were blind to cluster allocation.

The GP questionnaire with a summary of the intended learning outcomes and the scoring template is found in Supplementary data file 2.

Information about GPs’ gender, age, years in the profession, and degree (specialist in family medicine or in training to become one) was gathered at baseline. Other information gathered at baseline included data on the PHCC where they worked, such as ownership (county council or private), whether there was a nurse-led asthma/COPD clinic at the PHCC, and sociodemographic characteristics of the PHCC’s catchment area (Care Need Index [CNI]) (21). The CNI is a deprivation index based on sociodemographic factors, including percentage of older adults living alone, children under age 5, unemployed people, people with low educational status, single

parents, high mobility, and foreign-born people. A high CNI score indicates high sociodemographic burden. The mean CNI score PHCC catchment areas in Stockholm County is 2.49.

GP sample size was determined by the power calculation of the patient sample size in the PRIMAIR Study, which was determined to be 230 patients with COPD in GOLD stages 2 to 3 (2) in each arm. To keep the number of clusters reasonable, we chose to invite only PHCCs with more than 10,000 registered patients (n=80). We estimated that 10 to 12 PHCCs were needed per arm to achieve sufficient statistical power for the patient sample. Accordingly, the number of GPs was determined by the number of PHCCs we included. Unequal cluster sizes (5 to 10 GPs) were expected because of variations in staff numbers at baseline and dropouts at 12 months. The intraclass correlation coefficient (ICC) was set at 0.01 based on earlier studies on cluster randomizations in primary care (22-24).

Statistics

We performed the statistical analysis with STATA, version 14 (Stata Corp. 2015. Stata Statistical Software: Release 14. College Station, TX: Stata Corp. LP) and SPSS, version 23 (PSPP (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.). We computed summary statistics such as means, proportions, and measures with standard parametric methods. We used a McNemar test to compare matched pairs of scores per question at baseline and 12 months for proportions of GPs who scored “0 points” vs “1 or 2 points.” We used clttest and xtreg (adjusting for cluster) to analyze differences in total scores within the study arms and for adjusting for “total scores at baseline,” “CNI,” and “years in profession.” A transition model, adjusted for clusters, was applied to analyze associations between items (“0 points” or “1 or 2 points”) and study arms at baseline

and 12 months, which also provided odds ratios (ORs) and their 95% confidence intervals (CIs). In a transition model the outcome variable at a previous time point is included as a fixed effect covariate. We condition the response at time j on the response at time j-1. ICC was estimated by xtlogit. P-values <0.05 were considered indicative of statistical significance.

A detailed description of the methodology and interventions is found in the study protocol (25).

Ethics

The present CRCT, including a model consent form and other related documentation given to participants, was approved by the Regional Ethical Review Board of Stockholm (ref 2013/232-31/5). Prior to enrollment, all PHCC managers provided written informed consent to be involved in the study. All GPs provided written informed consent to participate in the study after they had been allocated to the different study arms (after cluster randomization). The study was registered at www.clinicaltrials.gov on 10 August 2014, Identifier NCT02213809. The first participant was enrolled 14 August 2014.

Patient and Public Involvement

No patients or public were involved in the study.

RESULTS

Description of the participants

At baseline, 207 GPs attended the CME sessions. Twenty-seven of them did not agree to participate in the study and thus did not fill in the GP questionnaire. In the

CM arm, 87 of 100 GPs (87%), in the TL arm, 93 of 107 GPs (87%) agreed to participate in the study. The reference group consisted of 75 GPs. The majority of the GPs who did not agree to participate worked at a PHCC without a nurse-led asthma/COPD clinic. They did not differ from the participants regarding age, gender, years in profession, educational degree, or PHCC's CNI scores or ownership form.

Of the 255 participants who responded to the questionnaire at baseline, 122 (48%) did not respond again at 12 months ("non-responders"). The remaining 133 GPs were the final participants ("responders"). There were no significant differences between any of the groups studied (the two intervention arms and the reference group) in the proportions of responders and non-responders. A higher percentage of the non-responders than responders were employed at PHCCs in socially deprived areas of Stockholm ($p<0.05$). The characteristics of the responders and non-responders are seen in Table 1.

A higher percentage of GPs in the CM arm than the TL arm and the reference group worked at a PHCC with a nurse-led asthma/COPD clinic (64% vs 36%-38%, $p=0.012$). A higher percentage of GPs in the reference group than the CM and TL arms worked at privately run PHCCs (72% vs 32%-42%, $p=0.001$). The means for gender, age, years in profession, and CNI scores did not differ significantly between the GPs in the groups studied (the two intervention arms and the reference group), and the participants were generally representative for Swedish GPs with regard to these characteristics (26).

Scores

Total scores – within and between the arms

After adjustment for the clusters (i.e. PHCCs) and mean scores at baseline, the mean scores in both intervention arms were significantly higher at 12 months than at baseline (CM: 10.34 vs 11.44; TL: 10.21 vs 10.91; $p<0.05$) (Figure 2). There was no statistically significant difference between the improvement in the CM and TL arms. No significant changes in scoring over time were observed in the reference group. All the non-responders had significantly lower mean baseline scores than the responders (9.11 vs 10.47, $p=0.003$). At baseline, the GPs who worked at PHCCs in the most socially deprived areas (CNI 2.29-5.05, 21% of all GPs) had lower mean scores than the others (8.50 vs 10.32, $p=0.000$), and the non-responders in the deprived areas scored lowest of all non-responders (7.98 vs 9.71, $p=0.007$). Scores were unrelated to whether or not there was a nurse-led asthma/COPD clinic at the PHCC.

Scores on individual questions – comparison of the arms

Table 2 compares the results for each of the 13 questions in the two intervention arms and the reference group by providing ORs of "scoring 1 or 2 points at 12 months." The TL arm had a statistically significantly higher OR of "scoring 1 or 2 points at 12 months" than the reference group on two of the questions: the question about the follow-up of stable patients (question 9) and the question about multimorbidity in a patient with airway symptoms (question 13). On the question about smoking cessation support for patients who were motivated to quit smoking (question 6), the TL arm had a higher OR of "scoring 1 or 2 points at 12 months" than the CM arm. The CM arm's ORs were not significantly higher for any of the questions than the TL arm or reference group's ORs. Regarding the effects of intracluster conditions, we found three significant ICCs (questions 1, 10, and 12), all of them

were approximately 0.10 (CIs could not be estimated because no standard error was available).

Scores on individual questions – within the arms

For 10 of 13 questions, there was no significant difference between baseline and 12 months in the proportion of participants who scored 1 or 2 points and who scored 0 points (Figure 3). Scores on two questions improved significantly (CM arm, question 2, spirometry interpretation; TL arm, question 9, follow-up of stable patients), and scores on one question dropped significantly (reference group, question 13, multimorbidity in a patient with airway symptoms) (Figure 4a-c).

DISCUSSION

Main findings

The results of our study do not bear out the hypothesis that CM leads to greater improvements in GPs' level of COPD-related knowledge and skills than TL. However, the hypothesis that CM would be superior to no intervention was confirmed. Both CM and TL led to small, yet significant, improvements in Swedish GPs' levels of knowledge of COPD and COPD management skills. Neither of the CME methods was more effective than the other. GPs' baseline level of knowledge was low, and improvements at 12 months were generally modest. Moreover, GPs' level of knowledge was unrelated to whether or not they worked at a PHCC with a nurse-led asthma/COPD clinic,

Over time, strong areas of knowledge remained strong, and weak areas weak

For the most part, the differences between strong and weak areas of knowledge about COPD were maintained over time. We were not surprised by the high level of knowledge about smoking cessation support, as most GPs are well aware of and do not question the importance of quitting smoking. However, there is a gap between what GPs know and what they do: earlier research has shown that doctors rarely take active measures to help patients quit smoking (27). The preliminary results of a questionnaire to randomly selected COPD patients at the PHCCs participating in this study indicate that approximately 60% of the patients who are current smokers or have quit smoking in the last five years (n=382) state they have *not been offered* smoking cessation support, and 80% state they have *not been given* such support by their GPs or nurses (Sandelowsky, in manuscript). As the benefits of smoking cessation far outweigh the benefits of diagnosing new cases or providing pharmacological treatments for COPD (28), the GP's role as a motivator and authority in patient education should not be overlooked and needs continuous attention in CME situations.

Insufficient skills in spirometry interpretation may be one of the major causes of problems with implementing evidence-based COPD practice (29). CM involved active participation in training spirometry interpretation and discussing spirometry results, which may explain the improvements in responses to the question that measured spirometry interpretation skills. However, this was the only question on spirometry interpretation, and conclusions based on the responses to one question may not be reliable. TL positively affected replies to the questions on smoking cessation support to motivated patients, follow-up of patients with stable COPD, and management of airway symptoms in multimorbid patients. We did not investigate whether this finding was due to factors related to the CME leaders (i.e. uneven focus on the different intended learning outcomes) or to the didactic lecturing style.

Neither CME method led to significant improvements in managing COPD in patients with multi- and comorbidities, managing acute exacerbation under time pressure, managing patients who lack motivation to quit smoking, or handling patients whose focus during the consultation is something other than COPD. Thus, these typical real-life conditions and problems in Swedish primary care, which represent important obstacles to implementing guidelines (20), remain difficult to overcome with two short sessions of CME, regardless of whether lectures or case methods are used.

Comparison with previous studies

Kiessling et al found that using CM to implement evidence-based practice in primary care was associated with decreased mortality in patients with coronary heart disease in Sweden 10 years after the training had taken place (12). The educational meetings in Kiessling's study were carried out similarly to those in our study; i.e., as short CM seminars for GPs at their workplaces, led by an external facilitator. COPD may be a more complex health issue than cardiovascular diseases, and evidence-based management may thus be more complex to implement. The complexity of COPD typically includes disabling comorbidities (1), confronting lifestyle choices (mainly smoking), low patient motivation to adhere to treatment (20, 30), GPs' negative views of COPD (20), consequences of COPD in patients' family lives (31), and the crucial role of interprofessional care (32).

We are not alone in finding that CM sessions brief enough for busy GPs to attend are of limited effectiveness. A 2016 Swedish study about the effectiveness of CM in CME for GPs on the topic of childhood asthma used CM similar to those in our study. That intervention had no effects on prescriptions of anti-asthmatic drugs for children (33).

In line with theories of adult learning, the American College of Chest Physicians recommends multiple teaching techniques, such as CM, audience response system, lectures, hands-on demonstrations, discussion groups, and role playing to effectively change physician knowledge, performance, and clinical outcomes (8). In fact, two previous CME studies from the United States, by Drexel et al and Adams et al, found that CME had positive effects on GPs' management of COPD when used as one of multiple educational methods, including a combination of short didactic lectures, case discussions, spirometry workshops, and inhaler demonstrations (13, 34). Moreover, Adams et al observed positive outcomes following interactive and collaborative CME for multidisciplinary participants, which is particularly relevant, as the current Swedish guidelines strongly recommend interprofessional COPD care (32). However, the follow-up measurements in both the Adams et al and Drexel et al studies were made shortly after the CME intervention and thus do not provide information about the sustainability of results. Additionally, in the Drexel et al study, no pre-intervention measurements were performed, which limits the researcher's ability to evaluate of the effects of the CME.

Methodological considerations

Strengths and weaknesses

One strength of this study was the cluster randomization of the PHCCs, which reduced the likelihood of possible contamination across individuals at each PHCC (cluster). Including a reference group enabled us to compare knowledge gained through our interventions with information gained through other sources during the study period. Using a transition model in the analysis of data was a strength because of its simplicity. The statistically significant ICCs we found for the questions were

higher than expected, indicating that intracluster conditions may have affected the GPs' results in some of the individual questions more than assumed prior to the intervention. This information may assist researchers conducting CRCTs in similar environments in the future. Our assessment indicated that there were practically no interactions between the clusters that could have biased the results.

Swedish GPs report they have little time for CME because of heavy workloads due to time constraints, staffing problems, and financial incentives at the PHCC that encourage multiple short visits (26). A previous study in a similar setting found that primary health care professionals appreciate CME outreach visits (35). The CME outreach visits in the current study were thus another strength, as they enabled the GPs to attend the CME sessions despite their busy schedules. Another strength was the choice to conduct the follow-up measurement 12 months after the intervention, which enabled us to describe the sustained effects of the interventions.

The recruitment of the reference group deviated from optimal CRCT design. Thus, some caution should be used when interpreting the results for the reference group. Another limitation of our study was the potential for reporting bias at 12 months due to non-response. High non-response impaired the statistical power of the 12-month analysis and decreased our ability to generalize the results. A high drop-out percentage was also observed in the Adams et al CME study. The high drop-out rates in the two studies may reflect the strenuous working conditions GPs often experience: reminders had practically no effect on response rate. Non-responders may also have been uncomfortable reporting their potential lack of knowledge gain after the CME. Moreover, it was alarming to find that many of the non-responders worked in deprived urban areas where smoking and COPD are common (36, 37).

A source of bias may have been the minor overlapping of the two pedagogical methods. Although we focused on providing didactic lectures in the TL sessions, some natural interplay may have taken place. On the other hand, CM consists of a mixture of didactic and participatory learning methods. The TL sessions were taught by four different CME leaders and the CM sessions were facilitated by one, which may have further biased the results, as the TL leaders may have stressed different content.

To achieve deeper knowledge via CM, participants must have previous knowledge and clinical experience in the subject area. Analysis indicated that GPs' baseline level of knowledge about COPD was surprisingly low. We reason that it may have been too low to enable them to take full advantage of the CM learning opportunity. Thus, a sequence of different CME interventions in which CM was not the first step might have been more effective. In retrospect, we could have improved the teaching activities by conducting a pilot survey to measure GPs' knowledge prior to designing the intervention or by designing the teaching activities after collecting and analyzing the baseline data.

The GP questionnaire had strengths and limitations. A "think-aloud" discussion with a group of non-participating GPs helped us improve the five case vignettes' understandability and relatability, increasing the chances of valid replies to the questions. However, written descriptions, such as in case vignettes and multiple-choice answers, always involve a risk of misinterpretation, and thus of biased replies. We suspect this could have happened in question 8, as it was expressed in inverted (negative) wording. Another limitation of the study was that the questionnaire was the only assessment method we used, so we were unable to assess whether the GPs' behaviors changed in practice. The use of mixed methods would have helped ensure

the best possible assessment validity (38). The narrow, 0-2 point scale, together with strict scoring requirements, may have contributed to difficulties in differentiating the participants' results. We tried to minimize the testing bias that can occur when the same questionnaire is administered twice by not revealing the answers and by using paper questionnaires to disable digital distribution of the questionnaire. Finally, participants may have received information about COPD through other channels during the study period.

Implications and future research

The findings of this study can be useful in developing CME interventions that are feasible to implement in a busy primary care practice and that target the management of complex, chronic health issues (26, 39). The particularly low competence in the subject of COPD among GPs in socially deprived areas sends an important message to policymakers, as smoking and COPD are particularly prevalent in these areas (36, 37).

An evaluation of patient-related outcomes before and after the CME intervention is underway as a part of the PRIMAIR study. Future research could evaluate the effects of a sequel to our CME intervention that incorporates other educational methods and/or angles the focus towards interprofessional learning activities to support team-based COPD care in primary care. However, such interventions would likely need to be longer than two short sessions, which would make them challenging to implement in primary care. As many people now acquire knowledge via digital media, future research could also investigate the effects of easy-to-access online handbooks and guides as support for GPs in clinical decision-making.

CONCLUSION

GPs' levels of knowledge of and skills for COPD were low at baseline, and the effects of both case methods and traditional lectures were equally modest. Thus, these common educational methods alone may not be sufficient to substantially improve GPs' level of knowledge and management of COPD. Critics are justified in challenging the use of a single CME method in short sessions as a strategy for improving management of patients with COPD or other complex chronic diseases characterized by multimorbidity.

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DATA SHARING STATEMENT

Data analyzed in this study are available from the corresponding author in response to requests that comply with ethical principles of good research.

AUTHORS' CONTRIBUTIONS

Hanna Sandelowsky (HS), Ingvar Krakau (IK), Sonja Modin (SM), Björn Ställberg (BS), and Anna Nager (AN) conceived and designed the study. HS and BS were two of the five CME leaders. HS collected the data. HS, BS, Sven-Erik Johansson (SEJ), and AN analyzed the data. HS wrote the paper. All authors edited, revised, and approved the final manuscript.

COMPETING INTERESTS

HS has received honoraria for educational activities from Boehringer Ingelheim, Novartis, AstraZeneca, and TEVA and an unrestricted research grant from AstraZeneca. AN has received compensation for educational activities from AstraZeneca and SM from Novartis. BS has received honoraria for educational activities and lectures from AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline, Meda, Novartis, and TEVA and has served on advisory boards arranged by AstraZeneca, Novartis, Meda, TEVA, GlaxoSmithKline, and Boehringer Ingelheim. IK and SEJ report no competing interests.

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References

1. Stallberg B, Janson C, Johansson G, Larsson K, Stratelis G, Telg G, et al. Management, morbidity and mortality of COPD during an 11-year period: an observational retrospective epidemiological register study in Sweden (PATHOS). Prim Care Respir J. 2014;23(1):38-45.

2. Global Initiative for Chronic Obstructive Lungdisease. 2013 [cited 17 Jan 2018]. Available from: ttp://www.goldcopd.com/

3. Lindberg A, Bjerg A, Ronmark E, Larsson LG, Lundback B. Prevalence and underdiagnosis of COPD by disease severity and the attributable fraction of

smoking Report from the Obstructive Lung Disease in Northern Sweden Studies. Respir Med. 2006;100(2):264-72.

4. Lisspers K, Johansson G, Jansson C, Larsson K, Stratelis G, Hedegaard M, et al. Improvement in COPD management by access to asthma/COPD clinics in primary care: Data from the observational PATHOS study. Respir Med. 2014 Sep;108(9):1345-54.

5. Arne M, Emtner M, Lisspers K, Wadell K, Stallberg B. Availability of pulmonary rehabilitation in primary care for patients with COPD: a cross-sectional study in Sweden. Eur Clin Respir J. 2016;3:31601.

6. Lisspers K, Stallberg B, Hasselgren M, Johansson G, Svardsudd K. Primary health care centres with asthma clinics: effects on patients knowledge and asthma control. Prim Care Respir J. 2009;19(1):37-44.

7. Pinnock H, Thomas M, Tsiligianni I, Lisspers K, Ostrem A, Stallberg B, et al. The International Primary Care Respiratory Group (IPCRG) Research Needs Statement 2010. Prim Care Respir J.19 Suppl 1:S1-20.

8. Davis D, Galbraith R, American College of Chest Physicians H, Science Policy C. Continuing medical education effect on practice performance: effectiveness of continuing medical education: American College of Chest Physicians Evidence-Based Educational Guidelines. Chest. 2009;135(3 Suppl):42S-8S.

9. Forsetlund L, Bjorndal A, Rashidian A, Jamtvedt G, O'Brien MA, Wolf F, et al. Continuing education meetings and workshops: effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2009(2):CD003030.

10. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implement Sci. 2012;7:50.

11. Nordquist J. Att undervisa med case i utbildningar inom hälso- och sjukvården. . Stockholm: : Karolinska Institutet, Mecical Care Centre 2009.

12. Kiessling A, Lewitt M, Henriksson P. Case-based training of evidence-based clinical practice in primary care and decreased mortality in patients with coronary heart disease. Ann Fam Med. 2011;9(3):211-8.

13. Drexel C, Jacobson A, Hanania NA, Whitfield B, Katz J, Sullivan T. Measuring the impact of a live, case-based, multiformat, interactive continuing medical education program on improving clinician knowledge and competency in evidence-based COPD care. Int J Chron Obstruct Pulmon Dis. 2011;6:297-307.

14. Mauffette-Leenders LA, Erskine JA, Leenders MR. Learning with cases. London [Ont.]: Richard Ivey School of Business, The University of Western Ontario; 1997.

15. Sandelowsky H, Natalishvili N, Krakau I, Modin S, Stallberg B, Nager A. COPD management by Swedish general practitioners - baseline results of the PRIMAIR study. Scand J Prim Health Care. 2018:1-9.

16. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661.

17. Biggs John CT, editor. Teaching for Quality Learning at University: The McGraw-Hill Companies; 2011.

18. National Board of Health and Welfare. Socialstyrelsens riktlinjer för vård av astma och kroniskt obstruktiv lungsjukdom (KOL). Faktadokument och beslutsstöd förprioriteringar. 2004.

19. Swedish Medical Products Agency. Läkemedelsverkets riktlinjer för behandling av kroniskt obstruktiv lungsjukdom. 2009 [cited 17 Jan 2018]. Available from: https://lakemedelsverket.se/upload/halso-och-sjukvard/behandlingsrekommendationer/KOL_rek_webb.pdf

20. Sandelowsky H, Hylander I, Krakau I, Modin S, Stallberg B, Nager A. Time pressured deprioritization of COPD in primary care: a qualitative study. Scand J Prim Health Care. 2016:1-11.

21. Sundquist K, Malmstrom M, Johansson SE, Sundquist J. Care Need Index, a useful tool for the distribution of primary health care resources. Journal of epidemiology and community health. 2003;57(5):347-52.

22. Adams G, Gulliford MC, Ukoumunne OC, Eldridge S, Chinn S, Campbell MJ. Patterns of intra-cluster correlation from primary care research to inform study design and analysis. J Clin Epidemiol. 2004;57(8):785-94.

23. Killip S, Mahfoud Z, Pearce K. What is an intracluster correlation coefficient? Crucial concepts for primary care researchers. Ann Fam Med. 2004;2(3):204-8.

24. Hayes RJ MH. Cluster Randomised Trials. Boca Baton, FL: Chapman & Hall/CRC, Taylor & Francis Group; 2009.

25. Sandelowsky H, Krakau I, Modin S, Stallberg B, Nager A. Case Method in COPD education for primary care physicians: study protocol for a cluster randomised controlled trial. Trials. 2017;18(1):197.

26. Pettersson S. [Swedish Medical Association's Primary Care Survey] In Swedish. Stockholm. Swedish Medical Association. 2015. p. 16-59.

27. Stead M, Angus K, Holme I, Cohen D, Tait G, Team PER. Factors influencing European GPs' engagement in smoking cessation: a multi-country literature review. Br J Gen Pract. 2009;59(566):682-90.

28. Black WC, Gareen IF, Soneji SS, Sicks JD, Keeler EB, Aberle DR, et al. Cost-effectiveness of CT screening in the National Lung Screening Trial. N Engl J Med. 2014;371(19):1793-802.

29. Foster JA, Yawn BP, Maziar A, Jenkins T, Rennard SI, Casebeer L. Enhancing COPD management in primary care settings. MedGenMed. 2007;9(3):24.

30. Roddy E, Antoniak M, Britton J, Molyneux A, Lewis S. Barriers and motivators to gaining access to smoking cessation services amongst deprived smokers--a qualitative study. BMC Health Serv Res. 2006;6:147.

31. Zakrisson AB, Theander K, Anderzen-Carlsson A. The experience of a multidisciplinary programme of pulmonary rehabilitation in primary health care from the next of kin's perspective: a qualitative study. Prim Care Respir J. 2013;22(4):459-65.

32. National Board of Health and Welfare. Nationella riktlinjer vid vård av astma och KOL. 2015 [cited Jan 24 2018]. Available from: http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19949/2015-11-3.pdf

33. Ingemansson M. Evidence-based practice for children with asthma in primary care – quality of management and effects of learning Stockholm: Karolinska Institutet, Stockholm, Sweden; 2016.

34. Adams SG, Pitts J, Wynne J, Yawn BP, Diamond EJ, Lee S, et al. Effect of a primary care continuing education program on clinical practice of chronic obstructive pulmonary disease: translating theory into practice. Mayo Clin Proc. 2012;87(9):862-70.

35. Berggren E, Odlund Olin A, Orrevall Y, Strang P, Johansson SE, Tornkvist L. Early palliative home care: Evaluation of an interprofessional educational intervention for district nurses and general practitioners about nutritional care. SAGE open medicine. 2017;5:2050312117726465.

36. Engstrom K, Magnusson C, Galanti MR. Socio-demographic, lifestyle and health characteristics among snus users and dual tobacco users in Stockholm County, Sweden. BMC Public Health. 2010;10:619.

37. Nacul LC, Soljak M, Meade T. Model for estimating the population prevalence of chronic obstructive pulmonary disease: cross sectional data from the Health Survey for England. Popul Health Metr. 2007;5:8.

38. Wass V, Van der Vleuten C, Shatzer J, Jones R. Assessment of clinical competence. Lancet. 2001;357(9260):945-9.

39. Baron RJ. What's keeping us so busy in primary care? A snapshot from one practice. N Engl J Med. 2010;362(17):1632-6.

Table 1. The main characteristics of the participants in the two intervention arms and reference group.

Main characteristics	Baseline	12 months	
Participants	**All**	**Responders**	**Non-responders**
n (%)	255 (100)	133 (52)	126 (48)
Number of participants per PHCC, mean (range)	7.5 (2-15)	4.3 (1-10)	
Gender, n (%)			
Women	149 (58)	81 (61)	68 (56)
Age, mean (range)	47 (27-69)	47 (27-68)	47 (27-69)
Degree in family medicine, n (%)			
Specialist in family medicine	184 (72)	102 (77)	82 (67)
Training to be a specialist in family medicine	71 (28)	31 (23)	40 (33)
Years worked in primary care, mean (range)	14 (0-41)	15 (0-37)	14 (0-41)
Asthma/COPD clinic at PHCC, n (%)			
Yes	114 (45)	70 (53)	51 (42)
Ownership of PHCC			
Stockholm County Council	132 (52)	71 (53)	61 (50)
Private	123 (48)	62 (47)	61 (50)
CNI of PHCC's location, mean (SD)	2.17 (0.78)	2.03[1](0.67)	2.32[1](0.86)
range	0.92-5.05	0.92-5.05	0.92-5.05

CNI, Care Need Index; COPD, chronic obstructive pulmonary disease; PHCC, primary health care center. The CNI is based on sociodemographic factors, including percentage of older adults living alone, children under age 5, unemployed people, people with low educational status, single parents, high mobility, and foreign-born people. High CNI = high sociodemographic burden; mean CNI in Stockholm County = 2.49.

[1]p of the difference between responders and non-responders <0.05

Table 2. Comparison of the odds ratios and 95% confidence intervals of scoring 1 or 2 rather than 0 points in the two intervention arms (case methods, CM; traditional lectures, TL) and the reference group (no continuing medical education) 12 months after the intervention. All measures are adjusted for clusters (primary health care centers) and total scores at baseline.

Question	Odds Ratio				
	CM and TL vs. Reference group [95% CI]			CM vs.TL [95% CI]	
	CM	TL	Reference group	CM	TL
1. Diagnostic procedures	0.55 [0.22 – 1.40]	0.55 [0.21 – 1.42]	1	1.00 [0.43 – 2.31]	1
2. Spirometry interpretation	1.29 [0.53 - 3.10]	0.61 [0.24 - 1.55]	1	2.10 [0.90– 4.95]	1
3. Smoking cessation (unmotivated patients)	N.A.[1]				
4. Acute exacerbation (treatment)	1.40 [0.57 – 3.45]	0.77 [0.31 – 1.96]	1	1.81 [0.77– 4.24]	1
5. Acute exacerbation (follow-up)	N.A.[2]				
6. Smoking cessation (motivated patients)	0.41 [0.14 - 1.24]	1.35 [0.39 – 4.69]	1	0.30 [0.10 – 0.88]	1
7. Maintenance treatement	1.04 [0.42 – 2.54]	0.72 [0.30 - 1.74]	1	1.44 [0.63 – 3.29]	1
8. Comorbidity: heart failure	2.46 [0.79 – 7.66]	1.70 [0.61 - 4.95]	1	1.45 [0.57 – 3.67]	1
9. Follow-up (stable patients)	2.37 [0.96 - 5.86]	4.48 [1.51 – 13.3]	1	0.53 [0.20 - 1.40]	1
10. Inter-professional interventions	1.82 [0.59 – 5.61]	1.42 [0.45 – 4.49]	1	1.29 [0.50 – 3.31]	1
11. Suspected respiratory failure	1.51 [0.62 - 3.72]	0.97 [0.39 - 2.41]	1	1.57 [0.68 - 3.62]	1
12. Multi-morbidity, no airway symptoms	1.36 [0.54 - 3.40]	0.97 [0.39 – 2.43]	1	1.39 [0.60 – 3.24]	1
13. Multi-morbidity, airway symptoms	1.34 [0.53 - 3.37]	2.64 [1.06 - 6.60]	1	0.51 [0.22 - 1.15]	1

[1]Odds ratios not applicable because there was no convergence in the model.

[2]Odds ratios not applicable because the model was questionable.

FIGURE LEGENDS

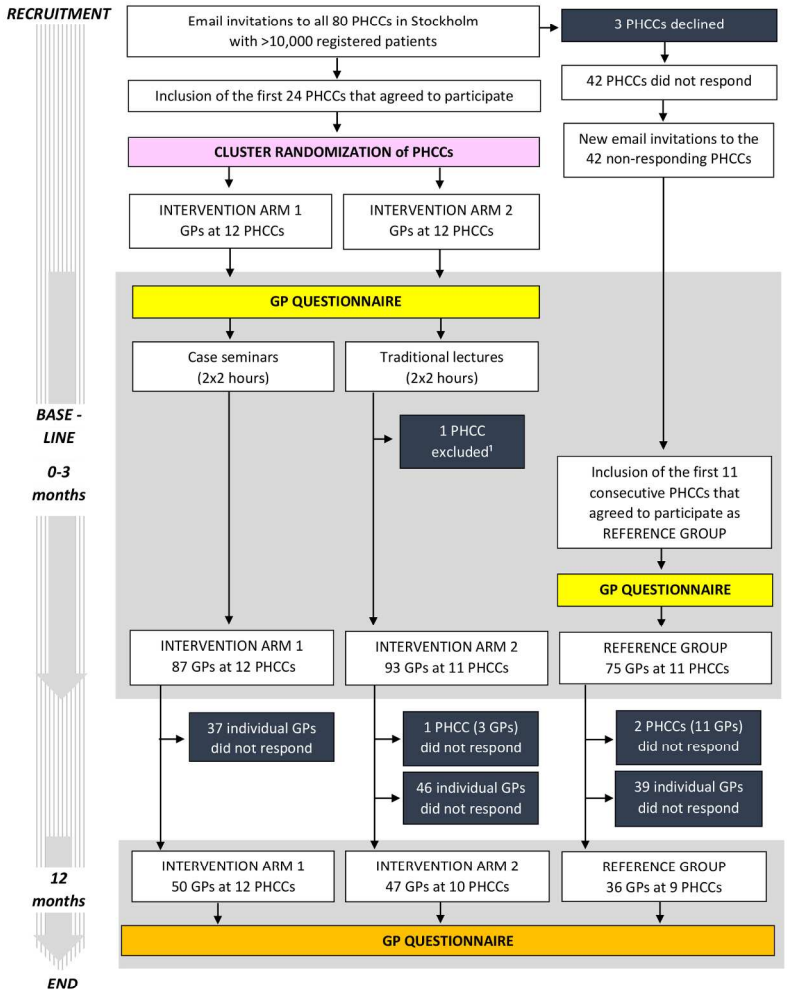
Figure 1. Study enrollment, general practitioner part of the PRIMAIR study.

Figure 2. Development of total scores in the two intervention arms and reference group over time. Total score minimum = 0 points, maximum = 26 points.

Figure 3. Baseline results per question in the two intervention arms and reference group, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

Figure 4a-c. Changes over time in the scores per question in each group studied, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

Figure 1. Study enrollment, general practitioner part of the PRIMAIR study.



GP, general practitioner; PHCC, primary health care center.

¹The main author started working as a GP at this particular PHCC.

Figure 1. Study enrollment, general practitioner part of the PRIMAIR study.

165x233mm (300 x 300 DPI)

Figure 2. Development of total scores in the two intervention arms and reference group over time. Total score minimum = 0 points, maximum = 26 points.

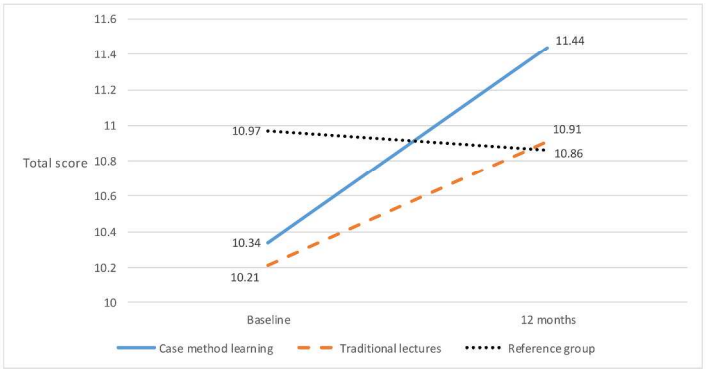
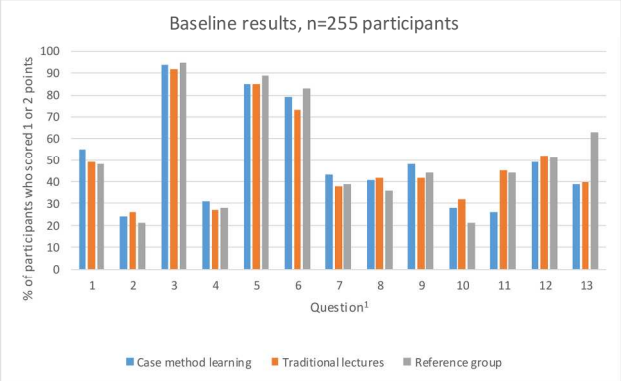


Figure 2. Development of total scores in the two intervention arms and reference group over time. Total score minimum = 0 points, maximum = 26 points.

233x330mm (600 x 600 DPI)

Figure 3. Baseline results per question in the two intervention arms and reference group, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

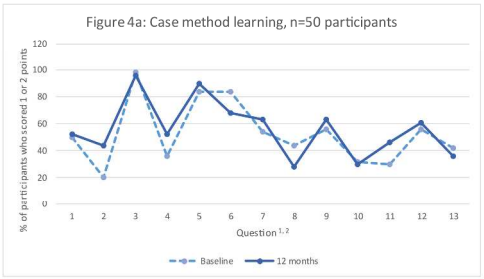


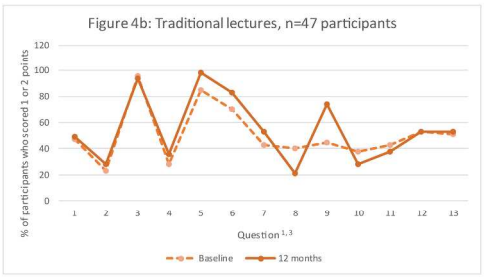
[1]Questions: 1) Diagnostic procedures; 2) Spirometry interpretation; 3) Smoking cessation (unmotivated patients); 4) Treatment of acute exacerbation; 5) Follow-up of acute exacerbation; 6) Smoking cessation (motivated patients); 7) Maintenance treatment of COPD (GOLD B patients); 8) Heart failure medication for patients with COPD; 9) Follow-up of patients with stable COPD; 10) Inter-professional interventions; 11) Managing a suspected respiratory failure; 12) Multi-morbidity in COPD patients without obvious symptoms from airways or COPD comorbidities (an annual check-up); 13) Multi-morbidity in COPD patients with symptoms from airways and/or COPD comorbidities (an annual check-up)

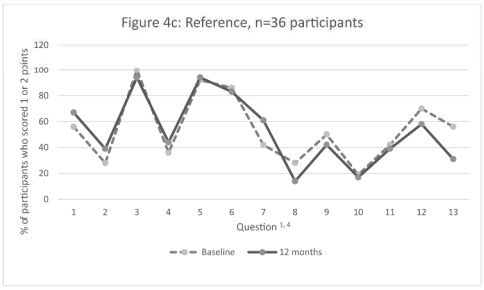
Figure 3. Baseline results per question in the two intervention arms and reference group, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

165x233mm (300 x 300 DPI)

Figure 4a-c. Changes over time in the scores per question in each group studied, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.







[1]Questions: 1) Diagnostic procedures; 2) Spirometry interpretation; 3) Smoking cessation (unmotivated patients); 4) Treatment of acute exacerbation; 5) Follow-up of acute exacerbation; 6) Smoking cessation (motivated patients); 7) Maintenance treatment of COPD (GOLD B patients); 8) Heart failure medication for patients with COPD; 9) Follow-up of patients with stable COPD; 10) Inter-professional interventions; 11) Managing a suspected respiratory failure; 12) Multi-morbidity in COPD patients without obvious symptoms from airways or COPD comorbidities (an annual check-up); 13) Multi-morbidity in COPD patients with symptoms from airways and/or COPD comorbidities (an annual check-up)

[2]In figure 4a, $p<0.05$ for question 2

[3]In figure 4b, $p<0.05$ for question 9

[4]In figure 4c, $p<0.05$ for question 13

Figure 4a-c. Changes over time in the scores per question in each group studied, presented as percent of participants who scored 1 or 2 points. Each response was given a score of between 0 and 2 points; the highest possible score was 2 points. On questions 2, 4, 7, 10, and 11, only two scores were possible: 0 or 2 points.

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Supplementary file 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	4, 6, Ref 24 (Study Protocol)
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	6, 7, Ref 24 (Study Protocol)
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	6, 9, Ref 24 (Study Protocol)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N.A.
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	6-7, Ref 24 (Study Protocol)
	4b	Settings and locations where the data were collected		6, Ref 24 (Study Protocol)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7-9, Ref 24 (Study Protocol)

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	7, 8, Supplementary File 2, Ref 24 (Study Protocol)
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N.A.
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N.A.
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		**6**
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	6 + Ref 24 (Study Protocol)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who	6, Ref 24 (Study Protocol)

			enrolled clusters, and who assigned clusters to interventions	
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	7, Ref 24 (Study Protocol)
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	10, Ref 24 (Study Protocol)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		N.A.
	11b	If relevant, description of the similarity of interventions		N.A.
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		9
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	10-11, Figure 1

	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	10-11, Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up		6, Figure 1
	14b	Why the trial ended or was stopped		N.A.
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	10-13, 26 (Table 1), Figures 2-4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	10-13, Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	11-12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		N.A.
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		11
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		N.A.
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias,		16-18

		imprecision, and, if relevant, multiplicity of analyses		
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	17-19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		19
Other information				
Registration	23	Registration number and name of trial registry		**3**
Protocol	24	Where the full trial protocol can be accessed, if available		Reference 24
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		3, 20

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

Supplementary file 2. The GP questionnaire, with the addition of the intended learning outcomes (light green arrows) and the scoring templates[1] (dark green arrows). The questionnaire and the scoring were based on the guidelines that were available prior to 2015[1].

Case I

Your patient, a 59-year old male computer technician, comes to see you complaining of severe breathlessness in the past year, especially when exerting himself. He has attributed it to being unfit, since he doesn't like exercising. He has smoked for all his adult life. He also has a phlegmy morning cough. He has no known allergies and no pets. His children are worried about him, hence his appointment with you. He says his family go on at him about his smoking, but he has no intention of quitting.

Question 1	After a clinical examination, you suspect him of having COPD. Which of the following options (you may choose more than one answer) form part of your initial investigation of this patient?	
	a	PEF measurement
	b	Spirometry
	c	Lung X-ray
	d	PEF curve
	e	NT-ProBNP
	f	BMI
⇨	**ILOs[2]**	Diagnostic procedures
⇨	**Scoring template**	b+c+e = 2 points b+c = 1 points b+c+e+a = 1 points b+c+a = 1 points

His spirometry reading:

		Before bronchial dilation		After bronchial dilation		
Variable	Normal value	Recorded value	% of normal	Recorded value	% of normal	% change
VC	5.2	3.5	67	3.6	69	+3
FVC	5.2	3.0	58	3.0	58	+3
FEV1	3.9	1.7	44	2.0	56	+18
FEV1/VC	0.75	0.49	65	0.55	73	+12
FEV1/FVC	0.75	0.57	76	0.67	89	+18

Question 2	Going by his spirometry values, the most probable diagnosis is:	
	a	Asthma

	b	COPD, stage 2
	c	Asthma and COPD, stage 2
	d	COPD, stage 1
	e	Asthma and COPD, stage 3
	f	COPD, stage 3
	g	Neither asthma nor COPD
	ILOs	Spirometry interpretation
	Scoring template	b = 2 points
Question 3	How do you deal with his reluctance to quit smoking?	
	Write your answer here	
	ILOs	Smoking cessation, unmotivated patients
	Scoring template	Explain/inform about smoking and COPD = 1 point Provide correct information about alternatives for supporting smoking cessation (e.g. motivational interviewing, medications) = 1 point

Case II

You are the emergency doctor on duty today at your medical centre. A 59-year old female smoker arrives complaining of an increase in breathlessness, phlegm and expectoration over the past few days.
You see from her records that she has been registered to your colleague, who ordered a spirometric examination four years ago on account of the patient being a smoker and having a cough for which she sought medical attention. Spirometry revealed COPD with an FEV1 reading at 60% of the expected value.
You also see that she had been prescribed an expectorant, a fast-acting beta-2 stimulant in dry powder inhaler form (with some repeat prescriptions) and antibiotics for a urinary infection.
You can hear that she is breathless and obstructive and that she has a cold. She has a temperature of 37.1 degrees, a CRP of 26 and an oxygen saturation of 91%.
You send her for bronchial dilatory inhalations. She subsequently feels better and her saturation rises to 95%.

Question 4	With which of the following drugs do you choose to treat her current symptoms following the emergency bronchial dilation? (You may choose more than one answer.)	
	a	One dose of Betapred, 16 tablets
	b	One dose Betapred, 8 tablets
	c	Doxycyklin (oral)
	d	Amoxicillin (oral)
	e	Phenoxymethylpenicillin (penicillin V)
	f	Steroids, e.g. prednisolon 20-30 mg per day, orally for 5-10 days
	g	Steroids, e.g. prednisolon 5-10 mg per day, orally for 5-10 days
	h	Inhaled steroids, high dose for 14 days
	ILOs	Pharmacological treatment of acute exacerbation

	Scoring template	(c or d) + f = 2 points
Question 5	Do you feel this patient needs monitoring? If yes, how? If no, why not?	
	Write your answer here	
⇨	**ILOs**	Follow-up of acute exacerbation *(Managing issues with time pressure)*
➡	**Scoring template**	Propose a clinical follow-up carried out by a GP (not by a nurse) some weeks after an emergency visit = 1 point Propose concrete actions at the follow-up (e.g. medication, investigations, symptom evaluations) = 1 point Propose a follow-up time obviously too far in the future or 'over-investigating' with irrelevant methods = reduction of 1 point
Question 6	She wants to quit smoking and asks for your help. What smoking cessation method do you recommend?	
	Write your answer here	
⇨	**ILOs**	Smoking cessation, motivated patients *(Local routines and practices in supporting smoking cessation)*
➡	**Scoring template**	Propose smoking cessation strategies that employ counseling and medications = 2 points Nicotine replacement therapy only = 1 point Counseling only = 1 point Varenicline/bupropion without counseling = 0 points

Case III

You meet a 60-year old male patient with previously untreated COPD. Spirometry shows FEV1 at 71% of the expected value. The man quit smoking a couple of years ago and he has no medical history of acute exacerbation periods. He now experiences increasing breathlessness while out walking, gardening and doing other effortful activities.

Question 7	Which of the following treatment options would you recommend for this patient if you wish to start maintenance therapy? (You may choose more than one answer.)	
	a	Only short-acting beta 2 stimulants as needed
	b	Long-acting beta-2 stimulants
	c	Short-acting anticholinergics
	d	Long-acting anticholinergics
	e	A combination of long-acting beta-2 stimulants and long-acting anticholinergics
	f	Inhaled steroids
	g	A combination preparation of long-acting beta-2 stimulants and inhaled steroids (e.g. Symbicort Forte® or Seretide Forte®)
	h	Roflumilast (Daxas®)
	I	Acetylcysteine effervescent tablets
⇨	**ILOs**	Maintenance treatment of COPD (GOLD B patients)
➡	**Scoring template**	b = 2 points alternatively d = 2 points alternatively b+d = 2 points alternatively e = 2 points
Question 8	The patient also has heart failure, which is common in patients with COPD. When it comes to treating heart failure with beta blockers in a "normal case", which of the following actions are **wrong**? (You may choose more than one answer.)	
	a	To opt for a beta-1 selective beta blocker, such as karvedidol (Kredex®)
	b	To opt for a beta blocker as per the heart failure recommendations, e.g. metoprolol
	c	To opt for no beta blockers
	d	To opt for a beta blocker as in (b) and to increase the beta agonist (beta-2 stimulant) in inhaled form
⇨	**ILOs**	Heart failure medication for patients with COPD
➡	**Scoring template**	c+d = 2 points c = 1 point
Question 9	When and how do you monitor the patient after your administration of maintenance therapy for COPD?	
	Write your answer here	
⇨	**ILOs**	Follow-up of patients with stable COPD (*Recognizing and prioritizing COPD patients without or with few airway symptoms)*
➡	**Scoring template**	Mention a clinical follow-up with symptom evaluation = 1 point Follow-up occurs 1–4 months after initiation of maintenance treatment for COPD = 1 point

		Pulmonary X-ray and spirometry are not recommended as routine monitoring of treatment = reduction of 1 point

Case IV

Your patient is a 65-year old female ex-smoker with stage 3 COPD. She has had a difficult year with three long exacerbation periods with obsructivity and has repeatedly received treatment from a hospital emergency unit and her local medical centre. In the past few years, she has met the centre's COPD nurse every six months or so. During a follow-up appointment, you find that she feels fine but has lost weight and loses her breath a little during conversation, especially directly after having walked some way down the corridor. Her saturation value is currently 93% and she has a BMI of 21.

Question 10	What do you do? (You may choose more than one answer.)	
	a	Refer her to the lung clinic
	b	Refer her to the physiotherapist
	c	Advise her to eat an extra energy-rich diet
	d	Refer her to a district nurse/dietician for a dietary consultation and prescribe a liquid nutritional supplement
	e	Prescribe Physical Activity in the Prevention and Treatment of Disease (FYSS)
	f	Send her for an arterial blood gas test
	g	Check that she is on optimal medication
⇨	**ILOs**	Interprofessional interventions (*Local routines for interprofessional management of COPD)*
➡	**Scoring template**	b+c+d+g = 2 points b+d+g = 2 points
Question 11	In which of the following situations would it be most appropriate for you to suspect respiratory insufficiency and send the patient for an arterial blood gas test?	
	a	The patient has started to experience exacerbations
	b	The patient's FEV1 is < 40% of the expected value
	c	The patient's saturation at rest is < 92%
	d	The patient's saturation drops to < 90 % on exertion
	e	The patient's saturation drops to < 92% on exertion
	f	The patient's saturation at rest is < 94%
	g	The patient feels the drugs are not helping
⇨	**ILOs**	Managing suspected respiratory failure
➡	**Scoring template**	c = 2 points

Case V

A 70-year old male smoker with heart failure, hypertension, COPD, mild depression and chronic back pain came to see you a year ago. He is taking Spiriva®, Enalapril, Lasix Retard®, Metoprolol, Citalopram and Alvedon®, and has now come for his annual checkup. He seems to be in good health. You open the conversation by asking how he is.

Two possible scenarios now present themselves (A and B):

A) The patient says he's fine. He mainly wants to have a PSA test, renew his prescriptions and get help with his bad back.

Question 12	How do you deal with the patient?
	Write your answer here
ILOs	Multimorbidity in COPD patients without obvious symptoms from airways or COPD comorbidities (an annual check-up) (*Patient or GP not becoming concerned about COPD because patient's agenda does not include airway symptoms.* *Managing multimorbidity and discussing COPD during limited consultation time.)*
Scoring template	Actively assess smoking status = 1 point Actively assess any symptoms from airways and/or COPD comorbidities = 1 point

B) The patient says he has no energy and gets easily out of breath.

Question 13	How do you deal with the patient?
	Write your answer here
ILOs	Multimorbidity in COPD patients with symptoms from airways and/or COPD comorbidities (an annual check-up) (*Connected to question 12, managing even more complicated multimorbidity during limited consultation time. Prioritizing COPD with comorbidities in the consultation.)*
Scoring template	All three of the following required for 2 points: Testing for anemia, evaluating heart function (NT-pro-BNP or echocardiography), and taking a chest X-ray. One of the above missing = reduction of 1 point (minimum score, 0 points).

BMI, body mass index; COPD, chronic obstructive pulmonary disease; CRP, C - reactive protein; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; GP, general practitioner; ILOs, intended learning outcomes; PEF, peak expiratory flow; PSA, prostate specific antigen; VC, vital capacity

[1] The scoring templates were based on the pre-2015 Swedish COPD guidelines (reference 14) and the results of a qualitative study exploring the barriers to and facilitators of the COPD guideline implementation process (reference 15).